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Office of Waste and Chemicals Management

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Interim Final Guidance:

Developing Risk-Based Cleanup Levels At Resource Conservation and Recovery Act Sites in Region 10

INTERIM FINAL GUIDANCE: DEVELOPING RISK-BASED CLEANUP LEVELS AT RESOURCE CONSERVATION AND RECOVERY ACT SITES IN REGION 10

Prepared for

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Waste and Chemicals Management
Seattle, WA 98101

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DISCLAIMER

This guidance document sets forth recommended approaches to conduct risk assessment and other activities which are integral to the process of developing risk-based cleanup levels at RCRA corrective action facilities in Region 10 of the United States Environmental Protection Agency. Alternative approaches may be more appropriate at specific sites. All approaches used should be described in full in documents generated as part of the cleanup level decision-making process. This guidance is intended to be updated as scientific developments occur and U.S. EPA and state rules and policies change. The user is encouraged to use the latest and best information available for developing media cleanup levels. Users are also encouraged to submit suggestions for updates to the guidance, or to report any errors noted, to Marcia Bailey, U.S. EPA Region 10, at (206) 553-0684, or Bailey.marcia@epamail.epa.gov.

This guidance is intended as guidance to U.S. EPA Region 10 personnel and to RCRA-regulated facilities undergoing corrective action or clean closures in Region 10. It does not constitute final U.S. EPA action and does not constitute rulemaking. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States government. U.S. EPA officials may decide that the guidance provided in this document should be follwed, or may decide to act at variance with the guidance, based on an analysis of specific site circumstances. U.S. EPA reserves the right to change the guidance at any time without public notice.

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ACRONYMS AND ABBREVIATIONS

2,4-D	2,4-Dichlorophenoxyacetic Acid
40 CFR	Title 40 of the Code of Federal Regulations
95th UCL	95th upper confidence limit on the arithmetic mean
AAC	Alaska Administrative Code
ABS	Dermal absorption factor
ADD	Average daily dose
ADEC	Alaska Department of Environmental Conservation
Ar1254	Aroclor 1254
ASTM	American Society for Testing and Materials
ATSDR	Agency for Toxic Substances and Disease Registry
AUF	Area use factor
AWQC	Ambient water quality criteria
BDL	Below detection limit
Cal/EPA	California Environmental Protection Agency
CDD	Chlorinated dibenzo-p-dioxins
CDF	Chlorinated dibenzofurans
CDI	Chronic daily intake
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CMS	Corrective measures study
COPC	Constituent of potential concern
CPF	Cancer potency factor
CSGWPP	Comprehensive state groundwater protection plan
CSM	Conceptual site model
DDT	Dichlorodiphenyltrichloroethane
DEFT	Decision error feasibility trials
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
DQA	Data quality assessment
DQI	Data quality indicators
DQO	Data quality objectives
Ecology	Washington Department of Ecology
EDQL	Ecological data quality levels
EPA	U.S. Environmental Protection Agency
FR	Federal Register
HI	Hazard index
HEAST	Health Effects Assessment Summary Tables
HHRA	Human health risk assessment
HQ	Hazard quotient
HSWA	Hazardous and Solid Waste Amendments of 1984
IAC	Idaho Administrative Code
IDEQ	Idaho Division of Environmental Quality
IEUBK	Integrated exposure uptake biokinetic model
IRIS	Integrated Risk Information System
LADD	Lifetime average daily dose
LD_{50}	Lethal dose 50

ACRONYMS AND ABBREVIATIONS (Continued)

L/day	Liters per day
LOAEL	Lowest-observable-adverse-effect-level
μg/dL	Micrograms per deciliter
μg/L	Micrograms per liter
m^3/hr	Cubic meter per hour
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
MDEP	Massachusetts Department of Environmental Protection
mg/kg	Milligrams per kilogram
mg/kg-day	Milligrams per kilogram per day
MRL	Minimal risk levels
MTCA	Model Toxics Control Act
NCEA	National Center for Environmental Assessment
NOAA	National Oceanic and Atmospheric Administration
NOAEL	No-observable-adverse-effect-level
OAR	Oregon Administrative Rules
ODEQ	Oregon Department of Environmental Quality
PAH	Polynuclear aromatic hydrocarbon
PCB	Polychlorinated biphenyl
PDF	Probability density function
PEF	Particulate emission factor
PRA	Probabilistic risk assessment
PRG	Preliminary remediation goal
Q/C	Dispersion factor
QA	Quality assurance
QAPP	Quality assurance project plan
QC	Quality control
QMP	Quality management plan
RAGS	Risk Assessment Guidance for Superfund
RBC	Risk-based concentration
RCRA	Resource Conservation and Recovery Act
RfC	Reference concentrations
RfD	Reference dose
RFI	RCRA facility investigation
RI/FS	Remedial investigation and feasibility study
RME	Reasonable maximum exposure
SAP	Sampling and analysis plan
SOP	Standard operating procedures
SWMU	Solid waste management unit
SVOC	Semivolatile organic compounds
TCDD	2,3,7,8-Tetrachlorodibenzo-p-dioxin
TEF	Toxicity equivalency factors
TEQ	Toxic equivalent
TPH	Total petroleum hydrocarbons
TR	Target risk

ACRONYMS AND ABBREVIATIONS (Continued)

TRV	Toxicity reference value
TWA	Time-weighted average
VF	Volatilization factor
VF_S	Soil-to-air volatilization factor
VF_w	Groundwater-to-indoor air volatilization factor
VOC	Volatile organic compounds
WAC	Washington Administrative Code

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GLOSSARY

GENERAL RISK ASSESSMENT TERMS

absorbed dose: The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose is calculated from the intake and the absorption efficiency. It usually is expressed as mass of a substance absorbed into the body per unit body weight per unit time (e.g., mg/kg-day).

acute effects: Adverse human or ecological impacts caused by very short-term exposure to hazardous constituents.

administered dose: The mass of a substance given to an organism and in contact with an exchange boundary (e.g., gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day).

carcinogenic risks: Incremental probability that an individual will develop cancer over a lifetime as a result of exposure to a carcinogen.

chronic effects: Adverse human or ecological impacts caused by long-term exposure to hazardous constituents.

cleanup levels: The hazardous constituent concentrations to which a contaminated environmental medium (e.g., soil, groundwater, surface water, sediment) must be remediated. EPA establishes cleanup levels on a facility-by-facility basis during the remedy selection process. Determination of target cleanup levels is a risk management decision.

conceptual site model: Schematic and/or narrative presentation of information about a facility conditions including known and potential sources of releases of hazardous constituents, exposure pathways, receptors, and all available information about constituents of potential concern at the facility.

data quality objectives (DQOs): Qualitative and quantitative statements relevant to facility-specific circumstances which are to ensure that sampling and analysis data of known, documented and adequate quality are obtained to support a risk assessment.

dose-response evaluations: The process of quantitatively evaluating toxicity information and characterizing the relationship between the dose of a hazardous constituent received and the incidence of adverse health effects in the exposed population.

exposure pathways: The various ways a hazardous constituent in a given medium can come into contact with a receptor. For example, possible exposure pathways for contaminated soil include ingestion of the soil, inhalation of the soil as dust, inhalation of volatile organics emanating from the soil, and dermal contact with the soil.

exposure route: The way an environmental hazardous constituent can enter an organism. The three primary routes are ingestion, inhalation, and dermal contact.

RCRA hazardous constituent: Substances that have been shown in scientific studies to have toxic, carcinogenic, mutagenic, or teratogenic effects on humans or other life forms. RCRA hazardous constituents used in 40 CFR 261, Appendix VIII.

CERCLA hazardous substance: Elements, compounds, mixtures, solutions, and substances, which, when released into the environment may present substantial danger to the public health or welfare or the environment. The terms means any substances designated under the federal water pollution control act, CERCLA, RCRA, the clean air act, and the toxic substances control act. CERCLA hazardous substance are listed in 40 CFR 3024.

hazard index: An estimate of the risk associated with a specified exposure to a noncarcinogenic hazardous constituent, expressed as the ratio of a substance exposure level over a specified time period to a reference dose for that substance derived from a similar exposure.

lifetime average daily intake: Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a lifetime.

linearized multistage model: One of a number of mathematical models and procedures used to extrapolate from carcinogenic responses observed at high doses to responses expected at low doses.

95 percent upper confidence limit (95 UCL) on the arithmetic mean: Value that, when calculated repeatedly for randomly drawn subsets of facility data, equals or exceeds the true mean 95 percent of the time. Provides a conservative estimate of the average concentration.

quality assurance project plan (QAPP): Describes the policy, organization, functional activities, and quality assurance and quality control protocols necessary to achieve DQOs dictated by the intended use of the data.

receptor: An organism (human, plant, or animal) that is potentially exposed to chemical contamination from a facility.

reference dose: An estimate (with uncertainty spanning an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to carry no appreciable risk of deleterious effects during a lifetime.

cancer potency factor: A plausible upper-bound estimate of the probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of potential carcinogen.

toxicity value: A numerical expression of a dose-response relationship for a particular substance. The most common values used in EPA risk assessments are reference doses (for noncarcinogenic effects) and cancer potency factors (for carcinogenic effects).

weight-of-evidence classification: An EPA classification system for characterizing the extent to which the available data indicate that an agent is a human carcinogen. Recently, EPA has developed weight-of-evidence classification systems for some other kinds of toxic effects, such as development effects.

weight-of-evidence: Classification of evidence from human and animal studies into categories of sufficient, limited, inadequate, no data, or no evidence of cancer effects.

ECOLOGICAL TERMS USED BY THE U.S. ENVIRONMENTAL PROTECTION AGENCY (1992f and 1994l)

area use factor: The fraction of an organism's home range, breeding range, or foraging range to the area of contamination or the facility area under investigation.

assessment endpoint: A clearly defined statement of the environmental value that is to be protected.

bioaccumulation: General term describing a process by which chemicals are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemical. EPA's 1994l (and new 1997) *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.*

bioavailability: The degree to which a material in environmental media is assimilated by an organism.

constituents of potential concern: Chemicals detected at a facility which have the potential to adversely affect ecological receptors because of their concentration, distribution, and mode of toxicity.

complete exposure pathway: Includes a source or release from a source, an exposure route (that is, soil), and an exposure point (that is, dermal contact). If the exposure point differs from the source, transport and exposure media are also included in the exposure pathway.

baseline ecological risk assessment: A comprehensive ecological risk assessment where uncertainties of the screening-level assessment are reduced, and nonfacility-specific TRVs are refined by incorporating data on facility-specific results from fate and transport modeling as well as exposure and ecological effects analyses.

conceptual site model: The conceptual site model describes a series of working hypotheses of how a stressor might affect ecological components. It also describes the ecosystem potentially at risk, the relationship between assessment endpoint and measurements and exposure scenarios.

ecological effect: An effect where the stressor acts directly on the ecological component of interest (direct effect). Also, an effect where the stressor acts on supporting ecological components of the ecosystem, which in turn have an indirect effect on the ecological components of interest.

ecological niche: The functional position of an organism in its environment, comprising the habitat in which the organism lives, the periods of time during which it occurs and is active there, and the resources it obtains there.

ecological receptor: The biotic component (for example, organism, population, community) exposed to a stressor.

ecological relevance: This term is typically used in the context of identifying assessment endpoints. Ecologically relevant assessment endpoints reflect important ecosystem components that are functionally related to other ecosystem components and assessment endpoints

ecological risk assessment: The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

ecosystem: The biotic community and the abiotic environment within a specified location in space and time. The abiotic environment includes non-living environmental media (for example, water, soil, sediment) and associated physical and chemical influences (for example, light, temperature, pH, humidity).

ecotone: A narrow and fairly sharply defined transition zone between two or more different biotic communities. These "edge" communities are typically species-rich. Reference: Allaby, M., editor. 1994. The Concise Oxford Dictionary of Ecology. Oxford University Press.

exposure: The contact or co-occurrence of a stressor with an ecological a receptor.

exposure area: A contaminated habitat where ecological receptors may be exposed to hazardous constituents that may cause adverse ecological effects.

exposure point concentration: The concentration of a constituent that an ecological receptor is exposed to through exposure routes such as ingestion, dermal contact, inhalation.

exposure profile: The product of the exposure analysis step in the ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the exposure scenarios described in the conceptual site model.

exposure scenario: A set of assumptions concerning how an exposure may occur, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

guild: A group of species that share common ecological characteristics (for example, feeding behavior). Guilds are defined by guild descriptors (for example, feeding guild) that may be general or specific. Guilds may contain many or few species in response to the number of guild descriptors.

hazard index: A sum of hazard quotients for hazardous constituents of ecological concern with the same ecological effect endpoint and/or the same mechanism of toxic effect.

hazard quotient: The ratio of a single exposure concentration or dose to a toxicity value selected for the risk assessment (for example, lowest observed adverse effect level or no observed adverse effect level).

keystone species: A species, the presence or abundance of which can be used to assess the extent to which ecological components of an ecosystem are impacted.

lowest observed adverse effect level: The lowest level of a stressor evaluated in a test that causes statistically significant differences from the controls.

measurement endpoint: A measurable ecological characteristic that is indirectly related to the assessment endpoint.

no observed adverse effect level: The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls.

population: A group of organisms of the same species, occupying a given area, and capable of interbreeding.

risk characterization: A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analysis to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery.

screening-level ecological risk assessment: Simplified assessments that can be conducted with limited data by assuming values for parameters for which data are lacking. Where data are lacking, assumed values are biased in the direction of overestimating risk so the assessment can provide a defensible conclusion of no unacceptable ecological risk.

stressor: Any physical, chemical, or biological entity that can induce an adverse response.

subpopulation: A portion of the population known or likely to be exposed to hazardous constituents at or from the facility.

toxicological test: Tests used to evaluate relative potency of a chemical by comparing its effect on living organisms with the effect of a standard preparation on the same type of organism.

trophic level: A functional classification of taxa within a community that is based on feeding relationships (for example, aquatic and terrestrial plants make up the first trophic level, and herbivores make up the second).

EXECUTIVE SUMMARY

This guidance document provides procedures for developing human and ecological risk-based cleanup levels for facilities undergoing corrective action and clean closure under the Resource Conservation and Recovery Act (RCRA). The procedures are intended for use by U.S. Environmental Protection Agency (EPA) permit writers and regulatory compliance officials as well as RCRA-regulated facilities.

This guidance document references EPA Region 10 state RCRA corrective action programs and relevant laws and regulations. EPA guidance on determining data quality objectives and performing a data quality assessment is summarized. The major risk assessment steps, including data evaluation, exposure assessment, toxicity assessment, and risk characterization, are described. Methods for determining human and ecological risk-based cleanup levels using deterministic and probabilistic techniques are presented. Screening-level ecological risk assessment methods are described. Procedures to follow when determining compliance with cleanup levels are also described. Federal, state, and general literature references that provide further details on the risk calculation processes are identified throughout the document. Consultation with Region 10 human health scientists and ecologists is recommended if complex aspects of the risk assessment process are encountered.

CHAPTER 1
INTRODUCTION

This guidance document provides procedures for developing human and ecological risk-based cleanup levels for contaminated facilities undergoing corrective action and clean closure under the federal Resource Conservation and Recovery Act (RCRA). The procedures are intended for use by permit writers and enforcement officials as well as by RCRA-regulated facilities. The guidance is intended to enable RCRA project managers to recommend cleanup level determinations based on risks posed to human health and the environment by releases from the facility. The document also describes situations likely to require expert technical assistance. A risk assessor or toxicologist should be involved at the beginning of the RCRA facility investigation or corrective action order negotiation process.

This guidance document updates and supersedes the previous U.S. Environmental Protection Agency (EPA) *Interim Final Guidelines for Developing Risk-Based Cleanup Levels at RCRA Sites in Region 10* document (1992a). The document also complements *RCRA Facility Investigation (RFI) Guidance* (EPA 1989a). The approach in this document is intended to be consistent with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), known as Superfund. In circumstances where there are no RCRA-specific guidelines or rules, Superfund guidance should be used. It is EPA Region 10's objective that cleanup activities conducted under the auspices of either Superfund or RCRA are comparably protective of human health and the environment (EPA 1994a).

Sections 1.1 through 1.3 provide overviews of (1) EPA's statutory and regulatory authorities for requiring corrective action, (2) processes for setting the human health and ecological cleanup levels, and (3) risk characterization principles, respectively.

> Additional sections of this guidance document summarize EPA Region 10 state programs (Chapter 2), data collection and useability issues (Chapter 3), human health risk-based methods for calculating cleanup levels (Chapter 4), ecological screening-level risk assessment and cleanup levels (Chapter 5), probabilistic risk assessment methods and applications (Chapter 6), and determination of compliance with cleanup levels (Chapter 7).

1.1 STATUTORY AND REGULATORY AUTHORITIES OVERVIEW

Application of the procedures described in this guidance is intended for RCRA facilities where releases of hazardous constituents require corrective action or where corrective action is necessary so that a RCRA-regulated unit may be clean-closed. EPA derives its authority for compelling corrective action at facilities regulated under RCRA Subtitle C by a variety of statutory provisions. Before the Hazardous and Solid Waste Amendments of 1984 (HSWA) were passed, the RCRA corrective action authorities were limited to Section 7003, which provides authority to compel action where solid or hazardous waste may present an imminent and substantial endangerment to human health or the environment, and Section 3013, which provides authority for requiring investigations where the presence of hazardous waste or releases of hazardous waste may present a substantial hazard to human health or the environment. HSWA substantially expanded corrective action authorities for both permitted RCRA facilities and facilities operating under interim status. Section 3004(u) of HSWA requires that any RCRA permit issued after November 8, 1984, address corrective action for releases of hazardous wastes or hazardous constituents from any solid waste management unit. Section 3004(v) authorizes EPA to require corrective action by permitted facilities beyond the facility boundary where appropriate. Section 3008(h) provides the authority to require corrective action when there has been a release of hazardous waste or hazardous constituents from a RCRA facility operating under interim status. EPA authority for setting cleanup levels at closing units stems from RCRA Section 3004 with regulations promulgated in Title 40 of the Code of Federal Regulations parts 264 and 265, subpart G, which require that, among other things, the facility must be closed in a manner that "controls, minimizes or eliminates, to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere."

1.2 HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENTS: AN OVERVIEW

Human health risk assessment (HHRA) and ecological risk assessment methods can be used to either (1) calculate the risk associated with exposure to a hazardous constituent or (2) calculate a risk-based concentration (RBC) that represents a level of exposure to a hazardous constituent that is not expected to result in unacceptable risks to human health or the environment health. RBCs may then be used as a

basis for determining risk-based cleanup levels. As described in Chapter 5, screening-level ecological risk assessments may be performed to determine the need for settings ecological RBCs. The human health and ecological risk assessment processes are similar in that they involve the identification of potential exposure pathways, the assessment of constituent toxicity, and the characterization of risk based on exposure and toxicity information. The output of a risk assessment is typically an estimate of the risk of getting cancer over a lifetime (for humans) or the likelihood of other toxic effects (referred to as hazards) occurring in humans or ecological receptors. The direct calculation of cancer risks or hazards can incorporate cumulative exposure occurring from more than one medium (for example, soil and groundwater exposures). Risk assessments require that data of sufficient quantity and quality be collected to determine the nature and magnitude of contamination released from a facility and the resulting level of potential exposures to human and ecological receptors. Uncertainty associated with the various risk assessment steps must be described, and in some cases, it may be quantified. When relevant, both human and ecological procedures should be applied at each facility, and the processes can be conducted either simultaneously or sequentially. For facilities where it has been decided that both human and ecological receptors should be protected, the protective levels for each should be compared, and the more stringent of the two should be proposed as the cleanup level.

When risk assessment methods are used to calculate RBCs, the output is the concentration of a specific hazardous constituent in a specific medium (for example, soil) that will not cause unacceptable cancer risks, systemic hazards, or ecological effects. For some hazardous constituents, federal standards or criteria have been promulgated, such as maximum contaminant levels (MCL) under the federal Safe Drinking Water Act. Criteria and standards consider exposure and toxicity information but may also incorporate other factors such as cost, treatment technology, and available analytical methods. Criteria and standards promulgated by both federal and state agencies should be considered when making cleanup level decisions, but they may not be deemed sufficiently protective on a site-specific basis. Chapter 2 summarizes state programs, while Chapters 4 and 5 provide additional details on federal and state agency programs related to cleanup level determination methods.

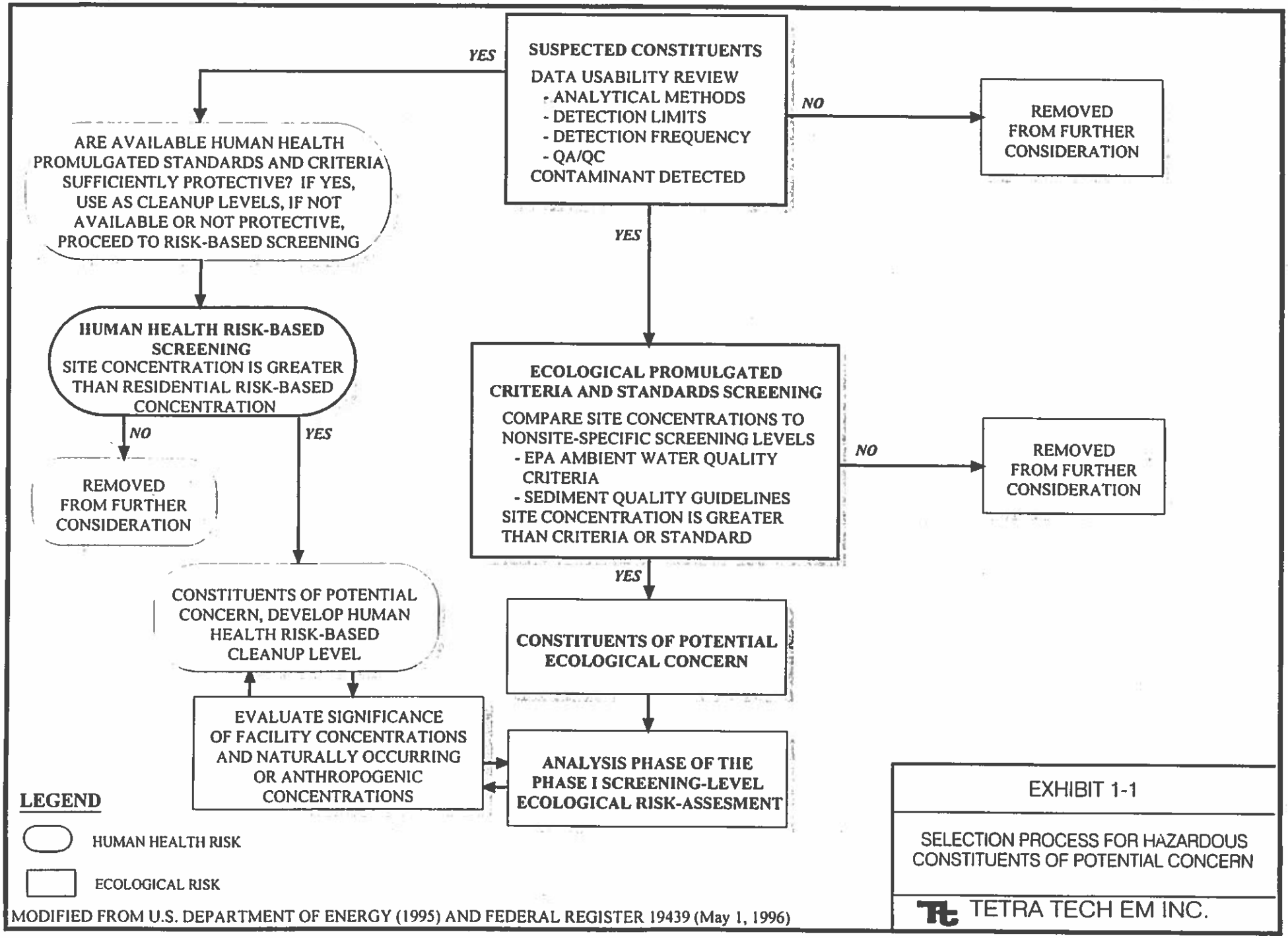
Where promulgated criteria and standards are not available or are determined to be insufficiently protective of human health or ecological components, RBCs should be calculated using risk assessment methods. Hazardous constituents of potential concern (COPC), contaminated media, and important

exposure pathway information are first identified. Exposure assumptions and toxicity values are then incorporated into risk assessment equations to derive RBCs for specific environmental media that do not pose unacceptable cancer risks, hazards, or ecological risks. The RBCs can be used in the risk management process to support the setting of cleanup levels.

A quantitative approach to deriving human health-based RBCs is presented in this guidance, while the development of ecological RBCs usually involves a tiered approach including a screening-level assessment (a qualitative assessment that is presented in this document) and a subsequent comprehensive assessment. For a HHRA, exposure and toxicity information is used to calculate specific constituent RBCs for each environmental medium. As explained in Section 4.4, constituent screening can also be performed using available human health risk-based concentrations that are based on significant exposure pathways. The HHRA is concerned with just one type of receptor: the human populations potentially affected by the facility. In an ecological risk assessment, there may be many potential ecological receptors, including both aquatic and terrestrial organisms. A complex set of exposure pathways may be associated with these receptors, based on how constituents may migrate through soil, water, sediment, air, and the food chain. Each facility will have a specific set of conditions based on the types of habitat and ecological receptors present in exposure areas. Ecological effects that may result from the complex interrelationships among chemicals taken up by the ecological receptors must be weighed and assessed in a series of judgements on the relative risks. In this way, one or more constituent-pathway-receptor combinations are identified as the greatest threats to ecological health at a facility.

Flowcharts presented in Exhibits 1-1 through 1-3 summarize the dual process of developing cleanup levels for a RCRA facility. Only environmental data of sufficient quality and quantity are used to identify COPCs. Data needs specific to the future determination of human health and ecological cleanup levels should be determined and incorporated into the RCRA facility investigation (RFI) work plan.

Exhibit 1-1 demonstrates how COPCs are identified by considering data quality, background chemical concentrations, and risk-based screening.



MODIFIED FROM U.S. DEPARTMENT OF ENERGY (1995) AND FEDERAL REGISTER 19439 (May 1, 1996)

EXHIBIT 1-1

SELECTION PROCESS FOR HAZARDOUS CONSTITUENTS OF POTENTIAL CONCERN

TETRA TECH EM INC.

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Sampling and analysis activities undertaken during the RFI should provide adequate data to evaluate all appropriate exposure pathways and chosen ecological endpoints. Chapter 3 provides guidance on data collection, data useability, and data evaluation issues. Steps to identify COPCs are also discussed in Chapter 3. Risk-based screening can be performed to focus cleanup level determinations on hazardous constituents that represent significant health concerns. Risk-based screening should be performed after facility concentrations have been compared with promulgated standards and criteria.

> Exhibit 1-2 demonstrates how human health-based cleanup levels are determined.

Once facility hazardous constituents are identified, the first step in the HHRA is identification of land use and exposure pathways. If promulgated standards and criteria are available for an identified exposure pathway and hazardous COPCs, these criteria can be used as cleanup levels. If no promulgated standards exist for a specific COPC or pathway, appropriate exposure assumptions should be made and combined with toxicity criteria to calculate RBCs. If no toxicity criteria exist, an experienced risk assessor should be consulted. If numerous COPCs are present on a facility, cleanup levels may require adjustment to assure that the total facility risk or hazard remaining after cleanup is acceptable.

> Exhibit 1-3 shows the steps in developing cleanup levels based on ecological assessment.

Problem formulation, the first step in the ecological assessment process, includes a facility reconnaissance to identify ecological components (habitats and biota) and potentially complete exposure pathways of ecological concern. Ecological COPCs are also identified during problem formulation. Incomplete exposure pathways are removed from the ecological risk assessment process but should be reevaluated if exposure pathways may be created based on future land use plans. If exposure pathways are identified for specific receptors, it should be determined whether promulgated standards or criteria exist for concentrations of COPCs for the appropriate medium. If applicable RBCs are identified, these RBCs should be considered cleanup levels. If not, it is likely that a comprehensive ecological risk assessment will be necessary to identify facility-specific cleanup levels. Interim corrective action may be determined appropriate if acute health effects (for example, fish kills) are occurring. Long-term risks require evaluation following interim

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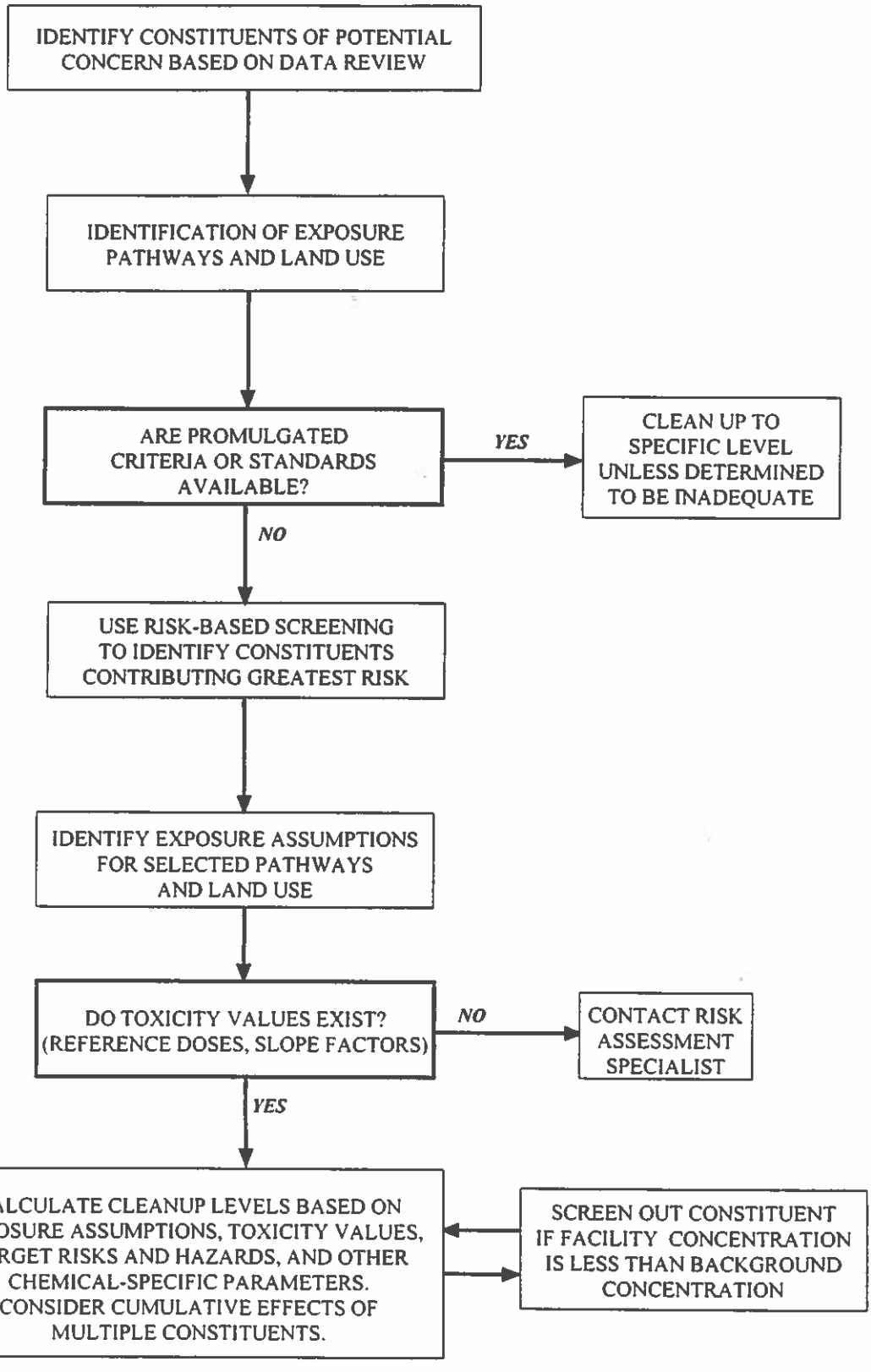

EXHIBIT 1-2

HUMAN HEALTH RISK ASSESSMENT
RCRA CLEANUP LEVEL DEVELOPMENT

TETRA TECH EM INC.

DATE 08-27-97 DDJ DN FILE NAME R:\CAD\251.R100\180700\SELCTN DS4

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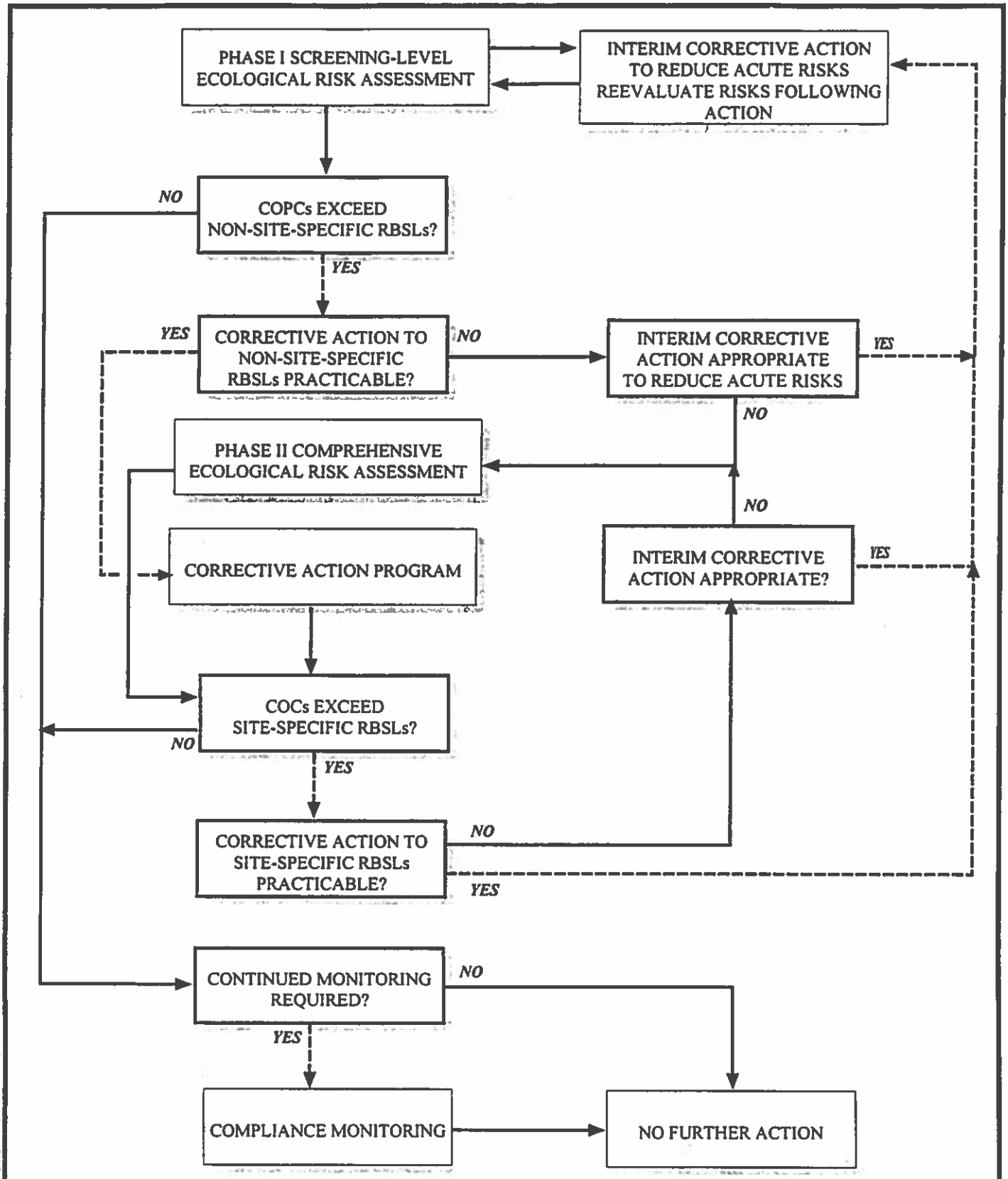

FIGURE 1-3

ECOLOGICAL RISK ASSESSMENT RISK-BASED CORRECTIVE ACTION FLOWCHART

MODIFIED FROM AMERICAN SOCIETY TESTING AND MATERIALS (1995b)

PRC ENVIRONMENTAL MANAGEMENT, INC.

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action; the focus of this guidance document is on long-term, chronic risks. Once all the necessary data are collected and evaluated, cleanup levels can be determined.

1.3 RISK CHARACTERIZATION PRINCIPLES

Data collected at a facility will typically be evaluated to determine whether corrective action is necessary and appropriate. Where risks are deemed to be significant enough to trigger remediation, cleanup levels must be determined. Risk characterization principles, which are summarized below, are an important part of the risk assessment process including the determination and communication of corrective action decisions.

Risk characterization is an important and requisite section of every risk assessment. Although the principles of risk characterization should be evident throughout, a separate section must summarize risk characterization. Risk characterization integrates information from the preceding components of the risk assessment (primarily exposure and toxicity assessment components) and synthesizes information in a manner that is complete, informative, and useful for risk managers, stakeholders, and the public. To support quantitative and qualitative estimates of risk, it is critical to provide information to explain and justify assumptions, methodologies used, and conclusions drawn. Risk characterizations should state and explain why any potential COPCs or exposure pathways were eliminated from the risk assessment at any time during the process. Risk characterizations should also discuss relative confidence in the methodologies used, the potential impact of alternative choices, and the limitations of the analysis.

Particularly critical to complete risk characterization is a clear and complete discussion of the uncertainties and variabilities associated with each of the components of the risk assessment. Uncertainty can be defined as a qualitative or quantitative lack of precise knowledge about the truth. Uncertainty is typically reducible through further measurement or study. Variability refers to the heterogeneity in a population and is usually not reducible through further measurement or study. Uncertainty discussions help to identify where additional information could contribute significantly to reducing uncertainties in risk assessment and aid decision-makers in deciding whether reduced uncertainty would add value to the overall objectives of the project. Sections 4.8 and 5.1.5 of this document identify specific risk assessment uncertainty issues for human and ecological receptors, respectively.

In a 1995 memorandum and associated policy statement concerning the EPA Risk Characterization Program (EPA 1995a and Attachment A), EPA Administrator Carol Browner stated that all risk assessments and in particular, risk characterizations, must embrace the following fundamental values:

Transparency in decision making process
Clarity in communication
Consistency between EPA programs
Reasonableness of assumptions and policies

"Transparency" refers to the decision-making process; risks must be characterized fully and openly. Risk characterizations should disclose the scientific analyses, uncertainties, and assumptions (both science- and policy-based) that underlie all decisions. "Clarity" refers to communication; the risk assessment process should help the public better understand the relative significance of environmental risks. It is important to note that risk characterization is a key component of risk communication, an interactive process involving exchange of information and expert opinion among individuals, groups, and institutions. "Consistency" and "reasonableness" refer to the core assumptions and scientific policies that are part of the risk assessment process. Consistency among EPA risk assessments is an important goal of EPA's risk characterization policy. For example, CERCLA risk assessment guidance is considered appropriate for the RCRA program, particularly because more detailed CERCLA guidance is often available. For RCRA corrective actions and Superfund remedial actions, the actual environmental results achieved through cleanup are expected to be environmentally equivalent. Further information on how the RCRA and CERCLA programs overlap is documented in the EPA Region 10 (1994a) *RCRA/CERCLA Interface-Interim Final Guidance*, which is included as Attachment B.

It is important that risk characterizations, like risk assessments themselves, be separate from risk management decisions; scientific information should be selected, evaluated, and presented without considering issues such as cost, feasibility, or how the scientific analysis might influence regulatory or facility-specific decisions. In addition, the risk assessment process does not include decisions on the public acceptability of risk levels, the value of reducing uncertainty by conducting further studies, and the appropriate procedures for reducing facility-specific risks. The risk assessment process should delineate both current and future risks because the time variable can impact site risks (for example, future risks may

be greater than current risks because of remedial activities and/or potential land usage at the site). Current or future site risks for decision making should be selected during the risk management proceedings rather than the risk characterization. The EPA (1997g) *Rules of Thumb for Superfund Remedy Selection* identifies principles that should be consulted for risk assessments and risk management decisions. These principles can be applied to RCRA corrective action programs.

CHAPTER 2
STATE PROGRAMS

U.S. Environmental Protection Agency (EPA) may grant states the authority to administer Resource Conservation and Recovery Act (RCRA) corrective action as part of their authorized RCRA permit programs. States may promulgate their own regulations. For authorized programs, these regulations must be at least as stringent as federal regulations, and EPA retains corrective action authority through statutory enforcement orders in all states regardless of authorization status.

Facilities in states without authorized RCRA permit program regulations must comply with federal regulations; however, according to the Federal Register 19457 (May 1, 1996), EPA recognizes that many states have developed independent Superfund-like authorities and cleanup programs. Consequently, when developing cleanup levels for a facility, the project manager should consider other promulgated state standards or criteria, including those regarding land use classifications that may influence cleanup level selection. Whether the corrective action is state-lead or EPA-lead, cleanup levels typically should be at least as stringent as state standards or criteria to avoid the need for the state to revisit the corrective measure taken at a facility. The burden is on the facility to ensure that both state and federal requirements are met. Unlike the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), RCRA statutory language does not include requirements to follow state standards as applicable or relevant and appropriate requirements. RCRA only requires that cleanups are "protective."

The following sections summarize the authorization status of each Region 10 state RCRA program. Only Washington State has specific regulations for an authorized RCRA corrective action program; however, other non-RCRA state cleanup programs are also identified, and the state agency and phone number are provided for obtaining further information. More specific information on state programs is included where appropriate under the human health risk assessment (HHRA) and ecological risk assessment procedure sections of this guidance. For example, state-promulgated human health standards and criteria are described in more detail under Section 4.3, Identification of Promulgated Standards and Criteria.

2.1 ALASKA DEPARTMENT OF ENVIRONMENTAL CONSERVATION

The Alaska Department of Environmental Conservation (ADEC) has not applied for authorization to manage any of the RCRA programs in lieu of EPA. ADEC is currently preparing cleanup standard regulations for contaminated sites and associated guidance documents on HHRA, petroleum risk evaluation methodology, and background calculation methodology. These cleanup regulations were proposed for public comment on December 18, 1996. Current and proposed regulations are available for download (http://www.state.ak.us/dec/dec-cal.htm#Regulation). The Contaminated Sites Remediation Program may be contacted for further information at (907) 465-5390.

2.2 IDAHO DIVISION OF ENVIRONMENTAL QUALITY

The Idaho Division of Environmental Quality (IDEQ) is authorized to operate a RCRA hazardous waste program; however, the state only has the authority to compel corrective action at RCRA facilities with RCRA permits. Idaho has not promulgated specific rules for setting cleanup levels at RCRA facilities and has followed EPA guidance. Idaho statutory language (Section 39-4404 of Idaho Code, Hazardous Waste Management Act of 1983) prohibits IDEQ from promulgating rules more stringent than existing EPA RCRA regulations. The IDEQ can be contacted at (208) 373-0502.

2.3 OREGON DEPARTMENT OF ENVIRONMENTAL QUALITY

The Oregon Department of Environmental Quality (ODEQ) is authorized to operate a RCRA hazardous waste program, including the corrective action program. According to its corrective action authorization application, ODEQ intends to rely on EPA risk assessment guidance documents and toxicological databases to determine the appropriate cleanup levels for a given facility. Oregon has not promulgated specific rules for setting cleanup levels at RCRA facilities. Facilities may calculate site-specific cleanup levels that must be approved in advance by ODEQ.

In 1995, Oregon amended its statutory authority for environmental cleanup rules (Oregon Revised Statutes 465.315 and 465.325), requiring that new rules be adopted for conducting risk assessments and defining hot spots. The rules, adopted on January 10, 1997, establish protocols for HHRA and ecological risk assessment that include deterministic and probabilistic methods. The rules apply to facilities subject

to the state's Superfund-like program. These rules are not currently a part of the state-authorized RCRA program. ODEQ's Waste Management and Cleanup Division can be contacted at (503) 229-5913 or on the Internet at http://www.deq.state.or.us/ for further information on the state's RCRA program.

2.4 WASHINGTON DEPARTMENT OF ECOLOGY

The Washington Department of Ecology (Ecology) is authorized to operate a RCRA hazardous waste program, including the corrective action program. Washington's Model Toxics Control Act (MTCA) Cleanup Regulation, amended in January 1996 under Chapter 173-340 of the Washington Administrative Code, establishes methods for calculating cleanup levels. Under the alternative authorities initiative of Ecology's corrective action authorization application, Ecology was authorized for a RCRA corrective action program that allows for the option of incorporating a MTCA order into RCRA permits to fulfill the RCRA Section 3004(u) and (v) requirements that all RCRA permits must include corrective action permit conditions. As previously noted, however, EPA retains corrective action authority through statutory enforcement orders regardless of Ecology's authorization status. In February 1996, Ecology published a *MTCA Cleanup Levels and Risk Calculations (CLARC II) Update* reference document (Ecology 1996). The MTCA cleanup regulation is described further in Chapter 4. Ecology has a comprehensive Internet site where dozens of guidances and regulations are available for download, including those pertinent to the Toxics Cleanup Program (http://www.wa.gov/ecology/tcp/cleanup.html). The Toxics Cleanup Program can also be contacted toll-free at (800) 826-7716.

The *Guidance for Clean Closure of Dangerous Waste Facilities* (Ecology 1994) provides closure guidance for interim and final status treatment, storage, and disposal facilities. The document provides direction for demonstrating compliance with the clean closure performance standards and recommends the use of MTCA residential cleanup standards.

CHAPTER 3

DATA COLLECTION TO CHARACTERIZE FACILITY AND DETERMINE HAZARDOUS CONSTITUENTS OF POTENTIAL CONCERN

Site-specific data of sufficient quality must be collected to determine facility conditions and the extent of any necessary cleanup. Guidance and reference documents that describe data collection and data review methods are summarized in the following subsections. Many of the EPA documents cited are available on the EPA Region 10 web site (http://www.epa.gov/r10earth/office/oea/r10qahome.htm). Two primary issues are addressed in Chapter 3. The first issue is identifying what data must be collected to characterize a facility. This issue can be addressed by following the data quality objectives (DQO) process defined by U.S. Environmental Protection Agency (EPA). Section 3.1 summarizes the DQO process. The second issue is identifying how the samples should be collected and analyzed to assure that the data meet useability requirements. Issues that should be considered to address data useability are described in Section 3.2. Following data generation, a data quality assessment is completed to assure that DQOs have been met. Following this assessment, the data are then used to identify constituents of potential concern (COPC). The data quality assessment and COPC identification steps are described in Sections 3.3 and 3.4, respectively. Existing facility data that have been or can be validated should be considered during the DQO process as well as used in COPC identification, risk assessment, and compliance determinations.

The DQO process must also be applied to determine whether compliance with cleanup goals has been achieved following remediation. Determining compliance with cleanup goals is described in Chapter 7 of this guidance.

3.1 DATA QUALITY OBJECTIVES PROCESS

> EPA's *Guidance for the Data Quality Objectives Process* (1994b) outlines a systematic planning process for ensuring that data of sufficient quantity and quality are collected to support defensible decision making.

EPA's DQO guidance applies to all EPA programs and can be used for Resource Conservation and Recovery Act (RCRA) corrective action situations, where the facility is typically responsible for proposing sampling and analysis activities through draft and final RCRA facility investigation (RFI) work plans. The DQO process provides a procedure for defining criteria that a data collection design should satisfy,

including when, where, and how many samples to collect. The DQO guidance recommends the use of statistical methods for identifying tolerable levels of decision errors (that is, type 1 and type 2 errors) and the number of samples required to meet these decision error levels. DQOs are defined during the first six steps of the process. The data collection design is then developed in a seventh step, based on the DQOs. All of the DQO steps should be specified in work plans submitted to the agency when sampling and analyses are being proposed.

EPA's DQO process is currently being developed and may change as guidance documents are developed and updated. The seven DQO steps are highlighted as follows and are briefly described in Sections 3.1.1 through 3.1.7. Current EPA guidance documents that provide more detail on the DQO process are also identified.

The DQO process combines elements of both planning and problem formulation in its seven-step format.

Step 1: **State the problem.** Review existing information to concisely describe the problem to be studied.

Step 2: **Identify the decision.** Determine what questions the study will try to resolve and what actions may result.

Step 3: **Identify the inputs to the decision.** Identify information and measures needed to resolve the decision statement.

Step 4: **Define boundaries of the study.** Specify time and spatial parameters as well as where and when data should be collected.

Step 5: **Develop a decision rule.** Define statistical parameter, action level, and logical basis for choosing alternatives.

Step 6: **Specify tolerable limits on decision errors.** Define limits based on the consequences of an incorrect decision.

Step 7: **Optimize the design for obtaining data.** Generate alternative data collection designs and choose most resource-effective design that meets all DQOs.

3.1.1 Step 1: State the Problem

Step 1 requires that the problem be defined. This step will include summarizing existing facility information, such as historical waste management activities and environmental data (including but not limited to information in the RCRA facility assessment). In the RFI stage, the problem is typically determining what additional data are required to characterize the type and concentration of hazardous constituents associated with releases from solid waste management units (SWMU). The problem should be defined as concisely as possible, focusing on such issues as the media of concern, land use, location of human and ecological receptors, and magnitude of contamination. A more specific problem may be what data are needed to determine whether hazardous constituents are present at concentrations greater than either preliminary background or risk-based screening concentrations.

A conceptual site model (CSM) is a useful tool for defining facility conditions and the types of data collection that may be required. EPA Superfund *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, Interim Final* (EPA 1988) provides information on how a CSM can be developed. As stated in that document, the CSM should include known and suspected sources of contamination, types of constituents and affected media, known and potential routes of migration, and known or potential human and environmental receptors. The American Society for Testing and Materials (ASTM) *Standard Guide for Developing Conceptual Site Models for Contaminated Sites* also provides guidance for developing a CSM (ASTM 1995a). The CSM can be used to help identify locations where sampling is necessary. The CSM can also be used to identify the types of exposures that may result from facility contamination and the cleanup levels required to address these potential exposures. Human health and ecological exposure issues are further discussed in Chapters 4 and 5 of this cleanup level guidance.

3.1.2 Step 2: Identify the Decision

Step 2 requires that the principle study question be identified and a decision statement defined to link the study question to possible alternative actions. The principle study question is defined by reviewing the Step 1 problem. In the RFI, the study question is likely to be "are hazardous constituents present on a SWMU at concentrations that exceed screening or preliminary background levels?" or a similar issue. Possible alternative actions that may be taken are then identified, including the alternative that "no action" is required. For example, the action related to the principle study question may be "remediation is

required if the screening level is exceeded" or alternatively, "no remediation is required if the screening level is not exceeded." These alternative actions form the basis for defining decision performance criteria in Step 6.

3.1.3 Step 3: Identify the Inputs to the Decision

In Step 3, the types of data or information that will be required to resolve the Step 2 decision statements are identified. This includes determining whether environmental measurements are required and further defining the types of measurement data. The sources of this information should be identified (for example, historical data or new data collection). For the RFI, constituent concentration levels in the media of concern will likely be required (for example, the average concentration of a constituent in soil). Other measurements such as soil and hydrogeological parameters may also be required to support site characterization through fate and transport information.

The basis for setting screening levels should also be defined in this step. Screening levels may be based on existing standards and criteria (for example, groundwater maximum contaminant levels), risk-based concentrations (RBC) (for example, soil RBCs based on residential land use), or preliminary site-specific background data (for example, background metals data).

3.1.4 Step 4: Define Boundaries of the Study

Step 4 requires that the spatial and temporal boundaries of the problem be defined. Spatial boundaries define the physical area to be studied and locations to collect samples. According to the *Geostatistical Sampling and Evaluation Guidance for Soils and Solid Media* published by EPA in 1996, temporal boundaries determine the time frame that the study data will represent and when samples should be collected (EPA 1996a).

The main purpose of this step is to identify, to the extent possible, a well defined data population that can be statistically evaluated. In an RFI, sampling should be conducted to characterize the nature and extent of contamination in areas where releases are suspected to have occurred. These study areas should focus on waste management activities to define areas with similar contamination (for example, the concentration of

a constituent released from a single SWMU). In practice, areas of homogenous contamination may not be present or readily identifiable. The EPA *Soil Screening Guidance: User's Guide* (1996b) recommends defining study areas by stratifying the site into known, suspected, and unlikely contaminated areas. The study area can also be defined as an area where contamination may be present as a hot spot, and a sampling program could provide acceptable probability that hot spots of a specific size will be detected.

In addition to segregation by waste management activities, study boundaries may be defined by the type of exposure that could occur. For example, if a large area of contaminated soil may be subdivided for future residential development, it may be necessary to subdivide the SWMU into smaller "residential size" exposure areas for data collection. Constituent releases that leave the SWMU area may enlarge the boundary of the study area (for example, a groundwater contaminant plume). In this situation, monitoring wells located along a plume's center line may define the study boundaries. The average groundwater concentration over a minimum of four calendar quarters of groundwater monitoring may define the temporal boundaries of the study (EPA 1993a).

Chapter 3 of *Methods for Evaluating the Attainment of Cleanup Standards, Volume 1: Soils and Solid Media* (EPA 1989b) provides further information on the identification of discrete study areas to determine cleanup decisions for soil. Section 2.3 of EPA's *Soil Screening Guidance: Users Guide* (1996b) also provides guidance on identifying surface and subsurface soil study areas. EPA's *Supplemental Guidance to RAGS: Estimating Risk from Groundwater Contamination* (1993a) discusses approaches for delineating groundwater exposure areas for Superfund risk assessments. Once study areas are defined, the areas will be sampled to determine whether the constituent's concentration exceeds a screening level or whether hot spots are present.

3.1.5 Step 5: Develop a Decision Rule

Step 5 requires that a decision rule be developed to define the conditions that would necessitate the choice of an alternative action. The decision rule is formed from elements defined during previous DQO tasks, including (1) the parameters of interest defined in Step 3, such as the average concentration of a constituent in soil; (2) the screening levels defined in Step 3, such as the soil RBC; (3) the study boundary defined in Step 4, such as soil located in a SWMU spill area; and (4) the principle study question and alternative actions defined in Step 2. The decision rule is an "if . . . then" statement that incorporates the

previous information. For example, if the parameter of interest (average concentration of constituent released to soil) within the study area (the SWMU spill area) is greater than the screening level (the soil RBC), then alternative action A should be taken (for example, remove contaminated soil); otherwise, alternative action B should be taken (for example, leave soil in place).

Step 3 requires that a general basis for defining facility conditions and screening criteria be defined. For example, the facility parameter of interest may be the constituent concentration at a SWMU, while the screening criteria may be a promulgated standard, a RBC, or a preliminary background level. In Step 5, the facility parameter and screening criteria must be specifically defined and incorporated into the decision rule. In the previous example, the average soil concentration of the constituent in a SWMU area is defined as the specific facility parameter, while the screening criteria is defined as a specific soil RBC (for example, residential land use RBC based on soil contact).

When determining the presence of hot spots, the decision rule must incorporate the size (radius) of the potential hot spot that may exist in the study area and the distance between sampling locations within the study area sampling grid.

More than one constituent may be present at a SWMU. For the purpose of SWMU characterization, the constituent that will require the most significant data collection to determine whether a release has occurred above screening levels should be identified and used in the decision rule. This constituent typically will exhibit the highest variability in concentration or will be detected in a concentration closest to the screening level.

3.1.6 Step 6: Specify Tolerable Limits on Decision Errors

Step 6 requires that the decisions maker's tolerable limits on decision errors be specified. The true value of the population parameter being measured (for example, the average constituent concentration) can never be exactly defined based on sampling design and measurement design errors. An error may be made during Step 5 since the decision is based on measurement data. A decision error occurs when the data mislead the decision maker into concluding that the parameter of interest is on one side of a screening level (for example, greater than the screening level) when it is actually on the other side (that is, less than

the screening level). The possibility of decision errors can never be totally eliminated, but it can be controlled. For example, a large number of samples may be collected to control sampling design errors.

Chapter 6 of *Guidance for the Data Quality Objectives Process* (EPA 1994b) explains how the probability of decisions errors can be controlled by adopting a scientific approach that incorporates hypothesis testing. The method includes (1) defining the two types of decision errors (that is, false positive [α] and false negative [β] decision errors), (2) evaluating the consequence of each error, (3) identifying the error with more severe consequences near the cleanup level, (4) defining a null hypothesis that is equal to the true state of nature that exists when the more severe decision error occurs, (5) estimating the range of parameter values near the cleanup level where the consequences of decision errors are relatively minor (defined as the grey area), and (6) assigning probability values to points above and below the grey area that reflect the decision maker's tolerable limits for making an incorrect decision.

For example, the decision maker may want to know whether a hazardous constituent is present in a SWMU at an average concentration that exceeds a screening level. The decision maker may view the consequence of deciding that the average concentration is less than the screening level when it is actually greater than the screening level as the more severe decision error. The null hypothesis would then be that the average concentration exceeds the screening level (enough data must now be collected to reject the null hypothesis if it is false). A conclusion that the concentration is less than the screening level when it is actually greater would be a false positive error, while a conclusion that the concentration is greater than the screening level when it is actually less would be a false negative error. The decision maker then establishes a grey area near the action level. The boundaries of the grey area are the action level and the point below the action level where the consequences of a false negative error begin to become significant. The actual grey area interval is the concentration range near the action level where the decision maker determines it is not necessary or feasible to control the probability of a false negative error (for example, because the consequences of this error are minor, or because the costs of collecting enough samples are prohibitively high). The decision maker then sets allowable decision error probabilities at points above (false positive errors) and below (false negative errors) the screening level, starting at the boundaries of the grey area where the consequences of errors are minor and/or expensive to control. The "tolerable limits" are the intervals of concentration above or below the grey area where allowable decision errors are set. Generally, the wider the interval, the lesser the decision error probability that will be accepted.

A similar DQO evaluation is performed when determining compliance with a cleanup level (see Chapter 7). Detailed examples of DQO evaluations have been developed by EPA (*Guidance for the Data Quality Objectives Process* [1994b], and *Data Quality Objectives Decision Error Feasibility Trials (DQO/DEFT) Users Guide* [1994c]) and are included in Attachment C.

3.1.7 Step 7: Optimize the Design for Obtaining Data

As stated in the *Guidance for the Data Quality Objectives Process* (EPA 1994b), DQOs are qualitative and quantitative statements derived from the outputs of Steps 1 through 6 that help to accomplish the following tasks:

- Clarify study objectives
- Define appropriate type of data to collect
- Determine conditions from which to collect the data
- Specify tolerable limits on decision errors to be used as the basis for establishing the quality and quantity of data needed to support the decision

Step 7 includes identifying a resource-effective data collection (sampling) strategy for generating data that are expected to satisfy the DQOs. The sampling strategy typically will focus on the sampling design, the sample size, and the analytical methods required to meet the DQOs. A primary requirement of Step 7 will be to define a statistical method for testing the Step 6 hypothesis and a sample size formula that corresponds to the statistical method and the sample design. EPA has published several guidance documents on the selection of appropriate statistical models for determining sample sizes and sample designs. These documents are listed in the Chapter 7 discussion of compliance with cleanup levels. Similar statistical models can be used in both site characterization and compliance determinations.

It is preferable to selected analytical methods that can be used to detect constituents at reasonable concentrations well below the screening levels, to reduce the potential for false negatives, and to increase confidence in the quantification of positive hits. A cost function that relates the number of samples to total cost may also be defined. The cost function may be used to support the proposal of a cost-effective

sampling strategy that meets the DQOs. Generally, the lower the probability of an error that the decision maker is willing to accept, the greater the sampling effort and costs required to meet the DQOs.

The output of Step 7 will be a sampling strategy that defines sampling design, sample numbers, and analytical methods. Section 3.2 further describes methods that should be followed to assure that the sample data collected are of acceptable quality.

3.2 DATA USEABILITY

Sampling and analysis activities should provide adequate data to evaluate all appropriate exposure pathways and chosen ecological endpoints. The sampling plan should be designed with all data uses (human health, ecological, and others uses) in mind, including attainment of cleanup levels. Hence, human health and ecological risk assessors and others must be involved in the designing of sampling plans. These plans should ensure that the issues in the data useability work sheet (Attachment D) can be adequately responded to after data have been collected.

The *Final Guidance for Data Useability in Risk Assessment Part A* (EPA 1992b) provides risk assessors and remedial project managers with nationally consistent procedures to plan and assess sampling and analysis of useable environmental data. Chapters 4 and 5 of EPA's *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A)* (EPA 1989c) discuss data collection and data evaluation, respectively.

> *The Final Guidance for Data Useability in Risk Assessment (Part A)* (EPA 1992b) discusses the six data useability criteria involved in planning an initial site investigation or an investigation to determine compliance with cleanup levels: data sources, documentation, analytical methods and quantitation limits, data quality indicators (DQI), data review, and reports to risk assessors.

3.2.1 Data Sources

The data sources selected (for example, field screening, field analytical, fixed analytical) depend on the type of data required and their intended use. The data sources must be comparable if data are combined for quantitative use. For example, field screening and fixed laboratory data should not be combined for a quantitative analysis. These separate data sources can, however, be used to complement one another. Field screening data may be used to delineate soil contamination, while fixed laboratory data would be

used to quantify the contamination. If field analytical screening results are going to be used quantitatively, it must be demonstrated that they are of sufficient quality to meet DQOs.

3.2.2 Documentation

Sample collection and analysis procedures must be fully and accurately documented to substantiate the reliability of the data derived from its analysis. The major types of documentation are quality assurance project plans (QAPP), quality management plans (QMP), standard operating procedures, field and analytical records, and chain-of custody records.

In addition, data quality indicators (DQI) (see Section 3.2.4) for assessing results against stated performance objectives should be documented in the QAPP.

EPA policy requires that all environmental data used in decision making be supported by an approved QAPP. A QAPP is required for each specific project or continuing operation. The QAPP documents how quality assurance (QA) and quality control (QC) are applied to an environmental data operation to assure that the results obtained are of the type and quality needed for a specific decision or use. QA is an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected. QC is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements.

Current EPA requirements for QAPPs are presented in the *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980). Current EPA requirements for QMPs are presented in the *Guidelines and Specifications for Preparing Quality Assurance Program Plans* (EPA 1979). EPA is updating the QA/QC requirements. The updated document, *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*, is currently in the draft interim final stage (EPA 1994d). A draft interim final version of *EPA Guidance on Quality Assurance Project Plans (QA/G-5)* is also available, as is the draft updated document, *EPA Requirements for Quality Management* Plans (EPA 1994e) which will replace the quality assurance program plan guidelines. EPA Region 10's quality assurance office has indicated that use of the draft documents is preferable to the use of older

documents, but ultimately that is the decision of the RCRA project manager. The EPA Region 10 web site contains news about the finalization of the draft documents (http://www.epa.gov/r10earth/office/oea/r10qahome.htm). In addition, Federal Register 19445 (May 1, 1996) cites *Quality Assurance Project Plans for RCRA Ground-Water Monitoring and Corrective Action Activities* (EPA 1993b) guidance for information on incorporating DQOs in the decision-making process at RCRA facilities.

The Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans (EPA 1980) describe 16 elements that must be considered for inclusion in all QAPPs, recommend the format to be followed, and specify how plans will be reviewed and approved. All QAPPs must describe procedures that will be used to document and report precision, accuracy, and completeness of environmental measurements. The 16 essential elements described must each be considered and addressed unless it is documented that a particular element is not relevant to the project.

3.2.3 Analytical Methods, Detection Limits, and Quantitation Limits

Analytical methods selected should meet the required detection limits for metals and quantitation limits for nonmetals that are at or below facility-specific screening or cleanup levels. If facility-specific cleanup levels have yet to be determined, the EPA Region 9 preliminary remediation goals (PRG) described in Section 4.5 and presented in Attachment E can be used to determine adequate detection and quantitation limits for protection of human health (using a hazard quotient [HQ] of 0.1; Region 9 PRGs are based on a HQ of 1.0) (EPA 1996c). The term "PRG" has the same meaning as "risk based concentration (RBC)." Appendix III of the *Final Guidance for Data Useability in Risk Assessment (Part A)* (EPA 1992b) lists various analytical methods and associated detection and quantitation limits by chemical for human health. Ecological data quality levels developed by EPA Region 5 (1995b) can be used to determine adequate detection and quantitation limits for ecological health. A chemist should be consulted for assistance in choosing an analytical method when those available have detection or quantitation limits near the cleanup level or PRG.

3.2.4 Data Quality Indicators

DQIs are identified during the development of the DQOs to quantitatively measure the achievement of QA objectives. The five DQIs discussed by EPA (1992b) are completeness, comparability, representativeness,

precision, and accuracy. QA objectives for these DQIs should be listed in the QAPP. Precision is a quantitative measure of variability, comparing facility samples to the mean. Results of QC samples (field and/or laboratory duplicates) are used to calculate the precision of the analytical or sampling process. Accuracy is a measure of the closeness of a reported concentration to the true values. This measure is usually expressed as bias (high or low) and is determined by calculating percent recovery from spiked samples. Completeness is a measure of the amount of useable data resulting from what was planned for a data collection effort. Representativeness is the extent to which data define the conditions at a facility. Comparability refers to the ability to combine or compare results across sampling episodes and time periods.

3.2.5 Data Review

DQOs dictate the level and amount of data review required. The level of data review refers to which evaluation criteria are selected, ranging from generalized criteria (for example, holding time) to analyte-specific criteria (for example, recovery of a surrogate spike for organic compounds or analyte spike recovery for inorganic compounds). Analytical results, QC sample results, and raw data for chemicals analyzed to determine compliance with cleanup levels should undergo a full data review. A full data review is very labor intensive and includes checking the raw laboratory data against a number of data review criteria and spot checking (recalculation) values reported by the laboratory. A partial data review may only involve looking at the summary QC information reported by the laboratory. A full data review minimizes false positives, false negatives, calculation errors, and transcription errors. EPA data review guidance for Contract Laboratory Program data includes *U.S. Environmental Protection Agency Contract Laboratory Program National Functional Guidelines for Organic Data Review* (1994f) and *U.S. Environmental Protection* Agency *Contract Laboratory Program National Functional Guidelines for Inorganic Data Review* (1994g). Data review criteria presented in these guidance documents must be considered when developing the site-specific QAPP; however, some aspects of these documents may not be applicable to a specific site or some types of analyses. Generalized and analyte-specific criteria must be presented in the site-specific QAPP. When large numbers of samples (50 or more) are collected, the amount of data to be reviewed should be determined based on expense, types of analyses, and historical knowledge.

The data review must provide a narrative summary describing specific sampling or analytical problems, data qualification flags, level of review (full or partial and what was reviewed), detection and quantitation limit definitions, and interpretation of QC data.

The decision maker must consider the completeness of the data and verify that detection and quantitation limits were adequate to distinguish constituent concentrations from cleanup levels. All validated, useable data should then be considered during the data quality assessment (Section 3.3) to determine whether the sample design and the resulting validated data set are adequate for characterizing the facility and determining compliance with cleanup levels.

3.2.6 Reports from Sampling and Analysis

Preliminary reports assist in identifying sampling or analytical problems early enough so that corrections can be made during data collection and before sampling or analysis resources are exhausted.

3.3 DATA QUALITY ASSESSMENT

Data collected and validated in accordance with the QAPP must be assessed to determine whether the DQOs have been satisfied. EPA *Guidance for Data Quality Assessment* (1996d) describes data quality assessment (DQA) methods. The primary objective is to determine whether the collected data meet the DQO assumptions and whether the data user can then make a decision with the desired confidence. A preliminary data review should also be performed to evaluate the structure of the data (for example, common statistical parameters and data distribution type) and assess the accuracy of the sampling design. Data characteristics should be consistent with statistical assumptions made during the DQO process (for example, distribution type, nondetection frequency, variance). If the data do not support underlying statistical assumptions, corrections must be performed to meet the decision maker's needs. This may include the selection of a different statistical approach or the need for additional data collection and a revised sampling design. Once an appropriate statistical test has been identified, the DQO decision rule is tested to reach a conclusion regarding compliance with the screening level (EPA 1996d).

3.4 IDENTIFICATION OF HAZARDOUS CONSTITUENTS OF POTENTIAL CONCERN

COPCs should be identified so that a risk assessment or cleanup level determination can be focused on hazardous constituents that pose the primary health threat. To identify COPCs, the data useability review and DQA discussed in Sections 3.2 and 3.3 are first performed. Sampling data that have been validated and determined to meet QAPP requirements should be considered, and all constituents detected should initially be included as COPCs. All data should be summarized and submitted to regulatory agency personnel. Deliverables should include the following information for all data including detected and non-detection sample results: sampling date, sample location map, sample media, sample detection limits, sample results, and sample qualifiers.

If the purpose of COPC identification is to perform a risk assessment, then risk-based screening is the next step of the COPC identification process. Hazardous constituents in each medium present at maximum concentrations which are below certain RBCs can be screened from further consideration. If the purpose of the COPC identification is to calculate cleanup levels, the risk-based screening step should be performed after promulgated standards and criteria have been considered for cleanup levels. As further described in Section 4.3, available criteria and standards should be used as cleanup levels unless determined on a facility-specific basis to be insufficiently protective of human health and the environment.

Since human health and ecological risk-based screening methods may vary, risk-based screening approaches are described in Section 4.4 (human health) and Chapter 5 (ecological). Following data evaluation and relevant risk-based screening, the remaining COPCs should be carried through the human health risk assessment or considered in the cleanup level determination. Exhibit 1-1 presents the COPC screening process relative to setting cleanup levels.

A preliminary background evaluation may be performed to determine whether the detected constituents are related to the facility or potentially associated with background or ambient conditions. The background evaluation is typically performed only for inorganic compounds that may naturally occur in soil or water; however, the evaluation of organic constituents may also be performed on a case-by-case basis if it can conclusively be determined that nonfacility-related organic contamination is present. Likewise, inorganic compounds associated with nonfacility-related anthropogenic sources may require evaluation, such as releases of lead from leaded gasoline. The DQO process and associated guidance

documents discussed in Section 3.1 and Chapter 7 should be followed when collecting data for facility and background comparisons. The collected data are evaluated to determine that requirements specified in the QAPP, including DQOs, have been met. The background data are then compared with site data using the appropriate statistical tests identified during the DQO and DQA steps.

Elimination of constituents from the quantification of facility risks, based on claims or assumptions that the constituents are not related to the facility, should not be allowed unless the following can be demonstrated: adequate sampling, analyses, and statistical tests conducted following DQO and DQA procedures should indicate that the constituents truly are not related to the facility. Any constituents that are eliminated from the quantification of risk based on background conditions must be carried through to the risk characterization section of the risk assessment, where they should be discussed qualitatively along with a description of the justifications for the elimination. In the absence of sufficient evidence, background screening should not be performed before risk assessment or cleanup level determinations. Additional data may be collected if constituents suspected (but not adequately demonstrated) to be nonfacility-related have a significant impact on cleanup level determinations (for example, if they are present at concentrations above cleanup levels or if they have a significant effect on a cleanup level incorporating risks from multiple constituents).

A generalized approach for comparing facility conditions with background is presented by the EPA (1994h) in the *Region 8 Superfund Technical Guidance, RA-03: Evaluating and Identifying Contaminants of Concern for Human Health*, included as Attachment F. In the guidance, EPA describes two types of statistical comparisons that can be made between samples collected from background and contaminated facilities: (1) distributional tests and (2) extreme value tests. EPA describes each comparison type and recommends specific distributional tests. The distribution of the facility and background data sets as well as the percent of detections in each data set are considered when selecting appropriate tests. Attachment F should be consulted for further information on background statistical testing. In addition, the following updated information should also be considered:

- The *Guidance for Data Quality Assessment, Practical Methods for Data Analysis* (EPA 1996d) provides information on summarizing data and performing statistical tests. EPA will also soon publish the "Data Quality Evaluation Statistical Toolbox (DATAQUEST)" software, which will include software for running some statistical tests.

- In addition to the Wilcoxon rank sum test and student's t-test cited by EPA Region 8 (1994h) for distributional tests, the quantile test can be used to check for extreme values. Other nonparametric (distribution free) outlier tests that are designed to test groups of data may be substituted for the quantile test.

- At the decision points involving percent detections on Figure 2 in Attachment F (EPA 1994h), if <u>either</u> data set (background or facility) is less than the criterion, use the "less than" or "yes" branch.

- If more than half of the results in either data set are nondetected, use a test of proportions with a suitable choice of percentile (see Section 3.3.2.1 of EPA 1996d) instead of the Wilcoxon rank sum or quantile tests. If the data set are not comparable (that is, there are major differences in the quantitation limits for the nondetected results), consult a statistician.

Additional reference information is presented in a letter regarding background comparison methods for Rocky Flats Plant prepared by Richard O. Gilbert, Ph.D. (1993). The letter identifies a variety of statistical tests that can be used for background comparisons, including many of the tests identified in the EPA documents cited in Chapters 3 and 7. The report describes a series of parametric and nonparametric tests and also recommends that a "hot measurement" comparison be performed to identify hot spots (extreme values). Examples of how to perform the statistical tests are presented. More detailed information on statistical testing can be obtained from *Statistical Methods for Environmental Pollution Monitoring* (Gilbert 1987).

The EPA *Determination of Background Concentrations of Inorganics in Soils and Sediments at Hazardous Waste Sites* (1995c) report also provides guidance on technical issues that must be considered when determining whether a site contains elevated levels of inorganic compounds relative to the local background concentrations. Technical issues discussed include the selection of background sampling locations, considerations in the selection of sampling procedures, and statistical analyses for determining whether constituent levels are significantly different on a potential waste site and a background site.

CHAPTER 4

HUMAN HEALTH RISK ASSESSMENT PROCEDURES

Data collected during a Resource Conservation and Recovery (RCRA) facility investigation (RFI), ongoing monitoring results, and any other available applicable and useful environmental sampling information are used to assess risks to human health and the environment so it can be determined whether there is a need for corrective action.

Four primary risk assessment steps:

- Data collection and evaluation
- Exposure assessment
- Toxicity assessment
- Risk characterization

The data collection and evaluation step is described in Chapter 3: relevant site data are collected, and the data are determined to be of acceptable quality for risk assessment. Exposure assessment, toxicity assessment, and risk characterization are described in this chapter. The exposure assessment and toxicity assessment steps may be performed concurrently. During the exposure assessment step, (1) constituent releases, (2) exposure pathways into which constituents may then migrate, and (3) potential human exposures to constituents that may occur are all identified. Constituent concentrations in exposure pathway media and resulting constituent doses to humans are calculated during the exposure assessment. During the toxicity assessment, toxicity factors are compiled. Toxicity factors represent the relationship between the constituent dose received by a person and the resulting adverse response that may occur. The results of the exposure and toxicity assessments are combined during the risk characterization step to characterize the potential for adverse health effects to occur. During the risk characterization step, cancer risks and noncancer hazards are estimated quantitatively where possible.

This chapter on human health procedures focuses on how to develop facility-specific media cleanup standards for the protection of human health. The type of exposure pathways and land uses that may occur on the facility must first be determined (Sections 4.1 and 4.2). Available media-specific criteria and standards are then identified (Section 4.3) since they are frequently used as cleanup levels. When promulgated standards and criteria do not exist, protective media cleanup standards can be developed using the human health risk assessment (HHRA) method. Hazardous constituents can first be screened using preliminary (that is, nonfacility-specific) risk-based concentrations (RBC) to identify constituents of potential concerns (COPC) (that is, those constituents present at concentrations at or above concentrations

that may be associated with significant health concern) (Section 4.4). Facility-specific RBCs are then calculated for the COPCs using the exposure assessment, toxicity assessment, and risk characterization steps. Exposure parameters and toxicity values are identified for COPCs (Sections 4.5 and 4.6). The exposure and toxicity information is then combined to calculate a health-based RBC that correlates with a target, or acceptable, risk level once that level has been determined (Section 4.7). Facility-specific RBCs may then be used as the basis for setting risk-based cleanup levels. COPCs that may be nonfacility-related, such as naturally occurring metals, should be compared with background levels before final cleanup level determinations are made. This process is discussed in Section 3.4.

4.1 EXPOSURE ASSESSMENT: IDENTIFICATION OF EXPOSURE PATHWAYS

The steps of an exposure assessment include characterization of the exposure setting, identification of exposure pathways, and quantification of exposure. In the first step, the facility is characterized with respect to the general physical characteristics (for example, climate, vegetation, groundwater hydrology, surface water) and the characteristics of the potentially exposed populations on or near the facility. This section discusses the second step: identification of exposure pathways. The third step, quantification of exposure, is discussed in Sections 4.5 through 4.7. For additional exposure assessment discussions, see the U.S. Environmental Protection Agency (EPA) *Exposure Assessment Guidelines* (1992c), *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A)*, (RAGs) Chapter 6 (1989c), and the *Exposure Factors Handbook* (1989d and 1996e update).

Exposure is defined as the contact of a person with a chemical or physical agent. There are three primary routes by which hazardous constituents released to the environment can enter the body: ingestion, inhalation, and dermal contact. Exposure pathways are the course a constituent takes from a source to an exposed organism (for example, soil ingestion, or inhalation of volatiles from groundwater). A **complete exposure pathway** consists of the following four elements: (1) a source and mechanism of chemical release, (2) a retention or transport medium, (3) a point of potential human contact with the contaminated medium, and (4) an exposure route (for example, ingestion) at the contact point.

Table 4-1 summarizes potential exposure pathways (also called exposure routes) for human receptors at a typical facility. The identification of complete exposure pathways at a facility is necessary to ensure that health-based cleanup levels protective of all potential receptors can be developed. Any person who might be exposed to facility-related constituents by one or more pathways is considered a receptor.

TABLE 4-1

POTENTIAL EXPOSURE PATHWAYS FOR HUMAN RECEPTORS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Contaminated Medium	Exposure Scenario	Potential Exposure Pathway	Important for Calculation of Cleanup Levels
Groundwater	Residential use as potable water	Ingestion of water	Yes
		Inhalation of volatile compounds	Yes, if volatiles present
		Dermal contact with water	Site-specific determination
	Agricultural uses	Transfer to food crops or livestock and subsequent ingestion	Site-specific determination
	Industrial use as potable water	Ingestion of water	Yes
		Inhalation of volatile compounds	Site-specific determination
		Dermal contact with water	Site-specific determination
Surface water and sediment	Residential or industrial use as potable water	Ingestion of water	Site-specific determination
		Inhalation of volatile compounds	Site-specific determination
		Dermal contact with water	Site-specific determination
	Agricultural uses	Transfer to food crops or livestock and subsequent ingestion	Site-specific determination
	Recreational or subsistence fishing	Consumption of fish and seafood	Site-specific determination
	Recreational use or trespasser	Ingestion of water	Site-specific determination
		Dermal contact with water	Site-specific determination
		Ingestion of sediment	Site-specific determination
		Dermal contact with sediment	Site-specific determination

TABLE 4-1 (Continued)

POTENTIAL EXPOSURE PATHWAYS FOR HUMAN RECEPTORS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Contaminated Medium	Exposure Scenario	Potential Exposure Pathway	Important for Calculation of Cleanup Levels
Soil	Residential uses	Incidental soil ingestion	Yes
		Dermal contact with soil	Yes
		Inhalation of particulates/volatile compounds from soil	Yes
		Soil as potential source to groundwater	Site-specific determination
	Agriculture uses	Consumption of produce, meat, milk	Site-specific determination
	Industrial uses	Soil ingestion	Yes
		Dermal contact with soil	Yes
		Inhalation of particulates/volatile compounds from soil	Yes
		Soil as potential source to groundwater	Site-specific determination
Air	Residential uses	Inhalation of particulates/volatile compounds from stack or other emissions	Site-specific determination
	Industrial uses	Inhalation of particulates/volatile compounds from stack or other emissions	Site-specific determination

Source: Modified from U.S. Environmental Protection Agency 1991a

Exposure pathways are identified within each pertinent exposure scenario. Several exposure scenarios may be applicable at a given facility. Those most commonly evaluated are the industrial and residential exposure scenarios. Other scenarios, including agricultural, recreational, and trespasser, may be important depending on facility location and identification of the most exposed individual. For example, if the individual subject to the greatest exposure to facility-related constituents is a recreational user of a surface water body, a recreational exposure scenario may be sufficiently protective. Classification of land use is further discussed in Section 4.2.

Cleanup levels should be determined for all exposures to a specific medium, such as soil. The cleanup level calculated for each medium should take into consideration all exposure pathways and all facility-related constituents that contribute to risk or hazard. For example, the cleanup levels for soil should be developed using all possible exposure routes for soil that are appropriate at a facility. It is recommended that ingestion, dermal contact, and inhalation exposure routes be considered when developing cleanup levels for all media. Where exposure may occur to a constituent in both soil and water, media-specific cleanup levels may require further downward adjustment to assure that an acceptable cumulative target risk level is met.

4.2 CLASSIFICATION OF LAND USE

The evaluation of a facility to determine appropriate cleanup levels is based in part on the appropriate land use scenario.

Depending on assumptions regarding future facility uses, either a residential scenario or an industrial scenario is typically chosen.

A residential scenario results in more conservative (that is, lower) cleanup levels, because it is assumed that adults and children live on the site and are exposed to hazardous constituents 24 hours a day. In the industrial scenario, exposure is assumed only for adults and only during working hours.

Selection of land use is most relevant when calculating cleanup levels that address direct contact with soils. The following two subsections discuss EPA and Region 10 state policies or regulations regarding land use and soil cleanup levels. An additional subsection discusses land use issues associated with setting

groundwater, surface water, and air cleanup levels. Later discussions in Section 4.3 identify specific numerical standards and criteria that must be considered when setting cleanup levels.

Of the Region 10 states, only the Washington Model Toxics Control Act (MTCA) regulations have been authorized for setting RCRA corrective action cleanup levels. Details of MTCA regulations relevant to land use are therefore summarized. More general information on other state regulatory programs is also presented because project managers and facilities are encouraged to take into consideration non-RCRA state standards or criteria, including those regarding land use classifications that may influence cleanup level selection. Consideration of state regulations and land use classifications will avoid the need for the state to revisit the corrective measure taken at a facility. Overall, the most stringent land use requirement that may apply to a facility should be used for risk assessment and setting cleanup levels.

4.2.1 U.S. Environmental Protection Agency Land Use Policy and Soil Cleanup Levels

EPA's policy is that "current and reasonable expected future land use and corresponding exposure scenarios should be considered both in the selection and timing of remedial actions" (Federal Register [FR] 19452, May 1, 1996). EPA's May 25, 1995, directive, *Land Use in the CERCLA Remedy Selection Process* addresses land use consideration under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) process (directive is attached as Attachment G) (EPA 1995d). The directive identifies sources and types of information that may aid EPA in determining the reasonable anticipated future land use at a site. Examples of such information include zoning laws, community master plans, site location in relation to current land uses and populations, groundwater protection programs, and environmental justice issues. The directive recommends early discussions between EPA and local land use planning authorities, local officials, and the public regarding reasonably anticipated future land uses.

The principles identified in the directive are equally applicable to the RCRA corrective action program (proposed Title 40 of the Code of Federal Regulations, Part 264 Subpart S Amendment, FR 19439, May 1, 1996). Available information and local input may indicate that nonresidential land use assumptions are appropriate for corrective action facilities if there is reasonable certainty that the facility will remain industrial. Factors such as residential properties located adjacent to or on an industrialized facility or child care areas operated on commercial and industrial facilities should be considered when determining land

use. If the type of future land use cannot be reasonably predicted or if future residential land use (as well as child care centers and recreational parks) cannot be reasonably ruled out, residential land use should be assumed.

EPA is committed to ensuring that the public fully participates in all aspects of the RCRA corrective action. EPA released a detailed guidance manual on public participation in RCRA programs (EPA 1993c) and followed this guidance with a RCRA Expanded Public Participation Rule (FR 63417, December 11, 1995). EPA regards public participation as an important activity that empowers all communities, including minority and low income communities, to become actively involved in local waste management activities. This should include public participation in making land use and exposure assumption decisions, particularly for communities potentially impacted by waste management activities and the risk management decisions associated with corrective action.

EPA expects that contaminated soils will be cleaned up as necessary to prevent the transfer of unacceptable concentrations of hazardous constituents from soils, including subsurface soils, to other media; therefore, the uses of groundwater and surface water potentially impacted by constituent migration from soil must be considered when cleanup levels are set. Likewise, the location of adjacent or nearby residents potentially exposed to airborne constituents must also be considered.

4.2.2 Region 10 State Land Use Policies and Soil Cleanup Levels

The Washington State MTCA cleanup regulations specify when cleanup levels may be based on residential or industrial land uses and were amended in 1996 under Chapter 173-340 of the Washington Administrative Code (WAC). WAC 173-340-740 requires that the residential land use scenario be assumed unless a demonstration of nonapplicability can be made under subsection 740(1)(a). Industrial property soil cleanup levels can be established as follows if the site meets the definition of an industrial property cited under the WAC 173-340-200:

"Industrial properties" means properties that are or have been characterized by or are to be committed to traditional industrial uses such as processing or manufacturing of materials, marine terminal and transportation areas and facilities, fabrication, assembly, treatment, or distribution of manufactured products, or storage of bulk materials. One of the following statements is true for industrial properties:

- Zoned for industrial use by a city or county conducting land use planning under Chapter 36.70A Revised Code of Washington (RCW) (Growth Management Act)
- For counties not planning under Chapter 36.70A RCW (Growth Management Act) and the cities within them, zoned for industrial use and adjacent to properties currently used or designated for industrial purposes

WAC 173-340-745 provides additional criteria for determining whether a land use not specified in the definition meets the "traditional industrial use" requirement or whether a land use zoning category meets the requirement of being "zoned for industrial use." In addition, WAC 173-340-745 requires an evaluation of comprehensive plan text or zoning code to verify that only industrial land uses may occur on the site. WAC 173-340-745 also requires that residential soil cleanup levels be used at industrial properties in close proximity to (generally, within a few hundred feet) residential areas, schools, or child care facilities, unless site or constituent inaccessibility and constituent immobility can be demonstrated. Likewise, residential soil cleanup levels should be used for current or potential future residential areas adjacent to properties currently used or designated for industrial purposes. State of Washington *Guidance for Clean Closure of Dangerous Waste Facilities* (Washington Department of Ecology [Ecology] 1994) specifies that according to WAC 173-303-610(2)(b)(I), numeric clean closure levels for soils, groundwater, surface water, and air must be determined using residential exposure assumptions.

State of Oregon environmental cleanup law (Oregon revised Statutes 465.315 and 465.325), promulgated on January 10, 1997, requires that current and reasonably anticipated future land uses be considered in risk assessments and feasibility studies. As previously stated, this law (and the rules promulgated pursuant thereto) is for state Superfund sites and is technically not part of the Oregon Department of Environmental Quality authorized corrective action program for RCRA-regulated facilities. Idaho and Alaska have not developed specific regulations or guidance documents that address land use issues. Idaho accepts the use of cleanup levels based on residential and industrial land use (Tetra Tech 1996a). Land use is addressed in proposed Alaska Cleanup Standard Regulations and Risk Assessment Guidance (proposed for public comment on December 18, 1996) (Tetra Tech 1996b). State-specific rules and regulations, which are evolving, should be consulted for further information.

4.2.3 Land Use Policies and Other Media

Determination of cleanup levels for groundwater, surface water, and air is the same for all facilities regardless of the site's land use classification as industrial or residential. EPA Region 10 recommends that residential exposures be assumed and that exceptions be made only for extenuating circumstances.

Corrective actions for soil and groundwater media should assure that discharges from either media do not exceed surface water, sediment, or air quality standards or risk-based criteria. Sections 4.2.3.2 (Surface Water), 4.2.3.3 (Air), 4.3 (Standards and Criteria) and Chapter 5 (Ecological Sediment Criteria) provide information on land use and standards and criteria for these media.

4.2.3.1 Groundwater

EPA expects to return useable groundwaters to their maximum beneficial uses wherever practicable. When restoration of groundwater is not practicable, EPA expects to prevent or minimize further migration of the plume, prevent exposure to the contaminated groundwater, and evaluate further risk reduction (FR 19448, May 1, 1996). State-designated uses should be considered when setting cleanup levels. As previously noted, however, although RCRA statutory language does not require nonauthorized state standards to be followed, it does require cleanups to be protective of human health and the environment.

EPA has initiated a comprehensive state groundwater protection program (CSGWPP) to encourage each state to coordinate its current and planned groundwater protection activities through a CSGWPP. EPA remediation program personnel should be familiar with and utilize CSGWPPs (EPA 1997h). Washington State has submitted a draft CSGWPP to EPA and was responding to EPA comments to the proposed plan at this printing. No other Region 10 states have submitted a CSGWPP to EPA; however, Oregon and Idaho have initiated CSGWPPs, and the following listed persons can be contacted regarding groundwater use issues (for example, for information on groundwater classified as a source of drinking water or as having significant ecological value).

STATE GROUNDWATER PROTECTION PROGRAM CONTACTS	
Washington	
Groundwater protection	Kurt Cook, Department of Ecology (360) 407-6415
Wellhead protection	David Jennings, Department of Health (360) 586-9041
Oregon	
Groundwater protection	Amy Patton, ODEQ (503) 229-5878
Wellhead protection	Cheree Stewart, ODEQ (503) 229-5413
Idaho	
Groundwater and wellhead protection	Donna Rodman (208) 373-0260

The Washington State draft CSGWPP proposes a groundwater protection goal based on the state's anti-degradation policy contained within Chapter 90.48 of the Revised Code of Washington (RCW) (Water Pollution Control), Chapter 90.54 RCW (Water Resources Act of 1971), and Chapter 173-200 WAC (Water Quality Standards for Groundwater). The antidegradation policy applies to all state regulatory programs and requires that existing and future beneficial uses of groundwater be maintained and that degradation that interferes with these uses be prevented. All groundwater in the state is similarly protected. Three tiers of groundwater quality standards are specified: (1) numerical Federal Safe Drinking Water Act maximum contaminant levels (MCL), (2) natural background concentrations, or (3) site-specific early warning values (WAC 173-200) (Ecology 1995a). When prevention of groundwater contamination is not possible and where remediation measures are required, Washington State has set attainment of federal safe drinking water act MCLs as remediation goals (Ecology 1995a). In addition, Washington State has promulgated cleanup regulations under MTCA (WAC 173-340).

Washington State MTCA regulations require that the highest beneficial use of groundwater (that is, drinking water and other domestic uses) be assumed when setting cleanup levels unless the following criteria cited in WAC 173-340-720 can be demonstrated. In general, these criteria include demonstrating

that the groundwater is not a current or future source of drinking water based on the following: (1) the groundwater is present in insufficient quantity to yield water for a domestic well; (2) natural background concentrations of organic or inorganic constituents are present and make use of the water for drinking not practicable; and (3) the groundwater cannot technically be recovered for drinking water purposes based on depth or location. It also must also be demonstrated that migration of contamination from an unusable aquifer to a useable aquifer cannot occur. Information on specific MTCA cleanup goals is presented in Section 4.3.2.

State of Alaska beneficial use regulations, applicable to both groundwater and surface water, are cited in Title 18 Alaska Administrative Code (AAC) Chapter 70, "Water Quality Standards." State of Oregon, groundwater beneficial use regulations are cited in Oregon Administration Rules (OAR), Chapter 340, Division 40, "Groundwater Quality Protection." State of Idaho groundwater beneficial use regulations are cited in the Idaho Administrative Code (IAC), Title 01, Chapter 02, Section 299, "Groundwater Quality Standards." The state-specific rules and regulations should be consulted for further information.

4.2.3.2 Surface Water

The proposed RCRA corrective action regulations recommend that state-designated uses of surface water be considered when setting cleanup levels (proposed 40 CFR 264 Subpart S Amendment, FR 30804, July 27, 1990). Promulgated state and federal drinking water standards or risk-based levels based on water ingestion can be used as cleanup levels for surface water designated for drinking water use. If surface water has been designated by a state for uses other than drinking water, the EPA may consider the state-designated use when establishing cleanup levels (FR 30818, July 27, 1990). In any case, federal Clean Water Act (CWA) prohibitions of releases of hazardous substances and oil to surface waters should be considered when determining cleanup levels [(CWA 311 (b) (3)].

Washington State MTCA regulations require that the highest beneficial use of surface water be assumed when setting cleanup levels (WAC 173-340-730). Promulgated standards or risk-based levels based on water ingestion should be used as cleanup levels for surface waters representing a source or potential future source of drinking water. Risk-based standards based on human ingestion of fish or shellfish should be considered when determining cleanup levels for surface waters that support or have the potential to support fish or shellfish populations. Federal (CWA) (EPA 1986a) and state water quality criteria based

on the protection of aquatic organisms must also be achieved. Washington State surface water beneficial use and water quality standard regulations are cited in WAC 173-201.

As noted in Section 4.2.3.1, State of Alaska surface water beneficial use and water quality standards are cited in Title 18, AAC, Chapter 70. Oregon surface water beneficial use and water quality standards are cited in OAR, Chapter 340, Division 41, "State-Wide Water Quality Maintenance Plan, Beneficial Uses, Policies." Idaho surface water beneficial use standards are cited in IAC, Title 01, Chapter 02, Section 200, "General Surface Quality Criteria." The state-specific rules and regulations should be consulted for further information.

4.2.3.3 Air

A residential exposure scenario is assumed when calculating air cleanup levels (FR 30831, July 27, 1990); however, the location of the most exposed resident must be identified when determining compliance with the cleanup level. The point where the maximum long-term human exposure to air releases would occur is typically outside of a facility boundary. Under the corrective action process, the most exposed individual is identified on a site-specific basis and may be identified as someone living across the street from the facility, as a worker living on the site, or wherever else maximum long-term human exposure would occur based on site characteristics (FR 30831, July 27, 1990). For clean closure, it is assumed that the most exposed individual is at the unit boundary and that air constituent concentrations must be equal to or below the health-based level at the unit boundary (EPA 1989e).

Alaska, Idaho, and Oregon do not have specific requirements for setting air cleanup standards at RCRA facilities. Washington State MTCA regulations require that cleanup levels to protect air quality be based on estimates of reasonable maximum exposure (RME) (WAC 173-340-750), the highest exposure that can be reasonably expected to occur at a site under current or potential future uses. The cleanup level, therefore, should be based on the residential scenario unless the criteria specified in WAC 173-340-750 for nonresidential site uses can be demonstrated. The WAC 173-340-750 criteria generally require that no current or future residential use of the site occur and that air emissions from the site not reduce the air quality of adjacent residential areas. WAC 173-340-750 requires that ambient air cleanup levels for nonresidential uses be established on a case-by-case basis.

4.3 IDENTIFICATION OF PROMULGATED STANDARDS AND CRITERIA

When developing cleanup levels for a facility, promulgated standards or criteria for environmental media contaminated by facility activities must be considered. Federal and state standards and criteria that should be considered when developing cleanup levels are summarized in Sections 4.3.1 (federal) and 4.3.2 (state). The state and federal policies and regulations addressing land use discussed in Section 4.2 require consideration when selecting appropriate standards and criteria.

4.3.1 Federal Standards and Criteria

Federal standards exist for drinking water supplies and surface water bodies. Under the federal Safe Drinking Water Act, MCLs, maximum contaminant level goals (MCLG), and secondary MCLs are established for a number of inorganic and organic chemicals in drinking water supplies. MCLs may be used as cleanup levels for groundwaters and surface waters that are current or potential drinking water resources, provided they are deemed to be sufficiently protective given the overall contamination at or from the facility. In other words, it is discretionary to use risk-based levels rather than MCLs for determining cleanup levels which may impact drinking water because some MCLs are based on technological barriers that no longer exist and/or do not consider additivity of risks when other chemicals are present at levels of concern (see Section 4.7.4 for an example risk calculation where multiple constituents with MCLs are present in groundwater). Other federal criteria for the protection of human health include CWA ambient water quality criteria (AWQC), which are established for surface waters. For the protection of human health, two types of AWQC have been established: (1) for the ingestion of water and fish and (2) for the ingestion of fish only (EPA 1986a). The CWA prohibits the release of oil to navigable surface waters in any quantity that causes a sheen, an emulsion, or a sludge, regardless of cleanup standards that may be imposed and/or complied with [CWA 311 (b) (3)]. This prohibition is federally enforceable in all states.

4.3.2 State Standards and Criteria

Washington State has promulgated cleanup regulations under MTCA (WAC 173-340). As stated in Chapter 2, Ecology was authorized for a corrective action program that uses MTCA regulations. MTCA establishes cleanup levels for soil, groundwater, surface water, and air.

MTCA requires that where groundwaters and surface waters are current or potential future sources of drinking water, cleanup levels be at least as stringent as promulgated federal and state standards, including federal MCLs and MCLGs, and Washington state MCLs published under WAC 248-54. In the absence of promulgated standards, MTCA provides a method for calculating RBCs based on drinking water ingestion (WAC 173-340-720).

For surface waters that support or have the potential to support fish or shellfish populations, MTCA requires that human health cleanup levels be at least as stringent as federal AWQC established for the protection of humans ingesting water and fish (WAC 173-340-730). In the absence of promulgated standards, MTCA provides a method for calculating risk-based surface water cleanup levels based on fish ingestion only (WAC 173-340-730).

MTCA requires that soil and air cleanup levels be at least as stringent as applicable state and federal laws. MTCA provides methods for calculating soil RBCs based on soil ingestion (WAC 173-340-740) and air RBCs based on inhalation (WAC 173-340-750). MTCA also requires that constituent concentrations in soil not cause contamination of groundwater to concentrations that exceed groundwater cleanup levels.

MTCA provides three methods (A, B, and C) for determining risk-based cleanup standards. Method A involves use of a table that identifies conservative, default cleanup levels for a limited number of common hazardous substances. Method B is applicable when there are more hazardous substances involved. Method C is applicable when Methods A and B cleanup levels are technically impossible to achieve, lower than background, or may cause more environmental harm than good. MTCA also defines a second Method C procedure for determining when soil cleanup levels for industrial land use can be used and how these cleanup levels should be calculated. Method B and Method C involve calculations of cleanup levels based on default exposure assumptions for different land-use scenarios. At this printing Ecology is preparing revised MTCA regulations and should be consulted for the latest regulatory update.

Washington State published a *MTCA Cleanup Levels and Risk Calculations (CLARC II) Update* (Ecology 1996) reference document. The document provides guidance on when Methods A, B, and C should be used and provides tables of chemical-specific Methods B and C cleanup levels for hazardous constituents in groundwater, surface water, and soils.

The ODEQ has no specific regulations for setting cleanup levels at RCRA facilities. As noted in Chapter 2, ODEQ was authorized to include corrective action in RCRA permits using EPA risk assessment guidance to determine cleanup levels for the corrective action program. Oregon does have rules that address contamination at state Superfund sites and recently enacted statutory language that, among other things, establishes target risk levels for cleanups and also requires development of a protocol for probabilistic risk assessment (Oregon Revised Statutes 465.315 and 465.325). ODEQ promulgated rules for these statutes on January 10, 1997. The state Superfund cleanup rules are not currently a part of Oregon's authorized RCRA corrective action program.

As noted in Chapter 2, Idaho and Alaska do not have authorized state-specific cleanup level regulations. Alaska has not applied for authorization to manage RCRA programs in lieu of EPA. In accordance with RCRA Section 3006 (b), Idaho's authorized program must be equivalent to the federal RCRA program; however, an Idaho statutory provision prohibits regulations more stringent than EPA's (Idaho Code Section 39-4404, Hazardous Waste Management Act of 1983.)

4.4 RISK-BASED SCREENING

When no promulgated standards or criteria are available for cleanup levels, facility-specific RBCs should be calculated for the remaining COPCs. Before RBCs are calculated, hazardous constituents can be screened from further consideration if they are present at concentrations below significant health concerns. Generic RBCs calculated using residential scenario assumptions can be used to screen constituents. This screening process should be performed as follows:

1. List maximum concentration of each constituent in each medium
2. List risk-based concentrations of each constituent, using PRGs calculated by EPA Region 9 (described in Section 4.5 and included in Attachment E) (EPA 1996c)

3. Eliminate constituent from screening if the maximum concentration is:

   - Less than 1E-6 cancer risk screening value (Region 9 carcinogenic PRGs are based on 1E-6 screening value so do not need to be altered) or
   - Less than 0.1 hazard index (HI) screening value (Since the Region 9 noncarcinogenic PRGs are based on an HI of 1.0, the PRG should be divided by 10 to meet 0.1 HI screening value)

4. Include remaining constituents for further consideration in calculating cleanup levels

RBCs are provided only for soil and tap (drinking) water and are based on ingestion, inhalation, and dermal contact (soil only) exposure pathways. Constituents present in other media or exposure pathways should not be screened using this method. In addition, if a constituent is retained for consideration in the risk analysis in one media, it generally should be retained in all media of concern to address possible constituent migration and multiple exposure routes for the constituent.

As indicated in Step 3, the default screening level at which carcinogenic constituents can be eliminated is based on a 1E-6 cancer risk. This screening level should be adequately protective of the cumulative risks that may result from multiple facility-related carcinogens. In accordance with the Region 10 *Supplemental Risk Assessment Guidance for Superfund* policy (EPA 1996f), Step 3 also shows that the screening concentration for noncarcinogens should be based on an HI of 0.1, rather than 1.0. The screening level of 0.1 is conservatively protective of cumulative effects that could occur when multiple noncarcinogenic hazardous constituents with similar toxic endpoints are present.

For purposes of assessing site risks, it may be assumed that if no single sample maximum value exceeds a screening concentration as described above, total exposure to the constituent is not of concern for human health.

Aluminum, calcium, iron, magnesium, potassium, and sodium are not associated with toxicity to humans under normal circumstances. No quantitative toxicity information is available for these elements from EPA sources. Unless these elements have promulgated standards or criteria or unless site-specific factors dictate, they generally can be eliminated from consideration during development of cleanup levels.

4.5 EXPOSURE ASSUMPTIONS

The exposure assumptions presented in this section are used to determine the magnitude of a potential chemical dose, which is the amount of a given chemical entering the human body during a specified time.

The exposure assumptions used to calculate cleanup levels include body weight, inhalation and ingestion rates, skin surface area, absorption fractions, exposure frequency and duration, and volatilization and particulate emission factors (PEF).

The default residential and industrial exposure assumptions recommended in this document to calculate RBCs are presented in Table 4-2. These exposure assumptions, which were primarily taken from EPA guidance documents, address human health concerns and are consistent with current federal and Region 10 CERCLA guidance. With the exception of the dermal exposure factors, the Table 4-2 factors are consistent with those recommended in the most recent version of the Region 9 PRGs (see Attachment E, [EPA 1996c]). Region 9 PRGs are updated annually and are available on the World Wide Web at http://www.epa.gov/region09/waste/sfund/prg/index/html and on the California Regional Water Board's Bulletin Board System at (510) 286-0404 (PRG2ND96.ZIP).

Table 4-3 compares the exposure pathways considered in soil, water, and air risk-based concentration calculations for EPA Regions 3 and 9. Region 3 has calculated risk-based concentrations for soil, water, and air that are similar to the EPA Region 9 PRGs. The Region 3 values were previously recommended by Region 10 for screening purposes; however, the use of Region 9 PRGs for risk-based screening is currently being recommended, primarily because they are more comprehensive in that they take into account more exposure pathways.

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TABLE 4-2

STANDARD DEFAULT EXPOSURE FACTORS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Category	Symbol	Definition (units)	Default	Reference
Toxicity Factors	CSFo	Cancer slope factor oral (mg/kg-d)-1	--	EPA 1996g, EPA 1997a, Section 4.6.2
	CSFi	Cancer slope factor inhaled (mg/kg-d)-1	--	
	RfDo	Reference dose oral (mg/kg-d)	--	
	RfDi	Reference dose inhaled (mg/kg-d)	--	
Target Risks and Hazards	TR	Target cancer risk	10^{-6}	--
	THQ	Target hazard quotient	1	--
Body Weight	BWa	Body weight, adult (kg)	70	EPA 1989c
	BWc	Body weight, child (kg)	15	EPA 1989c
Averaging Time	ATc	Averaging time - carcinogens (days)	25550	EPA 1989c
	ATn	Averaging time - noncarcinogens (days)	ED*365	
Dermal	SAa	Surface area exposed, adult	See Table 4-6	--
	SAc	Surface area expose , child	See Table 4-6	--
	AF	Adherence factor	See Table 4-6	--
	ABS	Skin absorption	See Table 4-5	--
Inhalation	IRAa	Inhalation rate - adult (m^3/day)	20	EPA 1991b
	IRAc	Inhalation rate - child (m^3/day)	10	EPA 1989c
Water Ingestion	IRWa	Drinking water ingestion - adult (L/day)	2	EPA 1989c
	IRWc	Drinking water ingestion - child (L/day)	1	Cal/EPA 1994
Soil Ingestion	IRSa	Soil ingestion - adult (mg/day)	100	EPA 1991b
	IRSc	Soil ingestion - child (mg/day)	200	EPA 1991b
	IRSo	Soil ingestion - occupational (mg/day)	50	EPA 1991b
Exposure Frequency and Duration	EFr	Exposure frequency - residential (days)	350	EPA 1991b
	EFo	Exposure frequency - occupational (days)	250	EPA 1991b
	EDr	Exposure duration - residential (years)	30[a]	EPA 1991b
	EDc	Exposure duration - child (years)	6	EPA 1991b

A

TABLE 4-2 (Continued)

STANDARD DEFAULT EXPOSURE FACTORS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Category	Symbol	Definition (units)	Default	Reference
Exposure Frequency and Duration	EDo	Exposure duration - occupational (years)	25	EPA 1991b
Age-adjusted Intake Rates[b]		Age-adjusted factors for carcinogens:		
	IFSadj	Ingestion factor, soils ([mg•yr]/[kg-d])	114	EPA 1991c
	SFSadj	Skin contact factor, soils ([mg•yr]/[kg-d])	503	EPA 1991c
	InhFadj	Inhalation factor ([m^3•yr]/[kg-d])	11	EPA 1991c
	IFWadj	Ingestion factor, water ([l•yr]/[kg-d])	1.1	EPA 1991c
Fate and Transport Models	VFw	Volatilization factor for water (L/m^3)	0.5	EPA 1991c
	PEF	Particulate emission factor (m^3/kg)	Chemical-specific (Table 4-8)[c]	EPA 1996b
	VFs	Volatilization factor for soil (m^3/kg)	Chemical-specific (Table 4-7)[c]	EPA 1996b
	sat	Soil saturation concentration (mg/kg)	Chemical-specific (Table 4-10)[c]	EPA 1996b

Source: Modified from U.S. Environmental Agency (EPA) 1996c

Notes:

a Exposure duration for lifetime residents is assumed to be 30 years total. For carcinogens, exposures are combined for children (6 years) and adults (24 years).
b Intake rates determined by analogy to age-adjusted soil ingestion factor published by EPA (1991c).
c Section 4.5.2 and Tables 4-7, 4-8, and 4-10 are presented in EPA's Interim Guidelines for Developing Risk-based Cleanup Levels at RCRA sites in Region 10 (this report).

mg/kg	Milligram per kilogram
cm^2	Square centimeter
m^3	Cubic meter
L	Liter
Cal/EPA	California Environmental Protection Agency

TABLE 4-2

STANDARD DEFAULT EXPOSURE FACTORS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Category	Symbol	Definition (units)	Default	Reference
Toxicity Factors	CSFo	Cancer slope factor oral (mg/kg-d)-1	--	EPA 1996g. EPA 1997a. Section 4.6.2
	CSFi	Cancer slope factor inhaled (mg/kg-d)-1	--	
	RfDo	Reference dose oral (mg/kg-d)	--	
	RfDi	Reference dose inhaled (mg/kg-d)	--	
Target Risks and Hazards	TR	Target cancer risk	10^{-6}	--
	THQ	Target hazard quotient	1	--
Body Weight	BWa	Body weight, adult (kg)	70	EPA 1989c
	BWc	Body weight, child (kg)	15	EPA 1989c
Averaging Time	ATc	Averaging time - carcinogens (days)	25550	EPA 1989c
	ATn	Averaging time - noncarcinogens (days)	ED*365	
~~Dermal~~	SAa	Surface area exposed, adult	See Table 4-6	--
	SAc	Surface area expose , child	See Table 4-6	--
	AF	Adherence factor	See Table 4-6	--
	ABS	Skin absorption	See Table 4-5	--
Inhalation	IRAa	Inhalation rate - adult (m^3/day)	20	EPA 1991b
	IRAc	Inhalation rate - child (m^3/day)	10	EPA 1989c
Water Ingestion	IRWa	Drinking water ingestion - adult (L/day)	2	EPA 1989c
	IRWc	Drinking water ingestion - child (L/day)	1	Cal/EPA 1994
Soil Ingestion	IRSa	Soil ingestion - adult (mg/day)	100	EPA 1991b
	IRSc	Soil ingestion - child (mg/day)	200	EPA 1991b
	IRSo	Soil ingestion - occupational (mg/day)	50	EPA 1991b
Exposure Frequency and Duration	EFr	Exposure frequency - residential (days)	350	EPA 1991b
	EFo	Exposure frequency - occupational (days)	250	EPA 1991b
	EDr	Exposure duration - residential (years)	30[a]	EPA 1991b
	EDc	Exposure duration - child (years)	6	EPA 1991b

TABLE 4-2 (Continued)

STANDARD DEFAULT EXPOSURE FACTORS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Category	Symbol	Definition (units)	Default	Reference
Exposure Frequency and Duration	EDo	Exposure duration - occupational (years)	25	EPA 1991b
Age-adjusted Intake Rates[b]		Age-adjusted factors for carcinogens:		
	IFSadj	Ingestion factor, soils ([mg•yr]/[kg-d])	114	EPA 1991c
	SFSadj	Skin contact factor, soils ([mg•yr]/[kg-d])	503	EPA 1991c
	InhFadj	Inhalation factor ([m^3•yr]/[kg-d])	11	EPA 1991c
	IFWadj	Ingestion factor, water ([l•yr]/[kg-d])	1.1	EPA 1991c
Fate and Transport Models	VFw	Volatilization factor for water (L/m^3)	0.5	EPA 1991c
	PEF	Particulate emission factor (m^3/kg)	Chemical-specific (Table 4-8)[c]	EPA 1996b
	VFs	Volatilization factor for soil (m^3/kg)	Chemical-specific (Table 4-7)[c]	EPA 1996b
	sat	Soil saturation concentration (mg/kg)	Chemical-specific (Table 4-10)[c]	EPA 1996b

Source: Modified from U.S. Environmental Agency (EPA) 1996c

Notes:

a Exposure duration for lifetime residents is assumed to be 30 years total. For carcinogens, exposures are combined for children (6 years) and adults (24 years).
b Intake rates determined by analogy to age-adjusted soil ingestion factor published by EPA (1991c).
c Section 4.5.2 and Tables 4-7, 4-8, and 4-10 are presented in EPA's Interim Guidelines for Developing Risk-based Cleanup Levels at RCRA sites in Region 10 (this report).

mg/kg	Milligram per kilogram
cm^2	Square centimeter
m^3	Cubic meter
L	Liter
Cal EPA	California Environmental Protection Agency

TABLE 4-3

U.S. ENVIRONMENTAL PROTECTION AGENCY REGION 3 AND REGION 9 SOIL, WATER, AND AIR EXPOSURE PATHWAYS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Medium	Pathway	Region 3[a]	Region 9[b]
Water	Ingestion	Yes	Yes
	Inhalation of volatiles	No	Yes
Soil	Ingestion	Yes	Yes
	Inhalation of particulates	No	Yes
	Inhalation of volatiles	No	Yes
	Dermal contact	No	Yes
Air	Inhalation	Yes	Yes

Notes:

a EPA 1996h
b EPA 1996c

TABLE 4-4

WASHINGTON STATE MODEL TOXICS CONTROL ACT
CLEANUP LEVEL EXPOSURE FACTORS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Exposure Factor	Method B		Method C		Method C (Industrial)	
	Non-Carcinogens	Carcinogens	Non-Carcinogens	Carcinogens	Non-Carcinogens	Carcinogens
Water Ingestion						
Intake Rate (L/day)	1	2	2	2	NA	NA
Exposure Frequency[b]	—	—	—	—	NA	NA
Exposure Duration (year)	—	30	—	30	NA	NA
Body Weight (kg)	16	70	70	70	NA	NA
Averaging Time (year)	—	75	—	75	NA	NA
Unit Conversion Factor (mg/kg)	1,000	1,000	1,000	1,000	NA	NA
Inhalation Correction Factor	2 (VOCs)	2 (VOCs)	2 (VOCs)	2 (VOCs)	NA	NA
Summary Factor						
Non-VOCs	16,000	8.75E-2	35,000	8.75E-1	NA	NA
VOCs	8,000	4.38E-2	17,500	4.38E-1	NA	NA
Soil & Dust Ingestion						
Intake Rate (mg/day)	200	200	100	100	50	50
Exposure Frequency[b]	1.0	1.0	0.5	0.5	0.4	0.4
Exposure Duration (year)	—	6	—	6	—	20
Body Weight (kg)	16	16	16	16	70	70
Averaging Time (year)	—	75	—	75	—	75
Unit Conversion Factor (mg/kg)	10^{-6}	10^{-6}	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Gastrointestinal Absorption	1.0	1.0	1.0	1.0	1.0	1.0
Summary Factor	80,000	1.0	320,000	40	3,500,000	131.3
Inhalation						
Intake Rate (m^3/day)	10	20	20	20	NA	NA
Exposure Frequency[b]	—	—	—	—	NA	NA
Exposure Duration (year)	—	30	—	30	NA	NA
Body Weight (kg)	16	70	70	70	NA	NA
Averaging Time (year)	—	75	—	75	NA	NA
Unit Conversion Factor (mg/kg)	1,000	1,000	1,000	1,000	NA	NA
Absorption Percentage	1.0	1.0	1.0	1.0	NA	NA
Summary Factor	1,600	7.5E-3	3,500	7.5E-2	NA	NA

Notes:

a Target hazard quotient is 1.0 for all cleanup levels; Target Risk levels are 10^{-6} for Method B and 10^{-5} for Method C

b Exposure frequency is presented as a fraction of a year. For example, 0.4 refers to an exposure frequency of 146 days per year.

Ecology Washington Department of Ecology

— Value is present in numerator and denominator of equation and therefore, does not affect calculation

L Liter

NA Not applicable

mg Milligram

VOC Volatile organic compound

kg Kilogram

Exposure parameters dictated by MTCA (Methods B and C) are presented in Table 4-4. For soil exposures, MTCA only considers the ingestion pathway. For water exposures, MTCA considers both ingestion and volatile organic compound inhalation pathways. MTCA rules do not have to be followed for EPA-lead corrective actions, but they should be considered in terms of preventing the need of future, additional corrective action under state authorities. No other EPA Region 10 states have developed specific exposure assumptions for RCRA facility RBC calculations; exposure parameters recommended by the EPA guidance should be used.

Additional information on dermal absorption factors is presented in Section 4.5.1. Information on how fate and transport models are used to incorporate hazardous constituent migration into cleanup levels is presented in Section 4.5.2.

As stated in Section 4.1, other scenarios including recreational, agricultural, and trespasser may be more appropriate at a given facility. An exposure parameter source for these and other scenarios is EPA's *Exposure Factors Handbook* 1989d, which EPA is updating [the EPA (1996e) update was currently available on the Internet at the time of this printing]. The *Exposure Factors Handbook* summarizes the current literature regarding human exposures to contaminated media via a variety of specific exposure conditions (for example, inhalation rates based on light, medium, and heavy activities). Values from the handbook can be used in lieu of the default exposure factors when reliable facility-specific exposure information is available. The *Draft Exposure Assessment Guidance, Attachment C of Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Waste* (EPA 1994i), further described in Section 4.5.2.4, also includes exposure parameters for human food chain exposure pathways, such as garden produce and fish ingestion rates.

New Policy on Evaluating Health Risks to Children (EPA 1995e) requires that exposures to infants and children be considered separately from adults. Children may be more or less sensitive to specific constituents. They may also experience different types and rates of exposures; therefore, separate risk and hazard estimates should be made for infants and children, or it should be clearly stated why this is not done (for example, demonstrate that infants and children are not expected to be exposed to the constituent

of concern). EPA's *Exposure Factors Handbook* (1989d) and the draft 1996e update include information on infant and children exposure rates.

4.5.1 Dermal Absorption Factors

Dermal absorption of chemicals from soil and water across the skin and into the blood stream may occur. The rate of absorption may be estimated by dermal absorption factors (for chemicals in soil) and dermal permeability constants (for chemicals in water). Both dermal absorption factors (ABS) and dermal permeability constants are used to calculate absorbed doses of chemicals via the dermal exposure route.

Few chemical-specific ABS values are available from EPA. Table 4-5 presents recommended ABS values. References for these values include literature sources and *Dermal Exposure Assessment: Principles and Applications* (EPA 1992d). The ABS value units are percentages (that is, percent absorbed through skin).

Differences in soil characteristics may affect chemical desorption from soil. For example, EPA (1992d) compiled an ABS range of 0.001 to 0.03 for dioxins based on experimental data and recommended that the lower end of the range could be used for soils with high organic content (dioxin less available to desorb) and the higher end of the range for soils with low organic content (dioxin more available to desorb). Limited experimental data are available to assign constituent-specific ABS values based on soil characteristics. To the extent that they are available and scientifically justifiable, constituent-specific ABS values identified in the literature should be used.

Default ABS values for volatile organic compounds (VOC) recommended by *Region III Technical Guidance Manual, Risk Assessment: Assessing Dermal Exposure from Soil* (EPA 1995f) may be used for calculating cleanup levels if constituent-specific values are not available: 0.0005 for volatiles with a vapor pressure equal to or greater than benzene (approximately 95.2 mm mercury) (Skowronski et al. 1988; Franz 1984) and 0.03 for volatiles with a vapor pressure lower than benzene.

An EPA workgroup has drafted but not yet published a supplementary Superfund risk assessment guidance specific to the dermal pathway; when available it should be referenced.

A

Exposure parameters dictated by MTCA (Methods B and C) are presented in Table 4-4. For soil exposures, MTCA only considers the ingestion pathway. For water exposures, MTCA considers both ingestion and volatile organic compound inhalation pathways. MTCA rules do not have to be followed for EPA-lead corrective actions, but they should be considered in terms of preventing the need of future, additional corrective action under state authorities. No other EPA Region 10 states have developed specific exposure assumptions for RCRA facility RBC calculations; exposure parameters recommended by the EPA guidance should be used.

Additional information on dermal absorption factors is presented in Section 4.5.1. Information on how fate and transport models are used to incorporate hazardous constituent migration into cleanup levels is presented in Section 4.5.2.

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New Policy on Evaluating Health Risks to Children (EPA 1995e) requires that exposures to infants and children be considered separately from adults. Children may be more or less sensitive to specific constituents. They may also experience different types and rates of exposures; therefore, separate risk and hazard estimates should be made for infants and children, or it should be clearly stated why this is not done (for example, demonstrate that infants and children are not expected to be exposed to the constituent

of concern). EPA's *Exposure Factors Handbook* (1989d) and the draft 1996e update include information on infant and children exposure rates.

4.5.1 Dermal Absorption Factors

Use RAGS Part E

Dermal absorption of chemicals from soil and water across the skin and into the blood stream may occur. The rate of absorption may be estimated by dermal absorption factors (for chemicals in soil) and dermal permeability constants (for chemicals in water). Both dermal absorption factors (ABS) and dermal permeability constants are used to calculate absorbed doses of chemicals via the dermal exposure route.

Few chemical-specific ABS values are available from EPA. Table 4-5 presents recommended ABS values. References for these values include literature sources and *Dermal Exposure Assessment: Principles and Applications* (EPA 1992d). The ABS value units are percentages (that is, percent absorbed through skin).

Differences in soil characteristics may affect chemical desorption from soil. For example, EPA (1992d) compiled an ABS range of 0.001 to 0.03 for dioxins based on experimental data and recommended that the lower end of the range could be used for soils with high organic content (dioxin less available to desorb) and the higher end of the range for soils with low organic content (dioxin more available to desorb). Limited experimental data are available to assign constituent-specific ABS values based on soil characteristics. To the extent that they are available and scientifically justifiable, constituent-specific ABS values identified in the literature should be used.

Default ABS values for volatile organic compounds (VOC) recommended by *Region III Technical Guidance Manual. Risk Assessment: Assessing Dermal Exposure from Soil* (EPA 1995f) may be used for calculating cleanup levels if constituent-specific values are not available: 0.0005 for volatiles with a vapor pressure equal to or greater than benzene (approximately 95.2 mm mercury) (Skowronski et al. 1988; Franz 1984) and 0.03 for volatiles with a vapor pressure lower than benzene.

An EPA workgroup has drafted but not yet published a supplementary Superfund risk assessment guidance specific to the dermal pathway; when available it should be referenced.

TABLE 4-5

RECOMMENDED DERMAL ABSORPTION FACTORS FOR SOIL REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Compound	Dermal Absorption Factor	Reference
Arsenic	0.03	Wester et al. (1993a)
Cadmium	ND 0.01 - .001	Wester et al. (1992a) EPA (1992d)
Chlordane	0.04	Wester et al. (1992b)
2,4-D	0.05	Wester et al. (1996)
DDT	0.03	Wester et al. (1990)
TCDD Low Organic Soil (<10%) High Organic Soil (>10%)	 0.03 0.001	 EPA (1992d) EPA (1992d)
Other Dioxins and Dibenzofurans	0.03	EPA (1992d)
PAHs	0.13	Wester et al. (1990)
PCBs	0.14	Wester et al. (1993b) EPA (1992d)
Pentachlorophenol	0.25	Wester et al. (1993c)
Generic Defaults		
Volatile organic compounds with vapor pressure ≥ benzene (95.2 millimeters mercury)	0.0005	EPA 1995f, Skowronski et al. 1988
Volatile organic compounds with vapor pressure < benzene (95.2 millimeters mercury)	0.03	EPA 1995f
Semivolatile organic compounds	0.1	Ryan et al. (1987)
Inorganic Compounds	0.01	Ryan et al. (1987)

Sources: EPA 1997b, EPA 1992d

Notes:

EPA	U.S. Environmental Protection Agency
2,4-D	2,4-dichlorophenoxy acetic acid
DDT	Dichlorodiphenyltrichloroethane
TCDD	Tetrachlorodibenzo-p-dioxin
PAH	Polynuclear aromatic hydrocarbon
PCB	Polychlorinated biphenyl

Table revised 10/16/98

A

To evaluate dermal contact with constituents in water, dermal absorption across the skin barrier is determined using constituent-specific dermal permeability constants, expressed in units of centimeters per hour. Equations for calculating dermal permeability constants are presented in *Dermal Exposure Assessment: Principles and Applications* (EPA 1992d); EPA recommends calculating permeability constants for organic compounds using the Potts and Guy equation presented on pages 5-36 through 5-38 (EPA 1992d). EPA recommends the use of the measured permeability constants for inorganic compounds presented in Table 5-3 of the dermal exposure assessment report (EPA 1992d). The dermal exposure to constituents in the water pathway was not incorporated into EPA Region 9 PRG equations. Equations for assessing this pathway are included in *Dermal Exposure Assessment: Principles and Applications* (EPA 1992d). Reduced equations for calculating risks or hazards resulting from dermal contact with constituents in water have been incorporated in the Section 4.7.2 RBC calculation equations. Adult and child residential exposures (during showering or bathing) are considered.

When evaluating the dermal contact exposure pathway (for both soil and water) the total surface area of body exposed must be estimated. For showering and bathing, whole-body surface area is assumed. For soil exposures, portions of the body (for example, hands, arms, lower legs, face, and neck) are assumed to contact soil. The duration of exposure must also be estimated (for example, assume a 15-minute-per-day showering time). EPA-recommended defaults for dermal contact exposure factors are presented in Table 4-6.

4.5.2 Fate and Transport Models

Table 4-1, discussed in Section 4.1, lists potential exposure pathways for human receptors. Many of the exposure pathways result from contamination migrating from one medium to another. For example, soil contamination may migrate into groundwater, subsequently causing exposure to persons using the contaminated aquifer as a drinking water source and/or discharge to surface waters, which may have both human health and ecological impacts, depending on use. Cleanup levels for the primary medium may require an adjustment to be protective of hazardous constituent migration into the secondary medium. Certain fate and transport modeling equations have been standardized for this purpose.

See RAGS Part E

TABLE 4-5

RECOMMENDED DERMAL ABSORPTION FACTORS FOR SOIL REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Compound	Dermal Absorption Factor	Reference
Arsenic	0.03	Wester et al. (1993a)
Cadmium	0.001	Wester et al. (1992a) EPA (1992d)
Chlordane	0.04	Wester et al. (1992b)
2,4-D	0.05	Wester et al. (1996)
DDT	0.03	Wester et al. (1990)
TCDD Low Organic Soil (<10%) High Organic Soil (>10%)	 0.03 0.001	 EPA (1992d) EPA (1992d)
Other Dioxins and Dibenzofurans	0.03	EPA (1992d)
PAHs	0.13	Wester et al. (1990)
PCBs	0.14	Wester et al. (1993b) EPA (1992d)
Pentachlorophenol	0.25	Wester et al. (1993c)
Generic Defaults		
Volatile organic compounds with vapor pressure ≥ benzene (95.2 millimeters mercury)	0.0005	EPA 1995f, Skowronski et al. 1988
Volatile organic compounds with vapor pressure < benzene (95.2 millimeters mercury)	0.03	EPA 1995f
Semivolatile organic compounds	0.1	Ryan et al. (1987)
Inorganic Compounds	0.01	Ryan et al. (1987)

Sources: EPA 1997b, EPA 1992d

Notes:

EPA	U S Environmental Protection Agency
2,4-D	2,4-dichlorophenoxy acetic acid
DDT	Dichlorodiphenyltrichloroethane
TCDD	Tetrachlorodibenzo-p-dioxin
PAH	Polynuclear aromatic hydrocarbon
PCB	Polychlorinated biphenyl

B

To evaluate dermal contact with constituents in water, dermal absorption across the skin barrier is determined using constituent-specific dermal permeability constants, expressed in units of centimeters per hour. Equations for calculating dermal permeability constants are presented in *Dermal Exposure Assessment: Principles and Applications* (EPA 1992d); EPA recommends calculating permeability constants for organic compounds using the Potts and Guy equation presented on pages 5-36 through 5-38 (EPA 1992d). EPA recommends the use of the measured permeability constants for inorganic compounds presented in Table 5-3 of the dermal exposure assessment report (EPA 1992d). The dermal exposure to constituents in the water pathway was not incorporated into EPA Region 9 PRG equations. Equations for assessing this pathway are included in *Dermal Exposure Assessment: Principles and Applications* (EPA 1992d). Reduced equations for calculating risks or hazards resulting from dermal contact with constituents in water have been incorporated in the Section 4.7.2 RBC calculation equations. Adult and child residential exposures (during showering or bathing) are considered.

When evaluating the dermal contact exposure pathway (for both soil and water) the total surface area of body exposed must be estimated. For showering and bathing, whole-body surface area is assumed. For soil exposures, portions of the body (for example, hands, arms, lower legs, face, and neck) are assumed to contact soil. The duration of exposure must also be estimated (for example, assume a 15-minute-per-day showering time). EPA-recommended defaults for dermal contact exposure factors are presented in Table 4-6.

4.5.2 Fate and Transport Models

Table 4-1, discussed in Section 4.1, lists potential exposure pathways for human receptors. Many of the exposure pathways result from contamination migrating from one medium to another. For example, soil contamination may migrate into groundwater, subsequently causing exposure to persons using the contaminated aquifer as a drinking water source and/or discharge to surface waters, which may have both human health and ecological impacts, depending on use. Cleanup levels for the primary medium may require an adjustment to be protective of hazardous constituent migration into the secondary medium. Certain fate and transport modeling equations have been standardized for this purpose.

TABLE 4-6 (amended 10/16/98)

RECOMMENDED DEFAULTS FOR DERMAL EXPOSURE FACTORS[a]
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

	Water Contact				Soil Contact	
	Bathing		Swimming			
	Central	Upper	Central	Upper	Central	Upper
Event time and frequency	10 minutes event 1 event/day 350 days/year	15 minutes/event 1 event/day 350 days/year	Site-specific 60 minute 1 event/month	Site-specific	site-specific	350 events/year
Exposure duration	9 years - adult 6 years - child	30 years	9 years	30 years	9 years	30 years
Skin surface area	18,000 cm^2 - adult[b] 6,500 cm^2 - child[b]	none[e]	18,000 cm^2 - adult[b] 6,500 cm^2 - child[b]	none[e]	2,500 cm^2 - adult[c] 2,200 cm^2 - child[d] 2,500 cm^2- occupational[c]	none[e]
Soil-to-skin adherence rate[f]	–	–	–	–	0.1 mg/cm^2 - event - adult 0.2 mg/cm^2 - event - child 0.1 mg/cm^2 - event - occ.[g]	child and adult – none[h] 0.2 mg/cm^2 - event - occ.[i]

Notes:

a Recommended defaults compiled by EPA (1997b), with background data and rationales for the defaults derived from EPA information (1992d) and the 1996 Science Advisory Board review draft of the *Exposure Factors Handbook* (1996e draft update of EPA 1989d)

b Assumes total body surface area for adult and child.

c For adult wearing short-sleeved shirt, shorts, and shoes, with exposed skin surface limited to head, hands, forearms, ~~and lower legs~~.

d For children wearing short-sleeved shirt and shorts, but no shoes, with exposed head, hands, forearms, lower legs, and feet.

e Skin surface area has no upper value since only one body weight per category is available.

f From Kissel (1996 and unpublished); values for adherence rates are under development and are subject to change. Consult a Region 10 Risk Assessor for currently recommended values.

g Value as established for a gardener.

h Only central values are recommended, as they are based on high-end activities and are therefore sufficiently conservative.

i Value as established for a utility worker.

– Not applicable.

Models that address volatile and particulate emissions from soil into air are described in Section 4.5.2.1. Fate and transport assumptions that estimate the transfer of VOC from water into indoor air during household water use are identified in Section 4.5.2.2. A model and partition equation that address migration of constituents from soil to groundwater are described in Section 4.5.2.3. Partition equations that address migration of constituents from soil into food chain organisms are discussed in Section 4.5.2.4.

Several of the models discussed in this section are recommend by *EPA's Soil Screening Guidance: Users' Guide* (EPA 1996b). These include models for estimating volatile and particulate emissions from soil, and a model for estimating soil-to-groundwater constituent migration. EPA's soil screening levels and associated models were developed for screening purposes, for use during early investigative processes such as the RFI. The use of conservative, facility-specific soil and aquifer parameters will result in the calculation of health-protective soil screening levels. The facility must adequately justify all facility-specific parameters used to calculate soil screening levels.

Although the EPA soil screening guidance (1996b) was developed for the CERCLA program, it can be considered for RCRA corrective action facilities. EPA does not intend for soil screening levels to serve as national cleanup standards. The screening levels are very conservative and can be used to determine that the soil-to-air or soil-to-groundwater pathways are either not significant or that further assessment of these pathways is warranted. The soil screening levels could be used as cleanup levels if conditions at the facility are representative of those assumed during the development of the screening levels. Higher cleanup levels that are still hea th protective may be identified using facility-specific fate and transport models.

4.5.2.1 Soil-to-Air

Volatilization and particulate emission factors (VF and PEF), which are described in the following section, are used in the soil RBC calculations to address long-term inhalation exposures. Equations for deriving these factors are presented in Tables 4-7 and 4-8. Section 4.7 and Exhibit 4-1 present how the factors are incorporated into RBC calculations. VFs should be estimated for VOCs, while PEFs should be estimated for compounds that may exert significant toxicity via dust inhalation. VOCs are defined in

See RAGS Part E

TABLE 4-6

RECOMMENDED DEFAULTS FOR DERMAL EXPOSURE FACTORS[a]
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

	Water Contact				Soil Contact	
	Bathing		Swimming			
	Central	Upper	Central	Upper	Central	Upper
Event time and frequency	10 minutes event 1 event/day 350 days/year	15 minutes/event 1 event/day 350 days/year	Site-specific 60 minute 1 event/month	Site-specific	site-specific	350 events/year
Exposure duration	9 years - adult 6 years - child	30 years	9 years	30 years	9 years	30 years
Skin surface area	18,000 cm^2 - adult[b] 6,000 cm^2 - child[b]	22,000 cm^2 - adult[b] 7,500 cm^2 - child[b]	18,000 cm^2 - adult[b] 6,500 cm^2 - child[b]	22,000 cm^2 - adult[b] 7,500 cm^2 - child[b]	5,700 cm^2 - adult[c] 2,900 cm^2 - child[d]	6,600 cm^2 - adult[c] 3,400 cm^2 - child[d]
Soil-to-skin adherence rate[e]	--	--	--	--	0.2 mg/cm^2 - event, child See footnote e	0.8 mg/cm^2 - event, child 0.2 mg/cm^2 - event, adult

See Marcia or Marc

Notes:

a Recommended defaults compiled by EPA (1997b), with background data and rationales for the defaults derived from EPA information (1992d) and the 1996 Science Advisory Board review draft of the *Exposure Factors Handbook* (1996e draft update of EPA 1989d)

b Assumes total body surface area for adult and child.

c For adult wearing short-sleeved shirt, shorts, and shoes, with exposed skin surface limited to head, hands, forearms, and lower legs.

d For children wearing short-sleeved shirt and shorts, but no shoes, with exposed head, hands, forearms, lower legs, and feet.

e From Kissel (1996 and unpublished); values for adherence rates are under development and are subject to change. Consult a Region 10 Risk Assessor for current values and for adherence rates for industrial scenarios which are dependent upon site-specific conditions.

cm^2 Square centimeter

mg milligrams

-- Not applicable

Models that address volatile and particulate emissions from soil into air are described in Section 4.5.2.1. Fate and transport assumptions that estimate the transfer of VOC from water into indoor air during household water use are identified in Section 4.5.2.2. A model and partition equation that address migration of constituents from soil to groundwater are described in Section 4.5.2.3. Partition equations that address migration of constituents from soil into food chain organisms are discussed in Section 4.5.2.4.

Several of the models discussed in this section are recommend by *EPA's Soil Screening Guidance: Users' Guide* (EPA 1996b). These include models for estimating volatile and particulate emissions from soil, and a model for estimating soil-to-groundwater constituent migration. EPA's soil screening levels and associated models were developed for screening purposes, for use during early investigative processes such as the RFI. The use of conservative, facility-specific soil and aquifer parameters will result in the calculation of health-protective soil screening levels. The facility must adequately justify all facility-specific parameters used to calculate soil screening levels.

Although the EPA soil screening guidance (1996b) was developed for the CERCLA program, it can be considered for RCRA corrective action facilities. EPA does not intend for soil screening levels to serve as national cleanup standards. The screening levels are very conservative and can be used to determine that the soil-to-air or soil-to-groundwater pathways are either not significant or that further assessment of these pathways is warranted. The soil screening levels could be used as cleanup levels if conditions at the facility are representative of those assumed during the development of the screening levels. Higher cleanup levels that are still health protective may be identified using facility-specific fate and transport models.

4.5.2.1 Soil-to-Air

Volatilization and particulate emission factors (VF and PEF), which are described in the following section, are used in the soil RBC calculations to address long-term inhalation exposures. Equations for deriving these factors are presented in Tables 4-7 and 4-8. Section 4.7 and Exhibit 4-1 present how the factors are incorporated into RBC calculations. VFs should be estimated for VOCs, while PEFs should be estimated for compounds that may exert significant toxicity via dust inhalation. VOCs are defined in

TABLE 4-7

DERIVATION OF THE VOLATILIZATION FACTOR
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

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

where

$$D_A = \frac{[(\theta_a^{10/3} D_i H' + \theta_w^{10/3} D_w)/n^2]}{\rho_b K_d + \theta_w + \theta_a H'}$$

Parameter	Definition (units)	Default
VF	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-s per kg/m^3)	68.81 (Los Angeles) or facility-specific (Table 4-9)
T	exposure interval (s)	9.5×10^8 (30 years)
ρ_b	dry soil bulk density (g/cm^3)	1.5
θ_a	air-filled soil porosity (L_{air}/L_{soil})	$n - \theta_w = 0.28$
n	total soil porosity (L_{pore}/L_{soil})	$1 - (\rho_b/\rho_s) = 0.43$
θ_w	water-filled soil porosity (L_{water}/L_{soil})	0.15
ρ_s	soil particle density (g/cm^3)	2.65
D_i	diffusivity in air (cm^2/s)	chemical-specific[a]
H′	dimensionless Henry's law constant	chemical-specific[a, b]
D_w	diffusivity in water (cm^2/s)	chemical-specific[a]
K_d	soil-water partition coefficient (cm^3/g) = $K_{oc} f_{oc}$ (organics)	chemical-specific[a]
K_{oc}	soil organic carbon partition coefficient (cm^3/g)	chemical-specific[a]
f_{oc}	fraction organic carbon in soil (g/g)	0.006 (0.6%) or facility-specific, if available

Source: U.S. Environmental Protection Agency 1996b

Notes: The Henry's Law constant used in the VF equation is dimensionless, and can be converted from a Henry's Law constant expressed in units of atmosphere-cubic meter per mole by multiplying by 41.

a See Attachment H
b Dimensionless Henry's Law constant
L_{air} Volume of air in liters
L_{soil} Volume of soil in liters
L_{pore} Pore volume in liters
L_{water} Volume of water in liters
g Gram
cm^3 Cubic centimeter
kg Kilogram
cm^2 Square centimeter
m^3 Cubic meter
s Second
m^2 Square meter

TABLE 4-8

DERIVATION OF THE PARTICULATE EMISSION FACTOR
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

$$PEF\ (m^3/kg) = Q/C \times \frac{3{,}600\ s/h}{0.036 \times (1-V) \times (U_m/U_t)^3 \times F(x)}$$

Parameter	Definition (units)	Default
PEF	particulate emission factor (m^3/kg)	1.32×10^9
Q/C	inverse of mean concentration at the center of a 0.5-acre-square source (g/m^2-s per kg/m^3)	90.80 - Minneapolis or facility-specific (Table 4-9)
V	fraction of vegetative cover (unitless)	0.5 (50%)
U_m	mean annual wind speed (m/s)	4.69
U_t	equivalent threshold value of wind speed at 7 m (m/s)	11.32
F(x)	function dependent on U_m/U_t derived using data published by Cowherd et al. (1985) (unitless)	0.194

Source: Modified from U.S. Environmental Protection Agency 1996b,f

Notes:

The defaults presented in this figure are intended to calculate a PEF that is adequately protective at most facilities. Cowherd et al. (1985) present methods for site-specific measurement of the parameters necessary to calculate a site-specific PEF.

g Gram
kg Kilogram
m Meter
m^2 Square meter
m^3 Cubic meter
s Second

EPA guidance as having a Henry's Law Constant greater than 10^{-5} atmosphere-cubic meter per mole and a molecular weight less than 200 grams per mole (EPA 1991c). The models discussed in this section concern modeling hazardous constituents from soil to outdoor air. Soil to indoor air may also need to be considered; however, models regarding this migration pathway are not described in this document. A model developed by P.C. Johnson and R.A. Ettinger (1991) can be used to predict the intrusion rate of constituent vapors into buildings through breaches such as foundation cracks. EPA Region 10 risk assessors should be consulted if soil to indoor air is a potential exposure pathway.

Volatilization Factor

The soil-to-air VF (referred to as VF_s) is used to define the relationship between the concentration of the constituent in soil and the flux of the volatilized constituent to air. The VF_s equation presented in EPA's *Soil Screening Guidance: Users' Guide* (1996c) should be used when calculating soil screening levels for VOCs and can also be used to calculate risk-based concentrations. This equation, which is presented in Table 4-7, is used to incorporate VOC inhalation exposures into Region 9 soil PRGs (1996d). The VF_s equation calculates the maximum flux of a constituent from contaminated soil and considers soil moisture conditions. Chemical-specific parameters that may be used to calculate VF_s including diffusivity in air, dimension less Henry's Law constant, diffusivity in water, and soil organic-carbon partition coefficient, are presented in EPA's *Soil Screening Guidance: Users' Guide* (1996c) and in Attachment F (Chemical Properties Table C from EPA [1996c]). These chemical-specific parameters are used to calculate Region 9 soil PRGs (EPA 1996d) and are presented in the electronic version of the PRGs (accessible through the World Wide Web address cited in Section 4.5 and presented in Attachment C).

The dispersion factor (Q/C) used in the VF_s equation was derived from a modeling exercise using a full year of meteorological data for 29 U.S. locations selected to be representative of the range of meteorological conditions across the nation. The results of these modeling runs have been compiled for nine climatic zones and sources of 0.5 to 30 acres (Table 4-9). A dispersion factor of 68.81 grams per square-meter second per kilogram per cubic meter (g/m^2-s per kg/m^3) (Los Angeles) is used by Region 9 to determine a default VF_s and may be used for screening purposes (EPA 1996c). To develop a facility-specific VF_s, place the facility into a climatic zone and choose a dispersion factor that best represents the site's size and meteorological conditions.

TABLE 4-9

DISPERSION FACTOR VALUES BY SOURCE AREA, CITY, AND CLIMATIC ZONE REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Zone and City	Q/C (g/m^2-s per kg/m^3)					
	0.5 Acre	1 Acres	2 Acres	5 Acres	10 Acres	30 Acres
Zone I						
Seattle, WA	82.72	72.62	64.38	55.66	50.09	42.86
Salem, OR	73.44	64.42	57.09	49.33	44.37	37.94
Zone II						
Fresno, CA	62.00	54.37	48.16	41.57	37.36	31.90
Los Angeles, CA	68.81	60.24	53.30	45.93	41.24	35.15
San Francisco, CA	89.51	78.51	69.55	60.03	53.95	46.03
Zone III						
Las Vegas, NV	95.55	83.87	74.38	64.32	57.90	49.56
Phoenix, AZ	64.04	56.07	49.59	42.72	38.35	32.68
Albuquerque, NM	84.18	73.82	65.40	56.47	50.77	43.37
Zone IV						
Boise, ID	69.41	60.88	53.94	46.57	41.87	35.75
Winnemucca, NV	69.23	60.67	53.72	46.35	41.65	35.55
Salt Lake City, UT	78.09	68.47	60.66	52.37	47.08	40.20
Casper, WY	100.13	87.87	77.91	67.34	60.59	51.80
Denver, CO	75.59	66.27	58.68	50.64	45.52	38.87
Zone V						
Bismarck, ND	83.39	73.07	64.71	55.82	50.16	42.79
Minneapolis, MN	90.80	79.68	70.64	61.03	54.90	46.92
Lincoln, NE	81.64	71.47	63.22	54.47	48.89	41.65
Zone VI						
Little Rock, AR	73.63	64.51	57.10	49.23	44.19	37.64
Houston, TX	79.25	69.47	61.53	53.11	47.74	40.76
Atlanta, GA	77.08	67.56	59.83	51.62	46.37	39.54

TABLE 4-9 (Continued)

QUALITY CONTROL VALUES BY SOURCE AREA, CITY, AND CLIMATIC ZONE
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Zone and City	Q/C (g/m^2-s per kg/m^3)					
	0.5 Acre	1 Acres	2 Acres	5 Acres	10 Acres	30 Acres
Atlanta, GA	77.08	67.56	59.83	51.62	46.37	39.54
Charleston, SC	74.89	65.65	58.13	50.17	45.08	38.48
Raleigh-Durham, NC	77.26	67.75	60.01	51.78	46.51	39.64
Zone VII						
Chicago, IL	97.78	85.81	76.08	65.75	59.16	50.60
Cleveland, OH	83.22	73.06	64.78	55.99	50.38	43.08
Huntington, IN	53.89	47.24	41.83	36.10	32.43	27.67
Harrisburg, PA	81.90	71.87	63.72	55.07	49.56	42.40
Zone VIII						
Portland, ME	74.23	65.01	57.52	49.57	44.49	37.88
Hartford, CT	71.35	62.55	55.40	47.83	43.00	36.73
Philadelphia, PA	90.24	79.14	70.14	60.59	54.50	46.59
Zone IX						
Miami, FL	85.61	74.97	66.33	57.17	51.33	43.74

Source: Modified from U.S. Environmental Protection Agency 1996b

Notes:

g Gram
kg Kilogram
m^2 Square meter
m^3 Cubic meter
s Second
Q/C Inversion of mean concentration at the center of a source

Because of its reliance on Henry's Law (which provides a measure of the extent of chemical partitioning between air and water) the VF model is applicable only when the constituent concentration in soil water is at or below saturation (that is, there is no free-phase constituent present). This corresponds to the constituent concentration in soil at which the adsorptive limits of the soil particles and the solubility limits of the available soil moisture have been reached. Above this point, pure liquid-phase constituent can be expected to exist in the soil. Table 4-10 presents the soil saturation concentration equation (originally presented by *Soil Screening Guidance: User's Guide* [EPA 1996b]).

In addition, EPA Region 9 (1996c) has calculated soil saturation concentrations for VOCs, and reported these concentrations as PRGs when they exceed the saturation limit (this is designated with a "SAT" qualifier in the tables).

Particulate Emission Factor

Inhalation of fugitive dusts is a consideration for nonvolatile constituents in surface soils. The PEF relates the concentration of constituent in soil to the concentration of dust particles in air and represents an annual average emission rate based on wind erosion. The PEF equation presented in EPA's *Soil Screening Guidance: Users' Guide* (1996b) should be used when calculating soil screening levels for compounds know to exert significant toxicity via the fugitive dust inhalation pathway (Table 4-8) and can also be used to calculate risk-based concentrations. This equation is also used by EPA Region 9 (1996c) when calculating soil PRGs. The Q/C used in the PEF equation was derived from a modeling exercise using a full year of meteorological data for 29 U.S. locations selected to be representative of the range of meteorological conditions across the nation. The results of these modeling runs have been compiled for nine climatic zones and sources of 0.5 to 30 acres (Table 4-9). A dispersion factor value of 90.80 g/m^2-s per kg/m^3 (Minneapolis) is used by Region 9 to determine a default PEF and may be used for screening purposes (EPA 1996c). To develop a facility-specific PEF, place the facility into a climatic zone and choose a dispersion factor and wind speeds that best represent the site's size and meteorological conditions.

TABLE 4-10

DERIVATION OF THE SOIL SATURATION LIMIT
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

$$C_{sat} = \frac{S}{\rho_b} (K_d \rho_b + \theta_w + H' \theta_a)$$

Parameter	Definition (units)	Default
C_{sat}	soil saturation concentration (mg/kg)	calculated
S	solubility in water (mg/L-water)	chemical-specific[a]
ρ_b	dry soil bulk density (kg/L)	1.5
K_d	soil-water partition coefficient (L/kg)	K_{oc} x f_{oc} (chemical-specific[a])
f_{oc}	fraction organic carbon in soil (g/g)	0.006 (0.6%) or facility-specific, if available
θ_w	water-filled soil porosity ($L_{water}L_{soil}$)	0.15
H'	dimensionless Henry's law constant	chemical-specific[a]
θ_a	air-filled soil porosity (L_{air}/L_{soil})	n - θ_w = 0.28
n	total soil porosity (L_{pore}/L_{soil})	1 - (ρ_b/ρ_s) = 0.43
ρ_s	soil particle density (kg/L)	2.65

Source: Modified from U.S. Environmental Protection Agency 1996b

Notes:

a See Attachment H
mg/kg Milligram per liter
L Liter
g Gram
L_{water} Volume of water
L_{soil} Volume of soil in liters
L_{air} Volume of air in liters
L_{pore} Pore volume in liters

Both EPA (1996b) and EPA Region 9 (1996c) acknowledge that when soil ingestion and fugitive dust inhalation are evaluated together, the risks and hazards associated with ingestion are significantly greater than those associated with inhalation. Exceptions are the metals chromium (hexavalent form) and cadmium; therefore, the inclusion of the fugitive dust inhalation pathway can be limited to these two metals or other compounds known to exert significant toxicity via dust inhalation. Default PEF modeling assumptions can normally be assumed; however, if site conditions are such that higher fugitive dust emissions than the defaults are likely (for example, dry, dusty soils, high average annual wind speeds, vegetative cover less than 50 percent) and cadmium or hexavalent chromium is present in surface soils, site-specific parameters should be used in the PEF equation (EPA 1996b).

4.5.2.2 Household Water-to-Indoor Air

A groundwater-to-indoor air VF (VF_w) of 0.005 x 1,000 L/m^3 is used to define the relationship between the concentration of the constituent in household water and the average concentration of the volatilized constituent in air (EPA 1991c). In the derivation, all uses of household water were considered (for example, showering, laundering, dish washing). It was assumed that the volume of water used in a residence for a family of four is 720 L/day, the volume of the home is 150,000 L, and the air exchange rate is 0.25 m^3/hour. Furthermore, it is assumed that the average transfer efficiency weighted by water use is 50 percent (that is, half of the concentration of each chemical in water will be transferred into air by all water uses. Note: the range of transfer efficiencies extends from 30 percent for toilets to 90 percent for dishwashers). The VF_w is used in the groundwater RBC calculation equation (presented in Section 4.7.2) to assess volatilization of constituents from tap water into indoor air. Use of the EPA (1991c) water-to-air Vf_w results in a conservative estimation of volatilized constituent concentrations. Updated estimates of water volume use, house volume, and air exchange rate are presented in the 1995 draft revised *Exposure Factors Handbook* (EPA 1996e) and may be used to recalculate a Vf_w if warranted by facility-specific conditions. In addition, the intrusion rate of vapors through building foundations into enclosed spaces may be predicted using a model developed by Johnson, et al. (1991).

4.5.2.3 Soil-to-Groundwater Estimations

EPA's *Soil Screening Guidance: Users' Guide* (EPA 1996b) recommends a dilution factor model and soil/water partition equation for estimating soil screening levels that are protective of groundwater. The approach requires that groundwater constituent concentrations at the downgradient edge of contaminated soil not exceed MCL or risk-based groundwater cleanup levels (that is, cleanup levels for residential use). The method is applied in step-by-step fashion. A groundwater cleanup level and dilution factor are identified. The dilution factor is based on facility-specific aquifer characteristics, including hydraulic conductivity, hydraulic gradient, mixing zone depth, and source length. The dilution factor is multiplied by the groundwater cleanup level to determine a target soil leachate concentration. The target soil leachate concentration represents a constituent concentration that, upon dilution in groundwater, will not result in an exceeded groundwater cleanup level directly beneath the site.

The target soil leachate concentration can be compared directly to leach test results for the site. EPA (1996b) provides some guidance on the availability of leach tests and suggests using the EPA Synthetic Precipitation Leaching Procedure [Method 1312 from the current edition of SW-846 (EPA 1986b)]. EPA (1996b) also provides a soil/water partitioning equation for converting the target soil leachate concentration into a total soil concentration. The equation requires that site-specific soil parameters, including fraction organic carbon, soil porosity, and soil density, be determined. Default soil parameters are also proposed. The total soil concentration can be used as a soil screening level.

The previous procedures assume an infinite source of contamination. Because this assumption can violate mass balance considerations, such as for small sources, EPA (1996b) also presents a model for calculating mass-limit soil screening levels. The mass-limit soil screening level represents a soil constituent concentration that is still protective of groundwater cleanup levels when the entire volume of contamination leaches to groundwater over an assumed 30-year exposure duration. The mass-limit soil screening model can be used when the area and depth of the source are known or can be estimated reliably. Both standard and mass-limit soil screening levels should be calculated, and the higher of the two values should be selected (EPA 1996b).

As previously stated, the soil screening concentrations are to be used in preliminary facility investigations and assume residential exposure circumstances. EPA did not intend that they would serve

as national cleanup standards. More detailed fate and transport models can be used to back-calculate soil cleanup levels that are protective of groundwater. Additional facility-specific data are required for these models. Multimedia models are available that simulate the hazardous constituent transport through both the vadose zone and the aquifer (for example, MEPAS, GWSCREEN, ROAM, RESRAD, and MULTIMED). Other models may only simulate vadose zone transport (for example SOLUTE, BIOPLUME, and AT123D). In this situation, two models should be used to simulate multimedia transport, and a mass balance conservation approach should be used to connect the models. Qualified hydrogeologists should be consulted when selecting a fate and transport model, and the use of the model should be subject to the approval of regulatory personnel overseeing the corrective action or closure activities. Further modeling and/or monitoring to assess groundwater discharges to surface water may be required on a facility-specific basis.

Washington State MTCA regulation (WAC 173-340-740) requires that soil cleanup standards be protective of groundwater. Historically, MTCA has required that the soil concentration be equal to or less than 100 times the groundwater cleanup standard unless it could be demonstrated that a higher soil concentration is protective of groundwater at the facility. At this printing, Ecology was preparing to propose a number of changes to MTCA regulations, including ways to calculate protection of groundwater from soil contamination. Ecology's web site should be consulted for proposed and final rules (http://www.wa.gov/ecology/tcp/cleanup.html). For further information, contact Charles San Juan of Ecology at (360) 407-7191.

4.5.2.4 Food Chain Exposure Pathways

Migration of contamination into human food chain pathways may require consideration in facility-specific situations. For example, if soil contamination is present in areas that are likely to be used for home gardening, this pathway should be considered when setting soil cleanup levels. EPA RCRA guidance for assessing indirect exposures at hazardous waste combustion facilities provides useful intermedia hazardous constituent partitioning equations for estimating constituent migration into the food chain. The draft *Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes* (EPA 1994i) compiles and streamlines intermedia partition equations proposed in earlier RCRA combustion guidance documents (EPA 1990, 1993d). The EPA (1994i) document contains RCRA program guidance issued by the Office of Emergency and Remedial Response,

while the EPA (1990, 1993d, and 1995g) reports are technical support documents. In addition, the draft *Estimating Exposure to Dioxin-Like Compounds* (EPA 1994j) presents similar intermedia partition equations for estimating dioxin uptake into plants, animals, and fish. EPA regional risk assessors should be contacted for further information on the availability of updated documents.

While much of the RCRA combustion guidance series addresses the fate of constituent air emissions, partitioning equations presented for secondary migration pathways can be used to derive soil and water RBCs. The EPA (1994i,j) guidance documents address the primary food chain pathways, including constituent migration into garden produce, fish, beef, and milk. Intermedia constituent partitioning equations for migration pathways, such as soil-to-root-vegetable and water-to-fish, are recommended. For example, the equations estimate the concentration of a constituent in a secondary media, such as a garden plant, that results from constituent uptake into the plant from soil. Similarly, estimates can be made of constituent concentrations in fish resulting from constituent uptake from water or sediment, or constituent concentrations in beef cattle and dairy cattle milk resulting from constituent uptake from soil and plants. These equations rely on constituent-specific biotransfer or bioconcentration factors that represent the ratio of constituent concentrations in the secondary media (for example, garden produce) to constituent concentrations in the primary media (for example, soil).

These equations can be used in a HHRA to first calculate constituent concentrations in food chain pathways resulting from air, soil, or water contamination. Human ingestion rates for these food chain pathways (for example, garden produce or fish ingestion rates) are then estimated. The dose and resulting risk or hazard are then calculated. Food chain pathways are not typically considered when calculating risks or RBCs, and their relevance should be determined on a case-by-case basis. Methods for assessing food chain exposure pathways are typically conservative and may result in RBCs that are lower than RBCs based on direct contact. They should not be evaluated at every facility, but should be considered on a case-by-case basis where the food chain pathway is known to be a complete exposure pathway. At sites where the plant ingestion pathway may reasonably exist, screening level estimates may be developed using the EPA Region 10 ASARCO plant uptake data for arsenic, cadmium, and lead. For other contaminants, applicable portions of EPA (1994i) should be used. Special situations where food chain organisms such as fish or shellfish are consumed at a subsistence level, such as in Alaska or for Native American populations, should be incorporated into RBCs. EPA Region 10 risk assessors should be consulted regarding rates of food consumption for such specific situations (for example, for

Puget Sound or Columbia River fisheries). EPA Region 10 risk assessors should also be contacted to confirm the selection of appropriate partitioning equations for use in determining either facility risks and hazards or facility-specific soil and water RBCs. EPA Region 10 has decided to assume that 10 percent of the inorganic arsenic in seafood is organic (see Attachment I).

4.6 TOXICITY ASSESSMENT

The toxicity assessment summarizes the toxicologic basis for all chemical-specific toxicity data using available dose-response information. Toxicity assessments should be conducted as described in Chapter 7 of *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A,* (EPA 1989c). The following sections present an overview of the types of dose-response information used to characterize carcinogenic and noncarcinogenic dose responses (Section 4.6.1), sources of EPA toxicity values (Section 4.6.2), and methods for assessing chemicals without EPA toxicity values (Section 4.6.3).

4.6.1 Dose-Response Information

In developing HHRA methods, EPA recognizes fundamental differences between carcinogenic and noncarcinogenic dose-response variables used to estimate risks. Because of these differences, human health risk is characterized separately for the carcinogenic and noncarcinogenic effects related to hazardous constituents. Some analytes have both carcinogenic and noncarcinogenic effects, although in many cases, EPA has published toxicity criteria for only one of them. It should not be assumed that in all cases this is the more sensitive type of toxic effect. Information sufficient to characterize and/or quantify the dose-response relationship may be lacking (for example, in the case of endocrine disruptors, or when no appropriate animal models exist).

Human epidemiologic data provide the strongest evidence of a positive association between hazardous constituents and human health effects; however, human health effects data adequate to develop quantitative dose-response relationships are available for only a few chemicals. As a result, toxicity information obtained from nonhuman mammalian experiments is often used to predict human dose-response relationships and to develop chemical-specific toxicity criteria. Animal toxicity data are typically derived from studies in which animals are exposed to relatively high doses of a chemical. In

contrast, the chronic exposures evaluated in the HHRA are for much lower doses. In addition, the animals are exposed for relatively short periods of time compared with chronic exposure risk assessments, which typically assume humans will be exposed for a lifetime. Both of these contribute to the uncertainties in HHRA (see Section 4.8).

4.6.1.1 Toxicity Information for Carcinogenic Effects

Currently, the key dose-response variable used to evaluate carcinogenic effects is the cancer potency factor (CPF), which is derived from carcinogenicity studies (typically conducted at high doses). To evaluate the probability of developing cancer at the lower doses more typically encountered by the public, the EPA-recommended linearized, multistage model is applied to the data. This mathematical model expresses individual excess cancer risk as a function of exposure and is based on the conservative assumption that even a single, low-dose exposure to a carcinogen may result in cancer. The CPF, expressed as risk per milligrams per kilogram per day [(mg/kg/day)$^{-1}$], quantitatively defines the relationship between dose and response.

In HHRA, chemical-specific CPFs are multiplied by the lifetime average daily dose (LADD) of a hazardous constituent from a given exposure route to assess the upper-bound cancer risk associated with that dose. Carcinogenic risk is expressed as the probability of an individual in a population developing cancer (for example, one in a million or 1E-6). Chemical-specific CPFs can be incorporated into RBC equations along with dose information to back-calculate RBCs that correspond to selected target risks (Section 4.7).

EPA assigns weight-of-evidence classifications to potential carcinogens. Under this system, chemicals are classified as belonging to one of six groups (EPA 1997a):

- Group A - chemicals for which sufficient data exist to support a causal association between exposure to the agent and the induction of cancer in humans

- Group B - Probable carcinogens:

  - Group B1 - chemicals for which there is limited evidence of carcinogenicity from human exposure studies but sufficient evidence of carcinogenicity from animal studies

  - Group B2 - chemicals for which there is inadequate evidence of carcinogenicity from human exposure studies but sufficient evidence of carcinogenicity from animal studies

- Group C - chemicals for which there is limited evidence of carcinogenicity from animal studies; possible carcinogens

- Group D - chemicals for which the carcinogenicity database is inadequate

- Group E - chemicals exhibiting no evidence of a carcinogenic response in humans or animals

For HHRAs, carcinogenic risks are evaluated only for chemicals with weight-of-evidence classifications of A, B1, B2, and C.

EPA issued *Proposed Guidelines for Carcinogen Risk Assessment* to incorporate advances in scientific knowledge into the risk assessment process (EPA 1996i). When finalized, this will essentially redefine EPA's approach to human cancer risk assessments. In particular, classification of a chemical as a carcinogen will involve all available evidence, including structure-activity relationships and comparative metabolism and toxicokinetics. The primary effects of this change in procedure will be to decrease the uncertainty in the toxicity assessment and to allow for risk estimates that more adequately reflect the scientific understanding of a specific chemical's role in the process leading to cancer. Other proposed changes include replacing the current A through E classification scheme for the weight-of-evidence by three classifications, with some subdivisions. These new classes will be exposure route-specific. After the proposed guidelines are finalized, the EPA intends to reevaluate carcinogens on an individual basis, probably a few per year; therefore, classification changes will be phased in over time. Project managers should ensure that facilities utilize and reference the most current information.

4.6.1.2 Toxicity Information for Noncarcinogenic Effects

The key dose-response variable used in quantitative HHRA of noncarcinogenic effects is the chronic reference dose (RfD). The chronic RfD, expressed in units of milligrams per kilogram-day for a specific chemical, is an estimate of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (EPA 1989c). Chronic RfDs consider exposures that occur over about 10 percent or more of a lifetime. RfDs are usually based on the relationship between the dose of a noncarcinogen and the frequency of systemic toxic effects in experimental animals or humans. It is a specific assumption of this method that there is a threshold intake rate below which toxic effects do not occur. The threshold of observed effects is divided by an uncertainty factor or factors to derive an RfD that protects the most sensitive members of the population. The uncertainty factors are usually multiples of 10, and each factor represents a specific area of uncertainty inherent in extrapolation from the available data.

Uncertainty factors are applied to data in the following cases (EPA 1989c):

- To account for variation in the general population (to protect sensitive subpopulations)
- To extrapolate the data from animals to humans
- To adjust for using a subchronic study rather than a chronic study
- To adjust for using a lowest-observable-adverse-effect-level instead of a no-observable-adverse-effect-level in developing an RfD
- To account for database deficiencies

A modifying factor ranging from 1 to 10 is also applied to the RfD to address uncertainties in the scientific studies used to develop RfDs.

Once an RfD for a compound has been verified by EPA, it is used to characterize the likelihood of noncarcinogenic hazards resulting from long-term chemical exposures at a facility. In HHRA, the RfD is compared to the average daily dose (ADD) calculated in the exposure assessment to determine whether chronic effects might occur. The ratio of the ADD and the RfD is called the hazard quotient (HQ). If the predicted ADD exceeds the RfD, the HQ is greater than 1.0, and there may be concern for potential noncancer effects (EPA 1989c). HQs for individual constituents can be added to calculate an exposure pathway or site hazard, referred to as the hazard index (HI). According to *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual, Part A*, the addition of HQs from all hazardous constituents is appropriate as a screening-level approach (EPA 1989c). If the resulting HI is greater than 1.0, however, it would be appropriate to calculate new HIs for hazardous constituents with similar critical effects and mechanisms of action. Further guidance on segregating COPCs by critical effects and mechanisms of action is presented in Section 4.7.4. Chemical-specific RfDs can be incorporated into RBC equations to back-calculate RBCs that corresponded to target hazards (Section 4.7).

EPA has also derived inhalation reference concentrations (RfC), which are estimates of daily exposures (via inhalation) to the human population including sensitive subgroups that are likely to be without appreciable risk of deleterious effects. RfCs are generally reported as a concentration in air (milligrams per cubic meter). For purposes of using standard RBC equations, however, RfCs can be converted to a corresponding inhaled dose (milligram per kilogram-day) by dividing by 70 kilograms (an assumed human body weight), multiplying by 20 cubic meters per day (an assumed human inhalation rate), and, preferably, adjusting by an appropriate, chemical-specific absorption factor. This conversion, however, may often be technically incorrect, and the appropriateness of doing this must be evaluated on a case-by-case basis (EPA 1997a). RfCs can be used in screening risk assessments to determine whether a constituent may contribute significantly to the HI; however, the appropriateness of RfC conversions and their use in baseline HHRA's should be verified by a EPA Region 10 risk assessor (EPA 1997a) prior to their use.

4.6.2 U.S. Environmental Protection Agency Toxicity Factors

Toxicity factors (RfDs, RfCs, and CPFs) are not always readily available, so multiple sources may need to be consulted. The EPA Region 10 hierarchy of sources for RfDs, RfCs, and CPFs is as follows:

1. Integrated Risk Information System (IRIS) on-line database (EPA 1996g). IRIS is the preferred EPA source for toxicity information. It provides RfDs, RfCs and CPFs that have been reviewed and verified by agency-wide work groups. Supporting discussion and references also appear in each chemical file. IRIS User Support at (513)569-7254 can provide information about how to access IRIS. IRIS is available to EPA Region 10 personnel on its automaxx menu and to the public on EPA's web site at http://www.epa.gov/iris.

2. Health Effects Assessment Summary Tables (HEAST) (EPA 1997a). HEAST summarizes all currently available toxicity factors developed by National Center for Environmental Assessment (NCEA) and a bibliography of Health Effects Assessments and related documents. These documents contain supporting information for toxicity values developed by EPA NCEA. The HEAST tables are revised quarterly. Toxicity factors that appear in IRIS do not appear in HEAST.

3. Provisional values developed by NCEA. Region 10 risk assessment staff should be contacted to obtain information from NCEA.

4. Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels (MRL). These MRLs are developed using an approach that is generally consistent with RfD methodology. These may be available for acute, intermediate, or chronic exposure durations and are potentially useful for situations of short-term exposure, for which verified RfDs are seldom available. They can be found in ATSDR Toxicity Profile documents (in the Health Effects Summary section, in the text and/or on the "thermometer" chart). MRLs can also be found on the Internet at http://atsdr1.atsdr.cdc.gov:8080/mrls.html. Concurrence with use of MRLs for a specific situation should be sought from Region 10 risk assessment staff.

5. Region 10 risk assessors may have access to additional toxicity numbers from other sources that may be appropriate for a given circumstance.

In addition to the RfDs, RfCs, and CPFs, the EPA weight-of-evidence classifications and the types of cancers observed in animal testing should be presented for all carcinogenic hazardous constituents, while the confidence levels, critical effect and target organs, and uncertainty and modifying factors associated with the available RfDs should also be presented. The identification of critical effects and target organs becomes important during risk characterization when segregating COPCs for HI calculations.

Since carcinogenic chemicals may also cause noncarcinogenic health effects, RfDs (when available) should be compiled for carcinogenic chemicals and used to evaluate potential noncarcinogenic effects for these chemicals. It should not be assumed that noncarcinogenic effects are negligible or even less important than cancer risks just because RfD or RfCs are not available.

4.6.3 Chemicals or Exposure Pathways With No U.S. Environmental Protection Agency Toxicity Values

This section identifies key constituents that do not have toxicity values in the EPA IRIS and HEAST databases. Recommendations for what toxicity values may be used to evaluate these constituents are presented. Methods for evaluating exposure pathways with limited or no EPA toxicity values are also presented. If it is determined that provisional or other alternative values may be used, their uncertainties must be discussed in the risk assessment document (specifically in the risk characterization section) and should be considered in risk management decisions.

4.6.3.1 Polynuclear Aromatic Hydrocarbons

Polynuclear aromatic hydrocarbons (PAH) are a very extensive group of organic compounds that contain at least two benzene rings. Sources of PAHs include petroleum and coal tar products. The major source of PAH releases to the environment is combustion of these products (EPA 1982). PAHs may be found at hazardous waste sites that used or generated these products, such as coal gasification plants, coal tar generators, power plants, wood treaters that used creosote, and coke manufacturers. Some PAHs are carcinogenic and some are not. Benzo(a)pyrene is currently the only carcinogenic PAH for which a CPF has been verified by EPA. It is recommended that toxicity equivalency factors (TEF) based on the relative potency of each PAH compound to that of benzo(a)pyrene be used to evaluate the toxicity of the remaining carcinogenic PAHs on the target compound list (see following list). The TEFs presented here were recommended by EPA's NCEA and are from the *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons* (EPA 1993e). Concentrations of specific carcinogenic PAHs should be multiplied by their respective TEFs to calculate their concentrations relative to benzo(a)pyrene potency. This benz(a)pyrene equivalent concentration should then be used for risk characterization. These TEFs are not in IRIS, and therefore are not necessarily accepted by all states and may be revisited by NCEA in the future.

POLYNUCLEAR AROMATIC HYDROCARBON TOXICITY EQUIVALENCY FACTORS

Compound	TEF
Benzo(a)pyrene	1.0
Benzo(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
Benzo(k)fluoranthene	0.01
Chrysene	0.001
Dibenzo(a,h)anthracene	1.0
Indeno(1,2,3-cd)pyrene	0.1

4.6.3.2 Chlorinated Dioxins and Furans

Dioxins and furans are created during combustion processes, such as during incineration of wastes or during the burning of fossil fuels. Dioxins and furans may also be created during the manufacture of chlorine and chlorinated products (for example, chlorinated phenols, chlorinated benzenes, PCBs, phenoxy herbicides, and other compounds), and during paper manufacturing involving chlorine bleaching (EPA 1994j). EPA has verified a CPF for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD); it is the only chlorinated dioxin or furan with a verified CPF. TEFs based on the relative potency of each dioxin and furan congener to that of TCDD have been developed by EPA and are presented in *Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and Dibenzofurans (CDDs and CDFs) and 1989 Update* (EPA 1989f). The TEFs are listed on the following page. Concentrations of specific dioxin and furan congeners should be multiplied by their respective TEFs to calculate their concentration relative to 2,3,7,8-TCDD potency (example follows list of TEFs). This 2,3,7,8-TCDD equivalent concentration should then be used for risk characterization. At the Dioxin '97 conference held in Indianapolis in August 1997, the World Health Organization presented an abstract in which a new TEF scheme for dioxins, furans, and dioxin-like PCBs was delineated for humans/mammals and separately for fish and for birds. This abstract is included as Attachment J. EPA may at some point decide to adopt some or all of these TEFs once the World Health

Organization publishes its complete report. A regional risk assessor should be consulted to determine EPA's TEF policies for PCBs and dioxins/furans when they are COPCs at a given site.

EPA published a draft comprehensive reassessment of dioxin toxicity in 1994 and is currently finalizing that reassessment. Several chapters of the draft reassessment are available on the Internet at http://www.epa.gov/docs/exposure/. Revised chapters are placed on that site as they become available. It is expected that the reassessment will be finalized in early 1998. While dioxin and furan noncarcinogenic effects are not insignificant, EPA has not quantified such effects.

DIBENZO-P-DIOXIN AND DIBENZOFURAN TOXICITY EQUIVALENCY FACTORS

Compound	TEF
Dioxins	
2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)	1.0
Pentachlorinated dibenzo-p-dioxin (2,3,7,8 chlorines)	0.5
Hexachlorinated dibenzo-p-dioxin (2,3,7,8 chlorines)	0.1
Heptachlorinated dibenzo-p-dioxin (2,3,7,8 chlorines)	0.01
Octachlorinated dibenzo-p-dioxin	0.001
Other chlorinated dibenzo-p-dioxins	0
Furans	
2,3,7,8-Tetrachlorodibenzofuran	0.1
1,2,3,7,8-Pentachlorodibenzofuran	0.5
2,3,4,7,8-Pentachlorodibenzofuran	0.05
Hexachlorinated dibenzofuran (2,3,7,8 chlorines)	0.1
Heptachlorinated dibenzofuran (2,3,7,8 chlorines)	0.01
Octachlorinated dibenzofuran	0.001
Other chlorinated dibenzofurans	0

EXAMPLE OF CALCULATING 2,3,7,8-TCDD EQUIVALENT CONCENTRATION USING TOXICITY EQUIVALENCY FACTORS			
Analyte	**Soil Concentration (mg/kg)**	**TEF**	**2,3,7,8-TCDD Equivalent Concentration (mg/kg)**
Octachlorinated dibenzofuran	1.5E+2	0.001	1.5E-1
2,3,7,8-Tetrachlorodibenzofuran	2.0E+1	0.1	2.0E+0
Total 2,3,7,8-TCDD equivalent concentration			**2.1E+0**

4.6.3.3 Polychlorinated Biphenyls

The following discussion of PCBs is based on PCB carcinogenicity information presented in *PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures* (EPA 1996j). PCBs are mixtures of synthetic organic chemicals. The primary PCB molecule consists of two six-carbon rings with one chemical bond joining a carbon from each ring. Commercial mixtures of PCBs have from one to ten chlorines attached to the other carbons on the two rings. There are 209 possible arrangements of chlorines on the two rings; these molecular arrangements are referred to as congeners. PCB congeners with the same number of chlorines are called isomers. Commercial PCB mixtures manufactured in the United States carry the trademark "Aroclor" (for example, Aroclor 1016, 1242, 1248, 1254, and 1260). Each of these Aroclors is made up of mixtures of PCB congeners, ranging from congeners with four chlorines or less (for example, Aroclor 1016) to congeners with five to nine chlorines (for example, Aroclor 1260).

PCBs are classified by EPA as probable human carcinogens, but PCB mixtures differentially contribute to excess cancer risk. Certain PCB mixtures (Aroclor 1254) and congeners (see following list) have demonstrated tumor-promoting activity. Congener information is useful when evaluating the potential for a PCB mixture to cause cancer, and as discussed below, is used to select a CPF appropriate to the mixture and to the exposure pathway(s).

When the two six-carbon rings that make up a PCB molecule are aligned on the same plain, the molecule is referred to as being "coplanar." Certain coplanar PCB congeners have toxicity mechanisms that are similar to that of dioxin (see list of these congeners on page 4-52). As discussed below, concentrations of these PCB congeners can be converted to equivalent concentrations of TCDD, and TCDD toxic equivalent risks can be calculated.

POLYCHLORINATED BIPHENYL MIXTURES AND CONGENERS THAT TESTED POSITIVE FOR TUMOR-PROMOTING ACTIVITY

Mixture	Congener
Aroclor 1254	2,4,2',4'-Tetrachlorobiphenyl (TECB)
Kanechlor 400	2,4,2',5-TECB
Kanechlor 500	2,5,2',5'-TECB
Clophen A50	3,4,3',4'-TECB
	2,3,4,3',4'-Pentachlorobiphenyl (PECB)
	2,4,5,3',4'-PECB
	3,4,5,3',4'-PECB
	2,4,5,2',4',5'-Hexachlorobiphenyl

Source: EPA 1996j

PCB mixtures in soil, sediment, air, water, and biota media may differ from the parent commercial mixture initially released to the environment, based on partitioning, bioaccumulation, and transformation processes. Anaerobic and aerobic biodegradation may result in the removal of chlorines and the breaking of carbon rings; however, PCB congeners are persistent, particularly those with a high chlorine content. These more chlorinated congeners can absorb onto soil and sediment particles and become concentrated in fish and animal fat. The make-up of a bioaccumulated PCB mixture can therefore vary from that of its parent commercial mixture and may contain a higher percentage of more persistent, highly chlorinated congeners.

Bioaccumulated mixtures appear to be more toxic than commercial mixtures (Aulerich et al. 1986). This toxicity is not necessarily based on chlorine content only; both the number and position of chlorines is important. Partitioning of more toxic PCB congeners in environmental media may result in increased toxicity to exposed humans compared to the toxicity of the parent commercial mixture. For example, the

cancer potencies of PCB mixtures in the food chain, soil, or sediment are predicted to be greater than the potency of more water-soluble PCBs.

Historically, the CPF for PCB was based on commercial mixture toxicity. EPA has developed new procedures to evaluate environmental mixtures of PCBs: *PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures* (EPA 1996j). This document presents updated toxicity information that can be used to evaluate the carcinogenic risks from environmental PCB exposure. These procedures and new PCB slope factors were incorporated into EPA's IRIS in October of 1996. This update approach presents and describes the following:

> A range of upper-bound and central cancer potency factors for PCB mixtures, depending on:
>
> - The effect of environmental processes on the mixture
> - The route and timing of human exposures to the mixture
> - Available information on the site-specific types of PCB congeners

The range of potency observed for commercial mixtures must be used to represent the potency of environmental mixtures since no toxicity data on environmental mixtures are available. The range reflects experimental uncertainty and variability of commercial mixtures, but not human heterogeneity or differences between commercial and environmental mixtures. As noted, environmental processes alter mixtures through partitioning, transformation, and bioaccumulation, which may decrease or increase toxicity. The overall effect can be considerable, and the potency range observed from commercial mixtures may underestimate the true range for environmental mixtures. Limiting the potency of environmental mixtures to the range observed for commercial mixtures reflected a choice to base potency estimates on experimental results, rather than apply safety factors to compensate for lack of information. EPA addressed this issue by developing CPFs that consider the make-up and fate of environmental mixtures. EPA (1996j) presents a range of PCB central and upper-bound CPFs with three reference points. Each reference point or CPF has criteria that should be met for that CPF to be used.

Criteria include the human exposure pathway evaluated and specific information on the congener composition of the mixture that must be obtained through environmental sampling.

A tiered approach is used that allows different types of information in estimating the potency of environmental mixtures of PCBs. Total PCBs or congener or isomer analyses are recommended. The first (default) tier is invoked when congener information is limited. Only the high-risk CPF should normally be used in the first tier since it is not possible to demonstrate the absence of persistent, dioxin-like, or tumor-promoting congeners without such analysis. The lowest-risk CPFs cannot be used without specific information on the congener composition of the mixture.

The second tier is invoked when congener or isomer information is available from sampling and analysis; it can be used to further refine a potency estimate that was chosen to reflect an exposure pathway. The lowest upper-bound CPF (0.07 $[mg/kg/day]^{-1}$) may be used if congener or isomer analyses verify that congeners with more than four chlorines comprise less than 0.5 percent of total PCBs. The higher CPF (2.0 $[mg/kg/day]^{-1}$) should be used if dioxin-like, tumor-promoting, and persistent congeners are present. When dioxin-like coplanar congener concentrations are available, the use of CPFs for PCBs may be supplemented by the calculation of TCDD toxic equivalent risks. Under this method, PCB congeners that are not dioxin-like are evaluated using the appropriate PCB CPF, while PCB congeners that are dioxin-like are evaluated using the TCDD CPF. TEFs for the dioxin-like PCB congeners (see the following list) would be used to estimate TCDD toxic equivalent concentrations by multiplying the concentrations of individual dioxin-like PCB congeners by the TEFs. TCDD toxic equivalent concentrations from all dioxin-like PCB congeners are then added together. This sum is used to calculate a lifetime average daily dose of dioxin, which is then multiplied by the dioxin CPF to estimate dioxin-like PCB risk. Section 4.6.3.2 describes possible changes in the TEFs for dioxin-like PCBs based on World Health Organization studies.

DIOXIN-LIKE POLYCHLORINATED BIPHENYLS AND TOXICITY EQUIVALENCY FACTORS

Non-Ortho Congeners	TEF	Mono-Ortho Congeners	TEF	Di-Ortho Congeners	TEF
3,4,3',4'-Tetrachlorobiphenyl (TECB)	0.0005	2,3,4,3',4'-PECB	0.0001	2,3,4,5,2',3',4'-HPCB	0.0001
3,4,5,3',4'-Pentachlorobiphenyl (PECB)	0.1	2,3,4,5,4'-PECB	0.0005	2,3,4,5,2',4',5'-HPCB	0.00001
3,4,5,3',4',5'-Hexachlorobiphenyl (HXCB)	0.01	2,4,5,3',4'-PECB	0.0001		
		3,4,5,2',4'-PECB	0.0001		
		2,3,4,5,3',4'-HXCB	0.0005		
		2,3,4,3',4',5'-HXCB	0.0005		
		2,4,5,3',4',5'-HXCB	0.00001		
		2,3,4,5,3',4',5'-Heptachlorobiphenyl (HPCB)	0.0001		

Source: EPA 1995j

Table 4-11 summarizes the range of CPFs for PCBs, indicating how exposure pathway and congener/isomer information is used to select CPFs. EPA (1996j) presents three examples that show how additional information regarding the types of PCB congeners present affects the CPFs used to evaluate risk and the subsequent risk estimates. Example 3 shows how PCB congener information, specifically regarding dioxin-like congeners, can be incorporated into the risk estimates. Essentially, lifetime average daily doses and risk estimates would be calculated for the dioxin-like and nondioxin-like portions of the mixture.

PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures (EPA 1996j) summarizes uncertainties associated with the proposed PCB CPFs. These include uncertainties inherent in the experimental information used to derive CPFs and uncertainties associated with applying the

TABLE 4-11

RANGES OF HUMAN POTENCY AND CANCER POTENCY FACTORS FOR ENVIRONMENTAL MIXTURES OF PCBS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Risk and Persistence	Central Cancer potency factor $(mg/kg/day)^{-1}$	Upper-bound Cancer potency factor $(mg/kg/day)^{-1}$	Site-Specific Criteria for Use
High[a]	1	2	Food chain exposure, ingestion of contaminated sediment or soil; inhalation of dusts or aerosols; presence of dioxin-like, tumor-promoting, or persistent congeners; early life exposure
Low	0.3	0.4	Ingestion of water soluble congeners, vapor inhalation, dermal contact (if no absorption factor is applied)
Lowest	0.04	0.07	Congener or isomer analyses verify that congeners with more than four chlorines comprise less than 0.5 percent of total PCBs.

Source: U.S. Environmental Protection Agency 1996j

Note:

a In the absence of congener-specific analytical information, the slope factor of two should normally be used since it is not possible to demonstrate the absence of dioxin-like, tumor-promoting, or persistent congeners without such analysis.

experimental information to human environmental exposures. Examples of uncertainties associated with human exposures include the following:

- It is crucial to recognize that commercial PCBs tested in laboratory animals were not subject to prior selective retention of persistent congeners through the food chain. For exposure through the food chain, risks can be higher than those estimated by EPA (1996j).
- PCBs persist in the body, providing a continuing source of internal exposure after external exposure stops. There may be greater-than-proportional effects from less-than-lifetime exposure, especially for persistent mixtures and for early-life exposures.

When planning for the collection of PCB samples, the ability of the laboratory to analyze for PCB congeners or isomers should be verified, and such analyses requested if relevant and appropriate based on facility conditions. For example, congener specification will be critical when it is suspected lower persistence and lower risk PCB congeners are present but verification is required. Likewise, confirmation that tumor-promoting or dioxin-like PCB congeners are present will require specific PCB analyses. Draft EPA method 8082 or similar analyses can be used to detect specific PCB congeners.

4.6.3.4 Manganese

A chronic, oral RfD is available on IRIS. It was revised in November 1995. The RfD reflects the total dietary intake of manganese. Manganese is a naturally occurring element and is present in the normal diet to a certain extent. When assessing the exposure to manganese from sources other than food, the narrative accompanying the IRIS value advises the use of a modifying factor of 3. This is especially important for the protection of infants who may be adversely affected, such as if they are fed formula made up with water which contains elevated levels of manganese. EPA Region I, in a technical bulletin called Risk Updates, published a description of how the modifying factor should be applied in risk assessments (See Attachment K). Region I Risk Updates are available on the Internet at http://www.epa.gov/region01/remed/riskupdates.html. The use of the modifying factor should always be used when determining acceptable levels of manganese in groundwater which is being used or may be

used in the future as drinking water. A site-specific determination should be made regarding the use of the modifying factor for soil. If it is a reasonable assumption that infants will not be exposed to the soil, the use of the modifying factor would not be necessary.

4.6.3.5 Total Petroleum Hydrocarbons

EPA verified toxicity values are not available for total petroleum hydrocarbons (TPH) or for most of the hundreds of individual chemicals that comprise petroleum products. Cleanup frameworks for TPH that have been developed and adopted by individual Region 10 states should generally be followed for petroleum releases in those states. The assessment of risks posed by TPH releases should always include at a minimum the measurement of benzene and the carcinogenic PAHs (see box in Section 4.6.3.1 for list). The leaching potential to ground and surface waters and vapor releases to ambient and enclosed breathing areas such as basements through structural breaches should be considered where applicable. The federal Water Pollution Prevention Act (also known as the Clean Water Act) prevents the discharge of oil to navigable waters of the United States such that it causes a film or sheen or causes a sludge or emulsion beneath the surface of the water (Clean Water Act 310(a)(1); 311(b)(3); and 40 CFR 110.3).

Each state in Region 10 is addressing TPH cleanups differently. For RCRA facilities where TPH releases are an issue, An EPA Region 10 underground storage tank technical expert in the groundwater protection unit should be consulted [(206) 553-1587] for the status of each state's TPH cleanup program. EPA's Office of Underground Storage Tanks is also developing guidance for TPH cleanups on Native American lands; however, the state in which the land is located may have a more sophisticated or more pertinent TPH cleanup framework. The Native American stakeholders should be consulted in making decisions about which cleanup framework to follow for petroleum releases on their lands.

4.6.3.6 Dermal Toxicity Factors

No RfDs or CPFs are available for the dermal route of exposure. In some cases, however, risks and hazards associated with dermal exposure can be evaluated using an oral toxicity factor. This route-to-route extrapolation assumes that the toxicity of a hazardous constituent is the same whether it is

experimental information to human environmental exposures. Examples of uncertainties associated with human exposures include the following:

- It is crucial to recognize that commercial PCBs tested in laboratory animals were not subject to prior selective retention of persistent congeners through the food chain. For exposure through the food chain, risks can be higher than those estimated by EPA (1996j).
- PCBs persist in the body, providing a continuing source of internal exposure after external exposure stops. There may be greater-than-proportional effects from less-than-lifetime exposure, especially for persistent mixtures and for early-life exposures.

When planning for the collection of PCB samples, the ability of the laboratory to analyze for PCB congeners or isomers should be verified, and such analyses requested if relevant and appropriate based on facility conditions. For example, congener specification will be critical when it is suspected lower persistence and lower risk PCB congeners are present but verification is required. Likewise, confirmation that tumor-promoting or dioxin-like PCB congeners are present will require specific PCB analyses. Draft EPA method 8082 or similar analyses can be used to detect specific PCB congeners.

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used in the future as drinking water. A site-specific determination should be made regarding the use of the modifying factor for soil. If it is a reasonable assumption that infants will not be exposed to the soil, the use of the modifying factor would not be necessary.

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Use MTCA

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4.6.3.6 Dermal Toxicity Factors

See Page D

No RfDs or CPFs are available for the dermal route of exposure. In some cases, however, risks and hazards associated with dermal exposure can be evaluated using an oral toxicity factor. This route-to-route extrapolation assumes that the toxicity of a hazardous constituent is the same whether it is

oral or dermal route. In certain instances, it may not be appropriate to use oral toxicity factors to evaluate the dermal pathway (for example, when a toxicant is known to exert a specific point-of-contact [skin] effect). A risk assessor can assist with the evaluation of the appropriateness of a route-to-route extrapolation.

Exposures via the dermal route are calculated and expressed as absorbed doses, while most oral toxicity factors are expressed as administered doses. An administered dose is the dose that is presented to a persons "exchange surfaces" or points of contact with the external world, including the mouth, skin, and nose. An absorbed dose in the portion of the administered dose that actually enters the general circulation of the body. For example, because the skin is an effective barrier to many chemicals, only a portion of the dose administered on the skin's surface will be absorbed through the skin into the blood stream. When evaluating dermal exposure to contaminants in water or soil, it may be necessary to adjust an oral toxicity value based on an administered dose to one based on an absorbed dose using a chemical's oral absorption efficiency. This section discusses the method for making this adjustment. If the oral toxicity factor is used unadjusted, the resulting risk or hazard estimates will be less conservative because adjusted values are more protective than unadjusted oral values (see examples below).

Information concerning absorption efficiencies may be found in various chemical-specific documents including ATSDR toxicological profiles and Health Effects Assessments. Another source of absorption efficiencies is a list compiled by the Health Sciences Research Division of the Oak Ridge National Laboratory. This list is included as Attachment L. A Region 10 risk assessor should be consulted before the adjustment of oral toxicity factors is considered.

The oral absorption efficiencies listed in the box to the right are recommended in *Supplemental Guidance to RAGs: Region 4 Bulletins, Human Health Assessment* and may be used as interim default values in the absence of chemical-specific values (EPA 1995h). An exception to the default value for inorganics should be made for cadmium. IRIS (EPA 1996g) states that the RfD for cadmium (based on drinking water) assumes an oral absorption efficiency of 5 percent. A risk assessor should be consulted for a value for arsenic.

- VOCs - 80 percent
- SVOC - 50 percent
- Inorganic Chemicals - 20 percent

As shown in the box to right, an oral CPF, expressed as an administered dose, is converted to an absorbed dose by dividing the oral CPF by the oral absorption efficiency.

Example: An oral CPF, unadjusted for absorption, equals 1.6 $(mg/kg/day)^{-1}$. Information (or an assumption) indicates a 20 percent oral absorption efficiency; therefore, the adjusted CPF would be 1.6 $(mg/kg/day)^{-1}$ / 0.20 = 8 $(mg/kg/day)^{-1}$.

Likewise, an oral RfD, expressed as an administered dose, is converted to an absorbed dose by multiplying the oral RfD by the oral absorption efficiency (either determined from literature or assumed) in the species on which the oral RfD is based.

Example: An oral RfD, unadjusted for absorption, equals 10 mg/kg/day. Information (or an assumption) indicates a 20 percent oral absorption efficiency; therefore, the adjusted RfD would be 10 mg/kg/day x 0.20 = 2 mg/kg/day.

4.6.3.7 Inhalation Toxicity Factors

Inhalation toxicity factors (RFC) are available for only a select number of hazardous constituents. Provisional inhalation toxicity values may be available from various sources such as EPA's NCEA or chemical-specific ATSDR toxicity profiles. EPA Region 10 risk assessors may be consulted as to the availability of inhalation toxicity factors.

For cases where EPA-derived toxicity factors are not available for the inhalation route of exposure but are available for the oral route, a Region 10 toxicologist should be contacted for guidance on route-to-route extrapolation. If an oral toxicity factor is used to evaluate inhalation risks or hazards, the uncertainty associated should be discussed. In certain instances, it may not be appropriate to use oral toxicity factors to evaluate the inhalation pathway (for example, when a toxicant is known to exert a specific point-of-contact [lung] effect). If it is recommended that route-to-route extrapolation not be considered and if no provisional toxicity values is available, the hazardous constituent in question should be discussed qualitatively, and its absence should be discussed in the uncertainty section.

4.7 CALCULATION OF RISK-BASED CONCENTRATIONS

EPA intends that contaminated RCRA sites be remediated in a manner consistent with available, protective, risk-based media cleanup standards (FR 19449, May 1, 1996). When appropriate promulgated standards and

promulgated standards and criteria do not exist, protective media cleanup standards can be developed using a facility-specific HHRA approach. The primary goal of HHRA is to calculate the chemical dose that a person may receive when exposed to contaminated media and to determine the type and magnitude of toxic effects that are known to occur at that dose level. The exposure and toxicity assessment methods described in Sections 4.5 and 4.6 are the major risk assessment tools used to accomplish this goal. Standardized risk characterization equations that incorporate exposure and toxicity information can be adjusted to calculate RBCs that correspond to selected target cancer risks or HQs.

The following subsections describe how target risks and HQs are selected (Section 4.7.1), what HHRA equations are used to calculate RBCs (Section 4.7.2 and Attachment E), how RBCs are calculated (including an example) (Section 4.7.3), how to calculate RBCs for multiple hazardous constituents (Section 4.7.4), how fate and transport models are used to determine RBCs for hazardous constituents in one media that may migrate into another media (Section 4.7.5), and how RBCs can be estimated for lead (Section 4.7.6).

4.7.1 Selection of Target Risks and Hazard Quotients

EPA's RCRA program risk reduction goal is to reduce the threat from facility-related carcinogenic hazardous constituents such that, for any medium, the excess risk of cancer to an individual exposed over a lifetime generally falls within a range from 1E-6 to 1E-4 (that is, 1 in one million to 1 in one hundred thousand) (FR 19449, May 1, 1996). Available risk-based media cleanup standards are thus considered protective if they achieve a level of risk that falls within the 1E-6 to 1E-4 cancer risk range. Program implementors and facility owners/operators should generally use 1E-6 as a point of departure when initially developing target site-specific media cleanup levels. For noncarcinogens, the HI should generally not exceed 1.0 (FR 19449, May 1, 1996).

Washington State MTCA regulations prescribe target risks of 1E-6 for Method B cleanup levels and 1E-5 for Method C or industrial cleanup levels for carcinogens, and HQ of 1.0 for all scenarios. Cleanups and closures at EPA-lead RCRA sites in Washington should typically be at least as conservative as MTCA requires to avoid the need for further action later. The Oregon State approved RCRA corrective action authorization package states that it will rely upon EPA risk assessment guidance documents to determine appropriate cleanup levels at RCRA facilities, including the use of a 1E-6 target

cancer risk and a 1.0 target HI. Idaho State relies on EPA's RFI guidance (EPA 1989a) for setting cleanup levels at RCRA facilities and bases residential land use cleanup levels on target cancer risks and HQs of 1E-6 and 1.0, respectively. Idaho has also indicated that industrial land use cleanup levels may be based on a upper-end target cancer risk of 1E-4 [Tetra Tech EM Inc. (Tetra Tech) 1996b].

4.7.2 Risk-Based Concentration Calculation Equations

As previously described in the introduction to Chapter 4, data collection and evaluation, exposure assessment, toxicity assessment, and risk characterization steps are used during HHRA to determine facility risks and hazards.

> During an exposure assessment, a daily dose is calculated by estimating the amounts of a hazardous constituent that a person may intake from soil, water, or air during typical residential, industrial, or other land use activities. In a toxicity assessment, data on toxic effects that occur at known dose levels are compiled, and toxicity values are derived from this information. CPFs are used to estimate an upper-bound probability of a person developing cancer if exposed to a specific dose of a constituent over a lifetime. Toxicity values for noncancer health effects (RfDs) predict the dose below which no toxic effects are expected to occur. Outputs from the exposure and toxicity assessments are combined to complete the risk characterization step.

For a carcinogen, a risk estimate represents an estimate of the incremental probability that an individual could develop cancer over a lifetime as a result of site-related exposure to that carcinogen (EPA 1989c). It does not include risks associated with exposure to the same or other carcinogens that are not facility-related (that is, background concentrations or occupational exposures).

These excessive lifetime cancer risks are calculated using equation 4-1:

$$\text{Lifetime cancer risk} = \text{LADD} \times \text{CPF} \qquad (4\text{-}1)$$

where

LADD = Lifetime average daily dose (mg/kg/day)
CPF = Cancer Potency Factor $(\text{mg/kg/day})^{-1}$

The LADD expresses the hazardous constituent dose for the facility based on exposure information. This dose is compared to the constituent's toxicity per unit dose to calculate the risk from exposure to the constituent attributed to releases from the facility.

For noncarcinogens, the potential for individuals to develop noncarcinogenic effects is evaluated by comparing an assumed intake developed over a specific exposure period to an RfD developed over a similar exposure period. This comparison takes the form of a ratio called an HQ and is expressed in equation 4-2:

$$HQ = ADD / RfD \tag{4-2}$$

where

HQ	=	Hazard quotient (unitless)
ADD	=	Average daily dose (mg/kg/day)
RfD	=	Reference dose (mg/kg/day)

The ADD and RfD are calculated over the same exposure period. The ADD expresses the constituent dose for the facility based on exposure information. The facility dose is compared to the RfD to estimate the likelihood of health effects.

Risk can be expressed as a lifetime excess cancer risk or as a noncarcinogenic hazard.

RBCs are calculated by the same methods used to calculate risks. The risk equations are simply reversed to solve for a daily constituent dose that is equivalent to a selected target risk or hazard level. The concentration of a hazardous constituent released from a facility that would cause such a dose is determined based on the site-specific exposure conditions assumed (for example, see Table 4-2) or measured. This concentration may serve as the basis of a cleanup level unless multiple hazardous constituents are present in concentrations above screening levels (see Section 4.7.4 for adjustments based on multiple constituents).

Examples of equations that may be used to calculate RBCs are presented in Exhibit 4-1. The equations are reduced versions of the PRG equations recommended by EPA Region 9 (1996c). The Region 9 equations are derived from standard EPA equations used to calculate risks or hazards. The standard

equations have been rearranged to solve for the soil or water constituent concentration that corresponds to target risk or HQ levels. The full EPA Region 9 equations and exposure assumptions are presented in Attachment E.

The ultimate selection of target risks and hazards are risk management decisions. EPA guidance for risk assessment (1989c, 1995a) anticipates that the risk assessment will proceed independent of and before risk management decisions. In Washington State, where MTCA is followed, many risk management decisions are already made by virtue of the exposure assumptions and levels of protectiveness required by Methods B and C.

Summary, reduced RBC equations are presented in Exhibit 4-1 for soil and water media. The reduced equations consider the primary direct exposure pathways for these media, including ingestion, inhalation, and dermal contact for soil and water. The exposure assumptions for each exposure pathway (presented in Table 4-2) were incorporated into the original Region 9 risk equation to arrive at the reduced equations. When available and determined to be appropriate to the facility assessment, chemical-specific parameters, including ABS values (Section 4.5.1), VF_s, PEFs (Section 4.5.2.1), and toxicity values (Section 4.6), must be entered into the reduced equations to calculate RBCs. The exposure pathway for dermal contact with constituents in water is not included in the Region 9 (1996c) PRG equations. This exposure pathway was incorporated in the Exhibit 4-1 groundwater equations. Depending on site-specific conditions, it may be determined that one or more exposure pathways are incomplete (that is, there are no actual or potential receptors to the constituents in questions, via a specific exposure pathway). In this event, the bracketed portion of the Exhibit 4-1 equations that correspond to that exposure pathway can be dropped from the equation.

Exhibit 4-2 presents the same reduced equations as Exhibit 4-1; however, in Exhibit 4-2, the equations are adjusted to solve for risk or HQ levels. Soil and water constituent concentrations and chemical-specific parameters (the same as those noted for Exhibit 4-1) can be entered into the Exhibit 4-2 equations to calculate risks and hazards for specific constituents. The soil and water constituent concentrations should represent the average concentration levels to which a human receptor could be exposed (this is defined as the exposure point concentration). Typically, the 95th percent upper confidence limit on the arithmetic mean (95th UCL) constituent concentration for the area of exposure is

EXHIBIT 4-2

REDUCED RISK AND HAZARD INDEX EQUATIONS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Soil Equations

For soils, equations are based on three exposure routes (ingestion, skin contact, and inhalation)[a].

Equation 1: Combined Exposures to a Single Carcinogenic Constituent in Residential Soil (adults and children)

$$R = C\ (mg/kg) \times \frac{\left[(1.1E\text{-}4 \times CPF_o) + (5E\text{-}4 \times ABS \times CPF_{o,adj}) + \left(\frac{11 \times CPF_i}{VF_s} \right) \right]}{73}$$

Equation 2: Combined Exposures to a Single Noncarcinogenic Constituent in Residential Soil (children)

$$HQ = C\ (mg/kg) \times \frac{\left[\left(\frac{2E\text{-}4}{RfD_o} \right) + \left(\frac{ABS}{RfD_{o,adj}} \times 4E\text{-}4 \right) + \left(\frac{10}{RfD_i \times VF_s} \right) \right]}{15.6}$$

Equation 3: Combined Exposures to a Single Carcinogenic Constituent in Industrial Soil (adults)

$$R = C\ (mg/kg) \times \frac{\left[(CPF_o \times 5E\text{-}5) + (CPF_{o,adj} \times ABS \times 1E\text{-}3) + (CPF_i/VF_s \times 20) \right]}{286}$$

Equation 4: Combined Exposures to A Single Noncarcinogenic Constituent in Industrial Soil (adults)

$$HQ = C\ (mg/kg) \times \frac{\left[\left(\frac{5E\text{-}5}{RfD_o} \right) + \left(\frac{ABS}{RfD_{o,adj}} \times 1E\text{-}3 \right) + \left(\frac{20}{RfD_i \times VF_s} \right) \right]}{102.2}$$

Groundwater Equations

For groundwater, equations are based on three exposure routes (ingestion, skin contact, and inhalation of volatiles).[a]

Equation 5: Combined Exposures to A Single Carcinogenic Constituent in Water (adults and children)

$$R = C\ (\mu g/L) \times \frac{\left[(1.1 \times CPF_o) + (5.5 \times CPF_i) + (2.6 \times K \times CPF_o) \right]}{73{,}000}$$

EXHIBIT 4-2 (Continued)

REDUCED RISK AND HAZARD INDEX
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Equation 6: Ingestion and Inhalation Exposures to A Single Noncarcinogenic Constituent in Water (adult)

$$HQ = C\ (\mu g/L) \times \frac{\left[\left(\frac{2}{RfD_o}\right) + \left(\frac{10}{RfD_i}\right) + \left(\frac{5.5 \times K_p}{RfD_o}\right)\right]}{73{,}000}$$

Air Equations

Equation 7: Inhalation Exposures to a Single Carcinogenic Constituent in Air (adults and children)

$$R = \frac{C\ (\mu g/m^3) \times CPF_i}{6{,}600}$$

Equation 8: Inhalation Exposures to a Single Noncarcinogenic Constituent in Air (adults)

$$HQ = \frac{C\ (\mu g/m^3)}{RfD_i \times 3{,}650}$$

Source: Modified from U.S. Environmental Protection Agency 1996g

Notes:

a	Volatile chemicals are defined as having a Henry's Law Constant [atm-m³/mol] greater than 10^{-5} and a molecular wei less than 200 grams/mol . Use Vf, for volatile chemicals and PEF for nonvolatile chemicals
ABS	Dermal absorption factor
C	Concentration
R	Cancer risk
HQ	Hazard quotient
CPF_o	Cancer potency factor, oral
$CPF_{o,adj}$	Cancer potency factor, oral, adjusted
CPF_i	Cancer potency factor, inhalation
K_p	Chemical-specific permeability coefficient (centimeters per hour)
VF_s	Volatilization factor, soil
RfD_o	Reference dose, oral
$RfD_{o,adj}$	Reference dose, oral, adjusted to account for percent gastrointestinal absorption of chemical
RfD_i	Reference dose, inhalation
µg/kg	Microgram per liter
mg/L	Milligram per liter
µg/m³	Microgram per cubic meter

used as the exposure point concentration. EPA's (1992e) *Supplemental Guidance to RAGs: Calculating the Concentration Term* details how to calculate 95th UCL exposure point concentrations for soil.

The *Supplemental Guidance to RAGs: Estimating Risk From Groundwater Contamination* (EPA 1993a) details how to calculate groundwater exposure point concentrations. Both documents are included as Attachment M. Additional information on determining exposure point concentrations and points of compliance is provided in Section 7.3.

An example of a constituent-specific calculation using the Exhibit 4-1 equations is presented in the following section. The same example can be applied to the Exhibit 4-2 equations, except that a constituent concentration is used to calculate a risk term instead of using a target risk term to calculate a RBC.

4.7.3 Examples of Risk-Based Concentration Calculations

As an example, the following assumptions have been made about a hypothetical RCRA facility:

- An RFI with adequate site characterization has been conducted
- Methylene chloride, an industrial solvent, has been determined to be a COPC in soil. The concentration of methylene chloride used in a facility HHRA was 2,100 mg/kg, representing the 95th percent upper confidence limit of the arithmetic mean. Calculated cancer risks and noncarcinogenic hazards exceeded target risk and target hazard levels
- Soil ingestion, dermal contact with soil, and inhalation of volatiles from soil have been determined to be the direct exposure pathways of concern
- A residential land use scenario has been determined to be appropriate
- A target excess cancer risk of 1E-6 and a target hazard of 1.0 have been identified by the program for this facility

No promulgated federal standards for methylene chloride in soil are available. An RBC can be calculated using equations 1 and 2 in Exhibit 4-1.

The following paragraphs discuss the specific information for methylene chloride that is needed to calculate carcinogenic and noncarcinogenic RBCs. Sections 4.7.3.1 and 4.7.3.2 present example RBC calculations based on carcinogenic and noncarcinogenic effects, respectively.

The IRIS (EPA 1996g) and HEAST (EPA 1997a) databases indicate that methylene chloride has toxicity values for both carcinogenic and noncarcinogenic effects. The oral CPF is 0.0075 $(mg/kg/day)^{-1}$, the inhalation CPF is 0.0016 $(mg/kg/day)^{-1}$, the oral RfD is 0.06 mg/kg/day, and the inhalation RfC is 3.0 milligrams per cubic liter, converted to an inhalation RfD by multiplying by 20 cubic meters and dividing by 70 kilograms (no absorption factor available). As discussed in Section 4.6.3, the oral CPF and RfD are adjusted to account for the oral absorption efficiency of methylene chloride when assessing the dermal exposure pathway. Following the recommendations in Section 4.6.3, a default oral absorption efficiency of 80 percent may be assumed for VOCs in the absence of chemical-specific information. The oral CPF is adjusted for 80 percent oral efficiency to 0.0094 $(mg/kg/day)^{-1}$ to arrive at a dermal CPF. The oral RfD is adjusted for 80 percent oral efficiency to 0.048 mg/kg/day to arrive at a dermal RfD.

An ABS is needed to estimate the amount of methylene chloride that is absorbed across the skin. In the absence of a methylene chloride-specific ABS value, a default ABS value for methylene chloride of 0.05 percent (0.0005) is used. This value is based on recommendations from *Region III Technical Guidance Manual, Risk Assessment: Assessing Dermal Exposure from Soil* (EPA 1995f). EPA Region 3 recommends two ABS values for VOCs: 0.05 percent for volatiles having a vapor pressure equal to or greater than benzene (approximately 95.2 millimeters mercury) and 3 percent for volatiles having a vapor pressure lower than benzene (EPA 1995f). Methylene chloride has a vapor pressure of 349 millimeter mercury; therefore, the ABS value of 0.05 percent is used.

Since methylene chloride is a VOC, a VF is derived to assess inhalation exposures. A VF of 2,815 m^3/kg is derived following the method described in Section 4.5.2.1.

Using the Exhibit 4-1 equations (derived from EPA Region 9 [1996c] equations) and the chemical-specific input factors, the following RBCs can be calculated for carcinogenic and noncarcinogenic effects of methylene chloride in groundwater.

4.7.3.1 Carcinogenic Effects

The equation for calculating RBCs in soil is as follows:

$$C\ (mg/kg) = \frac{73 \times TR}{(1.1E{-}4 \times CPF_o) + (5E{-}4 \times ABS \times CPF_{o,adj}) + \left(\frac{11 \times CPF_i}{VF_s}\right)} \quad (4\text{-}3)$$

(See Table 4-2 and Attachment E for further explanation of the individual terms in the equation).

Continuing with the example of methylene chloride, and substituting the chemical-specific values for cancer CPFs, ABS, VF, and target risk, results in the following equation:

$$C\ (mg/kg) = \frac{73 \times (10^{-6})}{(1.1E{-}4 \times 7.5E{-}3) + (5E{-}4 \times 5E{-}04 \times 9.4E{-}3) + \left(\frac{11 \times 1.6E{-}3}{2.8E{+}3}\right)} \quad (4\text{-}4)$$

The RBC is as follows:

$$C_{(mg/kg)} = 10.3\ mg/kg \quad (4\text{-}5)$$

4.7.3.1 Noncarcinogenic Effects

The equation for calculating health-based RBCs in soil for noncarcinogenic effects is as follows:

$$C\ (mg/kg) = \frac{15.6 \times THQ}{\left(\frac{2E{-}4}{RfD_o}\right) + \left(\frac{ABS \times 4E{-}4}{RfD_{o,adj}}\right) + \left(\frac{10}{RfD_i \times VF_s}\right)} \quad (4\text{-}6)$$

Substituting the appropriate value for the RfD, ABS, and VF results in the following equation:

$$C\ (mg/kg) = \frac{15.6 \times 1}{\left(\frac{2E-4}{6.0E-2}\right) + \left(\frac{5E-04 \times 4E-4}{4.8E-2}\right) + \left(\frac{10}{8.6E-1 \times 2.8E+3}\right)} \quad (4\text{-}7)$$

The RBC is as follows:

$$C_{(mg/kg)} = 1{,}877\ mg/kg \quad (4\text{-}8)$$

The RBC calculated based on carcinogenic effects is lower than that based on noncarcinogenic effects. It is also lower than the soil saturation limit concentration of 2,500 mg/kg calculated using the equation presented in Table 4-10. In such cases, the lower RBC should be selected as the health-protective level.

It should be noted that these RBC calculations do not account for potential migration of methylene chloride to groundwater. If discharge of methylene chloride to groundwater or surface water cannot be ruled out, the Section 4.5.2.3 methodology for evaluating these pathways should be followed. Either a soil screening level or a facility-specific soil-to-groundwater RBC should be developed and compared to the previously noted direct contact RBCs before determining a final RBC.

4.7.4 Adjustment of Risk-Based Concentrations for Multiple Hazardous Constituents

When developing RBCs for facilities at which multiple carcinogens are of concern, the target risk level or range must still be met. Risks from constituents having carcinogenic effects are assumed to be additive according to *Risk Assessment Forum Review of "Guidelines on Health Risk Assessment of Chemical Mixtures"* (EPA 1997c); therefore, target risk levels for individual constituents may need to be adjusted downward to ensure that the total residual facility risk is within the target risk range. This adjustment should be done on a facility-specific basis, depending on the number and nature of hazardous

COPCs present. Exhibit 4-3 demonstrates how RBCs for carcinogens can be adjusted to achieve an acceptable target risk range.

In general, cleanup levels for the constituent(s) contributing most significantly to total risk can be adjusted to keep total risk in the target risk range. For example, five carcinogens may be present: four representing total risks in the 10^{-6} range and one representing risk in the 10^{-3} range. Adjusting the cleanup level for the single constituent contributing most of the risk may be adequate to achieve a total facility risk in the target range. This would be more practicable if a corrective measure could be selected that is especially effective for the constituent constituting the highest risk (for example, if the constituent is highly vulnerable to bioremediation); however, this method may not be practicable in all situations. In that case, the target risk from carcinogens can be established overall and the remediation would continue until the combined risk from the mixture of the residual carcinogens had been reduced to the target risk or lower.

HQs from constituents having similar systemic toxic effects and similar mechanisms of action are also assumed to be additive. The IRIS (EPA 1996g) and HEAST (EPA 1997a) databases provide information on the types of toxic effects that are the basis for each RfD. Hazardous constituents with similar noncarcinogenic toxic affects should be grouped together to determine cleanup levels for multiple constituents. For example, many organic solvents typically affect the central nervous system or the liver. The target HQ level for individual constituents in each toxic effects group should be adjusted downward to ensure that the total residual facility HI is less than 1.0. This adjustment can be done on a facility-specific basis, depending on the number of hazardous constituents present. As with carcinogens, instead of adjusting the target HQ for individual constituents, the remediation results could be monitored to ensure that the target HI is achieved or surpassed.

Exhibit 4-4 demonstrates how cleanup levels for noncarcinogens can be adjusted to achieve an acceptable target HI. As was explained for carcinogens, adjusting the cleanup levels for the chemicals presenting most of the hazard may achieve an acceptable total hazard.

A regional risk assessment specialist should be consulted to confirm how chemicals are grouped according to types of toxic effects.

EXHIBIT 4-3

ADJUSTING CLEANUP LEVELS FOR CARCINOGENIC COMPOUNDS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Assume that five carcinogenic hazardous constituents are present in groundwater at the point of compliance and that each presents the following cancer risks at current concentrations and at MCL concentrations.

Constituent	Current Contaminant Concentration (μg/L)	Excess Cancer Risk	Maximum Contaminant Level (MCL) (μg/L)	Excess Cancer Risk at MCL
Benzene	50	1×10^{-4}	5	1×10^{-5}
1,2-Dichloroethane (1,2-DCA)	75	6×10^{-4}	5	4×10^{-5}
1,1-Dichloroethene (1,1-DCE)	14	2×10^{-4}	7	1×10^{-4}
Tetrachloroethene	50	4×10^{-5}	5	4×10^{-6}
Trichloroethene	50	3×10^{-5}	5	3×10^{-6}
Total Cancer Risk		1×10^{-3}		2×10^{-4}

If a total target risk in the low 10^{-5} range is required, the attainment of cleanup levels below MCLs will be necessary. One approach may be to set an overall target risk that must be met by corrective action and monitor constituent concentrations during remediation until the target risk is achieved. A second approach may be to set target cleanup levels for each constituent. For example, by setting cleanup levels for each constituent at one-tenth of their respective MCLs, an overall target risk of 2×10^{-5} would be achieved if the cleanup goals are met. The ability of remedial technologies to meet clean levels must be confirmed and may dictate the targeted reductions of constituent concentrations. Likewise, analytical methods capable of detecting constituents at the targeted cleanup levels must be available. For the purposes of this example, EPA method 8260 is capable of detecting the constituents at 0.1 μg/L and lower concentrations.

COPCs present. Exhibit 4-3 demonstrates how RBCs for carcinogens can be adjusted to achieve an acceptable target risk range.

In general, cleanup levels for the constituent(s) contributing most significantly to total risk can be adjusted to keep total risk in the target risk range. For example, five carcinogens may be present: four representing total risks in the 10^{-6} range and one representing risk in the 10^{-3} range. Adjusting the cleanup level for the single constituent contributing most of the risk may be adequate to achieve a total facility risk in the target range. This would be more practicable if a corrective measure could be selected that is especially effective for the constituent constituting the highest risk (for example, if the constituent is highly vulnerable to bioremediation); however, this method may not be practicable in all situations. In that case, the target risk from carcinogens can be established overall and the remediation would continue until the combined risk from the mixture of the residual carcinogens had been reduced to the target risk or lower.

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Exhibit 4-4 demonstrates how cleanup levels for noncarcinogens can be adjusted to achieve an acceptable target HI. As was explained for carcinogens, adjusting the cleanup levels for the chemicals presenting most of the hazard may achieve an acceptable total hazard.

A regional risk assessment specialist should be consulted to confirm how chemicals are grouped according to types of toxic effects.

Toxicity values are not up to date

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ADJUSTING CLEANUP LEVELS FOR CARCINOGENIC COMPOUNDS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

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Trichloroethene	50	3×10^{-3}	5	3×10^{-4}
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If a total target risk in the low 10^{-5} range is required, the attainment of cleanup levels below MCLs will be necessary. One approach may be to set an overall target risk that must be met by corrective action and monitor constituent concentrations during remediation until the target risk is achieved. A second approach may be to set target cleanup levels for each constituent. For example, by setting cleanup levels for each constituent at one-tenth of their respective MCLs, an overall target risk of 2×10^{-5} would be achieved if the cleanup goals are met. The ability of remedial technologies to meet clean levels must be confirmed and may dictate the targeted reductions of constituent concentrations. Likewise, analytical methods capable of detecting constituents at the targeted cleanup levels must be available. For the purposes of this example, EPA method 8260 is capable of detecting the constituents at 0.1 μg/L and lower concentrations.

Toxicity values may not be up to date

EXHIBIT 4-4

ADJUSTING CLEANUP LEVELS FOR NONCARCINOGENIC HEALTH EFFECTS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Assume that four hazardous constituents are present in groundwater at the point of compliance, and cause similar noncarcinogenic health effects. Initial cleanup levels (MCLs) and equivalent hazards quotients are as follows:

Constituent	Cleanup Level (μg/L)	Equivalent Hazard Quotient
1,2-Dichlorobenzene	600	1.6
1,1-Dichloroethane	810	1.0
1,2-Dichloroethene	70	1.3
Ethylbenzene	700	0.5
Hazard Index		4.4

If a hazard index of 1.0 is required, cleanup level for the first three constituents can be reduced by one order of magnitude, resulting in hazard quotients of 0.16, 0.10, and 0.13, respectfully, and a hazard index of 0.89. A second approach could be to monitor ongoing remediation until a target hazard index of 1.0 is achieved or surpassed.

4.7.5 Risk-Based Concentrations Based on Hazardous Constituent Migration

Hazardous constituent migration across media can be incorporated into RBC calculations. As described in Section 4.5.2.1, VFs and PEFs may be used to incorporate VOC and particulate air emissions into soil RBCs. It is recommended that these be considered. Section 4.5.2.3 describes a partition equation, models, and criteria that can be used to calculate soil RBCs that are protective of groundwater. Soil RBCs protective of groundwater should be compared to soil RBCs calculated based on direct soil exposures. The lower of the two RBCs should be selected.

Section 4.5.2.4 describes sources of partition equations that can be used to estimate hazardous constituent migration from primary media such as soil and groundwater into the food chain. An example

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of how the partition equations may be used follows. At a site where home gardening is an important exposure pathway, constituent migration from soil to garden root crops may be estimated using the partition equations in *Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes, Attachment C, Draft Exposure Assessment Guidance* (EPA 1994i). Using the HHRA equations presented by EPA (1994i), the amount of the root crop ingested by a home gardener would then be estimated, and the risk associated with plant ingestion would be calculated. Soil RBCs determined after constituent migration into plants has been considered can be back-calculated using the same HHRA equations. Chemical-specific parameters required for the calculation include oral toxicity values and soil-to-plant partition coefficients. Partition coefficients for common hazardous waste combustion facility constituents are included in the EPA (1994i) combustion guidance (that is, for dioxins, PAHs, PCBs, nitroaromatics, phthalates, and certain metals). Some of the primary sources of plant partition coefficients cited by the combustion guidance document series include *A Review and Analysis of Parameters for Assessing Transport of Environmentally Released Radionuclides Through Agriculture* (Baes et al. 1984) for inorganic compounds and *Bioconcentration of Organics in Beef, Milk, and Vegetation* (Travis and Arms 1988) for organic compounds. *Evaluation of Dredged Material Proposed for Ocean Disposal, Testing Manual* (EPA 1991d) also provides octanol-water partition coefficients for many chemicals that can be converted to plant partition coefficients using equations recommended by Travis and Arms (1988).

As previously noted, human food chain exposures are typically not significant pathways of concern at RCRA facilities, so indirect exposures to food chain organisms require consideration only on a case-by-case basis. Methods for incorporating food chain exposures into RBCs may also be conservative (for example, garden produce partitioning equations) and may overestimate actual site risks. If they are significant exposure pathways and are not included, however, risks would be underestimated.

4.7.6 Cleanup Levels for Lead

Cleanup levels for lead are not calculated using standard EPA risk assessment equations. Rather, EPA has developed an integrated exposure uptake biokinetic model (IEUBK) that predicts lead blood levels in

EXHIBIT 4-4

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4.7.6 Cleanup Levels for Lead

Cleanup levels for lead are not calculated using standard EPA risk assessment equations. Rather, EPA has developed an integrated exposure uptake biokinetic model (IEUBK) that predicts lead blood levels in

children. The model was developed for children because they are more sensitive to lead effects. The IEUBK is considered superior to the use of a RfD in a standard HHRA equation because the model (1) recognizes the multimedia nature of lead exposures, (2) incorporates important absorption and pharmacokinetic information, and (3) considers the potential distributions of exposures and risk likely to occur at a facility. The model allows for the incorporation of water, soil/dust, air, dietary, paint, and maternal-blood lead concentration levels into a lead dose estimate.

The *Memorandum Regarding Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities* (EPA 1994k) recommends a residential soil lead screening level of 400 mg/kg. This screening level is back-calculated using the IEUBK model, assuming a blood lead concentration of 10 micrograms per deciliter (μg/dL) in children and standard defaults for water, air, diet, paint, and maternal-blood lead levels. This target blood level is based on analyses conducted by the Centers for Disease Control and EPA that associate blood lead levels of 10 μg/dL or higher with health effects in children. No comparable soil lead screening level has been set for a nonresidential adult; the IEUBK model is designed specifically for children.

EPA is currently considering what industrial soil lead levels may be appropriate. An interim approach is recommended by EPA (1996k) in *Recommendations of The Technical Review Workgroup for Lead for An Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil.* This document recommends the use of a biokinetic slope factor, which relates the increase in typical adult blood lead concentrations for a women of child-bearing age to average lead uptake from contaminated soils. The document then recommends the use of a proportionality constant, which relates a fetal blood lead concentration at birth to a material blood lead concentration. Using a fetal blood lead goal of 10 μg/dL or less, a soil RBC can be calculated that should not result in an exceeded of the fetal blood lead goal. Using default parameters summarized in the EPA (1996k) review, RBCs ranging from 743 mg/kg to 1,738 mg/kg can be calculated, depending on the baseline level of adult blood lead and the blood lead standard deviation associated with adults exposed to similar on-site lead concentrations. EPA (1996k) should be consulted to confirm a facility-specific industrial soil lead RBC. The Region 10 representatives on the EPA Superfund technical review group should be consulted for information on current lead policy.

The EPA memorandum recommends using the IEUBK model on a site-specific basis to develop media cleanup standards at RCRA facilities where site data support modification of model default parameters (1994k).

4.8 UNCERTAINTY ANALYSIS

Once the HHRA process and the step-by-step process for developing cleanup levels are understood, facility and regulatory officials should be prepared to answer the questions listed in Exhibit 4-5 for a contaminated facility undergoing corrective action or clean closure under RCRA.

EXHIBIT 4-5

**RISK ASSESSMENT AND CLEANUP LEVEL DETERMINATION PROCESS
REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES**

- Have receptors and exposure pathways that are likely affected by facility contamination been identified?
- Are data of sufficient quantity and quality available to determine whether and to what extent on-site and off-site remediation is necessary to protect the health of the maximally exposed individual?
- Have contaminants of concern been identified?
- Are promulgated standards or criteria available? If so, are they sufficiently protective?
- Are there state methodologies, regulations, or policies that should be considered?
- Is the corrective action or clean closure being considered subject to a RCRA-authorized state program?
- Have current and future land use scenarios been identified?
- Have risk-based concentrations been calculated using published RfDs and CPFs for any of the COPCs?
- Have risk management decisions regarding target risk and hazard levels been identified by the lead regulatory agency?
- Have cleanup levels been adjusted (as appropriate) to account for multiple hazardous constituents?

RBCs are associated with varied levels of uncertainty. Uncertainty can be defined as a lack of precise knowledge of the qualitative or quantitative truth. As part of an ideal risk analysis, a complete uncertainty analysis would provide a risk manager with the ability to estimate risk for each individual in a given population in both actual and projected scenarios of exposures; it would also estimate the uncertainty in each prediction in quantitative, probabilistic terms (see Chapter 6). But even a less exhaustive treatment of uncertainty will serve a very important purpose: it can reveal whether the deterministic risk estimate overestimates or underestimates risk and if so, to what extent.

Uncertainties associated with all sections of the human health-based analysis should be discussed in all HHRAs. This section discusses uncertainty in qualitative terms; for a discussion of quantitative uncertainty, see Chapter 6 (Probabilistic Risk Assessment Methods). Additional uncertainty discussions can be found in the National Research Council's *Science and Judgement in Risk Assessment* (Chapter 9) (1994) and in EPA Administrator Carol Browner's memorandum of risk assessment (EPA 1995a) (Attachment A). The effect that each element of uncertainty has on the final cleanup levels should be included. For example, an assumption that future land use will be industrial will lead to less conservative (that is, higher) cleanup levels.

4.8.1 Data Uncertainty

Issues contributing to uncertainty in data evaluation include the identification of COPCs, data quality, data useability, adequacy of quantitation limits (relative to target risk levels), and data coverage.

All data that are used to evaluate compliance with a cleanup level should be reviewed with respect to data quality standards presented in the site-specific quality assurance project plan. Data that do not meet the data quality standards should be qualified as necessary, and the uncertainty associated with these data should be discussed. Uncertainty associated with data quality may result in an underestimation or overestimation of hazardous constituent concentrations, depending on the specific data quality issue.

By the time the uncertainty section is prepared, data should have been reviewed to ensure that the detection or quantitation limits achieved for the various analyses were sufficient to evaluate site-specific hazardous constituents at concentrations equal to or less than the hazardous constituent-specific cleanup levels. If a chemical's detection or quantitation limit is greater than its cleanup level, one cannot

determine whether the cleanup level has been met. Detection and quantitation limits should be compared to cleanup levels before chemical analyses. Chapter 3 of this guidance provides additional information on data evaluation procedures, while Chapter 7 describes how below detection limit data should be handled in HHRA.

Data coverage refers to the ability of the sampling plan and associated sample results to completely characterize the contamination. (Were sufficient data collected to evaluate all potential exposure pathways? Do the sampling locations adequately represent actual or potential exposure conditions?) For example, uncertainty would arise if groundwater sample points were not located downgradient of a source.

Data quality indicators were discussed in Section 3.2: completeness, representativeness, comparability, precision, and accuracy. Any problems associated with any of the data quality indicators should be discussed in the uncertainty section. Other issues that could adversely affect data quality are blank contamination, matrix interferences, sample holding times, and sample preservation.

4.8.2 Exposure Assessment Uncertainty

Uncertainty is inherent in the evaluation of exposure pathways and in the assumptions used to estimate exposure doses. Human activity patterns and individual characteristics (for example, body weight) can vary significantly within a given population. The degree of uncertainty depends to a large extent on the amount and adequacy of facility-specific data available. Typically, the most significant areas of uncertainty for the exposure assessment include exposure pathway identification, exposure assumptions, assumptions of steady-state conditions, environmental chemical characterization, and modeling procedures. These areas of uncertainty are described as follows:

- Exposure pathway identification: To the degree that actual or future human activity patterns are misrepresented, uncertainty is introduced into the cleanup levels. In most cases, there is uncertainty regarding future land use at a site. This uncertainty must be considered when evaluating exposure estimates developed under the future land use scenarios.

- Exposure assumptions: Standard default assumptions for population characteristics, such as body weight and surface area, life expectancy, period of exposure, and exposure characteristics such as frequency, duration, amount of intake or contact, and degree of absorption or soil adherence may not accurately represent exposure conditions. The exposure assumptions used may overestimate or underestimate actual exposure.

- Assumption of steady-state conditions: Estimated future exposure doses are based on an assumption of steady-state conditions. The inherent assumption is that future chemical concentrations are the same as those measured during sampling. This assumption ignores the effects of various fate-and-transport mechanisms, which will alter the composition and distribution of most chemicals present in the various media. The assumption of steady-state conditions usually results in overestimations of future chemical concentrations and exposure doses.

- Hazardous constituent characterization: It is impossible to completely characterize the nature and extent of hazardous constituents in the environment. Instead, the various environmental media are sampled to estimate hazardous constituent concentrations and to identify hazardous constituents actually present as a result of releases at the facility. Because no sampling can completely and accurately characterize environmental conditions, the exposure dose calculation will be somewhat uncertain. Uncertainties are introduced into exposure dose calculations during collection, analysis, and evaluation of environmental chemical data. Two areas of uncertainty that should be addressed in a risk assessment are the assumption of uniform concentrations in an exposure area and the treatment of nondetection results.

- Modeling procedures: Modeling assumptions are used to determine hazardous constituent concentrations in outdoor air resulting from VOC and particulate emissions and VOC concentrations in indoor air generated by household water use. The numerous assumptions included in these models introduce uncertainty to the degree that they do not reflect actual conditions. Use of models may overestimate or underestimate actual environmental concentrations.

- Analytical and numerical models are also used to estimate soil-to-groundwater contaminant migration. There are many soil-to-groundwater models available that have been developed by government agencies, universities, and the private sector. Models can simulate different fate and transport processes and migration mechanisms such as advection, dispersion, diffusion, retardation, chemical reactions, and microbial reactions. In addition, different models are designed to account for various phases of contamination (for example, vapor, water, or nonaqueous phase liquids) and various dimensions (one-, two-, or three-dimensional). Some of the models simulate complex geologic and hydrogeologic systems while other models are more appropriate for simple geology and groundwater flow conditions. The models use assumptions to simplify the real-world conditions and describe these conditions with mathematical equations (usually partial

differential equations). When a model is applied at a site, these assumptions should be carefully evaluated against the site-specific conditions. A sensitivity analysis should be performed to identify the most sensitive parameters. The uncertainty of the models can be determined by evaluating the agreement between model assumptions and site conditions as well as the accuracy of input parameters.

4.8.3 Toxicity Assessment Uncertainty

RfDs and CPFs must be viewed in light of uncertainties and gaps in toxicological data. For instance, direct information concerning toxic effects in humans is often limited to historical cases of accidental or industrial exposures. Animal studies conducted with specially bred homogeneous species are typically extrapolated to a heterogenous human population. The reliance on animal studies introduces uncertainties regarding effects on humans including sensitive subpopulations and differences in physiological characteristics between the animal species studied and humans, such as target organs, metabolism, organ sensitivity, and detoxification capabilities.

In addition, high-dose, short-term (acute) animal studies may not be applicable to low-level, long-term (chronic) exposures that humans are more likely to experience. Likewise, the quality of the animal study may introduce additional uncertainty if, for example, accepted scientific protocols were not employed.

The uncertainties discussed previously are addressed by dividing the no-observable-adverse-effect level (NOAEL) for a hazardous constituent from animal studies by uncertainty factors of 10 to 10,000 to obtain RfDs. The NOAEL is the highest level of a hazardous constituent evaluated in a study that does not cause statistically significant differences between the experimental and control animals. The lowest-observable-adverse-effect level (LOAEL), on the other hand, is the lowest level of a hazardous constituent evaluated in a study that causes statistically significant differences between experimental and control animals. Uncertainty factors are applied to data in the following cases (EPA 1989c):

- To account for variation in the general population (to protect sensitive subpopulations)
- To extrapolate data from animals to humans
- To adjust for using a NOAEL from a subchronic study rather than a chronic study
- To adjust for using a LOAEL instead of a NOAEL in developing an RfD

A modifying factor ranging from 1 to 10 is also applied to the RfD to address uncertainties in the scientific studies used to develop RfDs. Published RfDs already contain the necessary uncertainty and modifying factors.

Uncertainty associated with determining chemical carcinogenicity is reflected in the weight-of-evidence classification groups assigned to carcinogens. In addition, CPFs are derived from the low-dose end of the dose-response curve. The studies are usually conducted at the high-dose end of the curves. The selected 95th upper confidence limit of the slope of the dose-response curve is considered an upper-bound toxicity value (that is, there is only a 5 percent chance that the probability of a response could be greater than the estimated value on the basis of the experimental data and model used).

The use of oral toxicity factors to evaluate dermal exposures is associated with uncertainty. The use of oral toxicity factors as surrogates for this pathway is necessary because no dermal toxicity factors have been approved by EPA. Most of the uncertainty associated with the use of surrogate toxicity factors exists because the constituents in question are not known to exhibit similar toxicological effects (that is, degree of toxicity, target organ) during dermal contact and the oral pathway. In addition, dermal absorption assumptions add to uncertainty. Using surrogate toxicity factors is more conservative than ignoring the dermal pathway and allows for a quantitative cleanup level rather than a qualitative discussion.

4.8.4 Cleanup Level Uncertainty

Since the cleanup level calculations incorporate information from all the previous processes, the uncertainties associated with the data evaluation, exposure assessment, and toxicity assessment sections will all directly affect the cleanup level uncertainty.

Simulation Results

Using probabilistic simulations, an outcome is calculated repeatedly for a predetermined number of iterations, producing an associated PDF. The following forecast chart (Exhibit 6-5) displays the PDF for the B(a)P RBC.

EXHIBIT 6-5

CASE STUDY PROBABILITY DENSITY FUNCTION FOR BENZO(A)PYRENE RISK-BASED SOIL CONCENTRATIONS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

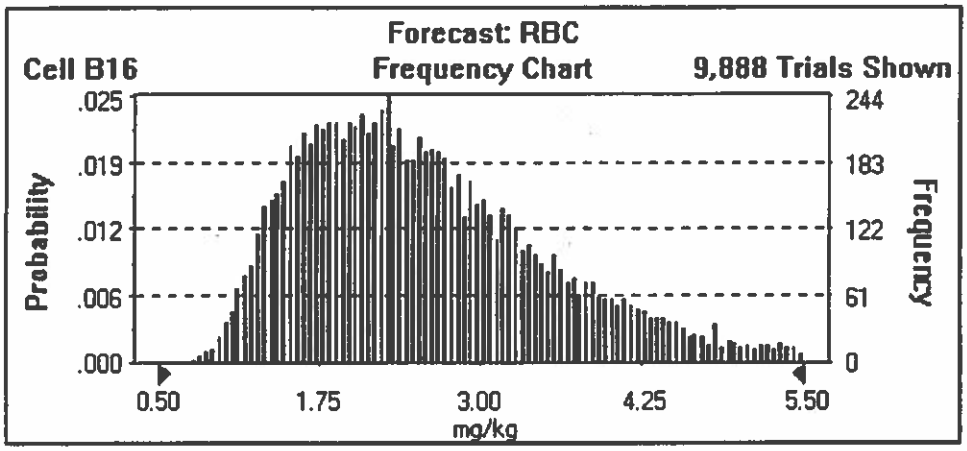

Figure 6-5 shows that the PDF is lognormal in shape, and the numerical output of the PRA indicates that the PDF has a minimum value of 7.4E-01 mg/kg and a maximum value of 7.72E+00 mg/kg. Output PDFs are often highly non-Gaussian (nonnormal) in shape for two reasons. First, some or all of the exposure factor inputs may not have normal or even symmetric distributions. Second, since the exposure factors enter the formula by multiplication and division, even if all the factors have normal distributions, the results will not (Thompson et al. 1992).

As noted in Section 6.2.2, a sensitivity analysis should be performed to identify critical input variables. The sensitivity analysis determines the degree to which a specific exposure factors will affect the final outcome. A sensitivity analysis could have been performed before the PRA simulation so that critical exposure factors could be identified. For this case study, however, PDFs were available for all of the exposure intake variables, so they were all included in the simulation, and the sensitivity analysis was

performed during the simulation. With Crystal Ball software, sensitivity is calculated by computing Spearman rank correlation coefficients (a common statistical measure of dependency) between every exposure factor and outcome calculation while the simulation is running (Decisioneering 1993). A positive correlation coefficient indicates that an increase in the exposure factor is associated with an increase in the outcome. A negative correlation coefficient indicates that an increase in the exposure factor is associated with a decrease in the outcome (Decisioneering 1993). The larger the absolute value of the correlation coefficient, the stronger the relationship; however, caution should be applied when interpreting the sensitivity analysis in simulations where exposure factors are correlated. For example, if a highly sensitive exposure factor were correlated with an insensitive one, the insensitive exposure factor would likely have a high sensitivity with regard to the outcome (Decisioneering 1993).

Exposure factors that are identified as being highly sensitive, contributing a high degree of uncertainty to the outcome, may be further refined so as to decrease the effect on the final outcome. Likewise, it may not be necessary to spend PRA resources on those factors that have little effect on the risk outcome.
In the Exhibit 6-6 sensitivity chart, exposure factors are listed on the left side, beginning with the exposure factor with the highest sensitivity.

In this simulation, adult exposure duration has the highest sensitivity ranking and can be considered the most important assumption in the model. Likewise, the child exposure frequency and the child soil ingestion rate have the lowest sensitivity rankings and can be considered the least important assumptions in the model. Considering this, collection of facility-specific exposure durations could be prioritized over the collection of child soil ingestion rates if further data collection was deemed necessary. Confidence must also be established in the child exposure frequency and child soil ingestion rate information used in the sensitivity analysis. For example, if it is believed that facility-specific child soil ingestion rates are significantly underestimated, further data collection and a second sensitivity analysis may be warranted.

Descriptive statistics shown in Table 6-1 were calculated for the B(a)P RBC PDF. Population percentiles and corresponding RBCs are also determined for the PDF, as presented in Table 6-2.

EXHIBIT 6-6

CASE STUDY SENSITIVITY CHART FOR EXPOSURE PARAMETERS REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

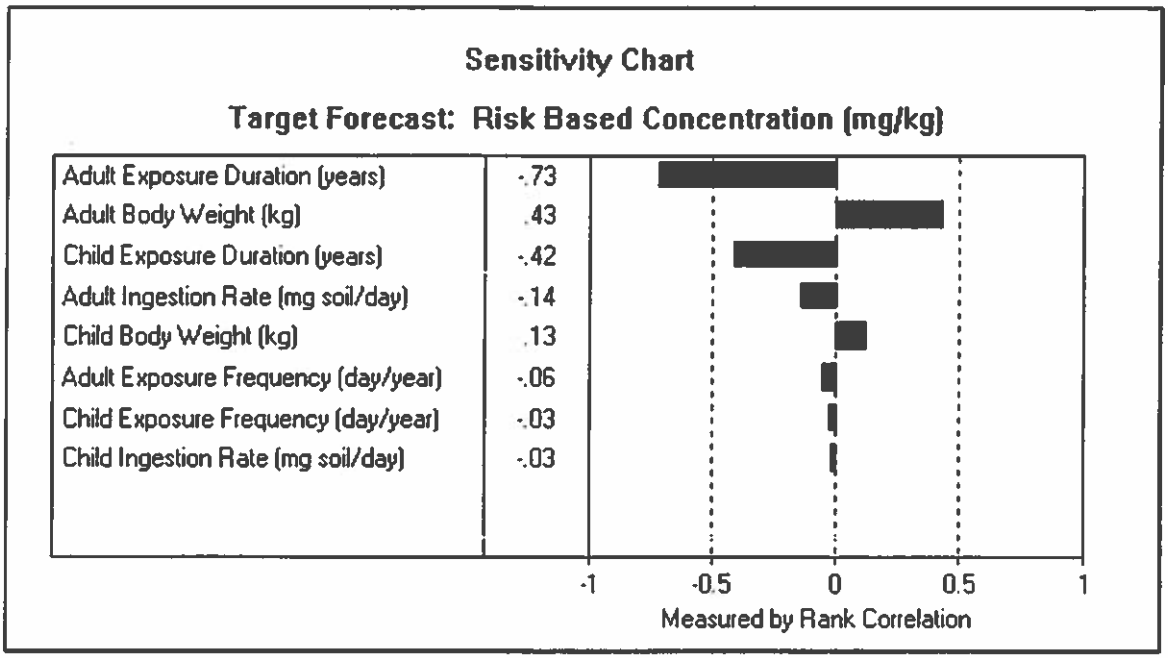

TABLE 6-1

DESCRIPTIVE STATISTICS FOR BENZO(A)PYRENE RISK-BASED CRITERIA PROBABILITY DENSITY FUNCTION REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Statistics	Value
Trials	10,000
Mean	2.59E+00
Median	2.41E+00
Standard Deviation	1.0E+00
Variance	1.0E+00
Skewness	9.6E-01
Kurtosis	3.99E+00
Coeff. of Variability	3.9E-01
Range Minimum	7.4E-01
Range Maximum	7.72E+00
Range Width	6.98E+00
Mean Std. Error	1.00E-02

Definitions:

Trials	Number of iterations
Mean	Arithmetic average of the risk-based concentration (RBC)
Median	Value midway between the smallest RBC value and largest RBC value
Mode	Value (if exists) that occurs most often in the data set
Standard deviation	Measurement of variability of the data set; square root of the variance
Variance	Average of the squares of the standard deviations of a number of observations from the mean value; square of the standard deviation
Skewness	The measure of the degree of deviation of a curve from the norm of an asymmetric distribution. The greater the degree of skewness, the more points of the curve lie to either side of the curve. A normal distribution curve, having no skewness, is symmetrical (Decisioneering 1993)
Kurtosis	The measure of the degree of peakedness of a curve. The higher the kurtosis, the closer the points of the curve lie to the mode of curve. A normal distribution curve has a kurtosis of 3 (Decisioneering 1993)
Coefficient of variability	A measure of relative variation that relates the standard deviation to the mean (Decisioneering 1993)
Mean standard error	The standard deviation of the distribution of possible sample means. This statistic describes the accuracy of the simulation (Decisioneering 1993)

TABLE 6-2

POPULATION PERCENTILES FOR BENZO(A)PYRENE RISK-BASED CRITERIA PROBABILITY DENSITY FUNCTIONS USING 1.0E-06 AS THE TARGET RISK REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Percentile	mg/kg
0.0%	7.4E-01
2.5%	1.2E+00
5.0%	1.3E+00
50.0%	2.4E+00
95.0%	4.5E+00
97.5%	5.0E+00
100.0%	7.7E+00

For example, 5 percent of the population exposed to 1.3E+00 mg/kg of B(a)P would have a carcinogenic risk of 1E-06.

6.4.2 Deterministic Risk Assessment

A B(a)P RBC was also calculated using the deterministic risk assessment approach for residential exposure via soil ingestion. The algorithm used to calculate the soil RBC is the same as that previously presented for the Monte Carlo simulation. RME exposure factors used for the calculation are presented in Table 6-3.

6.4.3 Summary of Results

Using the deterministic risk assessment approach, the calculated B(a)P RBC is 2.2E-01 mg/kg for residential RME exposure via soil ingestion. Because of compounding conservatism in the deterministic risk assessment approach, this B(a)P RBC falls well below the 1 percentile of the RBC distribution determined using the Monte Carlo simulation. Thus, information about the uncertainty surrounding the conservative assumptions in the deterministic risk assessment provided in the PRA will be useful to risk managers during the decision-making phase of the process.

TABLE 6-3

EXPOSURE FACTORS FOR RESIDENTIAL EXPOSURE INGESTION OF SOIL REGION 10 RCRA RISK-BASED CLEANUP LEVEL GUIDELINES

Exposure Factor	RME Value
TR = Target Risk	1.0E-06[a]
CSFo = Cancer Slope Factor for B(a)P (mg/kg-day)$^{-1}$	7.3
IR = Ingestion rate (mg/day) (EPA 1993h) Adult Child	 100 200
EF = Exposure frequency (days/year) (EPA 1993h)	350
ED = Exposure duration (years) (EPA 1993h) Adult Child	 24 6
CF = Conversion factor (kg/mg)	1.0E-06
BW = Body Weight (kg) (EPA 1991b) Adult Child	 70 15
AT = Averaging time (days) Carcinogenic	25550

Note:

a Point of departure target cancer risk

6.5 WORK PLANS, REPORTS, AND PRESENTATIONS

There are several minimal requirements for PRA work plans and reports to ensure sufficient data quality. In fact, it is important that the facility submit a work plan for EPA review before doing the PRA simulation. The work plan should include exposure variables for human receptors. Guidance for application to environmental receptors is not available at this time. The work plan should describe the software to be used, the exposure routes and models, and input probability distributions and references.

The following good principles of practice should be used to select input data and distributions for the PRA work plan (EPA 1997d, Items 11 through 16, page 17).

- A complete and thorough description of the exposure model and its equations should be provided.
- The presentation of the deterministic point estimate should always accompany a PRA analysis.
- Where possible, areas of uncertainty should be identified accompanied by an explanation of how it will be dealt with in the report.
- Sensitivity analysis should be used to identify model structures, exposure pathways, and model input assumptions and factors that make important contributions to the assessment endpoint and its overall uncertainty and variability.
- Probabilistic assessment should be restricted to significant pathways and variables.
- Sufficient data should be used to support the choice of input distributions for model input factors.
- Surrogate data can be used to develop distributions when they can be appropriately justified.
- Data should be collected to develop input distributions for the exposure model following the basic tenets of environmental sampling. Furthermore, particular attention should be given to the quality of information at the tails of the distribution.
- Expert judgment may be used to select appropriate input distributions, but the reasons and justification for subjective analysis should be included in detail.

Presentation of PRA simulation results should be tailored to the targeted audience. Entirely different types of reports are needed for scientific and nonscientific audiences. For example, descriptive and less detailed summary presentations may be appropriate for the nonscientific public. Graphs and tables showing and describing each input distribution, distribution of risk for each exposure route, and distributions of total risk should be included.

COMPLIANCE

CHAPTER 7

DETERMINATION OF COMPLIANCE WITH TARGET CLEANUP LEVELS

Following the selection of target cleanup levels and corrective actions to treat or remove a contaminated media, additional sampling is performed to determine whether the cleanup levels have been attained. This sampling is performed using the same data quality objectives (DQO) and data quality assessment (DQA) procedures described in Chapter 3 of this guidance. The DQO and DQA steps are summarized in Sections 7.1 through 7.6. Section 7.7 provides additional guidance on how to handle below-detection-limit (BDL) sampling results when calculating constituent concentrations.

7.1 DATA QUALITY OBJECTIVES STEPS 1 THROUGH 3

Steps 1 through 3 of the DQO process, as described in Chapter 3, apply directly to compliance determinations, with the exception that cleanup levels are considered that may differ from the screening levels or preliminary background levels considered during the Resource Conservation and Recovery Act (RCRA) facility investigation (RFI) stage. The decision rule is likely to be very similar to the Chapter 3 example (that is, have constituent levels been reduced to a concentration below the selected cleanup level concentration? If so, no further action would be called for; if not, further remedial action may be required). The remaining Chapter 7 sections provide additional information on DQO Steps 4 through 7 and the DQA as they apply to determination of compliance with target cleanup levels.

7.2 STEP 4: STUDY BOUNDARIES

In Step 4 of the DQO process, the spatial and temporal boundaries of the problem are defined. To determine compliance with cleanup levels, facility-specific points of compliance that were earlier established in the formal RCRA corrective action process should be used. A point of compliance is the location or locations at which media cleanup levels are to be achieved. No final U.S. Environmental Protection Agency (EPA) RCRA corrective action regulations defining points of compliance have been promulgated. In an update to the proposed Subpart S rule, EPA (Federal Register [FR] 19450, May 1, 1996) recommends that points of compliance be determined on a site-specific basis and notes that program implementors and facility owners have routinely established points of compliance in the following manner:

- For air releases, the location of the most exposed receptor or other specified point(s) of exposure closer to the source of release (for example, the unit boundary)
- For surface water, at the point at which releases could enter the surface water body; if sediments are affected by releases to surface water, a sediment point of compliance is also established
- Soil points of compliance are generally selected to protect human and ecological receptors against direct contact or food chain exposures and to protect other media from cross-media transfer
- For groundwater, throughout the area of contaminated groundwater or at and beyond the boundary of the waste management area encompassing the original sources of groundwater contamination when waste is left in place

Washington State Model Toxics Control Act (MTCA) regulation (Washington Administrative Code [WAC] 173-340) requires points of compliance for sites conducting cleanup under RCRA authorities as shown below.

MTCA Points of Compliance

- Compliance with air cleanup levels should be attained in the ambient air throughout the site. A conditional air point of compliance may be set at the property boundary of an industrial facility (WAC 173-340-750).
- Compliance with surface water cleanup levels should be the point or points where hazardous substances are released to surface waters of the state, unless a dilution zone is authorized (WAC 173-340-730).
- For soil cleanup levels based on groundwater protection, the point or points of compliance is soils throughout the site. For soil cleanup levels based on direct contact human exposures, the point of compliance is soils throughout the site from the ground surface to 15 feet below the ground surface (WAC 173-340-740).

> **MTCA Points of Compliance**
> **Continued**
>
> - Compliance with groundwater cleanup levels should be determined for each groundwater monitoring well or other monitoring points such as a spring (WAC 173-340-720).

In summary, the study boundaries for compliance decisions are primarily set by points of compliance. The points of compliance should be determined following EPA guidance or, in Washington, the specified MTCA regulation.

7.3 STEP 5: DEVELOP DECISION RULE

As described in Chapter 3, Step 5 requires that a decision rule be developed to define the conditions that would cause the decision maker to choose among alternative actions. The decision rule is an "if . . . then" statement that incorporates the information determined during DQO Steps 1 through 4. An example decision rule for a compliance decisions follows: if the parameter of interest (average concentration of constituent of concern) within the study area (the point of compliance) is less than the cleanup level (a standard, criterion, risk-based, or background concentration) following remediation, then alternative action A (no further remedial action) should be taken; otherwise, alternative action B (remove additional contamination) should be taken.

Note that for the previous example, the average concentration of the constituent was selected as the statistical parameter to compare with the cleanup level. The statistical parameter selected (for example, the mean, median, or an upper percentile constituent concentration) will be a measurement of the contamination present within the study boundaries. Because a receptor is assumed to move randomly across an exposure area over time, spending equivalent amounts of time in each location, EPA's *Supplemental Guidance to RAGs: Calculating the Concentration Term* (EPA 1992e) (Attachment M) recommends the use of the true mean to characterize long-term exposures in a specific study area. To be reasonably sure that the comparison value is at least as large as the true site mean, EPA (1992e) recommends use of the 95th upper confidence limit on the arithmetic mean (95th UCL) for the exposure point concentration and details how to calculate it. The 95 UCL is defined as a value that, when calculated repeatedly for randomly drawn subsets of site data, equals or exceeds the true mean 95 percent of the time.

The 95 UCL of the mean is used because it is not possible to know the true mean, particularly with limited sampling data. As sampling data become less limited, uncertainty decreases, and the UCL moves closer to the true mean (EPA 1992e). Other statistical parameters that characterize the population may be relevant. For example, an upper percentile of the distribution of constituent measurements in the study area (for example, the 95th percentile) may be compared to a cleanup level to determine whether a subpopulation (for example, a potential hot spot) is present. Statistical outlier tests may also be used to identify hot spots. *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities, Interim Final Guidance* (EPA 1989k), *Guidance for the Data Quality Objectives Process* (EPA 1994b), and *Determination of Background Concentrations of Inorganics in Soils and Sediments at Hazardous Waste Sites* (EPA 1995c) provide more detailed guidance on the selection of an appropriate statistical parameter to compare with a cleanup standard.

Washington State MTCA regulation (WAC 173-340-740) requires that upper percentile constituent concentrations be used to evaluate compliance with soil cleanup levels based on short-term or acute toxic effects. For cleanup levels based on chronic or carcinogenic effects, MTCA requires that the mean soil concentration generally be used to evaluate compliance unless large variations in constituent concentrations occur. To address hot spots, the MTCA rule also specifies that no single sample concentration exceed two times the cleanup level and that less than 10 percent of the sample concentrations exceed the cleanup level.

7.4 STEP 6: SPECIFY TOLERABLE LIMITS ON DECISION ERRORS

Step 6 requires that the decisions maker's tolerable limits on decision errors be specified. As noted in Chapter 3, the true value of the population parameter being measured (for example, the average constituent concentration) can never be exactly defined because of sampling design and measurement design errors. A decision error occurs when the data mislead the decision maker into concluding that the parameter of interest is on one side of a cleanup level when the true value of the parameter is on the other side of the cleanup level. As described in Chapter 3, the EPA DQO guidance (1994b) explains how the probability of decision errors can be controlled by adopting a scientific approach that incorporates hypothesis testing.

For example, following remediation, the decision maker may want to know whether a hazardous constituent is present at a solid waste management unit (SWMU) at an average concentration that is now

below the cleanup level. Because the extent of contamination is well delineated and is believed to have been completely removed, the decision maker may view the consequence of deciding that the average concentration is greater than the cleanup level when it is actually less than the cleanup level as a more severe decision error than concluding the concentration is less than the cleanup level when it is actually greater (for example, more cleanup would be required at significant cost when all parties believe the cleanup was successful). The null hypothesis would then be that the average concentration is less than the cleanup level. A conclusion that the concentration is greater than the cleanup level when it is actually less would be a false positive error, while a conclusion that the concentration is less than the screening level when it is actually greater would be a false negative error. The decision maker then sets allowable decision error probabilities at points below (false positive errors) and above (false negative errors) the cleanup level, starting at the boundaries of the grey area near the cleanup level where the consequences of errors are minor. As described in Section 3.1.6, the grey area is bound by the action level and the concentration where the decision maker wants to begin to control false negative error. For this example, the grey area extends from the action level to a concentration above the action level where a false negative error rate is assigned. Error will not be controlled at the concentration range within the grey area, based on the minimal consequences of making an error or the expense of collecting enough samples to control error.

Null and alternative hypotheses may be predetermined by regulations. For example, the MTCA cleanup regulations (WAC 173-340) recommend a confidence interval approach for evaluating compliance that requires a one-tailed test of the null hypothesis that the true media concentration exceeds the cleanup level. A tolerable false positive error probability of 5 percent is specified.

Detailed examples of DQO evaluations developed by EPA (EPA 1994b and 1996a) are included in Attachment C.

7.5 STEP 7: OPTIMIZE THE DESIGN FOR OBTAINING DATA

As noted in Chapter 3, Step 7 includes identifying a resource-effective data collection (sampling) strategy for generating data that are expected to satisfy the DQOs. The sampling strategy typically will focus on the sampling design, the sample size, and the analytical methods that will be required to meet the DQOs. A primary requirement of Step 7 will be to define a statistical method for testing the Step 6 hypothesis and a sample size formula that corresponds to the statistical method and the sample design. EPA has published

several guidance documents on the selection of appropriate statistical models for determining sample sizes and sample designs. These documents are listed and briefly described in the following paragraph; similar statistical models can be used in both corrective action investigations and compliance determinations.

EPA has published several guidance documents that specify mathematical models for testing statistical hypotheses. The previously noted *Methods for Evaluating the Attainment of Cleanup Standards, Volume 1: Soils and Soil Media* (EPA 1989b) and a follow-up document *Statistical Methods for Evaluating the Attainment of Cleanup Standards, Volume 3: Reference-based Standards for Soils and Soil Media* (EPA 1992i) describe statistical models for testing soil cleanup level attainment hypotheses. EPA (1989b) describes how to determine whether a mean or upper percentile site concentration is statistically less than a cleanup standard. The document also describes how the statistical models can be used to determine the sample size required to meet allowable decision error probabilities. The statistical models may assume that the data conform to a certain distribution type (for example, normal or lognormal) or that the data sets being compared (that is, site and background) have equal or unequal variances. Generally, the variability of constituent concentrations, the tolerable probability of error, and the size of the grey zone will have the greatest effect on the number of required samples. Guidance on designing a sampling plan is also presented by EPA (1989b). Parametric and nonparametric tests for comparing facility concentrations to cleanup levels are presented. The parametric tests are used when the distribution of contamination is known or assumed to be normal or lognormal. Otherwise, nonparametric tests (no distribution assumed) should be used (see Chapter 6 for information on distribution types). EPA (1992i) provides additional guidance on determining soil cleanup level achievement. This document focuses on two nonparametric statistical tests and a hot spot measurement comparison in addition to addressing other statistical data analysis issues, such as treatment of below quantitation limit data. In the more recent *Geostatistical Sampling and Evaluation Guidance for Soils and Solid Media* (EPA 1996a) review draft document, EPA proposes detailed guidance on using average, upper percentile, or hot spot facility data to determine compliance with cleanup levels. The document outlines sampling plans as well as scenarios and provides guidance on evaluating decision errors and uncertainty versus sampling costs. Guidance for sampling design and sample sizes for verifying the cleanup of PCB spills is provided in the EPA Office of Toxic Substances *Verification of PCB Spill Cleanup By Sampling and Analysis* (EPA 1985). This document describes sampling on a hexagonal grid centered on the cleanup area to determine residual PCB concentrations. The methodology described in this document can be applied to the cleanup of other constituents released to soils as well.

Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Interim Final Guidance (EPA 1989k) and a follow-up addendum (EPA 1992k) describe statistical models for testing groundwater cleanup level attainment hypothesis. EPA (1989k) describes how to determine whether contamination in a given well exceeds background or target cleanup level concentrations. Sampling sizes are recommended, and parametric and nonparametric tests are described. The EPA addendum (1992k) provides methods for determining whether constituent concentrations are normally distributed or whether unequal variances in constituent concentrations occur between wells. The document also focuses on nonparametric tests (that is, no distribution is assumed) for comparing compliance well data to background or target cleanup concentrations and provides recommendations for handling nondetect data. The EPA *Statistical Methods for Evaluating the Attainment of Cleanup Standards, Volume 2: Groundwater* (1992h) document also provides guidance on selecting statistical tests for determining sample sizes.

Data Quality Objectives Decision Error Feasibility Trials (DQO/DEFT) Users Guide, Version 4.0 (EPA 1994c) software package can be used to iterate through one or more DQO steps to identify a sample design that will meet the budget and generate adequate data. The DEFT software allows the user to change DQO constraints such as limits on decision errors or the grey region and evaluate how these changes affect sample sizes (and resulting costs) for several basic sample decisions.

7.6 DATA USEABILITY AND DATA QUALITY ASSESSMENT

The output of the DQO process will be a sampling strategy that defines sampling design, sample numbers, and analytical methods. Steps should also be taken to assure that the data collected are useable. Section 3.2 of Chapter 3 describes methods that should be followed to assure that the sample data collected are of acceptable quality to use in compliance decisions. Following the data useability determination, the DQA process briefly introduced in Section 3.3 of Chapter 3 should be performed. The purpose of the DQA is to verify DQO assumptions, complete statistical comparisons of target cleanup level concentrations with the levels measured through field sampling, and determine whether compliance with cleanup goals has been achieved. *Guidance for Data Quality Assessment, Practical Methods for Data Analysis* (EPA 1996d) provides specific details on how to perform the DQA.

7.7 DETECTION LIMITS

Facility constituent concentrations must be determined during either the risk assessment or a compliance determination. As noted in Section 7.3, the 95th UCL is typically calculated for risk assessment and compliance purposes. Other statistical parameters, such as a 95th percentile, may require calculation when making hot spot or background determinations. *Supplemental Guidance to RAGS: Calculating the Concentration Term* (EPA 1992e) provides a method for calculating the 95th UCL. The State of Washington's *Statistical Guidance for Ecology Site Managers* (Washington Department of Ecology 1992) describes methods for calculating a variety of statistical parameters, including means, median, and percentiles.

When calculating statistical parameters, environmental data sets often contain samples for which no constituents have been detected. In this situation, the only information available on the constituent concentration is the detection limit. Data sets that contain below detection limit (BDL) data are known as censored data sets. Such data sets are problematic when used to calculate statistical parameters such as 95th UCLs because of uncertainty in the actual concentration of the constituent in the BDL samples. Methods for incorporating BDL data into calculations of average facility constituent concentrations have been summarized in a quality assurance course module prepared by the National Center for Environmental Research and Quality Assurance (EPA 1997f). The EPA (1997f) course module is presented in Attachment P, and the options are summarized briefly as follows:

- Throw away or otherwise ignore BDL data
- Set all BDL data at zero
- Set all BDL data at the detection limit
- Set all BDL data at some value (for example, one-half the detection limit)
- Use a statistical approach to evaluate BDL data

As noted in Attachment P, application of the first three methods may result in overestimations or underestimations of the true mean and variance. If BDL data are not used when calculating statistical parameters, the true mean may be overestimated and variability may be underestimated. If BDL data are all set at zero, the true mean may be underestimated and variability overestimated. If BDL data are all set at the detection limit, the true mean may be overestimated and variability underestimated.

The fourth method, using one-half the detection limit for BDL data, is frequently assumed in risk assessments. The one-half detection limit method simply estimates a concentration half-way between that assumed by Method 2 (zero) or Method 3 (the detection limit). When using any of the first 4 methods (referred to as substitution methods), the resulting bias in estimating mean and variance is small when the BDL data make up less than 15 percent of the data set. When the BDL data make up between 15 percent and 50 percent of the data, however, the biases increase, and statistical approaches such as Cohen's adjustment, a trimmed mean, or the Winsorized mean and standard deviation can be applied (EPA 1997f). Use of the statistical approaches will reduce the bias associated with BDL data and the use of the substitution methods. Attachment P presents a further description of the substitution and statistical methods for handling BDL data.

Guidance for Data Quality Assessment, Practical Methods for Data Analysis (EPA 1996d) provides additional specific guidance on the statistical methods. *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A* (EPA 1989c) recommends that sample quantitation limits be used as the detection limits of first choice when applying BDL methods. If sample quantitation limits are not available, contract-required or method detection limits should be used.

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ATTACHMENT A

U.S. ENVIRONMENTAL PROTECTION AGENCY
CAROL BROWNER MEMORANDUM ON RISK ASSESSMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE ADMINISTRATOR

MAR 2 1 1995

RECEIVED

MAR 2 8 1995

OFFICE OF
REGIONAL ADMINISTRATOR

MEMORANDUM

SUBJECT: EPA Risk Characterization Program

TO: Assistant Administrators
Associate Administrators
Regional Administrators
General Counsel
Inspector General

EPA has achieved significant pollution reduction over the past 20 years, but the challenges we face now are very different from those of the past. Many more people are aware of environmental issues today than in the past and their level of sophistication and interest in understanding these issues continues to increase. We now work with a populace which is not only interested in knowing what EPA thinks about a particular issue, but also how we come to our conclusions.

More and more key stakeholders in environmental issues want enough information to allow them to independently assess and make judgments about the significance of environmental risks and the reasonableness of our risk reduction actions. If we are to succeed and build our credibility and stature as a leader in environmental protection for the next century, EPA must be responsive and resolve to more openly and fully communicate to the public the complexities and challenges of environmental decisionmaking in the face of scientific uncertainty.

As the issues we face become more complex, people both inside and outside of EPA must better understand the basis for our decisions, as well as our confidence in the data, the science policy judgments we have made, and the uncertainty in the information base. In order to achieve this better understanding, we must improve the way in which we characterize and communicate environmental risk. We must embrace certain fundamental values

so that we may begin the process of changing the way in which we interact with each other, the public, and key stakeholders on environmental risk issues. I need your help to ensure that these values are embraced and that we change the way we do business.

First, we must adopt as values transparency in our decisionmaking process and clarity in communication with each other and the public regarding environmental risk and the uncertainties associated with our assessments of environmental risk. This means that we must fully, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions as they are made throughout the risk assessment and risk management processes. I want to be sure that key science policy issues are identified as such during the risk assessment process, that policymakers are fully aware and engaged in the selection of science policy options, and that their choices and the rationale for those choices are clearly articulated and visible in our communications about environmental risk.

I understand that some may be concerned about additional challenges and disputes. I expect that we will see more challenges, particularly at first. However, I strongly believe that making this change to a more open decisionmaking process will lead to more meaningful public participation, better information for decisionmaking, improved decisions, and more public support and respect for EPA positions and decisions. There is value in sharing with others the complexities and challenges we face in making decisions in the face of uncertainty. I view making this change as essential to the long term success of this Agency.

Clarity in communication also means that we will strive to help the public put environmental risk in the proper perspective when we take risk management actions. We must meet this challenge and find legitimate ways to help the public better comprehend the relative significance of environmental risks.

Second, because transparency in decisionmaking and clarity in communication will likely lead to more outside questioning of our assumptions and science policies, we must be more vigilant about ensuring that our core assumptions and science policies are consistent and comparable across programs, well grounded in science, and that they fall within a "zone of reasonableness."

While I believe that the American public expects us to err on the side of protection in the face of scientific uncertainty, I do not want our assessments to be unrealistically conservative. We cannot lead the fight for environmental protection into the next century unless we use common sense in all we do.

These core values of transparency, clarity, consistency, and reasonableness need to guide each of us in our day-to-day work; from the toxicologist reviewing the individual cancer study, to the exposure and risk assessors, to the risk manager, and through to the ultimate decisionmaker. I recognize that issuing this memo will not by itself result in any change. You need to believe in the importance of this change and convey your beliefs to your managers and staff through your words and actions in order for the change to occur. You also need to play an integral role in developing the implementing policies and procedures for your programs.

I am issuing the attached EPA Risk Characterization Policy and Guidance today. I view these documents as building blocks for the development of your program-specific policies and procedures. The Science Policy Council (SPC) plans to adopt the same basic approach to implementation as was used for Peer Review. That is, the Council will form an Advisory Group that will work with a broad Implementation Team made up of representatives from every Program Office and Region. Each Program Office and each Region will be asked by the Advisory Group to develop program and region-specific policies and procedures for risk characterization consistent with the values of **transparency, clarity, consistency, and reasonableness** and consistent with the attached policy and guidance.

I recognize that as you develop your Program-specific policies and procedures you are likely to need additional tools to fully implement this policy. I want you to identify these needed tools and work cooperatively with the Science Policy Council in their development. I want your draft program and region-specific policies, procedures, and implementation plans to be developed and submitted to the Advisory Group for review by no later than May 30, 1995. You will be contacted shortly by the SPC Steering Committee to obtain the names of your nominees to the Implementation Team.

Carol M. Browner

Attachments

March 1995

POLICY FOR RISK CHARACTERIZATION

at the U.S. Environmental Protection Agency

INTRODUCTION

Many EPA policy decisions are based in part on the results of risk assessment, an analysis of scientific information on existing and projected risks to human health and the environment. As practiced at EPA, risk assessment makes use of many different kinds of scientific concepts and data (e.g., exposure, toxicity, epidemiology, ecology), all of which are used to "characterize" the expected risk associated with a particular agent or action in a particular environmental context. Informed use of reliable scientific information from many different sources is a central feature of the risk assessment process.

Reliable information may or may not be available for many aspects of a risk assessment. Scientific uncertainty is a fact of life for the risk assessment process, and agency managers almost always must make decisions using assessments that are not as definitive in all important areas as would be desirable. They therefore need to understand the strengths and the limitations of each assessment, and to communicate this information to all participants and the public.

This policy reaffirms the principles and guidance found in the Agency's 1992 policy (Guidance on Risk Characterization for Risk Managers and Risk Assessors, February 26, 1992). That guidance was based on EPA's risk assessment guidelines, which are products of peer review and public comment. The 1994 National Research Council (NRC) report, "Science and Judgment in Risk Assessment," addressed the Agency's approach to risk assessment, including the 1992 risk characterization policy. The NRC statement accompanying the report stated, "... EPA's overall approach to assessing risks is fundamentally sound despite often-heard criticisms, but the Agency must more clearly establish the scientific and policy basis for risk estimates and better describe the uncertainties in its estimates of risk."

This policy statement and associated guidance for risk characterization is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers (policy makers), from middle to upper management, and from the Agency to the public. Additionally, the policy will provide a basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across Agency programs. While most of the discussion and examples in this policy are drawn from health risk assessment, these values also apply to ecological risk assessment. A parallel effort by the Risk Assessment Forum to develop EPA ecological risk assessment guidelines will include guidance specific to ecological risk characterization.

Policy Statement

Each risk assessment prepared in support of decision-making at EPA should include a risk characterization that follows the principles and reflects the values outlined in this policy. A risk characterization should be prepared in a manner that is clear, transparent, reasonable and consistent with other risk characterizations of similar scope prepared across programs in the Agency. Further, discussion of risk in all EPA reports, presentations, decision packages, and other documents should be substantively consistent with the risk characterization. The nature of the risk characterization will depend upon the information available, the regulatory application of the risk information, and the resources (including time) available. In all cases, however, the assessment should identify and discuss all the major issues associated with determining the nature and extent of the risk and provide commentary on any constraints limiting fuller exposition.

Key Aspects of Risk Characterization

Bridging risk assessment and risk management. As the interface between risk assessment and risk management, risk characterizations should be clearly presented, and separate from any risk management considerations. Risk management options should be developed using the risk characterization and should be based on consideration of all relevant factors, scientific and nonscientific.

Discussing confidence and uncertainties. Key scientific concepts, data and methods (e.g., use of animal or human data for extrapolating from high to low doses, use of pharmacokinetics data, exposure pathways, sampling methods, availability of chemical-specific information, quality of data) should be discussed. To ensure transparency, risk characterizations should include a statement of confidence in the assessment that identifies all major uncertainties along with comment on their influence on the assessment, consistent with the Guidance on Risk Characterization (attached).

Presenting several types of risk information. Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high end of individual risk, population risk, important subgroups, if known) consistent with terminology in the Guidance on Risk Characterization, Agency risk assessment guidelines, and program-specific guidance. In decision-making, risk managers should use risk information appropriate to their program legislation.

EPA conducts many types of risk assessments, including screening-level assessments of new chemicals, in-depth assessments of pollutants such as dioxin

and environmental tobacco smoke, and site-specific assessments for hazardous waste sites. An iterative approach to risk assessment, beginning with screening techniques, may be used to determine if a more comprehensive assessment is necessary. The degree to which confidence and uncertainty are addressed in a risk characterization depends largely on the scope of the assessment. In general, the scope of the risk characterization should reflect the information presented in the risk assessment and program-specific guidance. When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed.

Risk Characterization in Context

Risk assessment is based on a series of questions that the assessor asks about scientific information that is relevant to human and/or environmental risk. Each question calls for analysis and interpretation of the available studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem at hand, and scientific conclusions regarding the question presented. For example, health risk assessments involve the following questions:

Hazard Identification -- What is known about the capacity of an environmental agent for causing cancer or other adverse health effects in humans, laboratory animals, or wildlife species? What are the related uncertainties and science policy choices?

Dose-Response Assessment -- What is known about the biological mechanisms and dose-response relationships underlying any effects observed in the laboratory or epidemiology studies providing data for the assessment? What are the related uncertainties and science policy choices?

Exposure Assessment -- What is known about the principal paths, patterns, and magnitudes of human or wildlife exposure and numbers of persons or wildlife species likely to be exposed? What are the related uncertainties and science policy choices?

Corresponding principles and questions for ecological risk assessment are being discussed as part of the effort to develop ecological risk guidelines.

Risk characterization is the summarizing step of risk assessment. The risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about risk that is complete, informative and useful for decisionmakers.

Risk characterizations should clearly highlight both the confidence and the uncertainty associated with the risk assessment. For example, numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk-assessment reports and regulatory documents. In essence, a risk characterization conveys the assessor's judgment as to the nature and existence of (or lack of) human health or ecological risks. Even though a risk characterization describes limitations in an assessment, a balanced discussion of reasonable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment.

"Risk characterization" is not synonymous with "risk communication." This risk characterization policy addresses the interface between risk assessment and risk management. Risk communication, in contrast, emphasizes the process of exchanging information and opinion with the public – including individuals, groups, and other institutions. The development of a risk assessment may involve risk communication. For example, in the case of site-specific assessments for hazardous waste sites, discussions with the public may influence the exposure pathways included in the risk assessment. While the final risk assessment document (including the risk characterization) is available to the public, the risk communication process may be better served by separate risk information documents designed for particular audiences.

Promoting Clarity, Comparability and Consistency

There are several reasons that the Agency should strive for greater clarity, consistency and comparability in risk assessments. One reason is to minimize confusion. For example, many people have not understood that a risk estimate of one in a million for an "average" individual is not comparable to another one in a million risk estimate for the "most exposed individual." Use of such apparently similar estimates without further explanation leads to misunderstandings about the relative significance of risks and the protectiveness of risk reduction actions.

EPA's Exposure Assessment Guidelines provide standard descriptors of exposure and risk. Use of these terms in all Agency risk assessments will promote consistency and comparability. Use of several descriptors, rather than a single descriptor, will enable EPA to present a fuller picture of risk that corresponds to the range of different exposure conditions encountered by various individuals and populations exposed to most environmental chemicals.

Legal Effect

This policy statement and associated guidance on risk characterization do not establish or affect legal rights or obligations. Rather, they confirm the importance of risk characterization as a component of risk assessment, outline relevant principles, and identify factors Agency staff should consider in implementing the policy.

The policy and associated guidance do not stand alone; nor do they establish a binding norm that is finally determinative of the issues addressed. Except where otherwise provided by law, the Agency's decision on conducting a risk assessment in any particular case is within the Agency's discretion. Variations in the application of the policy and associated guidance, therefore, are not a legitimate basis for delaying or complicating action on Agency decisions.

Applicability

Except where otherwise provided by law and subject to the limitations on the policy's legal effect discussed above, this policy applies to risk assessments prepared by EPA and to risk assessments prepared by others that are used in support of EPA decisions.

EPA will consider the principles in this policy in evaluating assessments submitted to EPA to complement or challenge Agency assessments. Adherence to this Agency-wide policy will improve understanding of Agency risk assessments, lead to more informed decisions, and heighten the credibility of both assessments and decisions.

Implementation

Assistant Administrators and Regional Administrators are responsible for implementation of this policy within their organizational units. The Science Policy Council (SPC) is organizing Agency-wide implementation activities. Its responsibilities include promoting consistent interpretation, assessing Agency-wide progress, working with external groups on risk characterization issues and methods, and developing recommendations for revisions of the policy and guidance, as necessary.

Each Program and Regional office will develop office-specific policies and procedures for risk characterization that are consistent with this policy and the associated guidance. Each Program and Regional office will designate a risk manager or risk assessor as the office representative to the Agency-wide Implementa-

tion Team, which will coordinate development of office-specific policies and procedures and other implementation activities. The SPC will also designate a small cross-Agency Advisory Group that will serve as the liaison between the SPC and the Implementation Team.

In ensuring coordination and consistency among EPA offices, the Implementation Team will take into account statutory and court deadlines, resource implications, and existing Agency and program-specific guidance on risk assessment. The group will work closely with staff throughout Headquarters and Regional offices to promote development of risk characterizations that present a full and complete picture of risk that meets the needs of the risk managers.

APPROVED: _____ DATE: MAR 2 1 1995

Carol M. Browner, Administrator

ELEMENTS TO CONSIDER WHEN DRAFTING EPA RISK CHARACTERIZATIONS

March 1995.

Background -- Risk Characterization Principles

There are a number of principles which form the basis for a risk characteriza

- Risk assessments should be transparent, in that the conclusions drawn fr science are identified separately from policy judgements, and the use of d values or methods and the use of assumptions in the risk assessment are articulated.

- Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as w describe the likelihood of harm. The summary should include a descript the overall strengths and the limitations (including uncertainties) of the assessment and conclusions.

- Risk characterizations should be consistent in general format, but recogn unique characteristics of each specific situation.

- Risk characterizations should include, at least in a qualitative sense, a di of how a specific risk and its context compares with other similar risks. T be accomplished by comparisons with other chemicals or situations in w Agency has decided to act, or with other situations which the public may familiar with. The discussion should highlight the limitations of such comparisons.

- Risk characterization is a key component of risk communication, which is interactive process involving exchange of information and export opinion among individuals, groups and institutions.

Conceptual Guide for Developing Chemical-Specific Risk Characterizations

The following outline is a guide and formatting aid for developing risk characterizations for chemical risk assessments. Similar outlines will be de for other types of risk characterizations, including site-specific assessments a ecological risk assessments. A common format will assist risk managers in evaluating and using risk characterization.

The outline has two parts. The first part tracks the risk assessment to bring its major conclusions. The second part draws all of the information togeth characterize risk. The outline represents the expected findings for a typical chemical assessment for a single chemical. However, exceptions for the

circumstances of individual assessments exist and should be explained as part of the risk characterization. For example, particular statutory requirements, court-ordered deadlines, resource limitations, and other specific factors may be described to explain why certain elements are incomplete.

This outline does not establish or affect legal rights or obligations. Rather, it confirms the importance of risk characterization, outlines relevant principles, and identifies factors Agency staff should consider in implementing the policy. On a continuing basis, Agency management is expected to evaluate the policy as well as the results of its application throughout the Agency and undertake revisions as necessary. Therefore, the policy does not stand alone; nor does it establish a binding norm that is finally determinative of the issues addressed. Minor variations in its application from one instance to another are appropriate and expected; they thus are not a legitimate basis for delaying or complicating action on otherwise satisfactory scientific, technical, and regulatory products.

PART ONE

SUMMARIZING MAJOR CONCLUSIONS IN RISK CHARACTERIZATION

I. Characterization of Hazard Identification

A. What is the key toxicological study (or studies) that provides the basis for health concerns?
   - How good is the key study?
   - Are the data from laboratory or field studies? In single species or multiple species?
   - If the hazard is carcinogenic, comment on issues such as: observation of single or multiple tumor sites; occurrence of benign or malignant tumors; certain tumor types not linked to carcinogenicity; use of the maximum tolerated dose (MTD).
   - If the hazard is other than carcinogenic, what endpoints were observed, and what is the basis for the critical effect?
   - Describe other studies that support this finding.
   - Discuss any valid studies which conflict with this finding.

B. Besides the health effect observed in the key study, are there other health endpoints of concern?
   - What are the significant data gaps?

C. Discuss available epidemiological or clinical data. For epidemiological studies:
   - What types of studies were used, i.e., ecologic, case-control, cohort?

- Describe the degree to which exposures were adequately described.
- Describe the degree to which confounding factors were adequately accounted for.
- Describe the degree to which other causal factors were excluded.

D. How much is known about <u>how</u> (through what biological mechanism) the chemical produces adverse effects?
- Discuss relevant studies of mechanisms of action or metabolism.
- Does this information aid in the interpretation of the toxicity data?
- What are the implications for potential health effects?

E. Comment on any non-positive data in animals or people, and whether these data were considered in the hazard identification.

F. If adverse health affects have been observed in wildlife species, characterize such effects by discussing the relevant issues as in A through E above.

G. Summarize the hazard identification and discuss the significance of each of he following:
- confidence in conclusions;
- alternative conclusions that are also supported by the data;
- significant data gaps; and
- highlights of major assumptions.

II. Characterization of Dose-Response

A. What data were used to develop the dose-response curve? Would the result have been significantly different if based on a different data set?
- If animal data were used:
  - which species were used? most sensitive, average of all species, or other?
  - were any studies excluded? why?
- If epidemiological data were used:
  - Which studies were used? only positive studies, all studies, or some other combination?
  - Were any studies excluded? why?
  - Was a meta-analysis performed to combine the epidemiological studies? what approach was used? were studies excluded? why?

B. What model was used to develop the dose-response curve? What rationale supports this choice? Is chemical-specific information available to support this approach?
- For non-carcinogenic hazards:
  - How was the RfD/RfC (or the acceptable range) calculated?

- What assumptions or uncertainty factors were used?
- What is the confidence in the estimates?

- For carcinogenic hazards:
  - What dose-response model was used? LMS or other linear-at-low-dose model, a biologically-based model based on metabolism data, or data about possible mechanisms of action?
  - What is the basis for the selection of the particular dose-response model used?. Are there other models that could have been used with equal plausibility and scientific validity? What is the basis for selection of the model used in this instance?

C. Discuss the route and level of exposure observed, as compared to expected human exposures.
- Are the available data from the same route of exposure as the expected human exposures? If not, are pharmacokinetic data available to extrapolate across route of exposure?
- How far does one need to extrapolate from the observed data to environmental exposures (one to two orders of magnitude? multiple orders of magnitude)? What is the impact of such an extrapolation?

D. If adverse health affects have been observed in wildlife species, characterize dose-response information using the process outlined in A-C.

III. Characterization of Exposure

A. What are the most significant sources of environmental exposure?
- Are there data on sources of exposure from different media? What is the relative contribution of different sources of exposure?
- What are the most significant environmental pathways for exposure?

B. Describe the populations that were assessed, including as the general population, highly exposed groups, and highly susceptible groups.

C. Describe the basis for the exposure assessment, including any monitoring, modeling, or other analyses of exposure distributions such as Monte-Carlo or krieging.

D. What are the key descriptors of exposure?
- Describe the (range of) exposures to: "average" individuals, "high end" individuals, general population, high exposure group(s), children, susceptible populations.
- How was the central tendency estimate developed? What factors and/or methods were used in developing this estimate?
- How was the high-end estimate developed?

- Is there information on highly-exposed subgroups? Who are they? What are their levels of exposure? How are they accounted for in the assessment?

E. Is there reason to be concerned about cumulative or multiple exposures because of ethnic, racial, or socioeconomic reasons?

F. If adverse health affects have been observed in wildlife species, characterize wildlife exposure by discussing the relevant issues as in A through E above.

G. Summarize exposure conclusions and discuss the following:
- results of different approaches, i.e. modeling, monitoring, probability distributions;
- limitations of each, and the range of most reasonable values; and
- confidence in the results obtained, and the limitations to the results.

PART TWO
RISK CONCLUSIONS AND COMPARISONS

IV. Risk Conclusions

A. What is the overall picture of risk, based on the hazard identification, dose-response and exposure characterizations?

B. What are the major conclusions and strengths of the assessment in each of the three main analyses (i.e., hazard identification, dose-response, and exposure assessment)?

C. What are the major limitations and uncertainties in the three main analyses?

D. What are the science policy options in each of the three major analyses?
- What are the alternative approaches evaluated?
- What are the reasons for the choices made?

V. Risk Context

A. What are the qualitative characteristics of the hazard (e.g., voluntary vs. involuntary, technological vs. natural, etc.)? Comment on findings, if any, from studies of risk perception that relate to this hazard or similar hazards.

B. What are the alternatives to this hazard? How do the risks compare?

C. How does this risk compare to other risks?
   1. How does this risk compare to other risks in this regulatory program, or other similar risks that the EPA has made decisions about?
   2. Where appropriate, can this risk be compared with past Agency decisions, decisions by other federal or state agencies, or common risks with which people may be familiar?
   3. Describe the limitations of making these comparisons.

D. Comment on significant community concerns which influence public perception of risk?

VI. Existing Risk Information

Comment on other risk assessments that have been done on this chemical by EPA, other federal agencies, or other organizations. Are there significantly different conclusions that merit discussion?

VII. Other Information

Is there other information that would be useful to the risk manager or the public in this situation that has not been described above?

March 1995

IMPLEMENTATION PROGRAM
FOR
THE EPA POLICY ON RISK CHARACTERIZATION

Introduction

The EPA Science Policy Council (SPC) is implementing the Administrator's policy on risk characterization through a year-long program of activities that will involve risk assessors and risk managers in the practice of fully characterizing risk. This interactive approach calls for inter- and intra-office activities to gain experience with the fundamentals of the policy and to resolve issues that were identified during Agency-wide review of early drafts. Implementation will include program-specific guidance development; case study development; and risk characterization workshops and rountables for risk assessors and managers.

A SPC-sponsored "advisory group" will plan and execute these implementation activities. This advisory group will organize an "implementation team" composed of representatives from the program offices, regions and ORD laboratories and centers. This team will work closely with the advisory group to coordinate implementation activities within their offices.

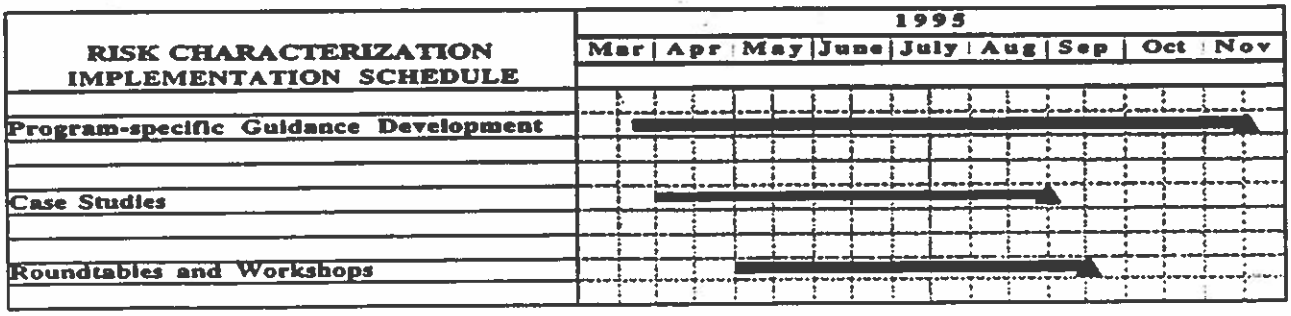
Program Guidance Development

Risk characterizations often differ according to the type of assessment involved. The aim is to work closely with the Program Offices and Regions to identify and address their specific risk characterization needs and, where appropriate, to develop assessment-specific guidance.

This program updates and implements the risk characterization guidance issued in early 1992. The policy features a paper entitled "Elements to Consider When Drafting EPA Risk Characterizations." This paper outlines generic elements for characterizing risk, and provides a prototype for assessment-specific guidance. Program and Regional offices will use this paper to identify and address risk characterization issues associated with specific assessment types that differ from the general prototype (e.g., site-specific and ecological risk assessments). Lessons learned from the case studies, roundtables and workshops (discussed below) will also contribute to program-specific guidance development.

Case Studies

Today, when asked to provide an example of a "good" risk characterization, few people can identify good examples, let alone examples that others would agree are



of high quality. As a first step, a selected number of risk characterization case studies will be developed for use as teaching tools. A "case study" will be an exercise to improve an existing risk characterization, using the information available in an existing risk assessment. While based on actual risk assessments, identifying information (e.g., site identification information) will be removed to avoid any implied judgement as to the adequacy of the original risk assessment and risk characterization. Examples of case studies may include a chemical assessment, a site-specific assessment, and a screening-level assessment. The case studies will be developed by the risk characterization advisory group, working in consultation with the implementation team, and will be used for discussion at the first risk characterization workshop.

Roundtables and Workshops

EPA decision-makers will be invited to participate in roundtable discussions on risk characterization. In addition, a minimum of two workshops are planned for EPA risk assessors and risk managers.

- ***Risk Decision-maker Rountables on Risk Characterization*** - The goal will be to determine the types of risk characterization information needed by managers for effective risk-based decision-making.

- ***Risk Characterization Workshop I*** - Will focus on identifying the qualities of "good" risk characterizations, program-specific plans and guidance development, and case studies.

- ***Risk Characterization Workshop II*** - Risk assessors and risk managers will meet to wrap-up program-specific plans and guidance, and discuss any necessary updates to the agency-wide risk characterization guidance.

GUIDANCE FOR RISK CHARACTERIZATION

U.S. Environmental Protection Agency
Science Policy Council
February, 1995

CONTENTS

PREFACE

This guidance contains principles for developing and describing EPA risk assessments, with a particular emphasis on risk characterization. The current document is an update of the guidance issued with the Agency's 1992 policy (Guidance on Risk Characterization for Risk Managers and Risk Assessors, February 26, 1992). The guidance has not been substantially revised, but includes some clarifications and changes to give more prominence to certain issues, such as the need to explain the use of default assumptions.

As in the 1992 policy, some aspects of this guidance focus on cancer risk assessment, but the guidance applies generally to human health effects (e.g., neurotoxicity, developmental toxicity) and, with appropriate modifications, should be used in all health risk assessments. This document has not been revised to specifically address ecological risk assessment, however, initial guidance for ecological risk characterization is included in EPA's Framework for Ecological Risk Assessments (EPA/630/R-92/001). Neither does this guidance address in detail the use of risk assessment information (e.g., information from the Integrated Risk Information System (IRIS)) to generate site- or media-specific risk assessments. Additional program-specific guidance will be developed to enable implementation of EPA's Risk Characterization Policy. Development of such guidance will be overseen by the Science Policy Council and will involve risk assessors and risk managers from across the Agency.

I. THE RISK ASSESSMENT-RISK MANAGEMENT INTERFACE

Recognizing that for many people the term risk assessment has wide meaning, the National Research Council's 1983 report on risk assessment in the federal government distinguished between risk assessment and risk management.

> "Broader uses of the term [risk assessment] than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions -- functions that we assign to risk management (emphasis added). (1)

In 1984, EPA endorsed these distinctions between risk assessment and risk management for Agency use (2), and later relied on them in developing risk assessment guidelines (3). In 1994, the NRC reviewed the Agency's approach to and use of risk assessment and issued an extensive report on their findings (4). This distinction suggests that EPA participants in the process can be grouped into two main categories, each with somewhat different responsibilities, based on their roles with respect to risk assessment and risk management.

A. Roles of Risk Assessors and Risk Managers

Within the Risk Assessment category there is a group that develops chemical-specific risk assessments by collecting, analyzing, and synthesizing scientific data to produce the hazard identification, dose-response, and exposure assessment portion of the risk assessment and to characterize risk. This group relies in part on Agency risk assessment guidelines to address science policy issues and scientific uncertainties. Generally, this group includes scientists and statisticians in the Office of Research and Development; the Office of Prevention, Pesticides and Toxics and other program offices; the Carcinogen Risk Assessment Verification Endeavor (CRAVE); and the Reference Dose (RfD) and Reference Concentration (RfC) Workgroups.

Another group generates site- or media-specific risk assessments for use in regulation development or site-specific decision-making. These assessors rely on existing databases (e.g., IRIS, ORD Health Assessment Documents, CRAVE and RfD/RfC Workgroup documents, and program-specific toxicity information) and media- or site-specific exposure information in developing risk assessments. This group also relies in part on Agency risk assessment guidelines and program-specific guidance to address science policy issues and scientific uncertainties. Generally, this group includes scientists and analysts in program offices, regional offices, and the Office of Research and Development.

Risk managers, as a separate category, integrate the risk characterization with other considerations specified in applicable statutes to make and justify regulatory decisions. Generally, this group includes Agency managers and decision-makers. Risk managers also play a role in determining the scope of risk assessments. The risk assessment process involves regular interaction between risk assessors and risk managers, with overlapping responsibilities at various stages in the overall process. Shared responsibilities include initial decisions regarding the planning and conduct of an assessment, discussions as the assessment develops, decisions regarding new data needed to complete an assessment and to address significant uncertainties. At critical junctures in the assessment, such consultations shape the nature of, and schedule for, the assessment. External experts and members of the public may also play a role in determining the scope of the assessment; for example, the public is often concerned about certain chemicals or exposure pathways in the development of site-specific risk assessments.

B. Guiding Principles

The following guidance outlines principles for those who generate, review, use, and integrate risk assessments for decision-making.

1. Risk assessors and risk managers should be sensitive to distinctions between risk assessment and risk management.

The major participants in the risk assessment process have many shared responsibilities. Where responsibilities differ, it is important that participants confine themselves to tasks in their areas of responsibility and not inadvertently obscure differences between risk assessment and risk management.

For the generators of the assessment, distinguishing between risk assessment and risk management means that scientific information is selected, evaluated, and presented without considering issues such as cost, feasibility, or how the scientific analysis might influence the regulatory or site-specific decision. Assessors are charged with (1) generating a credible, objective, realistic, and scientifically balanced analysis; (2) presenting information on hazard, dose-response, exposure and risk; and (3) explaining confidence in each assessment by clearly delineating strengths, uncertainties and assumptions, along with the impacts of these factors (e.g., confidence limits, use of conservative/non-conservative assumptions) on the overall assessment. They do not make decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks.

For users of the assessment and for decision-makers who integrate these assessments into regulatory or site-specific decisions, the distinction between risk assessment and risk management means refraining from influencing the risk

description through consideration of other factors -- e.g., the regulatory outcome -- and from attempting to shape the risk assessment to avoid statutory constraints, meet regulatory objectives, or serve political purposes. Such management considerations are often legitimate considerations for the overall regulatory decision (see next principle), but they have no role in estimating or describing risk. However, decision-makers and risk assessors participate in an Agency process that establishes policy directions that determine the overall nature and tone of Agency risk assessments and, as appropriate, provide policy guidance on difficult and controversial risk assessment issues. Matters such as risk assessment priorities, degree of conservatism, and acceptability of particular risk levels are reserved for decision-makers who are charged with making decisions regarding protection of public health.

2. **The risk assessment product, that is, the risk characterization, is only one of several kinds of information used for regulatory decision-making.**

Risk characterization, the last step in risk assessment, is the starting point for risk management considerations and the foundation for regulatory decision-making, but it is only one of several important components in such decisions. As the last step in risk assessment, the risk characterization identifies and highlights the noteworthy risk conclusions and related uncertainties. Each of the environmental laws administered by EPA calls for consideration of other factors at various stages in the regulatory process. As authorized by different statutes, decision-makers evaluate technical feasibility (e.g., treatability, detection limits), economic, social, political, and legal factors as part of the analysis of whether or not to regulate and, if so, to what extent. Thus, regulatory decisions are usually based on a combination of the technical analysis used to develop the risk assessment and information from other fields.

For this reason, risk assessors and managers should understand that the regulatory decision is usually not determined solely by the outcome of the risk assessment. For example, a regulatory decision on the use of a particular pesticide considers not only the risk level to affected populations, but also the agricultural benefits of its use that may be important for the nation's food supply. Similarly, assessment efforts may produce an RfD for a particular chemical, but other considerations may result in a regulatory level that is more or less protective than the RfD itself.

For decision-makers, this means that societal considerations (e.g., costs and benefits) that, along with the risk assessment, shape the regulatory decision should be described as fully as the scientific information set forth in the risk characterization. Information on data sources and analyses, their strengths and limitations, confidence in the assessment, uncertainties, and alternative analyses are as important here as they are for the scientific components of the regulatory decision. Decision-makers should be able to expect, for example, the same level of rigor from the economic analysis as they receive from the risk analysis. Risk management decisions involve numerous assumptions and uncertainties regarding technology, economics and social factors, which need to be explicitly identified for the decision-makers and the public.

II. RISK CHARACTERIZATION

A. Defining Risk Characterization in the Context of Risk Assessment

EPA risk assessment principles and practices draw on many sources. Obvious sources include the environmental laws administered by EPA, the National Research Council's 1983 report on risk assessment (1), the Agency's Risk Assessment Guidelines (3), and various program specific guidance (e.g., the Risk Assessment Guidance for Superfund). Twenty years of EPA experience in developing, defending, and enforcing risk assessment-based regulation is another. Together these various sources stress the importance of a clear explanation of Agency processes for evaluating hazard, dose-response, exposure, and other data that provide the scientific foundation for characterizing risk.

This section focuses on two requirements for full characterization of risk. First, the characterization should address qualitative and quantitative features of the assessment. Second, it should identify the important strengths and uncertainties in the assessment as part of a discussion of the confidence in the assessment. This emphasis on a full description of all elements of the assessment draws attention to the importance of the qualitative, as well as the quantitative, dimensions of the assessment. The 1983 NRC report carefully distinguished qualitative risk assessment from quantitative assessments, preferring risk statements that are not strictly numerical.

> The term risk assessment is often given narrower and broader meanings than we have adopted here. For some observers, the term is synonymous with quantitative risk assessment and emphasizes reliance on numerical results. Our broader definition includes quantification, but also includes qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. (1)

EPA's Exposure Assessment Guidelines define risk characterization as the final step in the risk assessment process that:

- Integrates the individual characterizations from the hazard identification, dose-response, and exposure assessments;
- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of risk and conclusions drawn;
- Describes risks to individuals and populations in terms of extent and severity of probable harm; and
- Communicates results of the risk assessment to the risk manager. (5)

Particularly critical to full characterization of risk is a frank and open discussion of the uncertainty in the overall assessment and in each of its components. The uncertainty discussion is important for several reasons.

1. Information from different sources carries different kinds of uncertainty and knowledge of these differences is important when uncertainties are combined for characterizing risk.

2. The risk assessment process, with management input, involves decisions regarding the collection of additional data (versus living with uncertainty); in the risk characterization, a discussion of the uncertainties will help to identify where additional information could contribute significantly to reducing uncertainties in risk assessment.

3. A clear and explicit statement of the strengths and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.

A discussion of uncertainty requires comment on such issues as the quality and quantity of available data, gaps in the data base for specific chemicals, quality of the measured data, use of default assumptions, incomplete understanding of general biological phenomena, and scientific judgments or science policy positions that were employed to bridge information gaps.

In short, broad agreement exists on the importance of a full picture of risk, particularly including a statement of confidence in the assessment and the associated uncertainties. This section discusses information content and uncertainty aspects of risk characterization, while Section III discusses various descriptors used in risk characterization.

B. Guiding Principles

1. **The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.**

Risk assessment is based on a series of questions that the assessor asks about the data and the implications of the data for human risk. Each question calls for analysis and interpretation of the available studies, selection of the data that are most scientifically reliable and most relevant to the problem at hand, and scientific conclusions regarding the question presented. As suggested below, because the questions and analyses are complex, a complete characterization includes several different kinds of information, carefully selected for reliability and relevance.

a. *Hazard Identification* -- What is known about the capacity of an environmental agent for causing cancer (or other adverse effects) in humans and laboratory animals?

Hazard identification is a qualitative description based on factors such as the kind and quality of data on humans or laboratory animals, the availability of ancillary information (e.g., structure-activity analysis, genetic toxicity, pharmacokinetics) from other studies, and the weight-of-the-evidence from all of these data sources. For example, to develop this description, the issues addressed include:

1) the nature, reliability, and consistency of the particular studies in humans and in laboratory animals;

2) the available information on the mechanistic basis for activity; and

3) experimental animal responses and their relevance to human outcomes.

These issues make clear that the task of hazard identification is characterized by describing the full range of available information and the implications of that information for human health.

b. *Dose-Response Assessment* – What is known about the biological mechanisms and dose-response relationships underlying any effects observed in the laboratory or epidemiology studies providing data for the assessment?

The dose-response assessment examines quantitative relationships between exposure (or dose) and effects in the studies used to identify and define effects of concern. This information is later used along with "real world" exposure information (see below) to develop estimates of the likelihood of adverse effects in populations potentially at risk. It should be noted that, in practice, hazard identification for developmental toxicity and other non-cancer health effects is usually done in conjunction with an evaluation of dose-response relationships, since the determination of whether there is a hazard is often dependent on whether a dose response relationship is present. (6) Also, the framework developed by EPA for ecological risk assessment does not distinguish between hazard identification and dose-response assessment, but rather calls for a "characterization of ecological effects." (7)

Methods for establishing dose-response relationships often depend on various assumptions used in lieu of a complete data base, and the method chosen can strongly influence the overall assessment. The Agency's risk assessment guidelines often identify so-called "default assumptions" for use in the absence of other information. The risk assessment should pay careful attention to the choice of a high-to-low dose extrapolation procedure. As a result, an assessor who is characterizing a dose-response relationship considers several key issues:

1) the relationship between extrapolation models selected and available information on biological mechanisms;

2) how appropriate data sets were selected from those that show the range of possible potencies both in laboratory animals and humans;

3) the basis for selecting interspecies dose scaling factors to account for scaling doses from experimental animals to humans;

4) the correspondence between the expected route(s) of exposure and the exposure route(s) utilized in the studies forming the basis of the dose-response assessment, as well as the interrelationships of potential effects from different exposure routes;

5) the correspondence between the expected duration of exposure and the exposure durations in the studies used in forming the basis of the dose-response assessment, e.g., chronic studies would be used to assess long-term, cumulative exposure concentrations, while acute studies would be used in assessing peak levels of exposure; and

6) the potential for differing susceptibilities among population subgroups.

The Agency's Integrated Risk Information System (IRIS) is a repository for such information for EPA. EPA program offices also maintain program-specific databases, such as the OSWER Health Effects Assessment Summary Tables (HEAST). IRIS includes data summaries representing Agency consensus on specific chemicals, based on a careful review of the scientific issues listed above. For specific risk assessments based on data from any source, risk assessors should carefully review the information presented, emphasizing confidence in the data and uncertainties (see subsection 2 below). Specifically, when IRIS data are used, the IRIS statement of confidence should be included as an explicit part of the risk characterization for hazard and dose-response information.

c. *Exposure Assessment* -- What is known about the principal paths, patterns, and magnitudes of human exposure and numbers of persons who may be exposed?

The exposure assessment examines a wide range of exposure parameters pertaining to the environmental scenarios of people who may be exposed to the agent under study. The information considered for the exposure assessment includes monitoring studies of chemical concentrations in environmental media, food, and other materials; modeling of environmental fate and transport of contaminants; and information on different activity patterns of different population subgroups. An assessor who characterizes exposure should address several issues:

1) The basis for the values and input parameters used for each exposure scenario. If the values are based on data, there should be a discussion of the quality, purpose, and representativeness of the database. For monitoring data, there should be a discussion of the data quality objectives as they are relevant to risk

assessment, including the appropriateness of the analytical detection limits. If models are applied, the appropriateness of the models and information on their validation should be presented. When assumptions are made, the source and general logic used to develop the assumptions (e.g., program guidance, analogy, professional judgment) should be described.

2) The confidence in the assumptions made about human behavior and the relative likelihood of the different exposure scenarios.

3) The major factor or factors (e.g., concentration, body uptake, duration/frequency of exposure) thought to account for the greatest uncertainty in the exposure estimate, due either to sensitivity or lack of data.

4) The link between the exposure information and the risk descriptors discussed in Section III of this Appendix. Specifically, the risk assessor needs to discuss the connection between the conservatism or non-conservatism of the data/assumptions used in the scenarios and the choice of descriptors.

5) Other information that may be important for the particular risk assessment. For example, for many assessments, other sources and background levels in the environment may contribute significantly to population exposures and should be discussed.

2) The risk characterization includes a discussion of uncertainty and variability.

In the risk characterization, conclusions about hazard and dose response are integrated with those from the exposure assessment. In addition, confidence about these conclusions, including information about the uncertainties associated with each aspect of the assessment in the final risk summary, is highlighted. In the previous assessment steps and in the risk characterization, the risk assessor must distinguish between variability and uncertainty.

Variability arises from true heterogeneity in characteristics such as dose-response differences within a population, or differences in contaminant levels in the environment. The values of some variables used in an assessment change with time and space, or across the population whose exposure is being estimated. Assessments should address the resulting variability in doses received by members of the target population. Individual exposure, dose, and risk can vary widely in a large population. The central tendency and high end individual risk descriptors (discussed in Section III below) are intended to capture the variability in exposure, lifestyles, and other factors that lead to a distribution of risk across a population.

Uncertainty, on the other hand, represents lack of knowledge about factors such as adverse effects or contaminant levels which may be reduced with additional study. Generally, risk assessments carry several categories of uncertainty, and each merits

consideration. Measurement uncertainty refers to the usual error that accompanies scientific measurements--standard statistical techniques can often be used to express measurement uncertainty. A substantial amount of uncertainty is often inherent in environmental sampling, and assessments should address these uncertainties. There are likewise uncertainties associated with the use of scientific models, e.g., dose-response models, models of environmental fate and transport. Evaluation of model uncertainty would consider the scientific basis for the model and available empirical validation.

A different kind of uncertainty stems from data gaps -- that is, estimates or assumptions used in the assessment. Often, the data gap is broad, such as the absence of information on the effects of exposure to a chemical on humans or on the biological mechanism of action of an agent. The risk assessor should include a statement of confidence that reflects the degree to which the risk assessor believes that the estimates or assumptions adequately fill the data gap. For some common and important data gaps, Agency or program-specific risk assessment guidance provides default assumptions or values. Risk assessors should carefully consider all available data before deciding to rely on default assumptions. If defaults are used, the risk assessment should reference the Agency guidance that explains the default assumptions or values.

Often risk assessors and managers simplify discussion of risk issues by speaking only of the numerical components of an assessment. That is, they refer to the alpha-numeric weight-of-the-evidence classification, unit risk, the risk-specific dose or the q_1^* for cancer risk, and the RfD/RfC for health effects other than cancer, to the exclusion of other information bearing on the risk case. However, since every assessment carries uncertainties, a simplified numerical presentation of risk is always incomplete and often misleading. For this reason, the NRC (1) and EPA risk assessment guidelines (2) call for "characterizing" risk to include qualitative information, a related numerical risk estimate and a discussion of uncertainties, limitations, and assumptions--default and otherwise.

Qualitative information on methodology, alternative interpretations, and working assumptions (including defaults) is an important component of risk characterization. For example, specifying that animal studies rather than human studies were used in an assessment tells others that the risk estimate is based on assumptions about human response to a particular chemical rather than human data. Information that human exposure estimates are based on the subjects' presence in the vicinity of a chemical accident rather than tissue measurements defines known and unknown aspects of the exposure component of the study.

Qualitative descriptions of this kind provide crucial information that augments understanding of numerical risk estimates. Uncertainties such as these are expected in scientific studies and in any risk assessment based on these studies. Such

uncertainties do not reduce the validity of the assessment. Rather, they should be highlighted along with other important risk assessment conclusions to inform others fully on the results of the assessment.

In many cases, assessors must choose among available data, models, or assumptions in estimating risks. Examining the impact of selected, plausible alternatives on the conclusions of the assessment is an important part of the uncertainty discussion. The key words are "selected" and "plausible;" listing all alternatives to a particular assumption, regardless of their merits would be superfluous. Generators of the assessment, using best professional judgment, should outline the strengths and weaknesses of the plausible alternative approaches.[1]

An adequate description of the process of alternatives selection involves several aspects.

a. A rationale for the choice.
b. Discussion of the effects of alternatives selected on the assessment.
c. Comparison with other plausible alternatives, where appropriate.

The degree to which variability and uncertainty are addressed depends largely on the scope of the assessment and the resources available. For example, the Agency does not expect an assessment to evaluate and assess every conceivable exposure scenario for every possible pollutant, to examine all susceptible populations potentially at risk, or to characterize every possible environmental scenario to estimate the cause and effect relationships between exposure to pollutants and adverse health effects. Rather, the discussion of uncertainty and variability should reflect the type and complexity of the risk assessment, with the level of effort for analysis and discussion of uncertainty corresponding to the level of effort for the assessment.

3. **Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public.**

The risk assessment process calls for identifying and highlighting significant risk conclusions and related uncertainties partly to assure full communication among risk assessors and partly to assure that decision-makers are fully informed. Issues are identified by acknowledging noteworthy qualitative and quantitative factors that make a difference in the overall assessment of hazard and risk, and hence in the ultimate regulatory decision. The key word is "noteworthy." Information that

[1]In cases where risk assessments within an Agency program routinely address similar sets of alternatives, program guidance may be developed to streamline and simplify the discussion of these alternatives.

significantly influences the analysis is explicitly noted -- in all future presentations of the risk assessment and in the related decision. Uncertainties and assumptions that strongly influence confidence in the risk estimate also require special attention.

Numerical estimates should not be separated from the descriptive information that is integral to risk characterization. Documents and presentations supporting regulatory or site-specific decisions should include both the numerical estimate and descriptive information; in short reports, this information can be abbreviated. Fully visible information assures that important features of the assessment are immediately available at each level of review for evaluating whether risks are acceptable or unreasonable.

III. EXPOSURE ASSESSMENT AND RISK DESCRIPTORS

A. Presentation of Risk Descriptors

The results of a risk assessment are usually communicated to the risk manager in the risk characterization portion of the assessment. This communication is often accomplished through risk descriptors which convey information and answer questions about risk, each descriptor providing different information and insights. Exposure assessment plays a key role in developing these risk descriptors since each descriptor is based in part on the exposure distribution within the population of interest.

The following guidance outlines the different descriptors in a convenient order that should not be construed as a hierarchy of importance. These descriptors should be used to describe risk in a variety of ways for a given assessment, consistent with the assessment's purpose, the data available, and the information the risk manager needs. Use of a range of descriptors instead of a single descriptor enables Agency programs to present a picture of risk that corresponds to the range of different exposure conditions encountered for most environmental chemicals. This analysis, in turn, allows risk managers to identify populations at greater and lesser risk and to shape regulatory solutions accordingly.

Agency risk assessments will be expected to address or provide descriptions of (1) individual risk that include the central tendency and high end portions of the risk distribution, (2) population risk, and (3) important subgroups of the population, such as highly exposed or highly susceptible groups. Assessors may also use additional descriptors of risk as needed when these add to the clarity of the presentation. With the exception of assessments where particular descriptors clearly do not apply, some form of these three types of descriptors should be routinely developed and presented for Agency risk assessments[2]. In other cases, where a descriptor would be relevant, but the program lacks the data or methods to develop it, the program office should design and implement a plan, in coordination with other EPA offices, to meet these assessment needs. While gaps continue to exist, risk assessors should make their best efforts to address each risk descriptor, and at a minimum, should briefly discuss the lack of data or methods. Finally, presenters of risk assessment information should be prepared to routinely answer questions by risk managers concerning these descriptors.

It is essential that presenters not only communicate the results of the assessment by addressing each of the descriptors where appropriate, but that they also

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[2]Program-specific guidance will need to address these situations. For example, for site-specific assessments, the utility and appropriateness of population risk estimates will be determined based on the available data and program guidance.

communicate their confidence that these results portray a reasonable picture of the actual or projected exposures. This task will usually be accomplished by frankly commenting on the key assumptions and parameters that have the greatest impact on the results, the basis or rationale for choosing these assumptions/parameters, and the consequences of choosing other assumptions.

B. Relationship Between Exposure Descriptors and Risk Descriptors

In the risk assessment process, risk is estimated as a function of exposure, with the risk of adverse affects increasing as exposure increases. Information on the levels of exposure experienced by different members of the population is key to understanding the range of risks that may occur. Risk assessors and risk managers should keep in mind, however, that exposure is not synonymous with risk. Differences among individuals in absorption rates, susceptibility, or other factors mean that individuals with the same level of exposure may be at different levels of risk. In most cases, the state of the science is not yet adequate to define distributions of factors such as population susceptibility. The guidance principles below discuss a variety of risk descriptors that primarily reflect differences in estimated exposure. If a full description of the range of susceptibility in the population cannot be presented, an effort should be made to identify subgroups that, for various reasons, may be particularly susceptible.

C. Guiding Principles

1. Information about the distribution of individual exposures is important to communicating the results of a risk assessment.

The risk manager is generally interested in answers to questions such as the following:

- Who are the people at the highest risk?
- What risk levels are they subjected to?
- What are they doing, where do they live, etc., that might be putting them at this higher risk?
- What is the average risk for individuals in the population of interest?

Individual exposure and risk descriptors are intended to provide answers to these questions so as to illuminate the risk management decisions that need to be made. In order to describe the range of risks, both high end and central tendency

descriptors are used to convey the variability in risk levels experienced by different individuals in the population.

a. High end descriptor

For the Agency's purposes, high end risk descriptors are plausible estimates of the individual risk for those persons at the upper end of the risk distribution. Given limitations in current understanding of variability in individuals' sensitivity to toxins, high end descriptors will usually address high end exposure or dose (herein referred to as exposure for brevity). The intent of these descriptors is to convey estimates of exposure in the upper range of the distribution, but to avoid estimates which are beyond the true distribution. Conceptually, high end exposure means exposure above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure. When large populations are assessed, a large number of individuals may be included within the "high end" (e.g., above 90th or 95th percentile) and information on the range of exposures received by these individuals should be presented.

High end descriptors are intended to estimate the exposures that are expected to occur in small, but definable, "high end" segments of the subject population.[3] The individuals with these exposures may be members of a special population segment or individuals in the general population who are highly exposed because of the inherent stochastic nature of the factors which give rise to exposure. Where differences in sensitivity can be identified within the population, high end estimates addressing sensitive individuals or subgroups can be developed.

In those few cases in which the complete data on the population distributions of exposures and doses are available, high end exposure or dose estimates can be represented by reporting exposures or doses at a set of selected percentiles of the distributions, such as the 90th, 95th, and 98th percentile. High end exposures or doses, as appropriate, can then be used to calculate high end risk estimates.

In the majority of cases where the complete distributions are not available, several methods help estimate a high end exposure or dose. If sufficient information about the variability in chemical concentrations, activity patterns, or other factors are available, the distribution may be estimated through the use of appropriate modeling (e.g., Monte Carlo simulation or parametric statistical methods). The

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[3]High end estimates focus on estimates of exposure in the exposed populations. Bounding estimates, on the other hand, are constructed to be equal to or greater than the highest actual risk in the population (or the highest risk that could be expected in a future scenario). A "worst case scenario" refers to a combination of events and conditions such that, taken together, produces the highest conceivable risk. Although it is possible that such an exposure, dose, or sensitivity combination might occur in a given population of interest, the probability of an individual receiving this combination of events and conditions is usually small, and often so small that such a combination will not occur in a particular, actual population.

determination of whether available information is sufficient to support the use of probabilistic estimation methods requires careful review and documentation by the risk assessor. If the input distributions are based on limited data, the resulting distribution should be evaluated carefully to determine whether it is an improvement over more traditional estimation techniques. If a distribution is developed, it should be described with a series of percentiles or population frequency estimates, particularly in the high end range. The assessor and risk manager should be aware, however, that unless a great deal is known about exposures and doses at the high end of the distribution, these estimates will involve considerable uncertainty which the exposure assessor will need to describe. Note that in this context, the probabilistic analysis addresses variability of exposure in the population. Probabilistic techniques may also be applied to evaluate uncertainty in estimates (see section 5, below). However, it is generally inappropriate to combine distributions reflecting both uncertainty and variability to get a single overall distribution. Such a result is not readily interpretable for the concerns of environmental decision-making.

If only limited information on the distribution of the exposure or dose factors is available, the assessor should approach estimating the high end by identifying the most sensitive variables and using high end values for a subset of these variables, leaving others at their central values.[4] In doing this, the assessor needs to avoid combinations of parameter values that are inconsistent (e.g., low body weight used in combination with high dietary intake rates), and must keep in mind the ultimate objective of being within the distribution of actual expected exposures and doses, and not beyond it.

If very little data are available on the ranges for the various variables, it will be difficult to estimate exposures or doses and associated risks in the high end with much confidence. One method that has been used in such cases is to start with a bounding estimate and "back off" the limits used until the combination of parameter values is, in the judgment of the assessor, within the distribution of expected exposure, and still lies within the upper 10% of persons exposed. Obviously, this method results in a large uncertainty and requires explanation.

b. Central tendency descriptor

Central tendency descriptors generally reflect central estimates of exposure or dose. The descriptor addressing central tendency may be based on either the arithmetic mean exposure (average estimate) or the median exposure (median estimate), either

[4]Maximizing all variables will in virtually all cases result in an estimate that is above the actual values seen in the population. When the principal parameters of the dose equation, e.g., concentration (appropriately integrated over time), intake rate, and duration, are broken out into sub-components, it may be necessary to use maximum values for more than two of these sub-component parameters, depending on a sensitivity analysis.

of which should be clearly labeled. The average estimate, used to approximate the arithmetic mean, can often be derived by using average values for all the exposure factors.[5] It does not necessarily represent a particular individual on the distribution. Because of the skewness of typical exposure profiles, the arithmetic mean may differ substantially from the median estimate (i.e., 50th percentile estimate, which is equal to the geometric mean for a log normal distribution). The selection of which descriptor(s) to present in the risk characterization will depend on the available data and the goals of the assessment. When data are limited, it may not be possible to construct true median or mean estimates, but it is still possible to construct estimates of central tendency. The discussion of the use of probabilistic techniques in Section 1(a) above also applies to estimates of central tendency.

2. Information about population exposure leads to another important way to describe risk.

Population risk refers to an assessment of the extent of harm for the population as a whole. In theory, it can be calculated by summing the individual risks for all individuals within the subject population. This task, of course, requires a great deal more information than is normally, if ever, available.

The kinds of questions addressed by descriptors of population risk include the following:

- How many cases of a particular health effect might be probabilistically estimated in this population for a specific time period?
- For non-carcinogens, what portion of the population is within a specified range of some reference level; e.g., exceedance of the RfD (a dose), the RfC (a concentration), or other health concern level?
- For carcinogens, what portion of the population is above a certain risk level, such as 10^{-6}?

These questions can lead to two different descriptors of population risk.

a. Probabilistic number of cases

The first descriptor is the probabilistic number of health effect cases estimated in the population of interest over a specified time period. This descriptor can be obtained either by (a) summing the individual risks over all the individuals in the population, e.g. using an estimated distribution of risk in the population, when

[5]This holds true when variables are added (e.g., exposures by different routes) or when independent variables are multiplied (e.g., concentration x intake). However, it would be incorrect for products of correlated variables, variables used as divisors, or for formulas involving exponents.

such information is available, or (b) through the use of a risk model that assumes a linear non-threshold response to exposure, such as many carcinogenic models. In these calculations, data will typically be available to address variability in individual exposures. If risk varies linearly with exposure, multiplying the mean risk by the population size produces an estimate of the number of cases.[6] At the present time, most cancer potency values represent plausible upper bounds on risk. When such a value is used to estimate numbers of cancer cases, it is important to understand that the result is also an upper bound. As with other risk descriptors, this approach may not adequately address sensitive subgroups for which different dose-response curve or exposure estimates might be needed.

Obviously, the more information one has, the more certain the estimate of this risk descriptor, but inherent uncertainties in risk assessment methodology place limitations on the accuracy of the estimate. The discussion of uncertainty involved in estimating the number of cases should indicate that this descriptor is not to be confused with an actuarial prediction of cases in the population (which is a statistical prediction based on a great deal of empirical data).

In general, it should be recognized that when small populations are exposed, population risk estimates may be very small. For example, if 100 people are exposed to an individual lifetime cancer risk of 10^{-4}, the expected number of cases is 0.01. In such situations, individual risk estimates will usually be a more meaningful parameter for decision-makers.

b. Estimated percentage of population with risk greater than some level

For non-cancer effects, we generally have not developed the risk assessment techniques to the point of knowing how to add risk probabilities, so a second descriptor is usually more appropriate: An estimate of the percentage of the population, or the number of persons, above a specified level of risk or within a specified range of some reference level, e.g., exceedance of the RfD or the RfC, LOAEL, or other specific level of interest. This descriptor must be obtained through measuring or simulating the population distribution.

3. Information about the distribution of exposure and risk for different subgroups of the population are important components of a risk assessment.

A risk manager might also ask questions about the distribution of the risk burden among various segments of the subject population such as the following: How do exposure and risk impact various subgroups?; and, what is the population risk of a

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[6]However, certain important cautions apply (see EPA's Exposure Assessment Guidelines). Also, this is not appropriate for non-carcinogenic effects or for other types of cancer models. For non-linear cancer models, an estimate of population risk must be calculated using the distribution of individual risks.

particular subgroup? Questions about the distribution of exposure and risk among such population segments require additional risk descriptors.

a. Highly exposed

Highly exposed subgroups can be identified, and where possible, characterized and the magnitude of risk quantified. This descriptor is useful when there is (or is expected to be) a subgroup experiencing significantly different exposures or doses from that of the larger population. These sub-populations may be identified by age, sex, lifestyle, economic factors, or other demographic variables. For example, toddlers who play in contaminated soil and high fish consumers represent sub-populations that may have greater exposures to certain agents.

b. Highly susceptible

Highly susceptible subgroups can also be identified, and if possible, characterized and the magnitude of risk quantified. This descriptor is useful when the sensitivity or susceptibility to the effect for specific subgroups is (or is expected to be) significantly different from that of the larger population. In order to calculate risk for these subgroups, it will sometimes be necessary to use a different dose-response relationship; e.g., upon exposure to a chemical, pregnant women, elderly people, children, and people with certain illnesses may each be more sensitive than the population as a whole. For example, children are thought to be both highly exposed and highly susceptible to the effects of environmental lead. A model has been developed that uses data on lead concentrations in different environmental media to predict the resulting blood lead levels in children. Federal agencies are working together to develop specific guidance on blood lead levels that present risks to children.

It is important to note, however, that the Agency's current methodologies for developing reference doses and reference concentrations (RfDs and RfCs) are designed to protect sensitive populations. If data on sensitive human populations are available (and there is confidence in the quality of the data), then the RfD is set at the dose level at which no adverse effects are observed in the sensitive population (e.g., RfDs for fluoride and nitrate). If no such data are available (for example, if the RfD is developed using data from humans of average or unknown sensitivity) then an additional 10-fold factor is used to account for variability between the average human response and the response of more sensitive individuals.

Generally, selection of the population segments is a matter of either a priori interest in the subgroup (e.g., environmental justice considerations), in which case the risk assessor and risk manager can jointly agree on which subgroups to highlight, or a matter of discovery of a sensitive or highly exposed subgroup during the assessment

process. In either case, once identified, the subgroup can be treated as a population in itself, and characterized in the same way as the larger population using the descriptors for population and individual risk.

4. **Situation-specific information adds perspective on possible future events or regulatory options.**

"What if...?" questions can be used to examine candidate risk management options. For example, consider the following:

- What if a pesticide applicator applies this pesticide without using protective equipment?
- What if this site becomes residential in the future?
- What risk level will occur if we set the standard at 100 ppb?

Answering these "What if...?" questions involves a calculation of risk based on specific combinations of factors postulated within the assessment[7]. The answers to these "What if...?" questions do not, by themselves, give information about how likely the combination of values might be in the actual population or about how many (if any) persons might be subjected to the potential future risk. However, information on the likelihood of the postulated scenario would also be desirable to include in the assessment.

When addressing projected changes for a population (either expected future developments or consideration of different regulatory options), it is usually appropriate to calculate and consider all the risk descriptors discussed above. When central tendency or high end estimates are developed for a future scenario, these descriptors should reflect reasonable expectations about future activities. For example, in site-specific risk assessments, future scenarios should be evaluated when they are supported by realistic forecasts of future land use, and the risk descriptors should be developed within that context.

5. **An evaluation of the uncertainty in the risk descriptors is an important component of the uncertainty discussion in the assessment.**

Risk descriptors are intended to address variability of risk within the population and the overall adverse impact on the population. In particular, differences between high end and central tendency estimates reflect variability in the population, but not the scientific uncertainty inherent in the risk estimates. As discussed above, there

[7]Some programs routinely develop future scenarios as part of developing a risk assessment. Program-specific guidance may address future scenarios in more detail than they are described here.

will be uncertainty in all estimates of risk. These uncertainties can include measurement uncertainties, modeling uncertainties, and assumptions to fill data gaps. Risk assessors should address the impact of each of these factors on the confidence in the estimated risk values.

Both qualitative and quantitative evaluations of uncertainty provide useful information to users of the assessment. The techniques of quantitative uncertainty analysis are evolving rapidly and both the SAB (8) and the NRC (4) have urged the Agency to incorporate these techniques into its risk analyses. However, it should be noted that a probabilistic assessment that uses only the assessor's best estimates for distributions of population variables addresses variability, but not uncertainty. Uncertainties in the estimated risk distribution need to be separately evaluated.

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ATTACHMENT B

RCRA/CERCLA INTERFACE-INTERIM FINAL GUIDANCE, EPA REGION 10 MEMORANDUM, AUGUST 3

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue
Seattle, Washington 98101

August 3, 1994

Reply To
Attn Of: HW-124

MEMORANDUM

SUBJECT: RCRA/CERCLA Interface - Interim Final Guidance

FROM: Michael Gearheard, Chief
Waste Management Branch

for Carol Rushin, Chief
Superfund Remedial Branch

for James Everts, Chief
Superfund Response/Investigation Branch

George C. Hofer, Chief
Federal Facilities Superfund Branch

TO: Hazardous Waste Division

INTRODUCTION

Over the years there have been some areas of confusion between the RCRA and CERCLA programs, as one might expect when you have two programs dealing with hazardous waste but using two separate statutes and sets of regulations and guidance. The RCRA/CERCLA Interaction Workgroup was formed to identify areas where the two programs have routinely overlapped, and there is reasonable expectation that a consolidated approach would result in efficiencies. A summary of their findings is attached. (If you want the full report please call Sharon Smith at 3-6637). We want to thank the Workgroup members for all their hard work and great product we now have to work with.

Judi Schwarz	Bill Adams
Christy Ahlstrom Brown	Thor Cutler
Dave Croxton	Nancy Harney
Marcia Bailey	Ed Jones

It was particularly significant to us that the Workgroup members all felt that they had learned as a result of their experience and that it clearly demonstrates the benefit of cross-program teaming.

This memo is intended to give greater clarity to and set out our expectations as how these potential overlaps should be handled. If you have general situations that are not covered here, please call Judi Schwarz as she is quite knowledgeable in both program areas. We branch chiefs would also welcome a call as a major part of our job is to work cross-program issues.

This guidance will not answer every question that may come up in developing a site-specific comprehensive and non-duplicative solution. We encourage creative solutions and discourage rigid interpretation of the regulations and guidance, but we also recognize that some solutions may require input from the section and branch chiefs. We encourage you to involve us early in the process rather than becoming frustrated by a situation.

We are issuing this guidance as an interim final product. We want to begin to apply this approach, but realize that we may not have thought of all of the implications and problems that may arise. If necessary, this guidance can be revised in the future to reflect what we will learn about integrating our two EPA programs. Other revisions may also be necessary if and when this approach is applied to EPA RCRA/State clean-up program or CERCLA/State RCRA program overlaps.

PARITY POLICY - THE BIG PICTURE

We are committed to doing everything we can to avoid duplication between the Region 10 RCRA and CERCLA programs. To this end, we believe RCRA and CERCLA program managers and staff need to: (1) be knowledgeable about both programs, (2) maintain close communication where sites may involve both programs and develop a coordinated strategy such as a site management plan for such sites, and (3) recognize that either program will produce substantially equivalent cleanup outcomes. Actions are set forth below to help achieve these goals.

Because we believe that the environmental outcome reached at a site managed under CERCLA or RCRA will be similar, we are declaring parity between RCRA corrective action and CERCLA remedial action decisions. Parity means that a site-specific decision under one program will be considered equivalent to a decision under the other program. The CERCLA and RCRA corrective action programs rely on similar risk-based approaches, and they address remediation of past activities/practices. Under parity, one program will normally not recheck or re-open unit-specific decisions made by the other program.

Declaring parity between the RCRA and CERCLA programs at RCRA regulated units[1] themselves is not as simple. Overlaps between these two programs are most likely to occur at facilities that have interim status for either operating or closing units or have illegal RCRA regulated units (e.g., they managed hazardous wastes in a unit without having achieved interim status). For those RCRA regulated units that have not yet been permitted, there may be RCRA interim status requirements such as groundwater monitoring, financial assurance, and closure and post-closure care that will still have to be met by the facility even if CERCLA is involved at the site. There may also be issues of regulatory compliance or violations. However, through the steps outlined in this memo, the requirements of both programs can and should be met with a single coordinated approach.

In summary, for RCRA corrective action and Superfund remedial actions, the actual environmental results achieved through cleanup are expected to be environmentally equivalent. In addition, application of RCRA closure and post-closure

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[1] "RCRA 101" - Definitions:

A regulated unit is a unit, such as a landfill, surface impoundment, storage area, etc., within a RCRA Treatment, Storage, or Disposal Facility (or TSDF), that managed RCRA hazardous waste at any time after the appropriate regulation went into effect. (Generally this means any time after November 1980.) A facility cannot be a TSDF unless it has at least one RCRA regulated unit. A Solid Waste Management Unit (or SWMU) is any discernible unit at a TSDF at which solid wastes have been placed at any time, irrespective of whether the unit was intended for the management of solid or hazardous waste. Regulated units are a subset of SWMUs. Areas of Concern (AOC) are areas within a facility that are known or suspected to be contaminated by hazardous constituents but which were not a location of solid waste management. A one time product spill is an example.

All TSDFs are required to eventually have RCRA permits or go through closure of the regulated units. Permits must include long-term post-closure care for units that cannot clean close. Until EPA or the delegated state has issued that permit, or until the facility is clean closed, the TSDF is subject to the interim status requirements found in 40 CFR 265.

Corrective action is required for all releases from SWMUs. For facilities that are being permitted, corrective action requirements must be part of the permit. Corrective action can also be required at interim status facilities through administrative orders.

A facility that only generates RCRA hazardous waste and stores this hazardous waste for less than 90 days in tanks or containers under certain conditions is a hazardous waste generator subject to the RCRA generator standards found in 40 CFR 262 and is conditionally exempt from the storage permit requirements. Such an exempt storage facility is generally not subject to RCRA corrective action under a RCRA 3008(h) order. However environmental problems could be addressed through RCRA's imminent hazard order authority (Section 7003) or RCRA's investigation authority (Section 3013.)

Please note that these definitions are somewhat simplified and should not be relied upon to give the correct answer in all situations.

processes and Superfund remedial actions are also expected to achieve environmentally equivalent results. The only exception to this is that some proposed/potential Superfund No Further Action decisions at regulated units may require additional steps to ensure that the RCRA clean closure standards are also met.

PROCEDURES

Clean-up decisions will continue to be routinely presented in documents such as fact sheets, Statement of Basis, Final Decision documents, and Records of Decision (RODs). However, these decision documents and the related public notices and Proposed Plans should explain that the selected action will satisfy the requirements for remediation under both statutes. In addition, as long as the clean-up action fits into the parity categories described above, the two hazardous waste programs will not cross-check decisions. The workgroup did recommend that informal peer review be used to inform and educate (see below).

Either program may perform or postpone some or all of the cleanup areas as long as there is no duplication and the decision is reflected in the site-specific coordinated strategy. The decision should be based on, among other things, timing, resources and environmental priority, and should involve consultation with the other program.

Where RCRA corrective action is being incorporated into Superfund activities, the need for action at all identified Solid Waste Management Units (SWMUs) and Areas of Concern (AOCs) will be considered by the Superfund program. Whenever possible, the RCRA Facility Assessment (RFA) should be started and completed early enough so that the results of the RFA can be factored into the Superfund process in a timely and coordinated manner. If for some reason, one or more SWMUs are not identified or considered in the Superfund evaluation process, the RCRA program may choose to evaluate the need for further investigation at such units, particularly where there is or will be a RCRA permit for regulated activities. Superfund should document their evaluations of SWMUs even if they are not addressed in the ROD.

BUT...

That is not the whole story. The existence of one or more RCRA <u>regulated units</u> at an NPL site raises several additional concerns regarding that regulated unit that must be addressed. These are:

1. If the regulated unit is not closing, it must obtain a RCRA permit. The permit must, by law, include site-wide corrective action. At NPL sites, this corrective action requirement can be met in the permit by referencing a legally enforceable CERCLA agreement

(e.g., see the permits for Elmendorf AFB, and Fort Wainwright).

2. If the regulated unit is closing by clean closure, certain requirements apply and must be considered even though the environmental outcome reached under RCRA and CERCLA is substantially equivalent. The Regulated Unit Checklist that will be developed and the discussion below on public participation requirements for closing regulated units will give guidance on how we can satisfy both programs' requirements.

3. If the regulated unit will be closed as a landfill - i.e., with waste in place - then different procedural, timing and substantive requirements may apply. Three of these requirements are outlined below. The Regulated Unit Checklist will provide a complete list. In these situations, the respective site managers need to develop a more detailed site-specific coordinated strategy.

USING CERCLA TO CLOSE INTERIM STATUS REGULATED UNITS

The purpose and scope of the RCRA regulatory provisions for closure and post-closure of regulated hazardous waste management units/activities are not identical in scope or purpose to RCRA Corrective Action or Superfund cleanup provisions. There may be regulatory obligations and schedules applicable at the facility, as well as procedural requirements, which make it more difficult to declare universal parity when we want CERCLA activities to achieve RCRA closure of regulated units. Nonetheless, we must strive for reduction or elimination of duplication of effort. The following addresses the major potential differences in approach or scope and identify considerations necessary to determine that Superfund activities satisfy regulated unit requirements.[2]

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[2] "CERCLA 101" - Applicable or Relevant and Appropriate Requirements (ARARs).

Any remedial action selected under CERCLA must meet two "threshold" criteria: protectiveness, and ARARs. To comply with the "applicable" part of ARARs requirement, a remedy must meet all substantive promulgated environmental requirements that would apply if the site was not a Superfund site. Under the "relevant and appropriate" part of the ARARs requirement, a remedy must meet all substantive promulgated environmental requirements that fit the circumstances at the site, even though those requirements would not apply if the site was not a Superfund site. If Superfund decides that remedial action is necessary at a RCRA regulated unit, the substantive parts of the RCRA regulations, such as landfill closure requirements, would be applicable and would have to be followed. Superfund could also require additional actions beyond the RCRA regulations if necessary to meet the "protectiveness" threshold criteria.

1. Groundwater Monitoring Requirements (40 CFR 265 Subpart F)

The RCRA groundwater monitoring requirements for interim status regulated land-based units are designed to detect unit specific releases from units that have yet to leak or to assess the nature, rate and extent of releases which have been detected. For regulated units that have leaked, there may be little reason to continue to strictly apply the interim status groundwater requirements in those cases where the contamination has been successfully assessed and where the priority is to remediate such contamination or to monitor the effectiveness of the remedial actions. Both Superfund and RCRA Corrective Action groundwater monitoring are oriented towards effective remediation. Therefore, in the future, we expect that for each facility where program overlaps occur, groundwater detection monitoring requirements will be designed to meet the requirements of both programs, so that the RCRA groundwater requirements at leaking regulated units can be sufficiently addressed by CERCLA.

2. Closure (40 CFR 265 Subpart G)[3]

The respective site managers should develop a coordinated strategy to determine which authority/program will address which closing units and to insure that either the closure plan approval process or CERCLA proposed plan and ROD are designed to satisfy the respective administrative and procedural requirements. A potential Superfund No Further Action decision at a regulated unit is a special case that requires early cross-program planning as part of this coordinated strategy.

Both programs have public participation requirements. The public notices and proposed plans should be written to satisfy the requirements of both programs. It may be also appropriate to include a discussion of this joint approach in documents seeking public comment.

With the consent of the programs and the facility, Superfund may manage the closure and post-closure care of a RCRA regulated unit. In such a case, an enforceable Superfund process may allow the RCRA program to delay formally processing a post-closure permit.

3. Financial Assurance Instruments (40 CFR 265 Subpart H)

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[3] "RCRA 101", continued - Types of permits:
Regulated units that are operating have to get an operating RCRA permit. Regulated units that are closing (and this is the majority of regulated units) either go through "clean" closure or "landfill closure." Clean closed units require no further controls or actions. "Landfill" closures are all other closures. Currently, "landfill" closure units are required to have a post-closure permit to ensure long-term care.

This RCRA regulatory requirement is not applicable at federal facilities. For non-federal facilities, facility owners/operators should be made aware that even if CERCLA is taking responsibility for investigation or remediation of a facility with RCRA regulated units, the self-implementing regulations of RCRA, including financial assurance, still apply. Depending on the financial viability of the owner/operator, it is sometimes not possible for them to meet this requirement. Violations may be addressed through various RCRA enforcement mechanisms.

IMPLEMENTATION

- Identification of facilities/sites where program overlap may occur. To aid in identifying where areas of overlap and therefore duplication of effort may occur, attached is a list of facilities which appear on both the CERCLA NPL and the RCRA treatment, storage, disposal facility (TSDF) list. This is not a static list so as new RCRA TSDFs are discovered, or as new sites are listed on the NPL, the RCRA staff should call David Bennett to see if this site is also on the NPL and the CERCLA staff should call Patricia Hanley to see if the site is a TSDF.

- Develop site-specific coordinated strategy that covers and integrates the points above. Site managers working on a facility on this list are expected to seek out their counterpart in the other program and develop a written coordinated strategy for the site. Such strategies should be reviewed by both programs' site managers at least annually and updated as needed. Our state counterparts should also be involved in the development of the site-specific strategies, where appropriate.

  The site-specific coordinated strategy may be fairly simple at those sites where CERCLA is handling only SWMUs and AOCs that may require corrective action. A more detailed plan may be appropriate where CERCLA is involved with any regulated units.

  When developing a coordinated strategy, it may be helpful to keep in mind that the differences between approaches to site remediation between the programs may be primarily a factor of the individual project managers rather than program specific differences. The workgroup observed that differences were more likely to be based on individual practices or philosophies, and less likely due to statutory or regulatory requirements. The workgroup also felt that similar differences exist among sections of the same branch and among individuals within the same section. In other

words, there is frequently room for flexibility when it is needed.

- Management follow-up. Managers should support and follow-up on the development of the site-specific strategies. Creative and effective approaches should be shared. In addition, managers should regularly ask questions like: Are there any RCRA regulated units or CERCLA operable units at this site? Where are these in relationship to our program's concerns? How are we coordinating our approach? What else might we be doing at this site (or in this document) to avoid re-work?

- Remedy Selection Information Exchanges. It is important that we do more to share information between our programs on our remedy selection decisions and our reasons for these decision. Three steps are planned.

    - Regular presentations. There will be three remedy selection presentation meetings a year, at which each clean-up branch would present one site or facility decision, to be followed by a discussion period. A technical staff group is working on setting up these presentations.

    - Decision summaries. All future remedy/corrective action decisions will be summarized and distributed on the LAN to HWD staff. These information exchanges will focus for now on clean-up level and action (or the "go do something") levels. The same technical staff group is working on setting up a format for these summaries.

    - Informal Peer Review. We encourage informal peer review at the appropriate decision points in the RCRA and CERCLA remedial processes. This review is intended to inform and educate both staffs; it is not intended to force either program to gain technical/regulatory approval from the other. Such a macro-scale peer review would not include review of detailed documents. One way to increase such informal peer review is to invite staff from other HWD programs to attend internal briefings or discussions. Judi and other workgroup members are available to help identify interested staff.

- State Delegated RCRA Programs and Other State Clean-up/Remedial Programs. The workgroup was created and this memo was written to address EPA Region 10 HWD concerns. However, this memo and our general approach will be shared with our state counterparts and discussed during our annual meetings.

The states may wish to participate in a similar approach either with EPA (e.g., at sites where the state has the RCRA lead and EPA has the CERCLA lead), or between two state-only programs. For now, a site-by-site decision is the recommended approach. Such mutual state-EPA decisions should be memorialized in writing.

OTHER ACTIONS TO IMPROVE RCRA/CERCLA INTERACTION

- Training. RCRA program managers will provide RCRA orientation training for all interested Superfund staff and managers. In addition, training which addresses the implementation and ramifications of this policy will be provided for CERCLA and RCRA Program Managers and staff.

- Regulated Unit Checklist. RCRA program managers and staff will develop and distribute to the CERCLA program a checklist of what, according to the regulations, has to happen for closure, and where necessary, post-closure care at regulated unit. This list will form the basis of negotiations between the programs. This list will also be the minimum list of items that must be addressed in the coordinated site strategy.

A schedule which outlines when these steps will be taken and by whom can be found in the second attachment.

We all recognize that improving RCRA/CERCLA interaction will be a continuing process. It is our hope that this memorandum and approach will make it easier for Regional RCRA and CERCLA staff to reduce duplication of effort in the context of remedial decision-making. Suggestions for further improvements are always welcomed and should be sent to any of us or to Judi Schwarz.

Attachments:
Summary of workgroup results
List of TSDF/NPL sites (June 1994 draft)
Implementation and next steps schedule

RCRA/CERCLA Interaction Workgroup Results - 2/94

ISSUES (in general priority order)

Tier I

Issue No. 1 - Closure of Regulated Units: Where Superfund is requiring remedial action at a regulated unit, is it enough to satisfy RCRA closure requirements?

Issue No. 2 - Closure of Regulated Units: Where Superfund has made a "No Action" decision at a regulated unit, what next?

Issue No. 3 - Removals at RCRA facilities are short-circuiting the RCRA process.

Tier II

Issue No. 4 - Different Corrective Action and Remedial Action approaches create uncertainty.

Tier III

Issue No. 5 - Groundwater Monitoring at Regulated Units: Different Groundwater monitoring requirements at regulated units result in inefficiencies.

Issue No. 6 - No action while site transfers from one authority to another.

Issue No. 7 - Superfund-type actions at sites with operating Regulated Units.

Issue No. 8 - Superfund investigations at facilities with regulated units are not always coordinated with RCRA - and RCRA inspections and other actions are not always coordinated with Superfund.

Issue No. 9 - The definitions of "Site" vs. "Facility" result in different universes under focus.

GENERAL OBSERVATIONS AND RECOMMENDATIONS

- Region 10 lacks a comprehensive list of sites/facilities which have the potential for dual program regulation. Such a list should be developed.

- There is a need for a formal statement of "parity" between the clean-up programs.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

Cy to Judi Schwarz
FYI Marcia

NOV 17 1994

file
RCRA/CERCA
Parity

MEMORANDUM

SUBJECT: Guidance on RCRA/CERCLA Overlap Issues

FROM: Elizabeth Cotsworth, Acting Deputy Director
Office of Solid Waste
Steve Luftig
Steve Luftig, Deputy Director
Office of Emergency and Remedial Response

TO: RCRA Branch Chiefs, Regions I-X
Superfund Branch Chiefs, Regions I-X

As you recall, the OERR/OSW Leadership Team was formed to improve coordination and consistency between the Superfund and RCRA programs. This fall, we received input from your offices on RCRA/CERCLA cross-cutting issues. We would like to share a guidance with you that Region X provided us to address issues that arise between the CERCLA and RCRA programs (attached).

Region X has invested considerable effort into the development of this guidance, which resulted from activities at its seventeen facilities which are both TSDs and NPL sites. The underlying theme of this guidance is a commitment to parity between the RCRA corrective action and the Superfund programs. The most difficult issues Region X has faced have been related to closure of regulated units at NPL sites.

We see a need for national guidance in this area, and invite comments from you on this document or on other approaches and issues which are not addressed in this guidance. Please provide any comments that you have with Elizabeth Cotsworth, on behalf of the OSW/OERR Leadership Team, at Mail Code 5301, by December 16, 1994.

cc: Waste Management Division Directors, Regions I-X
OSW/OERR Leadership Team Members

Attachment

June 1994 - draft

LIST OF CERCLA AND TSD FACILITIES

Washington:

U.S. Bremerton Naval Complex (was Navy Puget Sound Naval Shipyard)
USAF Fairchild
U.S. Army Fort Lewis
U.S. Navy NUWES Keyport
U.S. Navy Fuel Department NSC Puget Sound
Kaiser Aluminum and Chemical Corp. Mead Plant
Port Hadlock
U.S. DOE Hanford
McChord AFB
BPA Ross Complex

Oregon:

Teledyne Wah Chang
Umatilla

Idaho:

Mountain Home AFB
Union Pacific Railroad Company
INEL
Eastern Michaud Flats (i.e., includes FMC)

Alaska:

NAS ADAK
Eielson AFB
Elmendorf AFB
Fort Richardson
Fort Wainwright

Other RCRA/NPL Overlap Sites

Oregon:

Martin Marietta

7/21/94

RCRA/CERCLA INTERFACE: IMPLEMENTATION SCHEDULE

WHAT?	BY WHOM?	WHEN?
Identify sites with RCRA/CERCLA overlap		first draft attached; annual updates
Develop site-specific coordinated strategies - Review and update existing site strategies to reflect parity approach	RPMs, and RCRA permit writers or compliance staff	Complete by 11/1/94; annual updates
- Create written site strategies if none exist	RPMs, and RCRA permit writers or compliance staff	Complete by 11/1/94; annual updates
Management Follow-up	Managers	
Remedy Selection Information Exchanges - Regular presentations	Being set up by group (Susan Hutcherson, Chris Cora, Debbi Yamamoto, Jan Palumbo, John Sainsbury, Ann Dunn, Mike Fagan, Judi Schwarz)	Three presentation sessions a year, starting in October 1994
- Circulate decision summaries	Format being set up by above group; will then be implemented by RPMS and RCRA permit writers and compliance staff	Format to be established by 10/1/94
- Informal peer review	Everyone. RCRA/CERCLA workgroup can help find interested staff.	On-going
Share Policy with our State Counterparts	Managers	Summer 1994
ning - "RCRA 101" for CERCLA taff	Mike Gearheard and Betty Wiese	August 1994; any follow-up needed?
"Parity" policy mentation	Branch Chiefs and Randy	August 1994 - Division meeting following distribution of policy.
Checklist	Mike Gearheard and Dave Croxton	August 1, 1994 (Needed before site-specific strategies are begun.)

ATTACHMENT C

EXAMPLES OF DATA QUALITY ASSESSMENT APPLICATIONS

Appendix B from EPA (1994a)
Guidance for the Data Quality Objectives Process, EPA QA/G-4

APPENDIX B

DQO CASE STUDY: CADMIUM-CONTAMINATED FLY ASH WASTE

Introduction

This appendix presents a functional, but realistic example of the DQO outputs for a decision that could be made within the Resource Conservation and Recovery Act (RCRA) hazardous waste management program. The example is intended to illustrate the types of outputs that are common to the DQO Process. It is not intended, however, to represent the policy of the RCRA program for actual situations that may be similar to the example. Please consult with a knowledgeable representative within the RCRA program office about the current policy for making waste classification decisions for fly ash or other types of hazardous waste.

The case study has been chosen because it is simple and straightforward, and because the outputs are uncomplicated. Although some of the outputs from this example may seem intuitive, this is not often the case in practice. For many studies, the DQO Process is complicated and thought-provoking. Even so, some steps will require more effort than others. Keep in mind that all of the steps in the DQO Process are necessary to develop a data collection design. Once the first six steps have been completed and thoroughly thought-out, then development of the most resource-effective data collection design can proceed.

Background

A waste incineration facility located in the Midwest routinely removes fly ash from its flue gas scrubber system and disposes of it in a local sanitary landfill. Previously it was determined that the ash was not hazardous according to RCRA program regulations. The incinerator, however, recently began treating a new waste stream. The representatives of the incineration company are concerned that the waste fly ash could now contain hazardous levels of cadmium from the new waste sources. They have decided to test the ash to determine whether it should be sent to a hazardous waste landfill or continue to be sent to the municipal landfill. They have decided to employ the DQO Process to help guide their decision making.

Cadmium is primarily used as corrosion protection on metal parts of cars and electrical appliances. It is also used in some batteries. Cadmium and cadmium salts have toxic effects for humans through both ingestion and inhalation exposures. Ingestion exposure usually causes mild to severe irritation of the gastrointestinal tract, which can be caused by concentrations as low as 0.1 mg/kg/day. Chronic (long-term) inhalation exposure can cause increased incidence of emphysema and chronic bronchitis, as well as kidney damage.

Under the current Code of Federal Regulations, 40 CFR, Part 261, a solid waste can be considered "hazardous" if it meets specific criteria of ignitability, corrosivity, reactivity, and toxicity. One method that is used to determine if a solid substance, such as fly ash, meets the criteria for toxicity under the RCRA program regulations is to test a "representative sample" of the waste and perform a Toxicity Characteristic Leaching Procedure (TCLP) described in 40 CFR, Pt. 261, App. II. During this process, the solid fly ash will be "extracted" using an acid solution. The extraction liquid (the TCLP leachate) will then be subjected to tests for specific metals and compounds. For this example, the only concern is with the concentration of cadmium in the leachate. The primary benefit of the DQO Process will be to establish the data collection design needed to determine if the waste is hazardous under RCRA regulations within tolerable decision error rates.

As a precursor to the DQO Process, the incineration company has conducted a pilot study of the fly ash to determine the variability in the concentration of cadmium between loads of ash leaving the facility. They have determined that each load is fairly homogeneous. There is a high variability between loads, however, due to the nature of the waste stream. Most of the fly ash produced is not hazardous and may be disposed of in a sanitary landfill. Thus, the company has decided that testing each individual waste load before it leaves the facility would be the most economical. Then they could send loads of ash that exceeded the regulated standards to the higher cost RCRA landfills and continue to send the others to the sanitary landfill.

DQO Development

The following is a representative example of the output from each step of the DQO Process for the fly ash toxicity problem.

State the Problem — a description of the problem(s) and specifications of available resources and relevant deadlines for the study.

(1) *Identify the members of the planning team* — The members of the planning team will include the incineration plant manager, a plant engineer, a statistician, a quality assurance officer, an EPA representative who works within the RCRA program, and a chemist with sampling experience.

(2) *Identify the primary decision maker* — There will not be a primary decision maker; decisions will be made by consensus.

(3) *Develop a concise description of the problem* — The problem is to determine which loads should be sent to a RCRA landfill versus a sanitary landfill.

(4) *Specify available resources and relevant deadlines for the study* — While the project will not by constrained by cost, the waste generator (the incineration company) wishes to hold sampling costs below $2,500. They have also requested that the waste testing be completed within 1 week for each container load.

Identify the Decision — a statement of the decision that will use environmental data and the actions that could result from this decision.

(1) *Identify the principal study question* — Is the fly ash waste considered hazardous under RCRA regulations?

(2) *Define alternative actions that could result from resolution of the principal study question* —

(a) The waste fly ash could be disposed of in a RCRA landfill.

(b) The waste fly ash could be disposed of in a sanitary landfill.

(3) *Combine the principal study question and the alternative actions into a decision statement* — Decide whether or not the fly ash waste is hazardous under RCRA and requires special disposal procedures.

(4) *Organize multiple decisions* — Only one decision is being evaluated.

Identify the Inputs to the Decision — a list of the environmental variables or characteristics that will be measured and other information needed to resolve the decision statement.

(1) *Identify the information that will be required to resolve the decision statement* — To resolve the decision statement, the planning team needs to obtain measurements of the cadmium concentration in the leachate resulting from TCLP extraction.

(2) *Determine the sources for each item of information identified* — The fly ash should be tested to determine if it meets RCRA regulated standards for toxicity using the test methods listed in 40 CFR, Pt. 261, App. II. Existing pilot study data provide information about variability, but do not provide enough information to resolve the decision statement.

(3) *Identify the information that is needed to establish the action level* — The action level will be based on the RCRA regulations for cadmium in TCLP leachate.

(4) *Confirm that appropriate measurement methods exist to provide the necessary data* — Cadmium can be measured in the leachate according to the method specified in 40 CFR, Pt. 261, App. II. The detection limit is below the standard.

Define the Boundaries of the Study — a detailed description of the spatial and temporal boundaries of the problem, characteristics that define the population of interest, and any practical considerations for the study.

(1) *Specify the characteristics that define the population of interest* — Fly ash waste from the hazardous waste incinerator will be analyzed. The fly ash should not be mixed with any other constituents except water that is used for dust control. Each load of ash should fill at least 70% of the waste trailer. In cases where the trailer is filled less than 70%, the trailer must wait on-site until more ash is produced and fills the trailer to the appropriate capacity.

(2) *Define the spatial boundary of the decision statement* —

(a) *Define the geographic area to which the decision statement applies.* Decisions will apply to each container load of fly ash waste.

(b) *When appropriate, divide the population into strata that have relatively homogeneous characteristics.* Stratification is not necessary since the waste ash is relatively homogeneous within each container.

(3) *Define the temporal boundary of the decision statement* —

(a) *Determine the timeframe to which the decision statement applies.* It will be assumed that the sampling data represent both the current and future concentration of cadmium within the ash.

(b) *Determine when to collect data.* Contained in the trucks, the waste does not pose a threat to humans or the environment. Additionally, since the fly ash is not subject to change, disintegration, or alteration, the decision about the waste characteristics does not warrant any temporal constraints. To expedite decision making, however, the planning team has placed deadlines on sampling and reporting. The fly ash waste will be tested within 48 hours of being loaded onto waste hauling trailers. The analytical results from each sampling round should be completed and reported within 5 working days of sampling. Until analysis is complete, the trailer cannot be used.

(4) *Define the scale of decision making* — The scale of decision making will be each container of waste ash.

(5) *Identify practical constraints on data collection* — The most important practical consideration that could interfere with the study is the ability to take samples from the fly ash that is stored in waste hauling trailers. Although the trailers have open access, special procedures and methods will have to be implemented for the samples to be representative of the entire depth of the ash. It has been suggested that core samples may be one practical solution to this problem. To get additional samples from each truck and to minimize the cost, compositing of core samples has been suggested.

Develop a Decision Rule — to define the parameter of interest, specify the action level and integrate previous DQO outputs into a single statement that describes a logical basis for choosing among alternative actions.

(1) *Specify the statistical parameter that characterizes the population of interest* — The planning team is interested in the true mean concentration of cadmium in the TCLP leachate for each container.

(2) *Specify the action level for the study* — The action level for the decision will be the RCRA regulatory standard for cadmium of 1.0 mg/L in the TCLP leachate.

(3) *Develop a decision rule (an "if...then..." statement)* — If the mean concentration of cadmium from the fly ash leachate in each container load is greater than 1.0 mg/L (using the TCLP method as defined in 40 CFR 261), then the waste will be considered hazardous and will be disposed of at a RCRA landfill. If the mean concentration of cadmium from the fly ash waste leachate is less than 1.0 mg/L (using the TCLP method as defined in 40 CFR 261), then the waste will be considered non-hazardous and will be disposed of in a sanitary landfill.

Specify Tolerable Limits on Decision Errors — the decision maker's tolerable decision error rates based on a consideration of the consequences of making a decision error.

(1) *Determine the possible range of the parameter of interest* — From analysis of records of similar studies of cadmium in environmental matrices, the range of the cadmium concentrations is expected to be from 0-2 mg/L. Therefore the mean concentration is expected to be between 0-2 mg/L for this investigation.

(2) *Identify the decision errors and choose the null hypothesis* —

(a) *Define both types of decision errors and establish the true state of nature for each decision error.* The planning team has determined that the two decision errors are (i) deciding that the waste is hazardous when it truly is not, and (ii) deciding that the waste is not hazardous when it truly is.

The true state of nature for decision error (i) is that the waste is not hazardous.

The true state of nature for decision error (ii) is that the waste is hazardous.

(b) *Specify and evaluate the potential consequences of each decision error.*

The consequences of deciding that the waste is hazardous when it truly is not will be that the incinerator company will have to pay more for the disposal of the fly ash at a RCRA facility than at a sanitary landfill.

The consequences of deciding that the waste is not hazardous when it truly is will be that the incinerator company will dispose of the waste in a sanitary landfill which could possibly endanger human health and the environment. In this situation, they may also be liable for future damages and environmental cleanup costs. Additionally, the reputation of the incinerator company may be compromised, jeopardizing its future profitability.

(c) *Establish which decision error has more severe consequences near the action level.* The planning team has concluded that decision error (ii) has the more severe consequences near the action level since the risk of jeopardizing human health outweighs the consequences of having to pay more for disposal.

(d) *Define the null hypothesis (baseline condition) and the alternative hypothesis and assign the terms "false positive" and "false negative" to the appropriate decision error.*

The baseline condition or null hypothesis (H_o) is "the waste is hazardous."

The alternative hypothesis (H_a) is "the waste is not hazardous."

The false positive decision error occurs when the null hypothesis is rejected when it is true. For this example, the false positive decision error occurs when the decision maker decides the waste is not hazardous when it truly is hazardous. The false negative decision error occurs when the null hypothesis is not rejected when it is false. For this example, the false negative decision error occurs when the decision maker decides that the waste is hazardous when it truly is not hazardous.

(3) *Specify a range of possible values of the parameter of interest where the consequences of decision errors are relatively minor (gray region)* — The gray region is the area adjacent to the action level where the planning team feels that the consequences of a false negative decision error are minimal. To decide how to set the width of the gray region, the planning team must decide where the consequences of a false negative decision error are minimal. Below the action level, even if the concentration of cadmium were very close to the action level, the monetary costs of disposing of the waste at a RCRA facility are the same as if the waste had a much lower concentration of cadmium. Clearly any false negative decision error (to the left of the action level) will cause the incinerator company and their customers to bear the cost of unnecessary expense (i.e., sending nonhazardous waste to a RCRA facility). The planning team, however, also realizes that they must define a reasonable gray region that balances the cost of sampling with risk to human health and the environment and the ability of measurement instruments to detect differences. Therefore the planning team has specified a width of 0.25 mg/L for this gray region based on their preferences to detect decision errors at a concentration of 0.75 mg/L (see Figure B-1).

(4) *Assign probability values to points above and below the action level that reflect the tolerable probability for the occurrence of decision errors* — For this example, RCRA regulations allow a 5% decision error rate at the action level. The planning team has set the decision error rate to 5% from 1 mg/L to 1.5 mg/L and 1% from 1.5 mg/L to 2 mg/L as the consequences of health effects from the waste disposed of in the municipal landfill increase. On the other side of the action level, the planning team has set the tolerable probability of making a false negative error at 20% when the true parameter is from 0.25 to 0.75 mg/L and 10% when it is below 0.25 mg/L, based on both experience and an economic analysis that shows that these decision error rates are reasonable to balance the cost of sampling versus the consequence of sending clean ash to the RCRA facility (see Figure B-1).

Optimize the Design — select the most resource-effective data collection and analysis design for generating data that are expected to satisfy the DQOs. Optimizing the design is the one step of the DQO Process that will most likely be completed by a statistician or someone who has data collection design expertise. Using the case study as an example, the following section has been included to provide the reader with a background on the overall process that the statistician might follow to optimize the final data collection design.

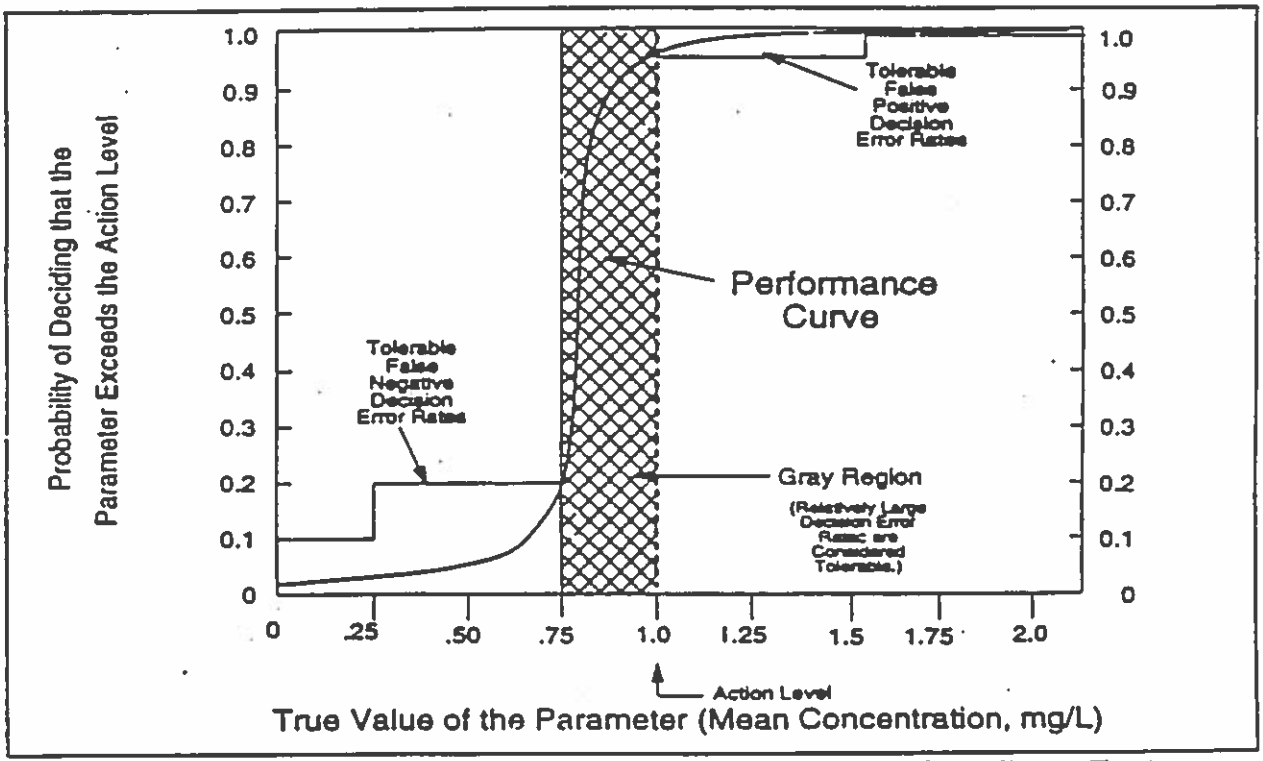

Figure B-1. Decision Performance Goal Diagram for Cadmium Compliance Testing Baseline Condition: Mean Exceeds Action Level.

Overview

Developing a data collection design requires an understanding of the sampled medium and the information that was generated in previous DQO steps. The statistician's job is to review the background information, determine the appropriate statistical application to adequately solve the problem, and develop one or more appropriate data collection designs. Once this is complete, the statistician will compare the cost and performance of the different data collection designs. This process can be broken down into five distinct steps:

(1) Review the DQO outputs and existing environmental data.

(2) Develop general data collection design alternatives.

(3) For each data collection design alternative, select the optimal sample size that satisfies the DQOs.

(4) Select the most resource-effective data collection design that satisfies all of the DQOs.

(5) Document the operational details and theoretical assumptions of the selected design in the sampling and analysis plan.

Activities

(1) *Review the DQO outputs and existing environmental data* — Because the statistician has participated in the DQO Process for this problem, there is no need to review the DQO outputs further. The only existing data relevant to this problem are the pilot study data. Based on the pilot study, the incineration company has determined that each load of ash is fairly homogeneous, and has estimated the standard deviation in the concentration of cadmium within loads of ash to be 0.6 mg/L.

(2) *Develop general data collection design alternatives* — Generally, the design alternatives are based on a combination of design objectives developed in previous DQO Process steps and knowledge of statistical parameters about the medium or contaminant. Below are four examples of possible designs that could apply to the case study:

(a) Simple Random Sampling — The simplest type of probability sample is the simple random sample. With this type of sampling, every possible point in the sampling medium has an equal chance of being selected. Simple random samples are used primarily when the variability of the medium is relatively small and the cost of analysis is relatively inexpensive. Simple random sample locations are generally developed through the use of a random number table or through computer generation of pseudo-random numbers.

In the case of the cadmium-contaminated ash, a fixed number of random grab samples would be selected and analyzed. Standard lab splits and QC samples would be taken according to standard procedures for the RCRA program. Each sample would be chosen randomly in three dimensions. A Student's t-test is suggested as a possible method for testing the statistical hypothesis.

(b) Composite Simple Random Sampling (composite sampling) — This type of sampling consists of taking multiple samples, physically combining (compositing) them, and drawing one or more subsamples for analysis. Composite samples are taken primarily when an average concentration is sought and there is no need to detect peak concentrations. By compositing the samples, researchers are able to sample a larger number of locations than if compositing was not used, while reducing the cost of analysis by combining several samples.

In the case of the cadmium-contaminated ash, a fixed number of random grab samples would be taken and composited. The number of grab samples contained in a composite sample (g) is also fixed. To determine sampling locations within the composite, a container would be divided into "g" equal-volume strata and samples would be chosen randomly within each strata. The use of strata ensure full coverage of each container. Standard lab splits and QC samples would be taken according to standard procedures for the RCRA program. A Student's t-test is suggested as the possible method for testing the statistical hypothesis.

(c) Sequential Sampling — Sequential sampling involves making several rounds of sampling and analysis. A statistical test is performed after each analysis to arrive at one of three possible decisions: reject the null hypothesis, accept the null hypothesis,[1] or collect more samples. This strategy is applicable when sampling and/or analysis costs are high, when information concerning sampling and/or measurement variability is lacking, when the waste and site characteristics of interest are stable over the timeframe of the sampling effort, and when the objective of the sampling is to test a single hypothesis. By taking samples in sequence, the researcher can hold down the cost of sampling and analysis.

In the case of the cadmium-contaminated ash, a sequential probability sample could be performed. The samples in each sampling round would be chosen randomly in three dimensions. If the decision to stop sampling has not been made before the number of samples required for the simple random sample are taken, sampling would stop at this point and the simple random sample test would be performed. Standard laboratory splits and QC samples would be taken according to standard procedures for the RCRA program. An approximate ratio test is

[1]Decide not to reject the null based on tolerable decision error limits.

suggested after each round of sampling is complete to decide whether or not to conclude that the waste is hazardous or to continue sampling.

(d) Stratified Random Sampling — Stratified sampling involves dividing the study area into two or more non-overlapping subsets (strata) which cover the entire volume to be sampled. These strata should be defined so that physical samples within a stratum are more similar to each other than to samples from other strata. Sampling depth, concentration level, previous cleanup attempts, and confounding contaminants can be used as the basis for creating strata. Once the strata have been defined, each stratum is then sampled separately using one of the above designs. Stratification is often used to ensure that important areas of a site are represented in the sample. In addition, a stratified random sample may provide more precise estimates of contaminant levels than those obtained from a simple random sample. Even with imperfect information, a stratified sample can be more resource-effective.

Since the incineration company has already determined that each load of ash is fairly homogeneous, stratification does not have any advantages over a simple random sample. In addition, since the company has decided to test each waste load individually before it leaves the facility, stratifying each waste load would be difficult and unnecessary. Therefore, this data collection design will not be considered further.

(3) *For each data collection design alternative, select the optimal sample size that satisfies the DQOs* — The formula for determining the sample size (number of samples to be collected) is chosen based on the hypothesis test and data collection design. Standard formulas can be found in several references, including:

- Cochran, W. 1977. *Sampling Techniques.* New York: John Wiley.
- Desu, M.M., and D. Raghavarao. 1990. *Sample Size Methodology.* San Diego, CA: Academic Press.
- Gilbert, Richard O. 1987. *Statistical Methods for Environmental Pollution Monitoring.* New York: Van Nostrand Reinhold.
- U.S. Environmental Protection Agency. 1989. *Methods for Evaluating the Attainment of Cleanup Standards: Volume 1: Soils and Solid Media.* EPA 230/02-89-042, Office of Policy, Planning and Evaluation.
- U.S. Environmental Protection Agency. 1992. *Methods for Evaluating the Attainment of Cleanup Standards: Volume 2: Ground Water.* EPA 230-R-92-014, Office of Policy, Planning and Evaluation.

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These formulas can also be found in many basic statistics textbooks. Different formulas are necessary for each data collection design, for each parameter, and for each statistical test. These formulas are generally a function of α; β; the detection difference, Δ (delta); and the standard deviation, σ. The detection difference, Δ, is defined to be the difference between the action level (AL) and the other bound of the gray region (U); i.e., Δ = AL - U. In this case the standard deviation was derived from pilot data under approximately the same conditions as expected for the real facility.

For example, a formula for computing the sample size necessary to meet the DQO constraints for comparing a mean against a regulatory threshold, when a simple random sample is selected, is:

$$n = \frac{\sigma^2(z_{1-\beta}+z_{1-\alpha})^2}{\Delta^2} + (0.5)z_{1-\alpha}^2$$

where:

σ^2 = estimated variance in measurements (from pilot study)
n = number of samples required,
z_p = the p^{th} percentile of the standard normal distribution (from standard statistical tables), and
Δ = U - AL

Simple Random Sample — Using the formula above, it was determined that 37 samples are necessary to achieve the specified limits on decision errors. This sampling plan satisfies all the DQOs including budget, schedule, and practical constraints.

Composite Sampling — To determine sample sizes for a composite sample, it is necessary to compute the number of composites samples, n; the number of samples, g, within each composite; and the number of subsamples, m, to be measured for each composite. Usually m=1; however, since this design is to be used repeatedly, it is suggested that two subsamples from each composite sample be measured to estimate composite variability, which can then be used to re-optimize the number of samples m and g.

For a composite sample, with random sample locations, it has been determined that eight composite samples of eight samples each are sufficient to meet the limits on decision errors that have been specified. This design is more than sufficient to

achieve the specified limits on decision errors and satisfies all the DQOs including budget, schedule, and practical constraints.

Sequential Sampling — For the purposes of comparing costs, the average number of samples in a sequential sampling design can be estimated, but these estimates are only averages. The average sample size for concluding that the waste is hazardous is 16 and the average sample size for concluding the waste is not hazardous is 22. The average sizes are different because the burden of proof is placed on disproving the null hypothesis, thus, more samples on average are required to prove that the alternative hypothesis (the waste is not hazardous) is true. However, these sample sizes are only averages. In some cases, fewer samples are necessary; in others, more may be necessary. This sampling plan satisfies all the DQOs including budget, schedule, and practical constraints.

(4) *Select the most resource-effective data collection design that satisfies the DQOs* — Compare the overall efficiency of each model and choose the one that will solve the problem most effectively.

Cost Estimates for Each Design

First, the costs for the three designs alternatives will be evaluated:

Simple Random Sampling — A simple random sampling scheme can be implemented for each load of fly ash by first generating three-dimensional random sampling points. This can most easily be done by using a computer. Samples can then be taken using a special grab sampler which will be forced into the ash, opened to take the sample, then closed and removed. The difficulty with this type of sampling scheme is measuring sampling locations in three dimensions, and it may be difficult to gain access to the correct sampling locations.

This design meets all of the required limits on decision errors. The cost of this design is calculated based on the assumed cost of selecting a sample ($10), and the cost of analyzing a sample ($150). Since 37 samples need to be taken and analyzed, the cost of this design is:

$$\begin{aligned} \text{Cost}_{SRS} &= 37 \times \$10 + 37 \times \$150 \\ &= \$370 + \$5550 = \$5920 \end{aligned}$$

Composite Sampling — Composite sampling will be performed similarly to simple random sampling except that after eight random samples are collected (one from each stratum), they will be combined and homogenized. Two sample aliquots for analysis will then be drawn from the homogenized mixture. This process will be repeated eight times.

This design meets all of the required limits on decision errors. The cost of this design is based on the cost of selecting ($10) and analyzing ($150) a sample. Eight samples will be used to make each composite sample for a sampling cost of $80; two subsamples will be analyzed from this composite sample for a cost of $300. Therefore, each composite sample will cost $380. The total cost of this design is:

$$Cost_{CS} = 8 \times \$380 = \$3040.$$

Sequential Sampling — Sequential sampling will be performed similarly to random sampling. The primary difference is that the ultimate number of samples will be determined by the results of one or more sampling rounds.

This design has the potential to reduce the number of samples required in the simple random sampling design and still meet the decision error limits. The average costs of the two decisions are used below:

The ash is hazardous:	16 × ($160) = $2,560
The ash is non-hazardous:	22 × ($160) = $3,520

To determine the expected cost, estimate the number of loads of ash that should be sent to a RCRA facility versus the number of loads that can be sent to a municipal facility. Suppose 25% of the loads are hazardous and should be sent to a RCRA facility. Then the expected cost (EC_{SS}) of this design should be

$$EC_{SS} = 0.25 \times (\text{cost of sampling when ash is hazardous}) + (0.75 \times \text{cost of sampling when ash is non-hazardous})$$

$$= 0.25 \times (\$2,560) + 0.75 \times (\$3,520) = \$\ 3,280$$

Selection of a Design

Because the simple random sampling design requires that many samples be taken and analyzed, it is inefficient for the goals of this study. Sampling will cost almost as much to determine whether the waste is hazardous or nonhazardous as it would cost to send all the waste to a RCRA hazardous waste landfill. Therefore, this decision is not resource-effective.

The sequential data collection design is more resource-effective than the simple random sampling design. The potential savings over sending all waste to a RCRA hazardous waste facility is $6,750 - $3,280 = $3,470. The site owner has expressed disapproval for this sampling plan because of the time it may take before a decision can be made. If the ash was not homogeneous within a container, however, this data collection design may be the design of choice.

The composite sample design is the best option. It is the most resource-effective design and requires the least amount of time to implement. In addition, the use of strata ensures full coverage of each container. It is recommended that each of the eight composite samples have two subsamples analyzed. In the future, after sufficient data have been collected to estimate the variability within each composite sample, it may be possible to reduce the number of samples that will be necessary to make a decision about the waste contents.

(5) *Document the operational details and theoretical assumptions of the selected design in the sampling and analysis plan* — A composite sample design should be used to determine whether each container of ash should be sent to a RCRA landfill or to a municipal landfill. Eight composite samples, consisting of eight grab samples, should be taken from each container and two subsamples from each composite should be analyzed at the laboratory. To form the composite samples, the containers will be divided into eight strata of equal size and one grab sample will be taken randomly within each stratum and composited. Sample locations will be generated randomly using computer-generated random numbers. The model assumes that the variability within a composite sample is negligible. Data from the subsamples can be used to test this assumption and make corrections to the model.

Beyond the DQO Process - Evaluation of the Design using the DQA Process

For this study, the data were collected using the composite sampling design. Once the samples were collected and analyzed, the data were evaluated statistically and scientifically using the DQA Process to inspect for anomalies, confirm that the model assumptions were correct, select a statistical test, and verify that the test assumptions such as distribution and independence can be met. For this study, a t-test satisfied the DQOs, and inspection of the data indicated that there was no reason to believe that the data were not normally distributed or that there was correlation between data points. It was also verified that the within-composite variability was negligible.

After three weeks of sampling, approximately 30% of the waste loads leaving the incinerator were found to have hazardous concentrations of cadmium in the fly ash. The data collection design was determined to be cost-effective because the combined cost of sampling and disposal was less than sending all of the waste to a RCRA landfill.

APPENDIX C

DERIVATION OF SAMPLE SIZE FORMULA FOR TESTING MEAN OF NORMAL DISTRIBUTION VERSUS AN ACTION LEVEL

This appendix presents a mathematical derivation of the sample size formula used in the DQO example of Appendix B.

Let $X_1, X_2, \ldots, X_n$ denote a random sample from a normal distribution with unknown mean μ and known standard deviation σ. The decision maker wishes to test the null hypothesis H_0: $\mu = AL$ versus the alternative H_A: $\mu > AL$, where AL, the action level, is some prescribed constant; the false positive (Type I) error rate is α (i.e., probability of rejecting H_0 when $\mu = AL$ is α); and for some fixed constant $U > AL$ (where U is the other bound of the gray region), the false negative (Type II) error rate is β (i.e., probability of rejecting H_0 when $\mu = U$ is $1-\beta$). Let $\bar{X}$ denote the sample mean of the Xs. It will have a normal distribution with mean μ and variance σ^2/n. Hence the random variable Z defined by

$$Z = \frac{(\bar{X}-\mu)\sqrt{n}}{\sigma} \qquad (1)$$

will have a standard normal distribution (mean 0, variance 1). Let z_p denote the p^{th} percentile of the standard normal distribution (available in most statistics books). Recall that the symmetry of the standard normal distribution implies that $z_p = -z_{1-p}$.

Case 1: Standard Deviation Known

The test of H_0 versus H_A is performed by calculating the test statistic

$$T = \frac{(\bar{X}-AL)\sqrt{n}}{\sigma}. \qquad (2)$$

If $T > z_{1-\alpha}$, the null hypothesis is rejected.

Note that

$$T = \frac{[(\bar{X}-\mu)+(\mu-AL)]\sqrt{n}}{\sigma} = Z+\varepsilon(\mu) \qquad (3)$$

where

$$\varepsilon(\mu) = \frac{(\mu - AL)\sqrt{n}}{\sigma}. \quad (4)$$

Thus T has a normal distribution with mean $\varepsilon(\mu)$ and variance 1, and in particular, $\varepsilon(AL) = 0$. Hence the Type I error rate is

$$Pr[\text{rejecting } H_0 | H_0] = Pr[T > z_{1-\alpha} | \mu = AL] = Pr[Z + \varepsilon(AL) > z_{1-\alpha}] = Pr[Z > z_{1-\alpha}] = \alpha. \quad (5)$$

Achieving the desired power $1-\beta$ when $\mu = U$ requires that

$$Pr[\text{reject } H_0 | \mu = U] = 1 - \beta.$$

Therefore,

$$Pr[T \le z_{1-\alpha} | \mu = U] = Pr[Z + \varepsilon(U) \le z_{1-\alpha}] = Pr[Z \le z_{1-\alpha} - \varepsilon(U)] = \beta \quad (6)$$

This implies

$$z_{1-\alpha} - \varepsilon(U) = z_{\beta},$$

or

$$z_{1-\alpha} - \frac{(U - AL)\sqrt{n}}{\sigma} = -z_{1-\beta}.$$

Let $\Delta = U - AL$, then rearrange terms to obtain

$$(z_{1-\alpha} + z_{1-\beta})\sigma = \Delta\sqrt{n},$$

or

$$n = \frac{(z_{1-\alpha} + z_{1-\beta})^2 \sigma^2}{\Delta^2}. \quad (7)$$

Case 2: Standard Deviation Unknown

If the standard deviation σ is unknown, then a test statistic like (2) is used except that σ is replaced by S, an estimate of the standard deviation calculated from the observed Xs. Such a statistic has a noncentral t distribution rather than a normal distribution, and the n computed by the above formula will be too small, although for large n (say n>40), the approximation is good. The particular noncentral t distribution involved in the calculation depends on the sample size n. Thus, determining the exact minimum n that will satisfy the

Type I and Type II error rate conditions requires an iterative approach in which the noncentral t probabilities are calculated for various n values until the desired properties are achieved. With the aid of a computer routine for calculating such probabilities, this is not difficult; however, a simple and direct approach for approximating n is available. This approach, whose derivation is described in the paragraphs below, leads to the following approximate but very accurate formula for n:

$$n = \frac{(z_{1-\alpha}+z_{1-\beta})^2\sigma^2}{\Delta^2} + \frac{1}{2}z_{1-\alpha}^2. \qquad (8)$$

In practice, since σ is unknown, a prior estimate of it must be used in (8).

The approach is based on the assumption that, for a given constant k, the statistic $\bar{X}$-kS is approximately normal with mean μ-kσ and variance $(\sigma^2/n)(1+k^2/2)$ (Guenther, 1977 and 1981).

The classical t-test rejects H_0 when $T = [(\bar{X} - AL)/(S/\sqrt{n})] > D$, where the critical value D is chosen to achieve the desired Type I error rate α. The inequality can be rearranged as $\bar{X}$-kS>AL, where $k = D/\sqrt{n}$. Subtracting the mean (assuming H_0) and dividing by the standard deviation of $\bar{X}$-kS on both sides of the inequality leads to

$$\frac{\bar{X}-kS-(AL-k\sigma)}{(\sigma/\sqrt{n})\sqrt{1+k^2/2}} > \frac{AL-(AL-k\sigma)}{(\sigma/\sqrt{n})\sqrt{1+k^2/2}} = \frac{k\sqrt{n}}{\sqrt{1+k^2/2}}. \qquad (9)$$

By the distributional assumption on $\bar{X}$-kS, the left side of (9) is approximately standard normal when μ = AL, and the condition that the Type I error rate is α becomes

$$Pr\left[Z > k\sqrt{n}/\sqrt{1+k^2/2}\right] = \alpha, \qquad (10)$$

$$i.e., \quad z_{1-\alpha} = k\sqrt{n}/\sqrt{1+k^2/2}. \qquad (11)$$

One can show that (11) is equivalent to

$$1/[1+k^2/2] = 1-z_{1-\alpha}^2/2n. \qquad (12)$$

The condition that the Type II error rate is β (or that power is 1-β) when μ = U means that the event of incorrectly accepting H_0 given $\bar{X}$-kS $\leq$ AL should have probability β. Subtracting the mean (U - kσ) and dividing by the standard deviation of $\bar{X}$-kS on both sides of this inequality yields

$$\frac{\bar{X}-kS-(U-k\sigma)}{(\sigma/\sqrt{n})\sqrt{1+k^2/2}} \leq \frac{AL-(U-k\sigma)}{(\sigma/\sqrt{n})\sqrt{1+k^2/2}}. \qquad (13)$$

Again, the left side is approximately standard normal and the Type II error rate condition becomes

$$Pr\left[Z \leq [AL-(U-k\sigma)]/[(\sigma/\sqrt{n})\sqrt{1+k^2/2}]\right] = \beta,$$

which implies

$$-z_{1-\beta} = z_{\beta} = \frac{(AL-U)+k\sigma}{(\sigma/\sqrt{n})\sqrt{1+k^2/2}}. \qquad (14)$$

Subtracting (14) from (11) yields

$$z_{1-\alpha}+z_{1-\beta} = \frac{(U-AL)}{(\sigma/\sqrt{n})\sqrt{1+k^2/2}}, \qquad (15)$$

or

$$\frac{(z_{1-\alpha}+z_{1-\beta})\sigma}{(U-AL)} = \frac{\sqrt{n}}{\sqrt{1+k^2/2}}. \qquad (16)$$

Substituting (12) into the denominator on the right side of (16) yields

$$\frac{(z_{1-\alpha}+z_{1-\beta})\sigma}{(U-AL)} = \sqrt{n}\sqrt{1-z_{1-\alpha}^2/2n}. \qquad (17)$$

Squaring both sides of (17) and solving for n yields equation (8).

References

Guenther, William C. 1977. *Sampling Inspection in Statistical Quality Control.* Griffin's Statistical Monographs and Courses, No. 37, London: Charles Griffin.

Guenther, William C. 1981. "Sample Size Formulas for Normal Theory T Test." *The American Statistician.* Vol. 35, No. 4.

APPENDIX D

GLOSSARY OF TERMS

action level: the numerical value that causes the decision maker to choose one of the alternative actions (e.g., compliance or noncompliance). It may be a regulatory threshold standard, such as a Maximum Contaminant Level for drinking water; a risk-based concentration level; a technological limitation; or a reference-based standard. [Note: the action level is specified during the planning phase of a data collection activity; it is not calculated from the sampling data.]

alternative hypothesis: *See hypothesis.*

bias: the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different than the sample's true value).

boundaries: the spatial and temporal conditions and practical constraints under which environmental data are collected. Boundaries specify the area or volume (spatial boundary) and the time period (temporal boundary) to which the decision will apply. Samples are then collected within these boundaries.

data collection design: A data collection design specifies the configuration of the environmental monitoring effort to satisfy the DQOs. It includes the types of samples or monitoring information to be collected; where, when, and under what conditions they should be collected; what variables are to be measured; and the Quality Assurance and Quality Control (QA/QC) components that ensure acceptable sampling design error and measurement error to meet the decision error rates specified in the DQOs. The data collection design is the principal part of the QAPP.

Data Quality Assessment (DQA) Process: a statistical and scientific evaluation of the data set to assess the validity and performance of the data collection design and statistical test, and to establish whether a data set is adequate for its intended use.

Data Quality Objectives (DQOs): Qualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Quality Objectives Process: a Quality Management tool based on the Scientific Method, developed by the U.S. Environmental Protection Agency to facilitate the planning of environmental data collection activities. The DQO Process enables planners to focus their planning efforts by specifying the intended use of the data (the decision), the decision criteria (action level), and the decision maker's tolerable decision error rates. The products of the DQO Process are the DQOs.

decision error: an error made when drawing an inference from data in the context of hypothesis testing, such that variability or bias in the data mislead the decision maker to draw a conclusion that is inconsistent with the true or actual state of the population under study. *See also false negative decision error, false positive decision error.*

defensible: the ability to withstand any reasonable challenge related to the veracity, integrity, or quality of the logical, technical, or scientific approach taken in a decision making process.

false negative decision error: a false negative decision error occurs when the decision maker does not reject the null hypothesis when the null hypothesis actually is false. In statistical terminology, a false negative decision error is also called a Type II error. The measure of the size of the error is expressed as a probability, usually referred to as "beta (β)"; this probability is also called the complement of power.

false positive decision error: a false positive decision error occurs when a decision maker rejects the null hypothesis when the null hypothesis actually is true. In statistical terminology, a false positive decision error is also called a Type I error. The measure of the size of the error is expressed as a probability, usually referred to as "alpha (α)," the "level of significance," or "size of the critical region."

gray region: a range of values of the population parameter of interest (such as mean contaminant concentration) where the consequences of making a decision error are relatively minor. The gray region is bounded on one side by the action level.

hypothesis: a tentative assumption made to draw out and test its logical or empirical consequences. In hypothesis testing, the hypothesis is labeled "null" or "alternative", depending on the decision maker's concerns for making a decision error.

limits on decision errors: the tolerable decision error probabilities established by the decision maker. Potential economic, health, ecological, political, and social consequences of decision errors should be considered when setting the limits.

mean: (i) a measure of central tendency of the population (population mean), or (ii) the arithmetic average of a set of values (sample mean).

measurement error: the difference between the true or actual state and that which is reported from measurements.

median: the middle value for an ordered set of n values; represented by the central value when n is odd or by the average of the two most central values when n is even. The median is the 50th percentile.

medium: a substance (e.g., air, water, soil) which serves as a carrier of the analytes of interest.

natural variability: the variability that is inherent or natural to the media, objects, or people being studied.

null hypothesis: *See hypothesis.*

parameter: a numerical descriptive measure of a population.

percentile: the specific value of a distribution that divides the distribution such that p percent of the distribution is equal to or below that value. Example for p=95: "The 95th percentile is X" means that 95% of the values in the population (or statistical sample) are less than or equal to X.

planning team: the group of people that will carry out the DQO Process. Members include the decision maker (senior manager), representatives of other data users, senior program and technical staff, someone with statistical expertise, and a QA/QC advisor (such as a QA Manager).

population: the total collection of objects, media, or people to be studied and from which a sample is to be drawn.

power function: the probability of rejecting the null hypothesis (H_o) over the range of possible population parameter values. The power function is used to assess the goodness of a hypothesis test or to compare two competing tests.

quality assurance (QA): an integrated system of management activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service (e.g., environmental data) meets defined standards of quality with a stated level of confidence.

Quality Assurance Project Plan (QAPP): a formal technical document containing the detailed QA, QC and other technical procedures for assuring the quality of environmental data prepared for each EPA environmental data collection activity and approved prior to collecting the data.

quality control (QC): the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer.

Quality Management Plan (QMP): a formal document describing the management policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation protocols of an agency, organization, or laboratory for ensuring quality in its products and utility to its users. In EPA, QMPs are submitted to the Quality Assurance Management Staff (QAMS) for approval.

range: the numerical difference between the minimum and maximum of a set of values.

[1]sample: a single item or specimen from a larger whole or group, such as any single sample of any medium (air, water, soil, etc.).

[2]sample: a set of individual samples (specimens or readings), drawn from a population, whose properties are studied to gain information about the whole.

sampling: the process of obtaining representative samples and/or measurements of a subset of a population.

sampling design error: the error due to observing only a limited number of the total possible values that make up the population being studied. It should be distinguished from errors due to imperfect selection; bias in response; and errors of observation, measurement, or recording, etc.

scientific method: the principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

standard deviation: the square root of the variance.

statistic: a function of the sample measurements; e.g., the sample mean or standard deviation.

statistical test: any statistical method that is used to determine which of several hypotheses are true.

total study error: the combination of sampling design error and measurement error.

true: being in accord with the actual state of affairs.

Type I error: A Type I error occurs when a decision maker rejects the null hypothesis when it is actually true. *See false positive decision error.*

Type II error: A Type II error occurs when the decision maker fails to reject the null hypothesis when it is actually false. *See false negative decision error.*

variable: The attribute of the environment that is indeterminant.

variance: a measure of (i) the variability or dispersion in a population (population variance), or (ii) the sum of the squared deviations of the measurements about their mean divided by the degrees of freedom (sample variance).

Appendix A from EPA (1996b)
Geostatistical Sampling and Evaluation Guidance for Soils and Solid Media, Review Draft

APPENDIX A

THE DATA QUALITY OBJECTIVES PROCESS

One planning tool available to help in the design and implementation of a sampling and analysis project is the data quality objective (DQO) process developed by the United States Environmental Protection Agency's (USEPA's) Quality Assurance Management Staff (QAMS). DQOs are qualitative and quantitative statements that clarify the study objective, define the type, quantity, and quality of required data, and specify the tolerable limits on decision errors. DQOs are used to define the quality control (QC) requirements for data collection, sampling and analysis, and data review and evaluation. These QC requirements are included in the quality assurance (QA) objectives for environmental measurements and the DQOs also are incorporated into a quality assurance project plan (QAPP). DQO development is an ongoing process involving discussions between management and technical staff. This process is a practical means for specifying and ensuring that the requested information is known to be of the "required" quality.

Failure to establish DQOs prior to implementing field and laboratory activities can cause difficulties for site investigators in the form of inefficiencies, increased costs, or generation of unusable data. For example, if low-cost analytical techniques will suffice, but higher cost techniques are selected, time and money are wasted.

THE DQO PROCESS

A seven-step DQO Process has been developed for uniform and consistent data generation activities:

Step 1: State the Problem
Step 2: Identify the Decision
Step 3: Identify Inputs to the Decision
Step 4: Define the Study Boundaries
Step 5: Develop a Decision Rule

Step 6: Specify Tolerable Limits on Decision Errors
Step 7: Optimize the Design for Obtaining Data.

The DQO process is based on the guidance document issued by QAMS as "final" in September 1994. *Guidance for the Data Quality Objectives Process* (EPA QA/G-4) provides general guidance to organizations for developing data quality criteria and performance specifications for decision making. Chapter One of the SW-846 Methods Manual also provides additional guidance on the QA program in the Office of Solid Waste (OSW).

Step 1: State the Problem

The first step in any decision-making process is to define the problem that has resulted in the inception of the study. A planning team is assembled and is tasked with developing the project-specific DQOs. The planning team comprises personnel representing all phases of the project and may include technical project managers, QA/QC managers, data users, and decision makers. The primary decision maker, or leader, must be identified. Where applicable, field and lab technicians, chemists, statisticians, and modelers also should be recruited for the planning team. The responsibilities of each team member should be clearly defined during this initial planning stage.

A concise description of the problem must be developed during this early stage of DQO development. Existing information should be summarized, and the need for additional information should be determined. Performance of literature searches or an evaluation of historical data or ongoing studies related to the current site can be studied.

Available financial and manpower resources must be identified and project milestones and deadlines also should be determined, if sufficient information is present.

Step 2: Identify the Decision

This step is used to define the decision statement that the study must resolve. The decision statement is a consolidation of the principal study question and alternative actions. The principal

study question identifies the key unknown conditions or unresolved issues that will be used to reveal the solution to the problem being investigated. Alternative actions, which are items that may be taken to solve the problem based on the outcome or on the decisions arrived at from the study, also are identified.

Step 3: Identify Inputs to the Decision

Specific information required to resolve the decision statement must be identified during this step in the DQO development process. The selected data acquisition approach will lead to the next set of questions that address the specific types of information needed to support the decision statement. Sources of the necessary information are then developed and can include regulatory guidance, scientific literature, historical data or past projects that were similar in scope to the current effort.

A bright-line, defined as the threshold value that provides the criterion for choosing between alternative actions, needs to be established.

Existing analytical methods are evaluated to determine if the method will perform as published, or if method modification or method development needs to be included in the study. Each analyte of interest should have a method detection limit or level of quantitation assigned, as this performance information is used later in the DQO Process (Steps 5 & 7).

Step 4: Define the Study Boundaries

Two types of boundaries must be defined and quantified: spatial and temporal. Spatial boundaries define the physical area to be studied and locations to collect samples. Temporal boundaries describe the timeframe that the study data will represent and when the samples should be collected. To arrive at these boundaries, the characteristics that define the population must be identified. For instance, the compounds of interest and the matrix that should be evaluated might need to be selected to determine if the compounds are present and at what typical concentrations.

The spatial boundaries, or the geographic area to be studied, must be specified using some physical feature or border, such as units of measure. Where possible, the population should be further segregated into more homogenous subsets, or strata, as a means of reducing variability.

Step 5: Develop a Decision Rule

A statement must be developed that combines the parameters of interest and the action levels with the DQO outputs already developed. The combination of these three elements forms the decision rule and summarizes what attributes the decision maker wants to study and how the information will assist in solving the central problem. The four elements that form the decision rule include: (1) the parameter of interest that describes a characteristic of the statistical population, (2) the scale of decision making defined in Step 4 when boundaries were defined, (3) the bright-line (action level or a measurement threshold value), used as a criterion to choose alternative actions through the use of "if/then" statements, and (4) identifying the alternative actions, as developed in Step 2.

Step 6: Specify Limits on Decision Errors

Decision makers are interested in knowing the true state of some feature of the environment (e.g., the concentration of the constituent of concern in soil). However, data generated from a sampling and analysis program can only be used to estimate this state, and there is a chance that the data are in error and the correct decision will not be made. This step in the DQO development process allows the decision makers to specify acceptable or tolerable limits on decision errors.

There are at least two primary reasons why the decision maker might not determine the true value of a population parameter. First, sampling design error occurs when the sampling design is unable to capture the complete extent of variability that exists in the true state of the environment. Second, measurement error, which is a combination of random and systematic errors, results from various steps in the measurement process including sample collection, sample handling, sample preparation, sample analysis, data reduction, and data handling. The combination of sampling design error and measurement error can be viewed as the total study error and may lead to decision errors.

To estimate the probability of decision errors, the anticipated range of results from the parameters of interest usually must be determined, perhaps through the use of historical data. Values between the observed upper and lower bounds or perhaps from a distribution modeled after the historical data can be used to estimate how likely are the various decision errors that might occur depending on the hypothesis framework that has been constructed. The statistical hypotheses associated with any decision criterion consist of a null hypothesis, supposed to represent the initially assumed condition of the site, and the alternative hypothesis, representing the condition of the site when the null hypothesis is not true. Often the null hypothesis indicates the location of the center (in terms of concentration levels) of the hypothesized sampling distribution, but it can describe other characteristics of the site population (e.g., an upper percentile). Both the null and alternative hypotheses make statements regarding a characteristic of the population rather than a characteristic of a sample. The probability of a decision error is determined by estimating the chance that one of the two hypotheses will be accepted when in fact the opposite hypothesis is true.

To identify the decision errors and to construct the hypothesis framework, performance of four steps must be accomplished. (1) Both types of decision errors must be defined, determining which occurs above the action level and which occurs below the action level. (2) Potential consequences of each decision error must be specified and the impact of arriving at the incorrect decision considered. The severity of the error may affect economic and social costs or have ramifications to human health and the environment. One of the two types of errors (e.g., above or below the action level) often will have a greater impact than the other. (3) The decision maker should evaluate which scenario results in more serious consequences. (4) The null hypothesis, or baseline condition, should be defined and the decision as to what constitutes a false-positive or false-negative result should be answered. The term false-positive is assigned to the decision error where the decision maker rejects the null hypothesis when it is true. Conversely, a false-negative is the resulting decision error if the null hypothesis is not rejected when it is false.

Some decision errors may be considered minor and of minimal impact to use of the data. This "grey region" should be specified as a range of values having little or no adverse

consequences to the project. Use of these grey area regions is often important as a tool for building tolerable limits on the probability of making an incorrect decision.

Step 7: Optimize the Design for Obtaining Data

The final step addresses the design of a resource-effective data collection system to satisfy the DQOs. Verify that the DQO outputs produced in all preceding steps are internally consistent. The design options should have been developed based on cost benefits versus achieving DQOs. General data collection designs can then be developed as either a factorial design, systematic sampling, composite sampling, or one of the following random sampling designs: simple, stratified, or sequential.

In general, three statistical expressions need to be selected to optimize the data collection design. (1) An appropriate method for testing the statistical hypothesis framework must be chosen. (2) A statistical model used to compare measured values to the modeled values must be developed and tested for consistency with the observed data. Once established, the model also can be used to more thoroughly describe the components of error or bias that may exist in the measured values. (3) Finally, a cost evaluation of number of samples versus the total cost of sampling and analysis must be developed. Using these statistical expressions, an optimal sample size and sampling layout can be chosen to meet the DQOs for each data collection design alternative.

Quality Assurance Review

Lastly, have the document peer reviewed, preferably by personnel experienced in statistical data collection designs. Ensure that all aspects of the project have been documented to minimize the numbers of assumptions made during performance of the project.

DQO Decision Error Feasibility Trials (DEFT) Software

The two most intensive steps in the DQO Process are Step 6: Specify Tolerable Limits on Decision Errors, and Step 7: Optimize the Design for Obtaining Data. During Step 7, the entire set of DQO outputs is incorporated into a sampling design. If the DQO constraints are not

feasible, it is necessary to iterate through one or more of the earlier steps of the DQO Process to identify a sampling design that will meet the budget and generate adequate data for the decision. This iteration can be time consuming and costly. EPA developed the DEFT User's Guide and software (USEPA 1994c) to streamline this iterative process. Users can change DQO constraints such as limits on decision errors or the "grey region" and evaluate how these changes affect the sample size for several basic sampling designs. The output of the DEFT software can be used to set upper and lower bounds on the sample size (i.e., the appropriate number of observations). Through this process, the planning team can evaluate whether these constraints are appropriate or feasible before the sampling and analysis plan is developed.

Users of the DEFT software are first prompted to enter information from the DQO outputs based on a series of entry screens. Specific information requested by the DEFT software includes:

- Parameter of interest
- Minimum and maximum values (range) of the parameter of interest
- Action level (i.e., the bright-line)
- Null and alternative hypothesis
- Bounds of the gray region
- Estimate of the standard deviation
- Cost per sample for sample collection (i.e., field cost per sample)
- Cost per sample for sample analysis (i.e., laboratory cost per sample)
- Probability limits on decision errors for the bounds of the gray region
- Any additional limits on decision errors.

The DEFT software automatically starts with a simple random sampling design, so the information requested corresponds to this design.

EXAMPLE APPLICATION OF THE DEFT SOFTWARE

At a site contaminated with polynuclear aromatic hydrocarbons (PAH) compounds, contaminated soil has been excavated and placed on a pad. Investigators are interested in

determining whether the mean concentration of benzo(a)pyrene (BAP) exceeds the bright-line standard of 90 mg/Kg. The investigators have decided to use the DEFT software during the DQO Process to help optimize the study design.

Parameter of Interest

The parameter of interest for this study is the population mean of the concentration of BAP.

Minimum and Maximum Values (Range) of the Parameter of Interest

Based on data generated during a preliminary study of the contaminated soil, the minimum concentration of BAP was 62 mg/Kg and the maximum was 120 mg/Kg.

Action Level

The action level, or bright-line, for BAP is 90 mg/Kg.

Null and Alternative Hypothesis

H_0: mean ≥ bright-line vs. H_a: mean < bright-line.

Bounds of the Gray Region

The gray region is bounded on one side by the bright-line (90 mg/Kg). For "H_0: mean ≥ bright-line vs. H_a: mean < bright-line," DEFT sets a default value for the other bound of the gray region at the midpoint between the minimum concentration (62 mg/Kg) and the bright-line. In this example, the lower bound of the gray region is 76 mg/Kg.

Estimate of the Standard Deviation

If there is no estimate of the standard deviation available, DEFT calculates a default value given by:

(Maximum Concentration - Minimum Concentration)/6

In this example, the estimate of the standard deviation is 9.7.

Cost Per Sample for Sample Collection

The cost of sample collection is approximately $67.00 per sample. This estimate is based on the following assumptions:

- Two field sampling technicians are required.
- Samplers can collect, prepare, and ship 12 samples per 8-hour day.
- Labor rate is $50.00/hour ("loaded" rate).

Cost Per Sample for Sample Analysis

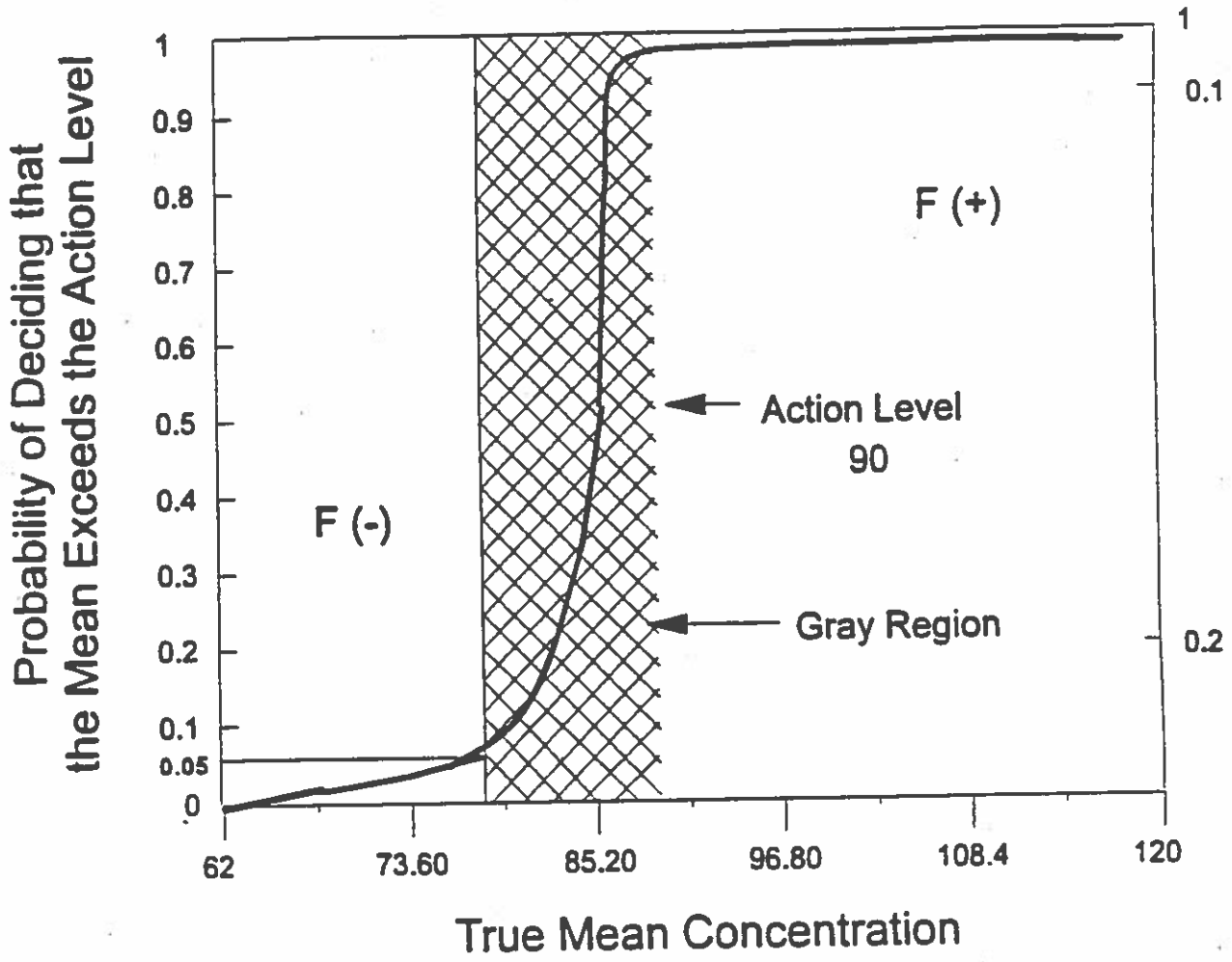
The cost per soil sample analysis for semi-volatile organic compounds, including BAP, is approximately $400.00 per sample.

Probability Limits on Decision Errors for the Bounds of the Gray Region

For this example, the probability of making a false positive error is set a $\alpha = .01$, and the probability of making a false negative error is set a $\beta = .05$.

After the above information is entered into the DEFT software, sampling design and DQO summary information is provided. For this example, a simple random sampling design would require 11 samples at a total cost of $5,137.00 (see attached "Design/DQO Summary Screen" and "Decision Performance Goal Diagram Screen with the Performance Curve").

```
**********************************************

     Design/DQO Summary Screen

For the Sampling Design of:  Simple Random Sampling
Total Cost: $5137.00
Laboratory Cost per Sample:  $400.00
Field Cost per Sample:  $67.00
Number of Samples:  11


     Data Quality Objectives
Action Level:  90.00
Gray Region:   76.00 - 90.00
Null Hypothesis: mean ≥ 90.00
Standard Deviation (SD):  9.67

     Decision Error Limits
          conc.          prob(error)      type
           ---             ----          F(-)
           ---             ----          F(-)
          76.00           0.0500         F(-)
          90.00           0.0100         F(+)
           ---             ----          F(+)
           ---             ----          F(+)

**********************************************
```


Probability of Deciding that the Mean Exceeds the Action Level
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.05
0
1
0.1
0.2
F (+)
F (-)
Action Level
90
Gray Region
62
73.60
85.20
96.80
108.4
120
True Mean Concentration

RELEVANT GUIDANCE ON DATA QUALITY OBJECTIVES

1. USEPA. 1994a. *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (Interim Final)*. EPA QA/R-5. Quality Assurance Management Staff (QAMS), Washington, DC.

   Presents detailed specifications and instructions for the information that must be contained in a QAPP for environmental data operations performed by or on behalf of USEPA and the procedures for its review and approval.

2. USEPA. 1994b. *Guidance for the Data Quality Objectives Process (Final)*. EPA QA/G-4. Quality Assurance Management Staff (QAMS), Washington, DC.

   Offers general guidance on developing data quality criteria and performance specifications for data operations. The document outlines the seven distinct steps of the DQO Process: state the problem; identify the decision; identify inputs to the decision; define the decision boundaries; develop a decision rule; specify limits on decision rule; and optimize the design for obtaining data. Includes a detailed example and a glossary.

3. USEPA. 1994c. *Data Quality Objectives Decision Error Feasibility Trials (DQO/DEFT) Version 4.0 Software and User's Guide*. EPA QA/G-4D (Final). Quality Assurance Management Staff (QAMS), Washington, DC.

   The DEFT software uses the outputs from Steps 1 through 6 of the DQO Process to allow a decision maker or member of the DQO planning team to quickly generate cost information about several simple sampling designs based on the DQO constraints.

4. USEPA. 1996. *Guidance for Data Quality Assessment (Final)*. EPA QA/G-9. Quality Assurance Management Staff (QAMS), Washington, DC.

   The purpose of this guidance is to demonstrate the use of EPA's data quality assessment (DQA) process in evaluating environmental data sets and to provide some graphical and statistical tools that are useful in performing DQA.

ATTACHMENT D

DATA USEABILITY WORKSHEETS

DATA USEABILITY WORKSHEET
Site:
Medium:

Requirement	Comment
Field Sampling	
Evaluate field sampler's trip report. Discuss any sampling problems that affect data useability.	
Discuss field conditions that affect data useability.	
Discuss changes to approved field sampling methodology	
Are samples representative of receptor exposure for this medium (e.g. sample depth, grab vs composite, filtered vs unfiltered, low flow, etc.)?	
Discuss the effect of field QC results on data useability.	
Summarize the effect of field sampling issues on the risk assessment, if applicable.	

DATA USEABILITY WORKSHEET
Site:
Medium:

Requirement	Comment
Analytical Techniques	
Discuss whether the analytical methods are appropriate for quantitative risk assessment.	
Discuss data useability limitations of non-routine analytical methods (e.g. immunoassay, low-concentration, etc.) for use in quantitative risk assessment.	
Were detection limits adequate?	
Summarize the effect of analytical technique issues on the risk assessment, if applicable.	

DATA USEABILITY WORKSHEET
Site:
Medium:

Requirement	Comment
Data Quality Objectives	
Precision - Indicate notable sources of variability in the data (e.g. similarity between duplicates and between splits, overall distribution of data, effect of total number of samples on variability). Discuss how duplicates were handled.	
Accuracy - Indicate any problems associated with accuracy and notable sources of bias (e.g. problems with spikes, dilutions, holding times, blank contamination).	
Representativeness - Indicate any problems associated with data representativeness (e.g., trip blank or rinsate blank contamination, COC problems, etc.).	
Completeness - Indicate any problems associated with data completeness (e.g., incorrect sample analysis, incomplete sample records, problems with field procedures, etc.).	
Comparability - Indicate any problems associated with data comparability.	
Were the DQOs specified in the QAPP satisfied?	
Summarize the effect of DQO issues on the risk assessment, if applicable.	

DATA USEABILITY WORKSHEET
Site:
Medium:

Requirement	Comment
Data Validation and Interpretation	
What are the data validation requirements for this region?	
What method or guidance was used to validate the data?	
Was the data validation method consistent with regional guidance? Discuss any discrepancies.	
Were all data qualifiers defined? Discuss those which were not.	
Which qualifiers represent usable data?	
Which qualifiers represent unusable data?	
How are tentatively identified compounds handled?	

DATA USEABILITY WORKSHEET
Site:
Medium:

Requirement	Comment
Summarize the effect of data validation and interpretation issues on the risk assessment, if applicable.	
Additional notes:	

Note: The purpose of this Worksheet is to succinctly summarize the data useability analysis and conclusions. Reference specific pages in the Risk Assessment text to further expand on the information presented here.

ATTACHMENT E

U.S. ENVIRONMENTAL PROTECTION AGENCY REGION 9 PRELIMINARY REMEDIATION GOALS

ATTACHMENT F

U.S. ENVIRONMENTAL PROTECTION AGENCY REGION 8
SUPERFUND TECHNICAL GUIDANCE NUMBER RA-03

EVALUATING AND IDENTIFYING CONTAMINANTS OF CONCERN FOR HUMAN HEALTH

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION VIII (8HWM-SM)
999 18th STREET - SUITE 500
DENVER, COLORADO 80202-2466

Region VIII

REGION 8 SUPERFUND TECHNICAL GUIDANCE

No. RA-03 Contaminants of Concern — September 1994
Risk Assessment (Short Title / Key Words)

TITLE: *Evaluating and Identifying Contaminants of Concern for Human Health*

authors: Region 8 Toxicologists
contact: Dr. Susan Griffin
ph: 303-294-1062

approvals: (Initials)
Chief, TS / date 10/5/94
Chief, SM / date 10/5/94
Director, HWM / date 10/6/94

HAZARDOUS WASTE MANAGEMENT DIVISION, SUPERFUND MANAGEMENT BRANCH, TECHNICAL SECTION

SUMMARY

This regional guidance is intended to clarify the evaluation process for selecting contaminants of concern (COCs) for the human health risk baseline risk assessment process, as generally described in EPA's Risk Assessment Guidance for Superfund (RAGS). This guidance sets forth objective criteria (e.g., comparison to background levels, frequency of detections, essentiality, etc.) and provides explicit recommendations on measuring attainment for each of these criteria in order to evaluate whether or not a site-related contaminant should be retained as a COC.

EVALUATING AND IDENTIFYING CONTAMINANTS OF CONCERN FOR HUMAN HEALTH

OBJECTIVE

The objective of this Regional Guidance is to outline and describe a selection process whereby preliminary lists of potentially site-related contaminants can be evaluated for elimination or retention as contaminants of concern (COCs) for the human health baseline risk assessment.

BACKGROUND

For certain sites, the list of potentially site-related contaminants and exposure pathways may be lengthy. Carrying a large number of contaminants through a quantitative risk assessment may be complex, and may consume significant amounts of time and resources. In these cases, a selection process should be used to further reduce the number of contaminants of potential concern for each medium to a reasonable and relevant amount. EPA's Risk Assessment Guidance for Superfund (RAGS): Part A (EPA, 1989a) describes general qualitative criteria which should be considered when evaluating contaminants for either elimination or retention as contaminants of concern (COCs) for the baseline risk assessment. The purpose of this Regional Guidance is to present those criteria in a selection process which can be applied on a generic basis to USEPA Superfund sites in Region 8. This Regional Guidance will also present detailed examples of how several criteria presented in the upcoming flow chart can be quantitatively evaluated.

DISCUSSION

EPA's RAGS: Part A (EPA 1989a) recommends that the following criteria be evaluated when determining which chemicals on the initial list of all potentially site-related contaminants should be retained or eliminated as COCs for the Baseline Risk Assessment:

1. Essential Nutrients
2. Exceedance of background concentrations
3. Detection frequency
4. Mobility, persistence, and bioaccumulation
5. Exceedance of ARARs
6. Historical Evidence
7. Concentration and Toxicity

Figure 1 presents a selection process which addresses each of the criteria present in RAGS: Part A (EPA 1989a) and can be used to arrive at a final list of COCs for the risk assessment evaluation. This selection process is explained below:

1. Is the contaminant an essential nutrient?

If the contaminant identified is an essential nutrient and is present at low concentrations (i.e., only slightly elevated above naturally occurring levels or below established EPA toxicity values or FDA recommended nutritive levels), it does not need to be considered further in the risk assessment. Examples of EPA toxicity values which can be used are the slope factors or Reference Doses listed on EPA's Integrated Risk Information System (IRIS) Database or Health Effects Assessment Summary Tables (HEAST). The FDA's Recommended Daily Allowance (RDA) of essential dietary minerals and safe supplemental levels of dietary minerals can be used as nutritive indexes. Table I shows the essential elements/nutrients which can be considered in the COC selection process and their corresponding toxicity value or safe nutritive level.

TABLE I

Element/nutrient	Dose (mg/kg/day)
Calcium	1.4E+01*
Phosphorous	1.4E+01*
Magnesium	5.7E+00*
Iron	2.6E-01*
Zinc	3.0E-01 i
Iodine	2.1E-03*
Copper	3.7E-02 h
Manganese	5.0E-03 i
Fluoride	6.0E-02 i
Sodium	No data
Chromium III	1.0E+00 i
Potassium	5.7E-01*
Chloride	5.1E-01*
Selenium	5.0E-03 i
Molybdenum	5.0E-03 i
Cobalt	6.0E-02 e

*FDA RDA of essential minerals or FDA supplemental dietary mineral levels
i = IRIS
h = HEAST
e = EPA provisional toxicity value

2. Does the contaminant exceed background concentrations?

For the purpose of comparing site-related contamination to background levels of chemicals, EPA's RAGS: Part A (EPA, 1989a) divides background types into naturally occurring chemicals and anthropogenic chemicals. Examples of

anthropogenic chemicals include pesticides from agriculture, lead from auto emissions, and PAHs from fossils fuel combustion. This COC selection process will automatically include comparisons of site-related contaminants to naturally occurring chemicals. Inclusion of site comparisons to background anthropogenic chemicals (whether localized or ubiquitous) will be considered on a site-specific basis.

The USEPA has issued guidance for ground water detection monitoring programs being conducted under the Resource Conservation and Recovery Act (RCRA). This guidance, entitled "Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities" (EPA, 1989b) provides a conceptual framework for determining and applying an appropriate statistical method for comparison of background and contaminated groundwater data. This statistical guidance could also be applied to soil background comparisons.

The RCRA guidance details two types of statistical comparisons that can be made between samples collected from background and contaminated sites. These two type of statistical comparisons are (1) distributional tests, and (2) extreme value tests. Distributional tests are statistical tests used to determine whether the central tendencies of two groups of data are similar. Extreme values tests are statistical tests used to compare individual results (i.e., results from an affected site) to results from a distribution (e.g., the distribution of the background data). The objective of the statistical analysis for the risk assessment is to determine if site concentrations differ significantly from background concentrations, <u>on the average.</u> Therefore, distributional tests, and generally not extreme value tests, should be chosen for risk analysis.

Figure 2 is an example of a flow chart (based on the RCRA guidance) for comparing background and site concentrations using distributional tests, which depend on the percent of detected values for each parameter and distribution of background and site concentrations. The data analysis process was divided in this way because each statistical method can handle a certain number of detected values before the method becomes ineffective in determining a significant difference. The risk assessor is not limited, however, to those statistical tests shown in Figure 2. The choice of appropriate test should be based on the distribution of the data, the percent of non-detects in background and/or site

data, the presence of multiple detection limits, etc.

Caution: Statistical comparisons of data sets may be inappropriate and the interpretation of those tests meaningless when the number of non-detects are high (e.g., > 50%) and the sample sizes are small (e.g., N < 20). It is recommended that a statistician be consulted on the appropriateness of the statistical test(s) especially for unstable data sets.

At some sites, a concern may exist for "hot spots" or situations where a small proportion of the site is contaminated above background, yet application of distributional tests show no difference between site and background levels of randomly sampled data. For example, there may have been too few samples collected at the site, so that perhaps only one or two measurements are elevated above background. One method for dealing with this situation is to compare each site measurement to a "hot measurement" concentration value (Gilbert and Simpson, 1992). This "hot measurement" value can be a risk based number, a standard, or some function of the background data (e.g., upper tolerance limit). Generally the hot measurement value should be selected to identify small areas that may individually present excessive health risk beyond that of average site-wide exposures. If one or more site measurements equal or exceed the hot measurement value, the contaminant can be retained as a COC.

3. Detection Frequency

A contaminant with a detection frequency of ≥5% proceeds into the toxicity concentration screen. A chemical with <5% detection frequency is further evaluated with up to four additional criteria.

4. Persistence, Mobility, and Bioaccumulation

A chemical is retained as a COC if it is either highly persistent or highly mobile. Several physico-chemical parameters describe these processes, including environmental half-life, water solubility, log K_{ow} and K_{oc}. The log octanol/water partition coefficient (log K_{ow}) is the ratio of the chemical concentration in octanol to the concentration in water. A high log K_{ow}, typically greater than 3, indicates higher concentrations in the octanol rather than in the water. K_{oc} is an equilibrium

constant that measures the partitioning between organic carbon and water. K_{oc} is useful for describing mobility potential because it correlates better with adsorption to soil and sediment. A chemical's mobility is generally proportional to its water solubility and inversely proportional to K_{ow} and K_{oc}. Chemicals with log K_{ow} < 2.7 and K_{oc} < 50 are considered to be highly mobile, while chemicals with log K_{ow} > 3 and K_{oc} > 500 generally have low mobility potential.

In general, chemicals with Log K_{ow} > 3 begin to have a high bioaccumulation potential. It is immediately obvious that these criteria would only exclude chemicals with K_{ow}'s of 2.8 and 2.9. For this reason, it is recommended that the parameters of bioaccumulation or mobility not be used to exclude contaminants.

Persistence is measured by the number of days required to reduce a chemical's concentration by one-half through biotic and abiotic degradation processes. Chemicals are considered highly persistent if their half-lives in water are >90 days, and not persistent in water with half-lives < 30 days.

PARAMETER POTENTIAL FOR ACTION:

K_{ow} > 3 : Bioaccumulation

OR

K_{ow} < 2.7 : Mobility
K_{oc} < 50 : "

Do not use criteria for eliminating contaminants. Proceed to Toxicity Concentration Screen.

$t_{1/2}$ > 90 : Persistence

Proceed to Toxicity Concentration Screen.

5. Do concentrations exceed Health- and Technology-based Numerical criteria (ARAR's)?

Numerical criteria are federal and duly-promulgated state environmental and public health laws, requirements, or regulations for the protection of human health from exposure to chemical contaminants. If the maximum contaminant concentration or the 95th percent upper confidence limit of the mean for chemical concentrations exceeds health- and technology-based criteria, proceed to the Toxicity Concentration Screen.

6. Is there Historical Evidence of the Compound at the Site?

Chemicals reliably associated with site activities based on historical information generally should not be eliminated from the quantitative risk assessment.

7. Toxicity/Concentration Screen

EPA's RAGS: Part A (EPA 1989a) suggests consideration of a toxicity concentration screen based on calculating individual risk factors and eliminating chemicals which do not contribute, for example, more than 1% of the total risk. If 1 or more chemicals are present at very high concentrations, this method may lead to the elimination of chemicals which do not contribute much to the overall risk, but exceed health-based levels, none the less. For this reason, it is recommended that the toxicity concentration screen be based on generic Preliminary Remediation Goals (PRGs) as calculated by RAGS: Part B (EPA 1991). Region III's Risk-Based Concentration Tables spreadsheet is one such example of screening levels based on the RAGS: Part B PRG equations. EPA's Soil Screening Levels (SSLs) are another example, albeit more conservative. Either the maximum contaminant value or the 95 percent upper confidence limit of the arithmetic mean can be compared to the PRG for exposure to that media. Use of the latter value is recommended as the more scientifically rigorous value for use in these comparisons. If the contaminant concentration is less than the PRG/10 for non-carcinogens, or less than the PRG calculated at a 10^{-6} risk for carcinogens, the contaminant may be excluded as a COC. For non-carcinogens, the comparison value of 0.1 PRG ensures that any additive adverse effects will still result in a hazard index of less than one.

RECOMMENDATION

For sites where the preliminary list of potentially site-related contaminants is quite lengthy, it is recommended that the selection process outlined and described above be used to evaluate the contaminants and derive the final list of COC's which will be carried through the baseline risk assessment. Use of this selection process, however, may not be appropriate for all sites. It takes a fair amount of time and resources to evaluate each preliminary contaminant in this selection process. Therefore, sites with

smaller lists of preliminary contaminants may find it easier to just to carry all of the identified contaminants through the quantitative risk assessment evaluation.

REFERENCES

1. Gilbert, R.O. and Simpson, J.S. (1992). Statistical Methods for Evaluating the Attainment of Cleanup Standards, Volume 3: Reference-Based Standards for Soils and Solid Media, PNL-7409 Vol. 3, Rev. 1, Pacific Northwest Laboratory, Richland, Washington.

2. U.S. Environmental Protection Agency (EPA). 1989a. Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual. Office of Emergency and Remedial Response. EPA/540/1-89/002.

3. U.S. Environmental Protection Agency (EPA). 1989b. Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Interim Final Guidance. Office of Solid Waste, Waste Management Division. EPA/530-SW-89-026, April 1989.

4. U.S. Environmental Protection Agency (EPA). 1991. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part B: "Development of Risk-based Preliminary Remediation Goals". Office of Emergency and Remedial Response. OSWER Directive 9285.7-01B.

Figure 1 - Selection Process for COC's

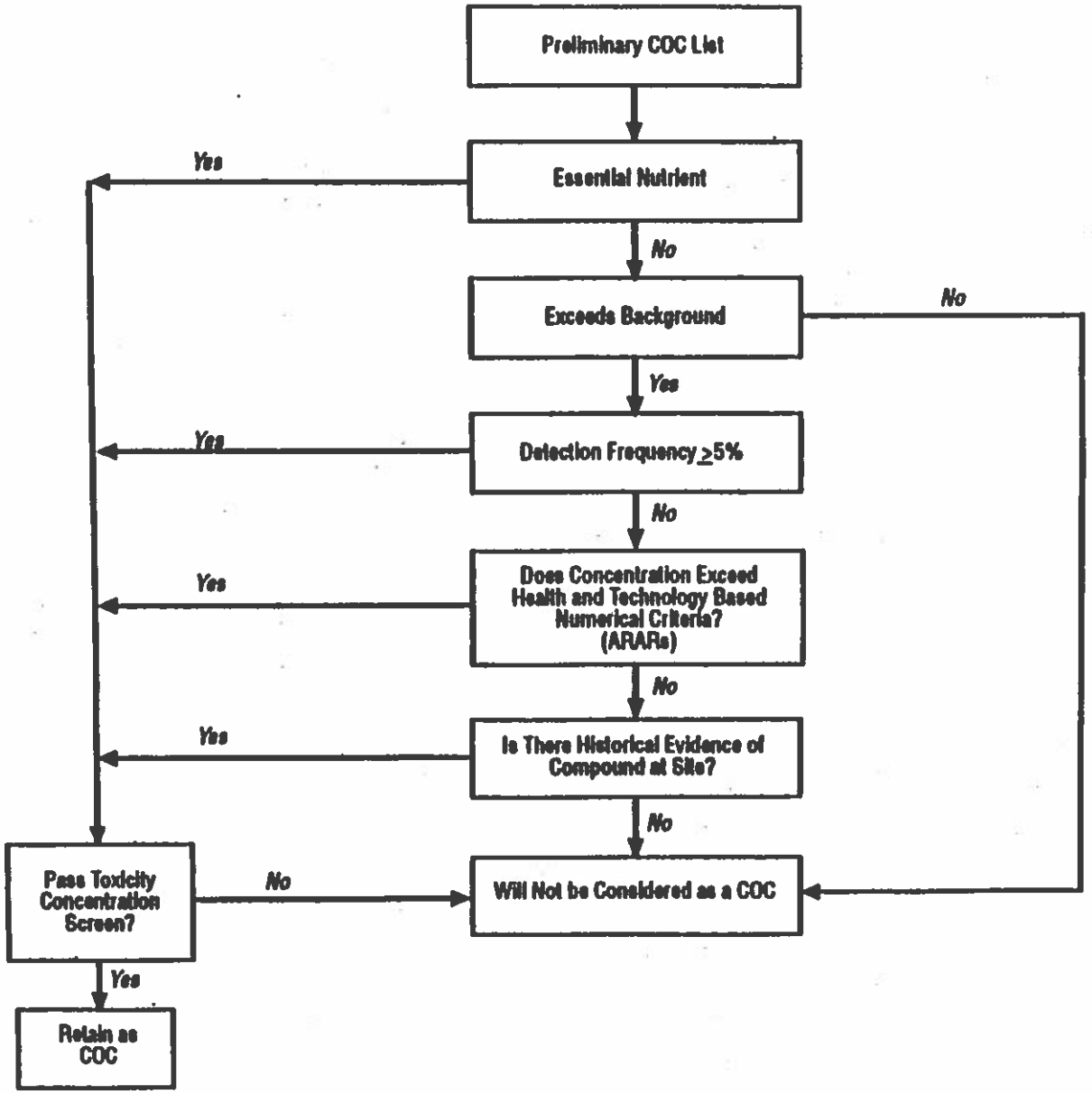
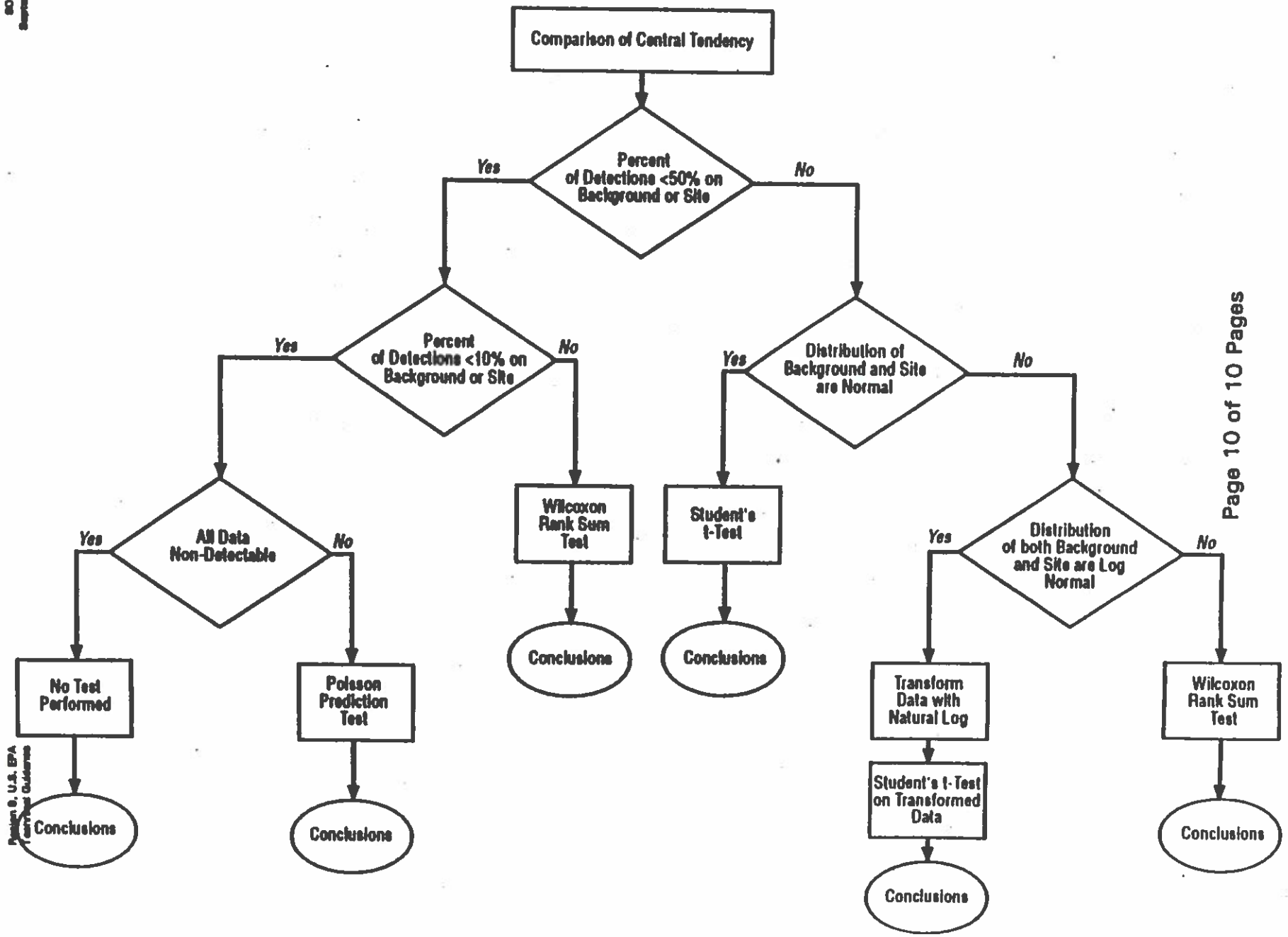


Figure 2 - Decision Tree for Comparisons of Central Tendency



ATTACHMENT G

U.S. ENVIRONMENTAL PROTECTION AGENCY
LAND USE MEMORANDUM

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 25 1995

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER Directive No. 9355.7-04

MEMORANDUM

SUBJECT: Land Use in the CERCLA Remedy Selection Process

FROM: Elliott P. Laws
Assistant Administrator

TO: Director, Waste Management Division
Regions I, IV, V, VII
Director, Emergency and Remedial Response Division
Region II
Director, Hazardous Waste Management Division
Regions III, VI, VIII, IX
Director, Hazardous Waste Division,
Region X
Director, Environmental Services Division
Regions I, VI, VII

Purpose:

This directive presents additional information for considering land use in making remedy selection decisions under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) at National Priorities List (NPL) sites. The U.S. Environmental Protection Agency (EPA) believes that early community involvement, with a particular focus on the community's desired future uses of property associated with the CERCLA site, should result in a more democratic decisionmaking process; greater community support for remedies selected as a result of this process; and more expedited, cost-effective cleanups.

The major points of this directive are:

- Discussions with local land use planning authorities, appropriate officials, and the public, as appropriate, should be conducted as early as possible in the scoping phase of the Remedial Investigation/Feasibility Study (RI/FS). This will assist EPA in understanding the

reasonably anticipated future uses of the land on which the Superfund site is located;

- If the site is located in a community that is likely to have environmental justice concerns, extra efforts should be made to reach out to and consult with segments of the community that are not necessarily reached by conventional communication vehicles or through local officials and planning commissions;

- Remedial action objectives developed during the RI/FS should reflect the reasonably anticipated future land use or uses;

- Future land use assumptions allow the baseline risk assessment and the feasibility study to be focused on developing practicable and cost effective remedial alternatives. These alternatives should lead to site activities which are consistent with the reasonably anticipated future land use. However, there may be reasons to analyze implications associated with additional land uses;

- Land uses that will be available following completion of remedial action are determined as part of the remedy selection process. During this process, the goal of realizing reasonably anticipated future land uses is considered along with other factors. Any combination of unrestricted uses, restricted uses, or use for long-term waste management may result.

Discussions with local land use authorities and other locally affected parties to make assumptions about future land use are also appropriate in the RCRA context. EPA recognizes that RCRA facilities typically are industrial properties that are actively managed, rather than the abandoned sites that are often addressed under CERCLA. Therefore, consideration of non-residential uses is especially likely to be appropriate for RCRA facility cleanups. Decisions regarding future land use that are made as part of RCRA corrective actions raise particular issues for RCRA (e.g., timing, property transfers, and the viability of long-term permit or other controls) in ensuring protection of human health and the environment. EPA intends to address the issue of future land use as it relates specifically to RCRA facility cleanups in subsequent guidance and/or rulemakings.

This guidance is also relevant for Federal Facility sites. Land use assumptions at sites that are undergoing base closure may be different than at sites where a Federal agency will be maintaining control of the facility. Most land management agency sites will remain in Federal ownership after remedial actions. In these cases, Forest Land Management Plans and other resource

management guidelines may help develop reasonable assumptions about future uses of the land. At all such sites, however, this document can focus the land use consideration toward appropriate options.[1]

Background:

Reasonably anticipated future use of the land at NPL sites is an important consideration in determining the appropriate extent of remediation. Future use of the land will affect the types of exposures and the frequency of exposures that may occur to any residual contamination remaining on the site, which in turn affects the nature of the remedy chosen. On the other hand, the alternatives selected through the National Oil and Hazardous Substance Contingency Plan (NCP) [55 Fed. Reg. 8666, March 8, 1990] process for CERCLA remedy selection determine the extent to which hazardous constituents remain at the site, and therefore affect subsequent available land and ground water uses.

The NCP preamble specifically discusses land use assumptions regarding the baseline risk assessment. The baseline risk assessment provides the basis for taking a remedial action at a Superfund site and supports the development of remedial action objectives. Land use assumptions affect the exposure pathways that are evaluated in the baseline risk assessment. Current land use is critical in determining whether there is a current risk associated with a Superfund site, and future land use is important in estimating potential future threats. The results of the risk assessment aid in determining the degree of remediation necessary to ensure long-term protection at NPL sites.

EPA has been criticized for too often assuming that future use will be residential. In many cases, residential use is the least restricted land use and where human activities are associated with the greatest potential for exposures. This directive is intended to facilitate future remedial decisions at NPL sites by outlining a public process and sources of information which should be considered in developing reasonable assumptions regarding future land use.

This directive expands on discussions provided in the preamble to the National Oil and Hazardous Substance Contingency Plan (NCP); "Risk Assessment Guidance for Superfund Vol. I, Human Health Evaluation Manual" (Part A) (EPA/540/1-89/002, Dec. 1989); "Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA" (OSWER Directive 9355.3-01, Oct. 1988); and

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[1] Federal agency responsibility under CERCLA 120(h)(3), which relates to additional clean up which may be required to allow for unrestricted use of the property, is not addressed in this guidance.

"Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (OSWER Directive 9355.0-30, April 22, 1991).

This land use directive may have the most relevance in situations where surface soil is the primary exposure pathway. Generally, where soil contamination is impacting ground water, protection of the ground water may drive soil cleanup levels. Consideration of future ground water use for CERCLA sites is not addressed in this document. There are separate expectations established for ground water in the NCP rule section 300.430 (a)(1)(iii)(F) that "EPA expects to return usable ground waters to their beneficial uses wherever practicable, within a timeframe that is reasonable given the particular circumstances of the site."

Objective

This directive has two primary objectives. First, this directive promotes early discussions with local land use planning authorities, local officials, and the public regarding reasonably anticipated future uses of the property on which an NPL site is located. Second, this directive promotes the use of that information to formulate realistic assumptions regarding future land use and clarifies how these assumptions fit in and influence the baseline risk assessment, the development of alternatives, and the CERCLA remedy selection process.

Implementation

The approach in this guidance is meant to be considered at current and future sites in the RI/FS pipeline, to the extent possible. This directive is not intended to suggest that previous remedy selection decisions should be re-opened.

Developing Assumptions About Future Land Use

In order to ensure use of realistic assumptions regarding future land uses at a site, EPA should discuss reasonably anticipated future uses of the site with local land use planning authorities, local officials, and the public, as appropriate, as early as possible during the scoping phase of the RI/FS. EPA should gain an understanding of the reasonably anticipated future land uses at a particular Superfund site to perform the risk assessment and select the appropriate remedy.

A visual inspection of the site and its surrounding area is a good starting point in developing assumptions regarding future land use. Discussions with the local land use authorities and appropriate officials should follow. Discussions with the public can be accomplished through a public meeting and/or other means. By developing realistic assumptions based on information gathered from these sources early in the RI/FS process, EPA may develop

remedial alternatives that are consistent with the anticipated future use.

The development of assumptions regarding the reasonably anticipated future land use should not become an extensive, independent research project. Site managers should use existing information to the extent possible, much of which will be available from local land use planning authorities. Sources and types of information that may aid EPA in determining the reasonably anticipated future land use include, but are not limited to:

- Current land use
- Zoning laws
- Zoning maps
- Comprehensive community master plans
- Population growth patterns and projections (e.g., Bureau of Census projections)
- Accessibility of site to existing infrastructure (e.g., transportation and public utilities)
- Institutional controls currently in place
- Site location in relation to urban, residential, commercial, industrial, agricultural and recreational areas
- Federal/State land use designation (Federal/State control over designated lands range from established uses for the general public, such as national parks or State recreational areas, to governmental facilities providing extensive site access restrictions, such as Department of Defense facilities
- Historical or recent development patterns
- Cultural factors (e.g., historical sites, Native American religious sites)
- Natural resources information
- Potential vulnerability of ground water to contaminants that might migrate from soil
- Environmental justice issues
- Location of on-site or nearby wetlands
- Proximity of site to a floodplain
- Proximity of site to critical habitats of endangered or threatened species
- Geographic and geologic information
- Location of Wellhead Protection areas, recharge areas, and other areas identified in a State's Comprehensive Ground-water Protection Program

These types of information should be considered when developing the assumptions about future land use. Interaction with the public, which includes all stakeholders affected by the site, should serve to increase the certainty in the assumptions made regarding future land use at an NPL site and increase the

confidence expectations about anticipated future land use are, in fact, reasonable.

For example, future industrial land use is likely to be a reasonable assumption where a site is currently used for industrial purposes, is located in an area where the surroundings are zoned for industrial use, and the comprehensive plan predicts the site will continue to be used for industrial purposes.

Community Involvement

NPL sites are located in diverse areas of the country, with great variability in land use planning practices. For some NPL sites, the future land use of a site may have been carefully considered through local, public, participatory, planning processes, such as zoning hearings, master plan approvals or other vehicles. When this is the case, local residents around the Superfund site are likely to demonstrate substantial agreement with the local land use planning authority on the future use of the property. Where there is substantial agreement among local residents and land use planning agencies, owners and developers, EPA can rely with a great deal of certainty on the future land use already anticipated for the site. For other NPL sites, however, the absence or nature of a local planning process may yield considerably less certainty about what assumptions regarding future use are reasonable. In some instances the local residents near the Superfund site may feel disenfranchised from the local land use planning and development process. This may be an especially important issue where there are concerns regarding environmental justice in the neighborhood around the NPL site. Consistent with the principle of fairness, EPA should make an extra effort to reach out to the local community to establish appropriate future land use assumptions at such sites.

Land Use Assumptions in the Baseline Risk Assessment

Future land use assumptions allow the baseline risk assessment and the feasibility study to focus on the development of practicable and cost-effective remedial alternatives, leading to site activities which are consistent with the reasonably anticipated future land use.

The baseline risk assessment generally needs only to consider the reasonably anticipated future land use; however, it may be valuable to evaluate risks associated with other land uses. The NCP preamble (55 Fed. Reg. 8710) states that in the baseline risk assessment, more than one future land use assumption may be considered when decision makers wish to understand the implications of unexpected exposures. Especially where there is some uncertainty regarding the anticipated future land use, it may be useful to compare the potential risks associated with several land use scenarios to estimate the impact

on human health and the environment should the land use unexpectedly change. The magnitude of such potential impacts may be an important consideration in determining whether and how institutional controls should be used to restrict future uses. If the baseline risk assessment evaluates a future use under which exposure is limited, it will not serve the traditional role, evaluating a "no action" scenario. A remedy, i.e. institutional controls to limit future exposure, will be required to protect human health and the environment. In addition to analyzing human health exposure scenarios associated with certain land uses, ecological exposures may also need to be considered.

Developing Remedial Action Objectives

Remedial action objectives provide the foundation upon which remedial cleanup alternatives are developed. In general, remedial action objectives should be developed in order to develop alternatives that would achieve cleanup levels associated with the reasonably anticipated future land use over as much of the site as possible. EPA recognizes, however, that achieving either the reasonably anticipated land use, or the land use preferred by the community, may not be practicable across the entire site, or in some cases, at all. For example, as RI/FS data become available, they may indicate that the remedial alternatives under consideration for achieving a level of cleanup consistent with the reasonably anticipated future land use are not cost-effective nor practicable. If this is the case, the remedial action objective may be revised which may result in different, more reasonable land use(s).

EPA's remedy selection expectations described in section 300.430(a)(1)(iii) of the NCP should also be considered when developing remedial action objectives. Where practicable, EPA expects to treat principal threats, to use engineering controls such as containment for low-level threats, to use institutional controls to supplement engineering controls, to consider the use of innovative technology, and to return usable ground waters to beneficial uses to protect human health and the environment. (Some types of applicable or relevant and appropriate requirements (ARARs) define protective cleanup levels which may, in turn, influence post-remediation land use potential.)

In cases where the future land use is relatively certain, the remedial action objective generally should reflect this land use. Generally, it need not include alternative land use scenarios unless, as discussed above, it is impracticable to provide a protective remedy that allows for that use. A landfill site is an example where it is highly likely that the future land use will remain unchanged (i.e., long-term waste management area), given the NCP's expectation that treatment of high volumes of waste generally will be impracticable and the fact that EPA's presumptive remedy for landfills is containment. In such a case,

a remedial action objective could be established with a very high degree of certainty to reflect the reasonably anticipated future land use.

In cases where the reasonably anticipated future land use is highly uncertain, a range of the reasonably likely future land uses should be considered in developing remedial action objectives. These likely future land uses can be reflected by developing a range of remedial alternatives that will achieve different land use potentials. The remedy selection process will determine which alternative is most appropriate for the site and, consequently, the land use(s) available following remediation.

As discussed in "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (OSWER Directive 9355.0-30, April 22, 1991), EPA has established a risk range for carcinogens within which EPA strives to manage site risks. EPA recognizes that a specific cleanup level within the acceptable risk range may be associated with more than one land use (e.g., an industrial cleanup to 10^{-6} may also allow for residential use at a 10^{-4} risk level.) It is not EPA's intent that the risk range be partitioned into risk standards based solely on categories of land use (e.g., with residential cleanups at the 10^{-6} level and industrial cleanups at the 10^{-4} risk level.) Rather, the risk range provides the necessary flexibility to address the technical and cost limitations, and the performance and risk uncertainties inherent in all waste remediation efforts.

Land Use Considerations in Remedy Selection

As a result of the comparative analysis of alternatives with respect to EPA's nine evaluation criteria, EPA selects a site-specific remedy. The remedy determines the cleanup levels, the volume of contaminated material to be treated, and the volume of contaminated material to be contained. Consequently, the remedy selection decision determines the size of the area that can be returned to productive use and the particular types of uses that will be possible following remediation.

The volume and concentration of contaminants left on-site, and thus the degree of residual risk at a site, will affect future land use. For example, a remedial alternative may include leaving in place contaminants in soil at concentrations protective for industrial exposures, but not protective for residential exposures. In this case, institutional controls should be used to ensure that industrial use of the land is maintained and to prevent risks from residential exposures. Conversely, a remedial alternative may result in no waste left in place and allow for unrestricted use (e.g., residential use).

Results of Remedy Selection Process

Several potential land use situations could result from EPA's remedy selection decision. They are:

- The remedy achieves cleanup levels that allow the entire site to be available for the reasonably anticipated future land use in the baseline risk assessment (or, where future land use is uncertain, all uses that could reasonably be anticipated).

- The remedy achieves cleanup levels that allow most, but not all, of the site to be available for the reasonably anticipated future land use. For example, in order to be cost effective and practicable, the remedy may require creation of a long-term waste management area for containment of treatment residuals or low-level waste on a small portion of the site. The cleanup levels in this portion of the site might allow for a more restricted land use.

- The remedy achieves cleanup levels that require a more restricted land use than the reasonably anticipated future land use for the entire site. This situation occurs when no remedial alternative that is cost-effective or practicable will achieve the cleanup levels consistent with the reasonably anticipated future land use. The site may still be used for productive purposes, but the use would be more restricted than the reasonably anticipated future land use. Furthermore, the more restricted use could be a long-term waste management area over all or a portion of the site.

Institutional Controls

If any remedial alternative developed during the FS will require a restricted land use in order to be protective, it is essential that the alternative include components that will ensure that it remain protective. In particular, institutional controls will generally have to be included in the alternative to prevent an unanticipated change in land use that could result in unacceptable exposures to residual contamination, or, at a minimum, alert future users to the residual risks and monitor for any changes in use. In such cases, institutional controls will play a key role in ensuring long-term protectiveness and should be evaluated and implemented with the same degree of care as is given to other elements of the remedy. In developing remedial alternatives that include institutional controls, EPA should determine: the type of institutional control to be used, the existence of the authority to implement the institutional control, and the appropriate entity's resolve and ability to

implement the institutional control. An alternative may anticipate two or more options for establishing institutional controls, but should fully evaluate all such options. A variety of institutional controls may be used such as deed restrictions and deed notices, and adoption of land use controls by a local government. These controls either prohibit certain kinds of site uses or, at a minimum, notify potential owners or land users of the presence of hazardous substances remaining on site at levels that are not protective for all uses. Where exposure must be limited to assure protectiveness, a deed notice alone generally will not provide a sufficiently protective remedy. While the ROD need not always specify the precise type of control to be imposed, sufficient analysis should be shown in the FS and ROD to support a conclusion that effective implementation of institutional controls can reasonably be expected.

Suppose, for example, that a selected remedy will be protective for industrial land use and low levels of hazardous substances will remain on site. An industry may still be able to operate its business with the selected remedy in place. Institutional controls, however, generally will need to be established to ensure the land is not used for other, less restricted purposes, such as residential use, or to alert potential buyers of any remaining contamination.

Future Changes in Land Use

Where waste is left on-site at levels that would require limited use and restricted exposure, EPA will conduct reviews at least every five years to monitor the site for any changes. Such reviews should analyze the implementation and effectiveness of institutional controls with the same degree of care as other parts of the remedy. Should land use change, it will be necessary to evaluate the implications of that change for the selected remedy, and whether the remedy remains protective. EPA's role in any subsequent additional cleanup will be determined on a site-specific basis. If landowners or others decide at a future date to change the land use in such a way that makes further cleanup necessary to ensure protectiveness, CERCLA does not prevent them from conducting such a cleanup as long as protectiveness of the remedy is not compromised. (EPA may invoke CERCLA section 122(e)(6), if necessary, to prevent actions that are inconsistent with the original remedy.) In general, EPA would not expect to become involved actively in the conduct or oversight of such cleanups. EPA, however, retains its authority to take further response action where necessary to ensure protectiveness.

Further Information

If you have any questions concerning this directive, please call Sherri Clark at 703-603-9043.

NOTICE: The policies set out in this memorandum are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this memorandum, or to act at variance with the guidance, based on an analysis of specific site circumstances. Remedy selection decisions are made and justified on a case-specific basis. The Agency also reserves the right to change this guidance at any time without public notice.

ATTACHMENT H

SOIL SCREENING GUIDANCE
CHEMICAL PROPERTIES TABLE C

Attachment C

Chemical Properties for SSL Development

Attachment C

Chemical Properties

This attachment provides the chemical properties necessary to calculate inhalation and migration to ground water SSLs (see Section 2.5.2) for 110 chemicals commonly found at Superfund sites. The *Technical Background Document for Soil Screening Guidance* describes the derivation and sources for these property values.

- Table C-1 provides soil organic carbon - water partition coefficients (K_{oc}), air and water diffusivities ($D_{i,a}$ and $D_{i,w}$), water solubilities (S), and dimensionless Henry's law constants (H').
- Table C-2 provides pH-specific K_{oc} values for organic contaminants that ionize under natural pH conditions. Site-specific soil pH measurements (see Section 2.3.5) can be used to select appropriate K_{oc} values for these chemicals. Where site-specific soil pH values are not available, values corresponding to a pH or 6.8 should be used (note that the K_{oc} values for these chemicals in Table C-1 are for a pH of 6.8).
- Table C-3 provides the physical state (liquid or solid) for organic contaminants. A contaminant's liquid or solid state is needed to apply and interpret soil saturation limit (C_{sat}) results (see Section 2.5.2, p.23).
- Table C-4 provides pH-specific soil-water partition coefficients (K_d) for metals. Site-specific soil pH measurements (see Section 2.3.5) can be used to select appropriate K_d values for these metals. Where site-specific soil pH values are not available, values corresponding to a pH of 6.8 should be used.

Except for air and water diffusivities, the chemical properties necessary to calculate SSLs for additional chemicals may be found in the Superfund Chemical Data Matrix (SCDM). Additional air and water diffusivities may be obtained from the CHEMDAT8 and WATER8 models, both of which can be downloaded off EPA's SCRAM electronic bulletin board system. Accessing information is

OAQPS SCRAM BBS
(919)541-5742 (24 hr/d, 7 d/wk except Monday AM)
Line Settings: 8 bits, no parity, 1 stop bit
Terminal emulation: VT100 or ANSI
System Operator: (919)541-5384 (normal business hours EST)

Table C-1. Chemical-Specific Properties used in SSL Calculations

CAS No.	Compound	K_{oc} (L/kg)	$D_{i,a}$ (cm^2/s)	$D_{i,w}$ (cm^2/s)	S (mg/L)	H' (dimensionless)
83-32-9	Acenaphthene	7.08E+03	4.21E-02	7.69E-06	4.24E+00	6.36E-03
67-64-1	Acetone	5.75E-01	1.24E-01	1.14E-05	1.00E+06	1.59E-03
309-00-2	Aldrin	2.45E+06	1.32E-02	4.86E-06	1.80E-01	6.97E-03
120-12-7	Anthracene	2.95E+04	3.24E-02	7.74E-06	4.34E-02	2.67E-03
56-55-3	Benz(*a*)anthracene	3.98E+05	5.10E-02	9.00E-06	9.40E-03	1.37E-04
71-43-2	Benzene	5.89E+01	8.80E-02	9.80E-06	1.75E+03	2.28E-01
205-99-2	Benzo(*b*)fluoranthene	1.23E+06	2.26E-02	5.56E-06	1.50E-03	4.55E-03
207-08-9	Benzo(*k*)fluoranthene	1.23E+06	2.26E-02	5.56E-06	8.00E-04	3.40E-05
65-85-0	Benzoic acid	6.00E-01	5.36E-02	7.97E-06	3.50E+03	6.31E-05
50-32-8	Benzo(*a*)pyrene	1.02E+06	4.30E-02	9.00E-06	1.62E-03	4.63E-05
111-44-4	Bis(2-chloroethyl)ether	1.55E+01	6.92E-02	7.53E-06	1.72E+04	7.38E-04
117-81-7	Bis(2-ethylhexyl)phthalate	1.51E+07	3.51E-02	3.66E-06	3.40E-01	4.18E-06
75-27-4	Bromodichloromethane	5.50E+01	2.98E-02	1.06E-05	6.74E+03	6.56E-02
75-25-2	Bromoform	8.71E+01	1.49E-02	1.03E-05	3.10E+03	2.19E-02
71-36-3	Butanol	6.92E+00	8.00E-02	9.30E-06	7.40E+04	3.61E-04
85-68-7	Butyl benzyl phthalate	5.75E+04	1.74E-02	4.83E-06	2.69E+00	5.17E-05
86-74-8	Carbazole	3.39E+03	3.90E-02	7.03E-06	7.48E+00	6.26E-07
75-15-0	Carbon disulfide	4.57E+01	1.04E-01	1.00E-05	1.19E+03	1.24E+00
56-23-5	Carbon tetrachloride	1.74E+02	7.80E-02	8.80E-06	7.93E+02	1.25E+00
57-74-9	Chlordane	1.20E+05	1.18E-02	4.37E-06	5.60E-02	1.99E-03
106-47-8	*p*-Chloroaniline	6.61E+01	4.83E-02	1.01E-05	5.30E+03	1.36E-05
108-90-7	Chlorobenzene	2.19E+02	7.30E-02	8.70E-06	4.72E+02	1.52E-01
124-48-1	Chlorodibromomethane	6.31E+01	1.96E-02	1.05E-05	2.60E+03	3.21E-02
67-66-3	Chloroform	3.98E+01	1.04E-01	1.00E-05	7.92E+03	1.50E-01
95-57-8	2-Chlorophenol	3.88E+02	5.01E-02	9.46E-06	2.20E+04	1.60E-02
218-01-9	Chrysene	3.98E+05	2.48E-02	6.21E-06	1.60E-03	3.88E-03
72-54-8	DDD	1.00E+06	1.69E-02	4.76E-06	9.00E-02	1.64E-04
72-55-9	DDE	4.47E+06	1.44E-02	5.87E-06	1.20E-01	8.61E-04
50-29-3	DDT	2.63E+06	1.37E-02	4.95E-06	2.50E-02	3.32E-04
53-70-3	Dibenz(*a*,*h*)anthracene	3.80E+06	2.02E-02	5.18E-06	2.49E-03	6.03E-07
84-74-2	Di-*n*-butyl phthalate	3.39E+04	4.38E-02	7.86E-06	1.12E+01	3.85E-08
95-50-1	1,2-Dichlorobenzene	6.17E+02	6.90E-02	7.90E-06	1.56E+02	7.79E-02
106-46-7	1,4-Dichlorobenzene	6.17E+02	6.90E-02	7.90E-06	7.38E+01	9.96E-02
91-94-1	3,3-Dichlorobenzidine	7.24E+02	1.94E-02	6.74E-06	3.11E+00	1.64E-07
75-34-3	1,1-Dichloroethane	3.16E+01	7.42E-02	1.05E-05	5.06E+03	2.30E-01
107-06-2	1,2-Dichloroethane	1.74E+01	1.04E-01	9.90E-06	8.52E+03	4.01E-02
75-35-4	1,1-Dichloroethylene	5.89E+01	9.00E-02	1.04E-05	2.25E+03	1.07E+00
156-59-2	*cis*-1,2-Dichloroethylene	3.55E+01	7.36E-02	1.13E-05	3.50E+03	1.67E-01
156-60-5	*trans*-1,2-Dichloroethylene	5.25E+01	7.07E-02	1.19E-05	6.30E+03	3.85E-01
120-83-2	2,4-Dichlorophenol	1.47E+02	3.46E-02	8.77E-06	4.50E+03	1.30E-04
78-87-5	1,2-Dichloropropane	4.37E+01	7.82E-02	8.73E-06	2.80E+03	1.15E-01
542-75-6	1,3-Dichloropropene	4.57E+01	6.26E-02	1.00E-05	2.80E+03	7.26E-01
60-57-1	Dieldrin	2.14E+04	1.25E-02	4.74E-06	1.95E-01	6.19E-04
84-66-2	Diethylphthalate	2.88E+02	2.56E-02	6.35E-06	1.08E+03	1.85E-05
105-67-9	2,4-Dimethylphenol	2.09E+02	5.84E-02	8.69E-06	7.87E+03	8.20E-05

Table C-1 (continued)

CAS No.	Compound	K_{oc} (L/kg)	$D_{l,a}$ (cm^2/s)	$D_{l,w}$ (cm^2/s)	S (mg/L)	H' (dimensionless)
51-28-5	2,4-Dinitrophenol	1.00E-02	2.73E-02	9.06E-06	2.79E+03	1.82E-05
121-14-2	2,4-Dinitrotoluene	9.55E+01	2.03E-01	7.06E-06	2.70E+02	3.80E-06
606-20-2	2,6-Dinitrotoluene	6.92E+01	3.27E-02	7.26E-06	1.82E+02	3.06E-05
117-84-0	Di-*n*-octyl phthalate	8.32E+07	1.51E-02	3.58E-06	2.00E-02	2.74E-03
115-29-7	Endosulfan	2.14E+03	1.15E-02	4.55E-06	5.10E-01	4.59E-04
72-20-8	Endrin	1.23E+04	1.25E-02	4.74E-06	2.50E-01	3.08E-04
100-41-4	Ethylbenzene	3.63E+02	7.50E-02	7.80E-06	1.69E+02	3.23E-01
206-44-0	Fluoranthene	1.07E+05	3.02E-02	6.35E-06	2.06E-01	6.60E-04
86-73-7	Fluorene	1.38E+04	3.63E-02	7.88E-06	1.98E+00	2.61E-03
76-44-8	Heptachlor	1.41E+06	1.12E-02	5.69E-06	1.80E-01	4.47E-02
1024-57-3	Heptachlor epoxide	8.32E+04	1.32E-02	4.23E-06	2.00E-01	3.90E-04
118-74-1	Hexachlorobenzene	5.50E+04	5.42E-02	5.91E-06	6.20E+00	5.41E-02
87-68-3	Hexachloro-1,3-butadiene	5.37E+04	5.61E-02	6.16E-06	3.23E+00	3.34E-01
319-84-6	α-HCH (α-BHC)	1.23E+03	1.42E-02	7.34E-06	2.00E+00	4.35E-04
319-85-7	ß-HCH (ß-BHC)	1.26E+03	1.42E-02	7.34E-06	2.40E-01	3.05E-05
58-89-9	γ-HCH (Lindane)	1.07E+03	1.42E-02	7.34E-06	6.80E+00	5.74E-04
77-47-4	Hexachlorocyclopentadiene	2.00E+05	1.61E-02	7.21E-06	1.80E+00	1.11E+00
67-72-1	Hexachloroethane	1.78E+03	2.50E-03	6.80E-06	5.00E+01	1.59E-01
193-39-5	Indeno(1,2,3-*cd*)pyrene	3.47E+06	1.90E-02	5.66E-06	2.20E-05	6.56E-05
78-59-1	Isophorone	4.68E+01	6.23E-02	6.76E-06	1.20E+04	2.72E-04
7439-97-6	Mercury	---	3.07E-02	6.30E-06	---	4.67E-01
72-43-5	Methoxychlor	9.77E+04	1.56E-02	4.46E-06	4.50E-02	6.48E-04
74-83-9	Methyl bromide	1.05E+01	7.28E-02	1.21E-05	1.52E+04	2.56E-01
75-09-2	Methylene chloride	1.17E+01	1.01E-01	1.17E-05	1.30E+04	8.98E-02
95-48-7	2-Methylphenol	9.12E+01	7.40E-02	8.30E-06	2.60E+04	4.92E-05
91-20-3	Naphthalene	2.00E+03	5.90E-02	7.50E-06	3.10E+01	1.98E-02
98-95-3	Nitrobenzene	6.46E+01	7.60E-02	8.60E-06	2.09E+03	9.84E-04
86-30-6	*N*-Nitrosodiphenylamine	1.29E+03	3.12E-02	6.35E-06	3.51E+01	2.05E-04
621-64-7	*N*-Nitrosodi-*n*-propylamine	2.40E+01	5.45E-02	8.17E-06	9.89E+03	9.23E-05
1336-36-3	PCBs	3.09E+05	---	---	7.00E-01	---
87-86-5	Pentachlorophenol	5.92E+02	5.60E-02	6.10E-06	1.95E+03	1.00E-06
108-95-2	Phenol	2.88E+01	8.20E-02	9.10E-06	8.28E+04	1.63E-05
129-00-0	Pyrene	1.05E+05	2.72E-02	7.24E-06	1.35E-01	4.51E-04
100-42-5	Styrene	7.76E+02	7.10E-02	8.00E-06	3.10E+02	1.13E-01
79-34-5	1,1,2,2-Tetrachloroethane	9.33E+01	7.10E-02	7.90E-06	2.97E+03	1.41E-02
127-18-4	Tetrachloroethylene	1.55E+02	7.20E-02	8.20E-06	2.00E+02	7.54E-01
108-88-3	Toluene	1.82E+02	8.70E-02	8.60E-06	5.26E+02	2.72E-01
8001-35-2	Toxaphene	2.57E+05	1.16E-02	4.34E-06	7.40E-01	2.46E-04
120-82-1	1,2,4-Trichlorobenzene	1.78E+03	3.00E-02	8.23E-06	3.00E+02	5.82E-02
71-55-6	1,1,1-Trichloroethane	1.10E+02	7.80E-02	8.80E-06	1.33E+03	7.05E-01
79-00-5	1,1,2-Trichloroethane	5.01E+01	7.80E-02	8.80E-06	4.42E+03	3.74E-02
79-01-6	Trichloroethylene	1.66E+02	7.90E-02	9.10E-06	1.10E+03	4.22E-01
95-95-4	2,4,5-Trichlorophenol	1.60E+03	2.91E-02	7.03E-06	1.20E+03	1.78E-04
88-06-2	2,4,6-Trichlorophenol	3.81E+02	3.18E-02	6.25E-06	8.00E+02	3.19E-04

Table C-1 (continued)

CAS No.	Compound	K_{oc} (L/kg)	$D_{i,a}$ (cm^2/s)	$D_{i,w}$ (cm^2/s)	S (mg/L)	H' (dimensionless)
108-05-4	Vinyl acetate	5.25E+00	8.50E-02	9.20E-06	2.00E+04	2.10E-02
75-01-4	Vinyl chloride	1.86E+01	1.06E-01	1.23E-06	2.76E+03	1.11E+00
108-38-3	*m*-Xylene	4.07E+02	7.00E-02	7.80E-06	1.61E+02	3.01E-01
95-47-6	*o*-Xylene	3.63E+02	8.70E-02	1.00E-05	1.78E+02	2.13E-01
106-42-3	*p*-Xylene	3.89E+02	7.69E-02	8.44E-06	1.85E+02	3.14E-01

K_{oc} = Soil organic carbon/water partition coefficient.
$D_{i,a}$ = Diffusivity in air (25 °C).
$D_{i,w}$ = Diffusivity in water (25 °C).
S = Solubility in water (20-25 °C).
H' = Dimensionless Henry's law constant (HLC [atm-m^3/mol] * 41) (25 °C).
K_d = Soil-water partition coefficient.

Table C-2. Koc Values for Ionizing Organics as a Function of pH

pH	Benzoic Acid	2-Chloro-phenol	2,4-Dichloro-phenol	2,4-Dinitro-phenol	Pentachloro-phenol	2,3,4,5-Tetrachloro-phenol	2,3,4,6-Tetrachloro-phenol	2,4,5-Trichloro-phenol	2,4,6-Trichloro-phenol
4.9	5.54E+00	3.98E+02	1.59E+02	2.94E-02	9.05E+03	1.73E+04	4.45E+03	2.37E+03	1.04E+03
5.0	4.64E+00	3.98E+02	1.59E+02	2.55E-02	7.96E+03	1.72E+04	4.15E+03	2.36E+03	1.03E+03
5.1	3.88E+00	3.98E+02	1.59E+02	2.23E-02	6.93E+03	1.70E+04	3.83E+03	2.36E+03	1.02E+03
5.2	3.25E+00	3.98E+02	1.59E+02	1.98E-02	5.97E+03	1.67E+04	3.49E+03	2.35E+03	1.01E+03
5.3	2.72E+00	3.98E+02	1.59E+02	1.78E-02	5.10E+03	1.65E+04	3.14E+03	2.34E+03	9.99E+02
5.4	2.29E+00	3.98E+02	1.58E+02	1.62E-02	4.32E+03	1.61E+04	2.79E+03	2.33E+03	9.82E+02
5.5	1.94E+00	3.97E+02	1.58E+02	1.50E-02	3.65E+03	1.57E+04	2.45E+03	2.32E+03	9.62E+02
5.6	1.65E+00	3.97E+02	1.58E+02	1.40E-02	3.07E+03	1.52E+04	2.13E+03	2.31E+03	9.38E+02
5.7	1.42E+00	3.97E+02	1.58E+02	1.32E-02	2.58E+03	1.47E+04	1.83E+03	2.29E+03	9.10E+02
5.8	1.24E+00	3.97E+02	1.58E+02	1.25E-02	2.18E+03	1.40E+04	1.56E+03	2.27E+03	8.77E+02
5.9	1.09E+00	3.97E+02	1.57E+02	1.20E-02	1.84E+03	1.32E+04	1.32E+03	2.24E+03	8.39E+02
6.0	9.69E-01	3.96E+02	1.57E+02	1.16E-02	1.56E+03	1.24E+04	1.11E+03	2.21E+03	7.96E+02
6.1	8.75E-01	3.96E+02	1.57E+02	1.13E-02	1.33E+03	1.15E+04	9.27E+02	2.17E+03	7.48E+02
6.2	7.99E-01	3.96E+02	1.56E+02	1.10E-02	1.15E+03	1.05E+04	7.75E+02	2.12E+03	6.97E+02
6.3	7.36E-01	3.95E+02	1.55E+02	1.08E-02	9.98E+02	9.51E+03	6.47E+02	2.06E+03	6.44E+02
6.4	6.89E-01	3.94E+02	1.54E+02	1.06E-02	8.77E+02	8.48E+03	5.42E+02	1.99E+03	5.89E+02
6.5	6.51E-01	3.93E+02	1.53E+02	1.05E-02	7.81E+02	7.47E+03	4.55E+02	1.91E+03	5.33E+02
6.6	6.20E-01	3.92E+02	1.52E+02	1.04E-02	7.03E+02	6.49E+03	3.84E+02	1.82E+03	4.80E+02
6.7	5.95E-01	3.90E+02	1.50E+02	1.03E-02	6.40E+02	5.58E+03	3.27E+02	1.71E+03	4.29E+02
6.8	5.76E-01	3.88E+02	1.47E+02	1.02E-02	5.92E+02	4.74E+03	2.80E+02	1.60E+03	3.81E+02
6.9	5.60E-01	3.86E+02	1.45E+02	1.02E-02	5.52E+02	3.99E+03	2.42E+02	1.47E+03	3.38E+02
7.0	5.47E-01	3.83E+02	1.41E+02	1.02E-02	5.21E+02	3.33E+03	2.13E+02	1.34E+03	3.00E+02
7.1	5.38E-01	3.79E+02	1.38E+02	1.02E-02	4.96E+02	2.76E+03	1.88E+02	1.21E+03	2.67E+02
7.2	5.32E-01	3.75E+02	1.33E+02	1.01E-02	4.76E+02	2.28E+03	1.69E+02	1.07E+03	2.39E+02
7.3	5.25E-01	3.69E+02	1.28E+02	1.01E-02	4.61E+02	1.87E+03	1.53E+02	9.43E+02	2.15E+02
7.4	5.19E-01	3.62E+02	1.21E+02	1.01E-02	4.47E+02	1.53E+03	1.41E+02	8.19E+02	1.95E+02
7.5	5.16E-01	3.54E+02	1.14E+02	1.01E-02	4.37E+02	1.25E+03	1.31E+02	7.03E+02	1.78E+02
7.6	5.13E-01	3.44E+02	1.07E+02	1.01E-02	4.29E+02	1.02E+03	1.23E+02	5.99E+02	1.64E+02
7.7	5.09E-01	3.33E+02	9.84E+01	1.00E-02	4.23E+02	8.31E+02	1.17E+02	5.07E+02	1.53E+02
7.8	5.06E-01	3.19E+02	8.97E+01	1.00E-02	4.18E+02	6.79E+02	1.13E+02	4.26E+02	1.44E+02
7.9	5.06E-01	3.04E+02	8.07E+01	1.00E-02	4.14E+02	5.56E+02	1.08E+02	3.57E+02	1.37E+02
8.0	5.06E-01	2.86E+02	7.17E+01	1.00E-02	4.10E+02	4.58E+02	1.05E+02	2.98E+02	1.31E+02

Table C-3. Physical State of Organic SSL Chemicals

Compounds liquid at soil temperatures			Compounds solid at soil temperatures		
CAS No.	Chemical	Melting Point (C)	CAS No.	Chemical	Melting Point (C)
67-64-1	Acetone	-94.8	83-32-9	Acenaphthene	93.4
71-43-2	Benzene	5.5	309-00-2	Aldrin	104
117-81-7	Bis(2-ethylhexyl)phthalate	-55	120-12-7	Anthracene	215
111-44-4	Bis(2-chloroethyl)ether	-51.9	56-55-3	Benz(*a*)anthracene	84
75-27-4	Bromodichloromethane	-57	50-32-8	Benzo(*a*)pyrene	176.5
75-25-2	Bromoform	8	205-99-2	Benzo(*b*)fluoranthene	168
71-36-3	Butanol	-89.8	207-08-9	Benzo(*k*)fluoranthene	217
85-68-7	Butyl benzyl phthalate	-35	65-85-0	Benzoic acid	122.4
75-15-0	Carbon disulfide	-115	86-74-8	Carbazole	246.2
56-23-5	Carbon tetrachloride	-23	57-74-9	Chlordane	106
108-90-7	Chlorobenzene	-45.2	106-47-8	*p*-Chloroaniline	72.5
124-48-1	Chlorodibromomethane	-20	218-01-9	Chrysene	258.2
67-66-3	Chloroform	-63.6	72-54-8	DDD	109.5
95-57-8	2-Chlorophenol	9.8	72-55-9	DDE	89
84-74-2	Di-*n*-butyl phthalate	-35	50-29-3	DDT	108.5
95-50-1	1,2-Dichlorobenzene	-16.7	53-70-3	Dibenzo(*a*,*h*)anthracene	269.5
75-34-3	1,1-Dichloroethane	-96.9	106-46-7	1,4-Dichlorobenzene	52.7
107-06-2	1,2-Dichloroethane	-35.5	91-94-1	3,3-Dichlorobenzidine	132.5
75-35-4	1,1-Dichloroethylene	-122.5	120-83-2	2,4-Dichlorophenol	45
156-59-2	*cis*-1,2-Dichloroethylene	-80	60-57-1	Dieldrin	175.5
156-60-5	*trans*-1,2-Dichloroethylene	-49.8	105-67-9	2,4-Dimethylphenol	24.5
78-87-5	1,2-Dichloropropane	-70	51-28-5	2,4-Dinitrophenol	115-116
542-75-6	1,3-Dichloropropene	NA	121-14-2	2,4-Dinitrotoluene	71
84-66-2	Diethylphthalate	-40.5	606-20-2	2,6-Dinitrotoluene	66
117-84-0	Di-*n*-octyl phthalate	-30	72-20-8	Endrin	200
100-41-4	Ethylbenzene	-94.9	206-44-0	Fluoranthene	107.8
87-68-3	Hexachloro-1,3-butadiene	-21	86-73-7	Fluorene	114.8
77-47-4	Hexachlorocyclopentadiene	-9	76-44-8	Heptachlor	95.5
78-59-1	Isophorone	-8.1	1024-57-3	Heptachlor epoxide	160
74-83-9	Methyl bromide	-93.7	118-74-1	Hexachlorobenzene	231.8
75-09-2	Methylene chloride	-95.1	319-84-6	α-HCH (α-BHC)	160
98-95-3	Nitrobenzene	5.7	319-85-7	ß-HCH (ß-BHC)	315
100-42-5	Styrene	-31	58-89-9	γ-HCH (Lindane)	112.5
79-34-5	1,1,2,2-Tetrachloroethane	-43.8	67-72-1	Hexachloroethane	187
127-18-4	Tetrachloroethylene	-22.3	193-39-5	Indeno(1,2,3-*cd*)pyrene	161.5
108-88-3	Toluene	-94.9	72-43-5	Methoxychlor	87
120-82-1	1,2,4-Trichlorobenzene	17	95-48-7	2-Methylphenol	29.8
71-55-6	1,1,1-Trichloroethane	-30.4	621-64-7	*N*-Nitrosodi-*n*-propylamine	NA
79-00-5	1,1,2-Trichloroethane	-36.6	86-30-6	*N*-Nitrosodiphenylamine	66.5
79-01-6	Trichloroethylene	-84.7	91-20-3	Naphthalene	80.2
108-05-4	Vinyl acetate	-93.2	87-86-5	Pentachlorophenol	174
75-01-4	Vinyl chloride	-153.7	108-95-2	Phenol	40.9
108-38-3	*m*-Xylene	-47.8	129-00-0	Pyrene	151.2
95-47-6	*o*-Xylene	-25.2	8001-35-2	Toxaphene	65-90
106-42-3	*p*-Xylene	13.2	95-95-4	2,4,5-Trichlorophenol	69
			88-06-2	2,4,6-Trichlorophenol	69
			115-29-7	Endosulfan	106

NA = Not available.

Table C-4. Metal K_d Values (L/kg) as a Function of pH[a]

pH	As	Ba	Be	Cd	Cr (+3)	Cr (+6)	Hg	Ni	Ag	Se	Tl	Zn
4.9	2.5E+01	1.1E+01	2.3E+01	1.5E+01	1.2E+03	3.1E+01	4.0E-02	1.6E+01	1.0E-01	1.8E+01	4.4E+01	1.6E+01
5.0	2.5E+01	1.2E+01	2.6E+01	1.7E+01	1.9E+03	3.1E+01	6.0E-02	1.8E+01	1.3E-01	1.7E+01	4.5E+01	1.8E+01
5.1	2.5E+01	1.4E+01	2.8E+01	1.9E+01	3.0E+03	3.0E+01	9.0E-02	2.0E+01	1.6E-01	1.6E+01	4.6E+01	1.9E+01
5.2	2.6E+01	1.5E+01	3.1E+01	2.1E+01	4.9E+03	2.9E+01	1.4E-01	2.2E+01	2.1E-01	1.5E+01	4.7E+01	2.1E+01
5.3	2.6E+01	1.7E+01	3.5E+01	2.3E+01	8.1E+03	2.8E+01	2.0E-01	2.4E+01	2.6E-01	1.4E+01	4.8E+01	2.3E+01
5.4	2.6E+01	1.9E+01	3.8E+01	2.5E+01	1.3E+04	2.7E+01	3.0E-01	2.6E+01	3.3E-01	1.3E+01	5.0E+01	2.5E+01
5.5	2.6E+01	2.1E+01	4.2E+01	2.7E+01	2.1E+04	2.7E+01	4.6E-01	2.8E+01	4.2E-01	1.2E+01	5.1E+01	2.6E+01
5.6	2.6E+01	2.2E+01	4.7E+01	2.9E+01	3.5E+04	2.6E+01	6.9E-01	3.0E+01	5.3E-01	1.1E+01	5.2E+01	2.8E+01
5.7	2.7E+01	2.4E+01	5.3E+01	3.1E+01	5.5E+04	2.5E+01	1.0E+00	3.2E+01	6.7E-01	1.1E+01	5.4E+01	3.0E+01
5.8	2.7E+01	2.6E+01	6.0E+01	3.3E+01	8.7E+04	2.5E+01	1.6E+00	3.4E+01	8.4E-01	9.8E+00	5.5E+01	3.2E+01
5.9	2.7E+01	2.8E+01	6.9E+01	3.5E+01	1.3E+05	2.4E+01	2.3E+00	3.6E+01	1.1E+00	9.2E+00	5.6E+01	3.4E+01
6.0	2.7E+01	3.0E+01	8.2E+01	3.7E+01	2.0E+05	2.3E+01	3.5E+00	3.8E+01	1.3E+00	8.6E+00	5.8E+01	3.6E+01
6.1	2.7E+01	3.1E+01	9.9E+01	4.0E+01	3.0E+05	2.3E+01	5.1E+00	4.0E+01	1.7E+00	8.0E+00	5.9E+01	3.9E+01
6.2	2.8E+01	3.3E+01	1.2E+02	4.2E+01	4.2E+05	2.2E+01	7.5E+00	4.2E+01	2.1E+00	7.5E+00	6.1E+01	4.2E+01
6.3	2.8E+01	3.5E+01	1.6E+02	4.4E+01	5.8E+05	2.2E+01	1.1E+01	4.5E+01	2.7E+00	7.0E+00	6.2E+01	4.4E+01
6.4	2.8E+01	3.6E+01	2.1E+02	4.8E+01	7.7E+05	2.1E+01	1.6E+01	4.7E+01	3.4E+00	6.5E+00	6.4E+01	4.7E+01
6.5	2.8E+01	3.7E+01	2.8E+02	5.2E+01	9.9E+05	2.0E+01	2.2E+01	5.0E+01	4.2E+00	6.1E+00	6.6E+01	5.1E+01
6.6	2.8E+01	3.9E+01	3.9E+02	5.7E+01	1.2E+06	2.0E+01	3.0E+01	5.4E+01	5.3E+00	5.7E+00	6.7E+01	5.4E+01
6.7	2.9E+01	4.0E+01	5.5E+02	6.4E+01	1.5E+06	1.9E+01	4.0E+01	5.8E+01	6.6E+00	5.3E+00	6.9E+01	5.8E+01
6.8	2.9E+01	4.1E+01	7.9E+02	7.5E+01	1.8E+06	1.9E+01	5.2E+01	6.5E+01	8.3E+00	5.0E+00	7.1E+01	6.2E+01
6.9	2.9E+01	4.2E+01	1.1E+03	9.1E+01	2.1E+06	1.8E+01	6.6E+01	7.4E+01	1.0E+01	4.7E+00	7.3E+01	6.8E+01
7.0	2.9E+01	4.2E+01	1.7E+03	1.1E+02	2.5E+06	1.8E+01	8.2E+01	8.8E+01	1.3E+01	4.3E+00	7.4E+01	7.5E+01
7.1	2.9E+01	4.3E+01	2.5E+03	1.5E+02	2.8E+06	1.7E+01	9.9E+01	1.1E+02	1.6E+01	4.1E+00	7.6E+01	8.3E+01
7.2	3.0E+01	4.4E+01	3.8E+03	2.0E+02	3.1E+06	1.7E+01	1.2E+02	1.4E+02	2.0E+01	3.8E+00	7.8E+01	9.5E+01
7.3	3.0E+01	4.4E+01	5.7E+03	2.8E+02	3.4E+06	1.6E+01	1.3E+02	1.8E+02	2.5E+01	3.5E+00	8.0E+01	1.1E+02
7.4	3.0E+01	4.5E+01	8.6E+03	4.0E+02	3.7E+06	1.6E+01	1.5E+02	2.5E+02	3.1E+01	3.3E+00	8.2E+01	1.3E+02
7.5	3.0E+01	4.6E+01	1.3E+04	5.9E+02	3.9E+06	1.6E+01	1.6E+02	3.5E+02	3.9E+01	3.1E+00	8.5E+01	1.6E+02
7.6	3.1E+01	4.6E+01	2.0E+04	8.7E+02	4.1E+06	1.5E+01	1.7E+02	4.9E+02	4.8E+01	2.9E+00	8.7E+01	1.9E+02
7.7	3.1E+01	4.7E+01	3.0E+04	1.3E+03	4.2E+06	1.5E+01	1.8E+02	7.0E+02	5.9E+01	2.7E+00	8.9E+01	2.4E+02
7.8	3.1E+01	4.9E+01	4.6E+04	1.9E+03	4.3E+06	1.4E+01	1.9E+02	9.9E+02	7.3E+01	2.5E+00	9.1E+01	3.1E+02
7.9	3.1E+01	5.0E+01	6.9E+04	2.9E+03	4.3E+06	1.4E+01	1.9E+02	1.4E+03	8.9E+01	2.4E+00	9.4E+01	4.0E+02
8.0	3.1E+01	5.2E+01	1.0E+05	4.3E+03	4.3E+06	1.4E+01	2.0E+02	1.9E+03	1.1E+02	2.2E+00	9.6E+01	5.3E+02

[a] non pH-dependent inorganic K_d values for antimony, cyanide, and vanadium are 45, 9.9, and 1,000 respectively.

ATTACHMENT I

REGION 10 EPA MEMORANDUM ON INORGANIC ARSENIC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue
Seattle, Washington 98101

March 26, 1997

Reply To
Attn Of: OEA095

MEMORANDUM

SUBJECT: Inorganic Arsenic in Fish

FROM: Dana Davoli

TO: Karen Keeley

After talking with Roseanne about this, we have decided to assume that 10% of the arsenic in seafood is inorganic. If use of this value results in arsenic in seafood (e.g., fish, shellfish, seaweed) driving a remediation, we would take a closer look at the site-specific data (e.g., types and amounts of species consumed, speciated arsenic analyses in seafoods).

The reasons we chose 10% are listed below:

(1) A review of the literature (see Attachment 1) shows that the range of inorganic arsenic in aquatic species ranges from below detection to as high as about 9.0%.

(2) Although most values are well below 10%, we chose 10% due to the uncertainties listed below:

(i) Inorganic arsenic data are missing on many species, including ones that might be expected to have high levels of inorganic arsenic (e.g., seaweed, bottomfish, shellfish, crustaceans).

(ii) Although it has always been assumed that methylation of inorganic arsenic to form dimethyl arsenic (DMA) results in

detoxification, more recent data have shown that DMA may be a probable human carcinogen (see Attachment 2). Data that we have from a Superfund site in Washington show that the DMA levels are much higher than the inorganic levels (see attached report). We have no way of including this potential risk in our risk assessments because the Agency has not yet developed a potency factor for DMA.

ATTACHMENT J

WORLD HEALTH ORGANIZATION ABSTRACT ON DIOXIN TOXIC EQUIVALENCY FACTORS

WHO Toxic Equivalency Factors (TEFs) for dioxin-like compounds for humans and wildlife

Introduction

Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) are persistent - and toxic - environmental chemicals. They enter the food chain and accumulate in fatty tissues of humans and other humans. Several representatives of these groups of chemicals have been shown to cause similar toxic effects as 2,3,7,8-TCDD, the most toxic dioxin. Their health effects include dermal toxicity, immunotoxicity, reproductive effects and teratogenicity, endocrine effects and carcinogenicity. These chemicals are also found in human milk, which raises serious health concerns.

As a result of their different chemical properties, the relative concentrations of the various PCDD, PCDF and PCB compounds vary from sample to sample. They also differ from the mixtures originally released into the environment. This complex situation hampers the evaluation of the health risk for humans and for the environment and the establishment of regulatory control of exposure to mixtures of these compounds.

TEF concept

The concept of toxic equivalency factors (TEFs) has been developed to deal with this problem. The TEF concept is based on the evidence that dioxin-like compounds share a common mechanism of action - binding to the Ah-receptor. By applying this TEF concept, the toxicity of the different compounds relative to that of 2,3,7,8-TCDD is determined on the basis of in vivo and in vitro data.

Several TEF schemes have been developed for PCDDs and PCDFs and for dioxin-like PCBs. Recognizing the need for a harmonized approach in setting internationally agreed TEFs, the WHO European Centre for Environment and Health and the International Programme on Chemical Safety (IPCS) have initiated a programme to derive consensus TEFs for compounds with dioxin-like activity for assessing the impact of these compounds on human health. The first Consultation on the Derivation of TEFs for Dioxin-like PCBs was convened in December 1993. For this meeting data on the relative toxicity of dioxin-like PCBs for mammalian species were collected and criteria for deriving TEFs were established.

These data were entered into a database set up by the Karolinska Institute in Stockholm, Sweden, and evaluated with respect to the applicability for the derivation of TEFs. As a result of this process, consensus TEFs for human intake were derived for 13 different PCBs (1). In addition, it became apparent that the database should be extended to include PCDDs and PCDFs, as well as data on the relative toxicity of dioxin-like compounds for wildlife.

Risks for wildlife?

One of the open questions was whether or not the TEFs derived for human risk assessment purposes were appropriate for estimating the risk for wildlife, or whether a separate set of TEFs for wildlife should be developed. This was discussed at an initial WHO consultation on the derivation of TEFs for wildlife for PCBs, PCDDs, PCDFs and other dioxin-like compounds, convened in August 1996. This WHO meeting identified the type of data necessary for the derivation of TEFs for wildlife, and defined a workplan and the way data should be collected. It decided to combine the efforts to derive TEFs for wildlife with the update of existing TEFs for human risk assessment. Furthermore, it recommended that TEFs for human health and wildlife be harmonized to the extent possible.

Derivation of TEFs

Many scientific articles on PCDDs, PCDFs and PCBs were analysed, of which 185 fulfilled the selection criteria. Based on the information available in these articles about 1600 sets of information have been inserted into the database. Following collection of all available information, a WHO meeting on the derivation of toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs and other dioxin-like compounds for humans and wildlife was held at the Institute of Environmental Medicine of the Karolinska Institute in June 1997. The meeting evaluated the information in the database and discussed several general issues related to the TEF concept.

The term TEF was defined to be an *order of magnitude* estimate of the toxicity of a compound relative to the toxicity of TCDD that is derived using careful scientific judgement after considering all available data. The relative potency of a compound obtained in a single in vivo or in vitro study will be referred to as a relative potency (REP) value. TEFs, in combination with chemical residue data can be used to calculate toxic equivalent (TEQ) concentrations in various media, including animal tissues, soil, sediment and water. TEQ concentrations in samples containing PCDDs, PCDFs and PCBs are calculated using the following equation:

$$TEQ = ([PCDD_i \times TEF_i]_n) + ([PCDF_i \times TEF_i]_n) + ([PCB_i \times TEF_i]_n)$$

Substantial evidence indicated that the TEF approach is equally valid for human risk assessment as for wildlife, although wildlife risk assessments usually attempt to estimate population-level effects (unlike traditional human risk assessments, which focus on protecting individuals) because effects on populations are of greater ecological relevance than are effects on individuals. The criteria used for including a compound in a wildlife TEF scheme are the same as those used for human TEFs. Compounds must:

- show a structural relationship to the PCDDs and PCDFs
- bind to the Ah receptor
- elicit dioxin-specific biochemical and toxic responses
- be persistent and accumulate in the food chain.

Attention was paid in particular to those compounds that are either abundant in nature or have

New WHO TEF scheme

Based on the available information ,both the previously established TEFs for PCDDs and PCDFs (2) and the WHO TEFs for PCBs (1) for human risk assessment were re-evaluated. For revision of the existing TEFs for PCDDs, PCDFs and PCBs it was agreed by the working group that if the available information was considered insufficient to warrant a change, the existing value would be adopted.

In deriving TEFs for wild mammals it was concluded that there was insufficient evidence to discriminate between laboratory and wild mammalian species, and it was therefore decided that the TEFs for human risk assessment based on laboratory animals would be equally applicable for wild mammal species.

The relative potency factors were primarily taken from *in vivo* toxicity data, which were given more weight than *in vitro* and/or QSAR data. *In vivo* toxicity data were prioritized according to the ranking scheme chronic > subchronic > subacute > acute. In the final TEF selection different Ah-receptor specific endpoints were also ranked according to toxic > biochemical (e.g. enzyme induction) response.

Also for the derivation of TEFs for PCDDs, PCDFs, and coplanar and mono-ortho PCBs for fish, and birds a tieredapproach was followed that gives a higher weight to overt toxicity in vitro studies than to biochemical effects. An even lower weight was given to biochemical effects (enzyme induction) in vitro. In case none of these data were available an estimate was made based on quantitative structure-activity relationships (QSAR).

When comparing the final TEF values across different taxa the working group tried to harmonize the TEFs to the extent possible, as this would have a clear advantage from a risk assessment and management perspective. However total synchronisation of TEFs between mammals, birds and fish was considered to be not feasible in case of obvious indications of orders of a magnitude difference between the taxa.

In line with the already existing TEF values new TEFs were rounded to a value of either 1or 5, irrespective of the order of magnitude difference with the reference compound, TCDD. It is important to point out that in this rounding procedure a conservative approach has been chosen to provide optimal protection of humans and wildlife.

1. Ahlborg et al.(1994), Toxic equivalency factors for dioxin-like PCBs: Report on a WHO-ECEH and IPCS consultation, December 1993. Chemosphere, Vol. 28, No. 6, 1049-1067.

2. NATO (1988), International toxicity equivalency factor (I-TEF) method of risk assessment for complex mixtures of dioxins and related compounds. Report No. 176, Brussels, Belgium.

For more information please contact F.X.Rolaf van Leeuwen, WHO European Centre for Environment and Health, P.O. Box 10, NL-3730 AA De Bilt, tel. 31 30 2295 307, fax 31 30 2294 252, email rlv@who.nl

Table 1. WHO-TEFs for humans, mammals, fish and birds

CONGENER	TOXIC EQUIVALENCY FACTOR (TEF)		
	HUMANS/ MAMMALS	FISH [a]	BIRDS [a]
2,3,7,8-TCDD	1	1	1
1,2,3,7,8-PeCDD	1	1	1 [f]
1,2,3,4,7,8-HxCDD	0.1 [a]	0.5	0.05 [f]
1,2,3,6,7,8-HxCDD	0.1 [a]	0.01	0.01 [f]
1,2,3,7,8,9-HxCDD	0.1 [a]	0.01 [e]	0.1 [f]
1,2,3,4,6,7,8-HpCDD	0.01	0.001	<0.001 [f]
OCDD	0.0001 [a]	-	-
2,3,7,8-TCDF	0.1	0.05	1 [f]
1,2,3,7,8-PeCDF	0.05	0.05	0.1 [f]
2,3,4,7,8-PeCDF	0.5	0.5	1 [f]
1,2,3,4,7,8-HxCDF	0.1	0.1	0.1 [c,f]
1,2,3,6,7,8-HxCDF	0.1	0.1 [c]	0.1 [c,f]
1,2,3,7,8,9-HxCDF	0.1 [a]	0.1 [c,e]	0.1 [c]
2,3,4,6,7,8-HxCDF	0.1 [a]	0.1 [c]	0.1 [c]
1,2,3,4,6,7,8-HpCDF	0.01 [a]	0.01 [b]	0.01 [b]
1,2,3,4,7,8,9-HpCDF	0.01 [a]	0.01 [b,c]	0.01 [b]
OCDF	0.0001 [a]	0.0001 [b,e]	0.0001 [b]
3,4,4',5-TCB (81)	0.0001 [a,b,c,e]	0.0005	0.1 [e]
3,3',4,4'-TCB (77)	0.0001	0.0001	0.05
3,3',4,4',5-PeCB (126)	0.1	0.005	0.1
3,3',4,4',5,5'-HxCB (169)	0.01	0.00005	0.001
2,3,3',4,4'-PeCB (105)	0.0001	<0.000005	0.0001
2,3,4,4',5-PeCB (114)	0.0005 [a,b,c,d]	<0.000005 [b]	0.0001 [g]
2,3',4,4',5-PeCB (118)	0.0001	<0.000005	0.00001
2',3,4,4',5-PeCB (123)	0.0001 [a,c,d]	<0.000005 [b]	0.00001 [g]
2,3,3',4,4',5-HxCB (156)	0.0005 [b,c]	<0.000005	0.0001
2,3,3',4,4',5'-HxCB (157)	0.0005 [b,c,d]	<0.000005 [b,c]	0.0001
2,3',4,4',5,5'-HxCB (167)	0.00001 [a,d]	<0.000005 [b]	0.00001 [g]
2,3,3',4,4',5,5'-HpCB (189)	0.0001 [a,c]	<0.000005	0.00001 [g]

"-" indicates no TEF because of lack of data
a) limited data set
b) structural similarity
c) QSAR modelling prediction from CYP1A induction (monkey, pig, chicken, or fish)
d) no new data from 1993 review
e) in vitro CYP1A induction
f) in vivo CYP1A induction after in ovo exposure
g) QSAR modelling prediction from class specific TEFs

ATTACHMENT K

EPA REGION 1 RISK UPDATES, REVISED MANGANESE REFERENCE DOSE

EPA
Region 1, New England

RISK UPDATES

Number 4 November 1996

RISK UPDATES is a periodic bulletin prepared by EPA - Region I, New England risk assessors to provide information on new regional guidance. Risk Updates is distributed to contractors supporting Superfund and RCRA, regulators, and interested parties. Risk assessment questions may be directed to the following EPA scientists (area code 617):

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Air Modeling
Brian Hennessey 565-3572
Combustion Risk Issues
Jui-Yu Hsieh 565-3501
Comparative Risk
Katrina Kipp 565-3520
Cost Benefit Analysis
Ronnie Levin 565-9351
Drinking Water
Maureen McClelland 565-3543
Air Risk Issues
Jerri Weiss 565-9448

ORD Technical Liaison
Ruth Bleyler 573-5792

EPA Region I, New England receives additional ecological technical support from Ken Finkelstein (223-5537) of the National Oceanic Atmospheric Administration (NOAA), and US Fish & Wildlife (Steve Mierzykowski 207/827-5938, Ken Munney 603/225-1411, and Tim Prior 401/364-9124).

Editors
Stephanie Carr and Jayne Michaud
Layout *Glona Hume*

Contents

Revised Manganese Reference Dose

The manganese reference dose (RfD) in the IRIS data base was revised in November, 1995. This revision results in a lower risk (and thus, higher cleanup level) for drinking water compared to the previous RfD. The IRIS RfD of 1.4E-1 mg/kg/day is for the total oral intake of manganese. As stated in the IRIS file, it is recommended that a modifying factor of 3 be applied to the RfD for non-dietary exposures.

Background

Prior to November, 1995 the IRIS data base provided two references doses for manganese, one for food and one for water. The food RfD was based on dietary intake of manganese. The water RfD was based on a study of humans who had ingested drinking water containing elevated levels of manganese as well as on assumptions regarding differences in absorption of manganese in food as opposed to water.

The drinking water RfD was withdrawn from IRIS in November, 1995 because of concerns about the validity of the human exposure study and because new information indicated that the disparity between absorption of manganese from food as opposed to water was overestimated.

New Approach

The revised RfD for manganese is for the total oral intake of manganese. This value is 0.14 mg/kg/day and is derived as follows:

- 10 mg/day of manganese may be consumed without adverse effects (the "critical dose"). This value comes from several dietary studies.
- average adult body weight = 70 kg

Therefore, the RfD =

$$\frac{10\ \text{mg/day}}{70\ \text{kg}} = 0.14\ \text{mg/kg/day}$$

A modifying factor of 3 is recommended in IRIS when assessing exposure from drinking water.

Drinking Water Exposures

The average dietary manganese content of the U.S. population, 5 mg/day, is subtracted from the "critical dose" of 10 mg/day:

10 mg/day - 5mg/day = 5 mg/day

Apply modifying factor of 3 per IRIS recommendation:

$$\frac{5\ \text{mg/day}}{3} = 1.67\ \text{mg/day}$$

Compute RfD:

$$\frac{1.67\ \text{mg/day}}{70\ \text{kg}} = .024\ \text{mg/kg day}$$

The Hazard Index (HI) for drinking water is calculated as follows (using a simplified equation):

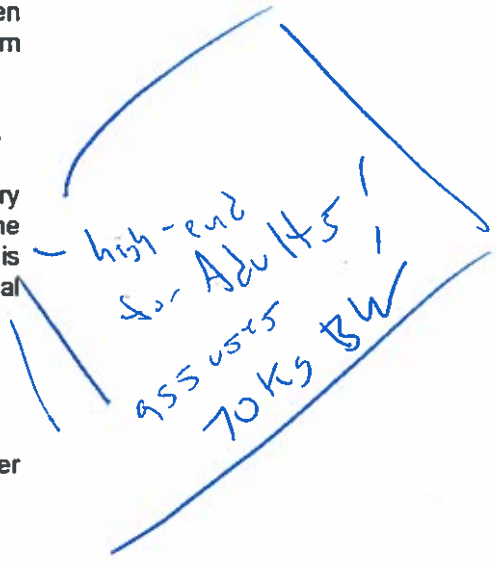
$$\frac{\text{Concentration(mg/L)} * \text{2liters/day}}{0.024\ \text{mg/kg/day} * 70\ \text{kg}}$$

A HI of 1 corresponds to a concentration of 840 ug/L.

Soil Exposure

A modifying factor of 3 may be appropriate for assessing risks via exposure to soils if neonates (a child 12 months or younger) are a potentially exposed population. For most RCRA and Superfund risk assessments neonates are unlikely to be exposed to significant amounts of soils. Therefore, a modifying factor of 1 is appropriate. Assuming exposure to a young child under a residential scenario, a hazard index of 1 for manganese in soil would correspond to a soil concentration of 5,500 mg/kg.

written by Margaret McDonough



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See RAGS Part D

ATTACHMENT L

AN APPROACH FOR DETERMINING TOXICITY VALUES FOR DERMAL EXPOSURE, OAK RIDGE NATIONAL LABORATORY INTERNAL PAPER

ATTACHMENT L

AN APPROACH FOR DETERMINING TOXICITY VALUES FOR DERMAL EXPOSURE, OAK RIDGE NATIONAL LABORATORY INTERNAL PAPER

AN APPROACH FOR DETERMINING TOXICITY VALUES FOR DERMAL EXPOSURE.

C. B. Bast and H. T. Borges. Biomedical and Environmental Information Analysis. Health Sciences Research Division. Oak Ridge National Laboratory*, Oak Ridge, TN.

*Managed by Martin Marietta Energy Systems, Inc., for the U.S. Department of Energy under contract No. DE-AC05-84OR21400.

ABSTRACT

Oral-toxicity data are available for many chemicals allowing for the calculation of Oral Reference Doses (RfD) for noncarcinogenic effects and slope factors (q_1^*) for carcinogenic effects. In contrast, dermal toxicity data for long-term exposure are not available for most chemicals which precludes calculation of dermal RfDs and slope factors. Health risks from dermal exposure to chemicals may be estimated by modification of the oral RfD or slope factor by a chemical-specific gastrointestinal absorption factor following SUPERFUND guidelines. This transforms the administered doses (oral RfDs and slope factors) into absorbed doses for comparison to intake amounts determined from dermal exposures. A computer program was developed to calculate the dermal RfD and slope factors from absorption data obtained from the published literature. When no quantitative data were available, estimates were made using structural analogs or a scheme developed to assign quantitative values to qualitative data. When quantitative data were available, the most conservative absorption factor from the species phylogenetically closest to the human was selected. The computer program uses two data bases for calculating dermal toxicity values. The first, updated quarterly, contains oral and inhalation risk values for over 600 chemicals. The second contains the absorption factor and the reference citation for over 100 chemicals. The program compares the CAS numbers of all chemicals in both data bases. When a match is found and if oral data and absorption factors are present, the program computes the dermal RfD and slope factors, prints the calculated results, the reference citations, and the source of the oral data (IRIS or HEAST). Using this methodology, RfDs ranging from 3.00E-08 to 4.00E+00 mg/kg/day and slope factors ranging from 7.89E-03 to 4.30E+02 $(mg/kg/day)^{-1}$ have been derived for over 60 chemicals.

INTRODUCTION

Oral toxicity data are available for many chemicals enabling Oral Reference Doses (RfD) for noncarcinogenic effects and slope factors (q_1^*) for carcinogenic effects to be calculated. In contrast, dermal toxicity data for long-term exposure are not available for most chemicals. This precludes the calculation of dermal RfDs and slope factors. However, the health risks from dermal exposure to chemicals can be characterized by modification of the oral RfD or slope factor by a chemical-specific gastrointestinal absorption factor. This transforms the administered doses (oral RfDs and slope factors) into absorbed doses which can then be compared to intake amounts determined from dermal exposures.

METHOD

1. *Identification of Potential Acute Effects.* A first step in dermal risk assessment is to review dermal toxicity of the compound and determine if it causes point of entry effects (direct skin effects). For example, strong acids and bases cause direct skin destruction, and mercury, chromium, and lead can cause skin irritation at relatively low concentrations. Even if the amount of chemical involved in dermal exposure is small compared to the amount inhaled or ingested, dermal toxicity may be important if acute skin effects exist. Also, when applying the following risk equations, it is important to evaluate the risk value obtained in reference to the contribution of contact site toxicity.

2. *Identification of Gastrointestinal Absorption Factors.* Absorption data were obtained through on-line literature searches of National Library of Medicine (NLM) databases and from hardcopy sources. Secondary sources such as monographs, surveys, review articles, and criteria documents were used to obtain gastrointestinal absorption data when possible. However, if no absorption data were present in the secondary sources or if the absorption data were not clearly presented, primary publications were consulted.

Gastrointestinal (GI) absorption values calculated and reported in the literature were utilized when the methods employed appeared to be scientifically sound. In cases where no absorption factors were reported or where the factors appeared to be derived by inappropriate methods, attempts were made to estimate absorption factors from the published absorption and excretion data. In these instances, absorption was estimated by adding amounts of compound recovered in all reported organs (excluding the luminal contents of the stomach and intestines) at necropsy and/or from amounts measured from sampling of plasma, saliva, urine, and breath. In many cases it was possible to estimate only a lower limit of absorption since it could not be determined if compound detected in the feces was actually absorbed. In these cases, absorption is reported as "greater than or equal to" a given value.

In some cases qualitative descriptions of gastrointestinal absorption, such as "readily absorbed" or "poorly absorbed" are available. When comparing qualitative and quantitative GI absorption data, the terms "rare, little, sparse, and low" tend to refer to absorptions between 1-20%, "readily and rapidly" to absorptions between 20-90%, and "well and almost complete" between 70-100%. Because terms such as readily and rapidly may refer to rate rather than amount of absorption, it is difficult to devise a qualitative absorption ranking system based on the terms most commonly found in the literature. The following system is suggested when no quantitative data exist but qualitative data are present:

Negligibly Absorbed:	<1%
Poorly Absorbed:	1-20%
Moderately Absorbed:	21-50%
Well Absorbed:	51-80%
Very Well Absorbed:	>80%

If no quantitative or qualitative data were available for specific chemicals, an attempt was made to estimate absorption factors by structural analogy.

3. Selection of Gastrointestinal Absorption Factors for Use in Dermal Risk Assessment. The following scheme was developed to select GI absorption factors for use in dermal risk assessment:

For chemicals with quantitative absorption data:

1) Select absorption data from the species whose skin most closely mimics human skin (U.S. EPA, 1992).

Human > Non-human Primate, Pig > Rat, Guinea Pig > Mouse, Rabbit

2) Select the most conservative absorption value (lowest percentage absorption) from the appropriate species. (When the only value available was expressed as "greater than or equal to" a given absorption, the value itself was selected.)

For chemicals with only qualitative absorption data:

1) Utilize the qualitative system previously presented.

Subjectively select the most appropriate absorption category, and select the lower limit of the range as the absorption factor.

4. Conversion from Administered to Absorbed Dose. GI absorption factors for 135 chemicals of interest at DOE's Oak Ridge Reservation were identified in the literature and placed into a dermal risk database. The CAS numbers of these chemicals were compared electronically with the CAS numbers of a database containing the RfD and Slope Factors of over 600 hundred chemicals. When an exact match was found, the RfD and Slope Factor was inserted into the dermal risk database and converted to toxicity values based on absorbed dosed for dermal exposure as follows (U.S. EPA, 1992; U.S. EPA, 1989):

$$RfD_{absorbed} = RfD_{administered} \times ABS_{GI}$$

$$q_1{}^*_{absorbed} = q_1{}^*_{administered} / ABS_{GI}$$

RESULTS

Using this methodology, RfDs ranging from 3.00E-08 to 4.00E+00 mg/kg/day and slope factors ranging from 7.89E-03 to 4.30E+02 $(mg/kg/day)^{-1}$ have been derived for over 60 chemicals. The computer-generated table provides a consistent mathematical method for calculating dermal toxicity values and is presented below.

REFERENCES*

U.S. EPA. 1989. Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual (Part A). Interim Final. Office of Emergency and Remedial Response, Washington, DC. December, 1989. EPA/540/1-89/002.

U.S. EPA. 1992. Dermal Exposure Assessment: Principles and Applications. Interim Report. Office of Health and Environmental Assessment. Washington, DC. January, 1992. EPA/600/6-91/011B.

**References from which gastrointestinal absorption factors were obtained are listed at the end of the computer-generated table.*

DERMAL RISK VALUES DERIVED BY CALCULATION
FROM GASTROINTESTINAL (GI) ABSORPTION DATA IN ALPHABETICAL ORDER

Chemical	CAS Number	GI Absorption Factor (%)[a]	GI Absorption Reference	Oral RfD (mg/kg/day)		Oral Slope Factor (mg/kg/day)$^{-1}$	Dermal RfD (mg/kg/day)		Dermal Slope Factor (mg/kg/day)$^{-1}$
				Chronic	Subchronic		Chronic	Subchronic	
Acenaphthene	000083-32-9	31	2	6.00E-02[b]	6.00E-01[c]	NA	1.86E-02	1.86E-01	NA
Acenaphthylene	000208-96-8	31	2	NA	NA	NA	NA	NA	NA
Acetone	000067-64-1	83	3	1.00E-01[b]	1.00E+00[c]	NA	8.30E-02	8.30E-01	NA
Aldrin	000309-00-2	50	65	3.00E-05[b]	3.00E-05[c]	1.70E+01[b]	1.50E-05	1.50E-05	3.40E+01
Aluminum	007429-90-5	10	4,5	NA	NA	NA	NA	NA	NA
Anthracene	000120-12-7	76	6	3.00E-01[b]	3.00E+00[c]	NA	2.28E-01	2.28E+00	NA
Antimony (metallic)	007440-36-0	2.0	7	4.00E-04[b]	4.00E-04[c]	NA	8.00E-06	8.00E-06	NA
Aroclor 1016	012674-11-2	90	46	7.00E-05[b]	NA	NA	6.30E-05	NA	NA
Aroclor 1254	011097-69-1	90	46	2.00E-05[b]	5.00E-05[c]	NA	1.80E-05	4.50E-05	NA
Aroclor 1260	011096-82-5	90	46	NA	NA	NA	NA	NA	NA
Arsenic Salts	NA	80	26	NA	NA	NA	NA	NA	NA
Arsenic, Inorganic	007440-38-2	41	8	3.00E-04[b]	3.00E-04[c]	NA	1.23E-04	1.23E-04	NA
Barium	007440-39-3	7.0	9	7.00E-02[b]	7.00E-02[c]	NA	4.90E-03	4.90E-03	NA
Benz[a]anthracene	000056-55-3	31	2	NA	NA	NA	NA	NA	NA
Benzene	000071-43-2	97	10	NA	NA	2.90E-02[b]	NA	NA	2.99E-02
Benzene Hexachloride	NA	97	10	NA	NA	NA	NA	NA	NA
Benzene, Ethyldimethyl	NA	97	10	NA	NA	NA	NA	NA	NA
Benzene, Ethylmethyl	NA	97	10	NA	NA	NA	NA	NA	NA
Benzene, Methylpropenyl	NA	97	10	NA	NA	NA	NA	NA	NA
Benzene, Methylpropyl	NA	97	10	NA	NA	NA	NA	NA	NA
Benzene, Trimethyl	025551-13-7	97	10	NA	NA	NA	NA	NA	NA
Benzidine	000092-87-5	80	11	3.00E-03[b]	3.00E-03[c]	2.30E+02[b]	2.40E-03	2.40E-03	2.88E+02
Benzo[a]pyrene	000050-32-8	31	2	NA	NA	7.30E+00[b]	NA	NA	2.35E+01
Benzo[b]fluoranthene	000205-99-2	31	2	NA	NA	NA	NA	NA	NA
Benzo[g,h,i]perylene	000191-24-2	31	2	NA	NA	NA	NA	NA	NA
Benzo[k]fluoranthene	000207-08-9	31	2	NA	NA	NA	NA	NA	NA

DERMAL RISK VALUES DERIVED BY CALCULATION
FROM GASTROINTESTINAL (GI) ABSORPTION DATA IN ALPHABETICAL ORDER

Chemical	CAS Number	GI Absorption Factor (%)[a]	GI Absorption Reference	Oral RfD (mg/kg/day)		Oral Slope Factor (mg/kg/day)$^{-1}$	Dermal RfD (mg/kg/day)		Dermal Slope Factor (mg/kg/day)$^{-1}$
				Chronic	Subchronic		Chronic	Subchronic	
Benzoic Acid	000065-85-0	100	12	4.00E+00[b]	4.00E+00[c]	NA	4.00E+00	4.00E+00	NA
Benzyl Alcohol	000100-51-6	66	12	3.00E-01[c]	1.00E+00[c]	NA	1.98E-01	6.60E-01	NA
Beryllium	007440-41-7	1.0	13, 14	5.00E-03[b]	5.00E-03[c]	4.30E+00[b]	5.00E-05	5.00E-05	4.30E+02
Bis(2-ethylhexyl)phthalate	000117-81-7	19	15	2.00E-02[b]	2.00E-02	1.40E-02[b]	3.80E-03	3.80E-03	7.37E-02
Boron And Borates Only	007440-42-8	90	75	9.00E-02[b]	9.00E-02[c]	NA	8.10E-02	8.10E-02	NA
Bromodichloromethane	000075-27-4	98	67	2.00E-02[b]	2.00E-02[c]	6.20E-02[b]	1.96E-02	1.96E-02	6.33E-02
Bromoform	000075-25-2	60	69	2.00E-02[b]	2.00E-01[c]	7.90E-03[b]	1.20E-02	1.20E-01	1.32E-02
Butanone-2, 4-chloro-4,4-difluoro	NA	80	1	NA	NA	NA	NA	NA	NA
Butyl Benzyl Phthlate	000085-68-7	61	78	2.00E-01[b]	2.00E+00[c]	NA	1.22E-01	1.22E+00	NA
Cadmium (Diet)	007440-43-9	1.0	16, 17, 18, 19	1.00E-03[b]	NA	NA	1.00E-05	NA	NA
Cadmium (Water)	007440-43-9	1.0	16, 17, 18, 19	5.00E-04[b]	NA	NA	5.00E-06	NA	NA
Carbazole	000086-74-8	70	76	NA	NA	2.00E-02	NA	NA	2.86E-02
Carbon Disulfide	000075-15-0	63	20	1.00E-01[b]	1.00E-01[c]	NA	6.30E-02	6.30E-02	NA
Carbon Tetrachloride	000056-23-5	65	21	7.00E-04[b]	7.00E-03	1.30E-01[b]	4.55E-04	4.55E-03	2.00E-01
Chlordane	000057-74-9	50	22	6.00E-05[b]	6.00E-05	1.30E+00[b], 35	3.00E-05	3.00E-05	2.60E+00
Chlorobenzene	000108-90-7	31	23	2.00E-02[b]	2.00E-01	NA	6.20E-03	6.20E-02	NA
Chloroform	000067-66-3	20	24	1.00E-02[b]	1.00E-02	6.10E-03[b]	2.00E-03	2.00E-03	3.05E-02
Chromium (III) (Insoluble Salts)	016065-83-1	0.50	74	1.00E+00[b]	1.00E+00[c]	NA	5.00E-03	5.00E-03	NA
Chromium (VI)	018540-29-9	2.0	25	5.00E-03[b]	2.00E-02	NA	1.00E-04	4.00E-04	NA
Chromium Salts	NA	2.0	74	NA	NA	NA	NA	NA	NA
Chrysene	000218-01-9	31	2	NA	NA	NA	NA	NA	NA
Cobalt	007440-48-4	80	26	NA	NA	NA	NA	NA	NA
Copper	007440-50-8	30	27	NA	NA	NA	NA	NA	NA
Cresol, p-	000106-44-5	65	72	5.00E-03[c]	5.00E-03[c]	NA	3.25E-03	3.25E-03	NA
Cyanide (CN-)	000057-12-5	17	37	2.00E-02[b]	2.00E-02[c]	NA	3.40E-03	3.40E-03	NA
DDD	000072-54-8	70	28	NA	NA	2.40E-01[b]	NA	NA	3.43E-01

DERMAL RISK VALUES DERIVED BY CALCULATION FROM GASTROINTESTINAL (GI) ABSORPTION DATA IN ALPHABETICAL ORDER

Chemical	CAS Number	GI Absorption Factor (%)[a]	GI Absorption Reference	Oral RfD (mg/kg/day)		Oral Slope Factor (mg/kg/day)$^{-1}$	Dermal RfD (mg/kg/day)		Dermal Slope Factor (mg/kg/day)$^{-1}$
				Chronic	Subchronic		Chronic	Subchronic	
DDE	000072-55-9	70	28	NA	NA	3.40E-01[b]	NA	NA	4.86E-01
DDT	000050-29-3	70	28	5.00E-04[b]	5.00E-04[c]	3.40E-01[b]	3.50E-04	3.50E-04	4.86E-01
Dibenz[a,h]anthracene	000053-70-3	31	2	NA	NA	NA	NA	NA	NA
Dibromochloromethane	000124-48-1	60	69	2.00E-02[b]	2.00E-01[c]	8.40E-02[b]	1.20E-02	1.20E-01	1.40E-01
Dibutyl Phthalate	000084-74-2	100	29	1.00E-01[b]	1.00E+00[c]	NA	1.00E-01	NA	NA
Dichlorobenzene, 1,4-	000106-46-7	90	82	NA	NA	2.40E-02	NA	NA	2.67E-02
Dichlorodifluoromethane	000075-71-8	23	12	2.00E-01[c]	9.00E-01[c]	NA	4.60E-02	2.07E-01	NA
Dichloroethane, 1,1-	000075-34-3	100	80	1.00E-01[c]	1.00E+00[c]	NA	1.00E-01	NA	NA
Dichloroethane, 1,2-	000107-06-2	100	30	NA	NA	9.10E-02[b]	NA	NA	9.10E-02
Dichloroethylene, 1,1-	000075-35-4	100	31	9.00E-03[b]	9.00E-03[c]	6.00E-01[b]	9.00E-03	9.00E-03	6.00E-01
Dichlorophenol, 2,4-	000120-83-2	82	81	3.00E-03[b]	3.00E-03[c]	NA	2.46E-03	2.46E-03	NA
Dichloropropane, 1,2-	000078-87-5	74	68	NA	NA	6.80E-02	NA	NA	9.19E-02
Dichloropropene, 1,3-	000542-75-6	55	73	3.00E-04[b]	3.00E-03[c]	1.80E-01	1.65E-04	1.65E-03	3.27E-01
Dieldrin	000060-57-1	50	65	5.00E-05[b]	5.00E-05[c]	1.60E+01[b]	2.50E-05	2.50E-05	3.20E+01
Diethyl Phthalate	000084-66-2	90	79	8.00E-01[b]	8.00E+00[c]	NA	7.20E-01	7.20E+00	NA
Dimethylphthalate	000131-11-3	90	79	NA	NA	NA	NA	NA	NA
Dinitro-o-cresol, 4,6-	000534-52-1	100	12	NA	NA	NA	NA	NA	NA
Dinitrobenzene, 1,2-	000528-29-0	93	32	4.00E-04[c]	4.00E-03[c]	NA	3.72E-04	3.72E-03	NA
Dinitrotoluene, 2,4-	000121-14-2	85	33	2.00E-03[b]	2.00E-03[c]	6.80E-01[b,d]	1.70E-03	1.70E-03	8.00E-01
Dinitrotoluene, 2,6-	000606-20-2	85	33	1.00E-03[c]	1.00E-02[c]	6.80E-01[b,d]	8.50E-04	8.50E-03	8.00E-01
Endrin	000072-20-8	2.0	77	3.00E-04[b]	3.00E-04[c]	NA	6.00E-06	6.00E-06	NA
Ethylbenzene	000100-41-4	97	10	1.00E-01[b]	NA	NA	9.70E-02	NA	NA
Fluoranthene	000206-44-0	31	2	4.00E-02[b]	4.00E-01[c]	NA	1.24E-02	1.24E-01	NA
Fluoride	007782-41-4	97	34	6.00E-02[b]	6.00E-02[c]	NA	5.82E-02	5.82E-02	NA
Heptachlor	000076-44-8	72	35	5.00E-04[b]	5.00E-04[c]	4.50E+00[b]	3.60E-04	3.60E-04	6.25E+00
Heptachlor Epoxide	001024-57-3	72	35	1.30E-05[b]	1.30E-05[c]	9.10E+00[b]	9.36E-06	9.36E-06	1.26E+01

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DERMAL RISK VALUES DERIVED BY CALCULATION
FROM GASTROINTESTINAL (GI) ABSORPTION DATA IN ALPHABETICAL ORDER

Chemical	CAS Number	GI Absorption Factor (%)[a]	GI Absorption Reference	Oral RfD (mg/kg/day)		Oral Slope Factor (mg/kg/day)$^{-1}$	Dermal RfD (mg/kg/day)		Dermal Slope Factor (mg/kg/day)$^{-1}$
				Chronic	Subchronic		Chronic	Subchronic	
Hexachlorocyclohexane, Alpha-	000319-84-6	97	70	NA	NA	6.30E+00[b]	NA	NA	6.49E+00
Hexachlorocyclohexane, Beta-	000319-85-7	91	70	NA	NA	1.80E+00[b]	NA	NA	1.98E+00
Hexachlorocyclohexane, Gamma-	000058-89-9	97	10	3.00E-04[b]	3.00E-03[c]	1.30E+00	2.91E-04	2.91E-03	1.34E+00
Hexanone, 2-	000591-78-6	66	36	NA	NA	NA	NA	NA	NA
Indeno[1,2,3-cd]pyrene	000193-39-5	31	2	NA	NA	NA	NA	NA	NA
Iron	007439-89-6	15	26	NA	NA	NA	NA	NA	NA
Isopropanol	000067-63-0	100	12	NA	NA	NA	NA	NA	NA
Lead And Compounds	007439-92-1	15	26	NA	NA	NA	NA	NA	NA
Lithium	007439-93-2	80	26	NA	NA	NA	NA	NA	NA
Magnesium	007439-95-4	20	26	NA	NA	NA	NA	NA	NA
Manganese (Diet)	007439-96-5	4.0	38	1.40E-01[b]	1.40E-01[c]	NA	5.60E-03	5.60E-03	NA
Manganese (Water)	007439-96-5	4.0	38	5.00E-03[b]	5.00E-03[c]	NA	2.00E-04	2.00E-04	NA
Mercury, Inorganic	007439-97-6	0.01	26, 39	3.00E-04[c]	3.00E-04[c]	NA	3.00E-08	3.00E-08	NA
Methyl Ethyl Ketone	000078-93-3	80	1	6.00E-01[b]	2.00E+00[c]	NA	4.80E-01	1.60E+00	NA
Methyl Mercury	022967-92-6	90	26, 39, 40	3.00E-04[b]	3.00E-04[c]	NA	2.70E-04	2.70E-04	NA
Methylene Chloride	000075-09-2	95	41	6.00E-02[b]	6.00E-02[c]	7.50E-03[b]	5.70E-02	5.70E-02	7.89E-03
Molybdenum	007439-98-7	38	42	5.00E-03[b]	5.00E-03[c]	NA	1.90E-03	1.90E-03	NA
Naphthalene	000091-20-3	80	43	NA	NA	NA	NA	NA	NA
Naphthalene, 1-Methyl	000090-12-0	80	43	NA	NA	NA	NA	NA	NA
Naphthalene, 2-Methyl	000091-57-6	80	43	NA	NA	NA	NA	NA	NA
Nickel Soluble Salts	007440-02-0	27	44	2.00E-02[b]	2.00E-02[c]	NA	5.40E-03	5.40E-03	NA
Nitrobenzene	000098-95-3	97	10	5.00E-04[b]	5.00E-03[c]	NA	4.85E-04	4.85E-03	NA
Nitrophenol, 4-	000100-02-7	100	12	NA	NA	NA	NA	NA	NA
Nitroso-di-N-propylamine, N-	000621-64-7	25	45	NA	NA	7.00E+00[b]	NA	NA	2.80E+01
Nitrosodiphenylamine, N-	000086-30-6	25	45	NA	NA	4.90E-03[b]	NA	NA	1.96E-02
Octyl Phthalate, di-N-	000117-84-0	90	79	2.00E-02[c]	2.00E-02[c]	NA	1.80E-02	1.80E-02	NA

DERMAL RISK VALUES DERIVED BY CALCULATION
FROM GASTROINTESTINAL (GI) ABSORPTION DATA IN ALPHABETICAL ORDER

Chemical	CAS Number	GI Absorption Factor (%)[a]	GI Absorption Reference	Oral RfD (mg/kg/day)		Oral Slope Factor (mg/kg/day)$^{-1}$	Dermal RfD (mg/kg/day)		Dermal Slope Factor (mg/kg/day)$^{-1}$
				Chronic	Subchronic		Chronic	Subchronic	
Pentachlorophenol	000087-86-5	100	71	3.00E-02[b]	3.00E-02[c]	1.20E-01[b]	3.00E-02	3.00E-02	1.20E-01
Pentyl Alcohol, N-	000071-41-0	50	12	NA	NA	NA	NA	NA	NA
Phenanthrene	000085-01-8	73	2	NA	NA	NA	NA	NA	NA
Phenol	000108-95-2	90	12	6.00E-01[b]	6.00E-01[c]	NA	5.40E-01	5.40E-01	NA
Polybrominated Biphenyls	059536-65-1	93	64	7.00E-06[c]	7.00E-05[c]	8.90E+00	6.51E-06	6.51E-05	9.57E+00
Polychlorinated Biphenyls	001336-36-3	90	46	NA	NA	7.70E+00[b]	NA	NA	8.56E+00
Pyrene	000129-00-0	31	2	3.00E-02[b]	3.00E-01[c]	NA	9.30E-03	9.30E-02	NA
Selenious Acid	007783-00-8	87	47	5.00E-03[b]	5.00E-03[c]	NA	4.35E-03	4.35E-03	NA
Selenite	014124-67-5	70	48	NA	NA	NA	NA	NA	NA
Selenium	007782-49-2	44	47	5.00E-03[b]	5.00E-03[c]	NA	2.20E-03	2.20E-03	NA
Silver	007440-22-4	18	49	5.00E-03[b]	5.00E-03[c]	NA	9.00E-04	9.00E-04	NA
Sulfate	014808-79-8	20	50	NA	NA	NA	NA	NA	NA
Tetrachloroethane, 1,1,2,2-	000079-34-5	70	51	NA	NA	2.00E-01[b]	NA	NA	2.86E-01
Tetrachloroethylene	000127-18-4	100	63	1.00E-02[b]	1.00E-01[c]	NA	1.00E-02	1.00E-01	NA
Thallium	007440-28-0	15	52	NA	NA	NA	NA	NA	NA
Thorium	007440-29-1	1.0	53	NA	NA	NA	NA	NA	NA
Tin	007440-31-5	10	26	6.00E-01[c]	6.00E-01[c]	NA	6.00E-02	6.00E-02	NA
Titanium	007440-32-6	3.0	26	NA	NA	NA	NA	NA	NA
Toluene	000108-88-3	80	54	2.00E-01[b]	2.00E+00[c]	NA	1.60E-01	1.60E+00	NA
Trichloroethane, 1,1,1-	000071-55-6	90	55	NA	NA	NA	NA	NA	NA
Trichloroethane, 1,1,2-	000079-00-5	81	56	4.00E-03[b]	4.00E-02[c]	5.70E-02[b]	3.24E-03	3.24E-02	7.04E-02
Trichloroethylene	000079-01-6	15	57	NA	NA	NA	NA	NA	NA
Trichlorofluoromethane	000075-69-4	23	12	3.00E-01[b]	7.00E-01[c]	NA	6.90E-02	1.61E-01	NA
Uranium	007440-61-1	85	26	NA	NA	NA	NA	NA	NA
Uranium, Soluble Salts	NA	85	26	3.00E-03	NA	NA	2.55E-03	NA	NA
Vanadium, Metallic	007440-62-2	1.0	58, 59	7.00E-03[c]	7.00E-03[c]	NA	7.00E-05	7.00E-05	NA

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DERMAL RISK VALUES DERIVED BY CALCULATION FROM GASTROINTESTINAL (GI) ABSORPTION DATA IN ALPHABETICAL ORDER

Chemical	CAS Number	GI Absorption Factor (%)[a]	GI Absorption Reference	Oral RfD (mg/kg/day)		Oral Slope Factor $(mg/kg/day)^{-1}$	Dermal RfD (mg/kg/day)		Dermal Slope Factor $(mg/kg/day)^{-1}$
				Chronic	Subchronic		Chronic	Subchronic	
Vinyl Acetate	000108-05-4	65	60	1.00E+00 [c]	1.00E+00 [c]	NA	6.50E-01	6.50E-01	NA
Vinyl Chloride	000075-01-4	100	66	NA	NA	1.90E+00	NA	NA	1.90E+00
Xylene, Mixture	001330-20-7	92	61	2.00E+00 [b]	NA	NA	1.84E+00	NA	NA
Zinc (Metallic)	007440-66-6	20	62	3.00E-01 [b]	3.00E-01 [c]	NA	6.00E-02	6.00E-02	NA
Zirconium	007440-67-7	80	12	NA	NA	NA	NA	NA	NA

[a] GI absoprtion factors obtained from literature by BEIA staff
[b] Source: Integrated Risk Information System (IRIS)
[c] Source: Health and Environmental Affects Summary Table (HEAST) 1993
[d] Listed as "Dinitrotoluene mixture, 2,4-/2,6-" in IRIS. The value is based on a study using technical grade DNT.

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ATTACHMENT M

EPA GUIDANCE FOR CALCULATING EXPOSURE POINT CONCENTRATIONS

United States Environmental Protection Agency | Office of Solid Waste and Emergency Response Washington, D.C. 20460 | Publication 9285.7-08I May 1992

EPA

Supplemental Guidance to RAGS: Calculating the Concentration Term

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division, OS-230

Intermittent Bulletin
Volume 1 Number 1

The overarching mandate of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances. To help meet this mandate, the U.S. Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response has developed a human health risk assessment process as part of its remedial response program. This process is described in *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual* (RAGS/HHEM). Part A of RAGS/HHEM addresses the baseline risk assessment, and describes a general approach for estimating exposure to individuals from hazardous substance releases at Superfund sites.

This bulletin explains the concentration term in the exposure/intake equation to remedial project managers (RPMs), risk assessors, statisticians, and other personnel. This bulletin presents the general intake equation as presented in RAGS/HHEM Part A, discusses basic concepts concerning the concentration term, describes generally how to calculate the concentration term, presents examples to illustrate several important points, and, lastly, identifies where to get additional help.

THE CONCENTRATION TERM

How is the concentration term used?

RAGS/HHEM Part A presents the Superfund risk assessment process in four "steps": (1) data collection and evaluation; (2) exposure assessment; (3) toxicity assessment; and (4) risk characterization. The concentration term is calculated for use in the exposure assessment step. Highlight 1 presents the general equation Superfund uses for calculating exposure, and illustrates that the concentration term (C) is one of several parameters needed to estimate contaminant intake for an individual.

For Superfund assessments, the concentration term (C) in the intake equation is an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling results. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated.

Why use an average value for the concentration term?

An estimate of average concentration is used because:

Highlight 1
GENERAL EQUATION FOR ESTIMATING EXPOSURE TO A SITE CONTAMINANT

$$I = C \times \frac{CR \times EFD}{BW} \times \frac{1}{AT}$$

where:

I = intake (i.e., the quantitative measure of exposure in RAGS/HHEM)
C = contaminant concentration
CR = contact (intake) rate
EFD = exposure frequency and duration
BW = body weight
AT = averaging time

(1) carcinogenic and chronic noncarcinogenic toxicity criteria[1] are based on lifetime average exposures; and

(2) average concentration is most representative of the concentration that would be contacted at a site over time.

For example, if you assume that an exposed individual moves randomly across an exposure area, then the spatially averaged soil concentration can be used to estimate the true average concentration contacted over time. In this example, the average concentration contacted over time would equal the spatially averaged concentration over the exposure area. While an individual may not actually exhibit a truly random pattern of movement across an exposure area, the assumption of equal time spent in different parts of the area is a simple but reasonable approach.

When should an average concentration be used?

The two types of exposure estimates now being required for Superfund risk assessments, a reasonable maximum exposure (RME) and an average, should both use an average concentration. To be protective, the overall estimate of intake (see Highlight 1) used as a basis for action at Superfund sites should be an estimate in the high end of the intake/dose distribution. One high-end option is the RME used in the Superfund program. The RME, which is defined as the highest exposure that could reasonably be expected to occur for a given exposure pathway at a site, is intended to account for both uncertainty in the contaminant concentration and variability in exposure parameters (e.g., exposure frequency, averaging time). For comparative purposes, Agency guidance (U.S. EPA, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, February 26, 1992) states that an average estimate of exposure also should be presented in risk assessments. For decision-making purposes in the Superfund program, however, RME is used to estimate risk.[2]

Why use an estimate of the arithmetic mean rather than the geometric mean?

The choice of the arithmetic mean concentration as the appropriate measure for estimating exposure derives from the need to estimate an individual's long-term average exposure. Most Agency health criteria are based on the long-term average daily dose, which is simply the sum of all daily doses divided by the total number of days in the averaging period. This is the definition of an arithmetic mean. The

[1] When acute toxicity is of most concern, a long-term average concentration generally should not be used for risk assessment purposes, as the focus should be to estimate short-term, peak concentrations.

[2] For additional information on RME, see RAGS/HHEM Part A and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 55 *Federal Register* 8710, March 8, 1990.

arithmetic mean is appropriate regardless of the pattern of daily exposures over time or the type of statistical distribution that might best describe the sampling data. The geometric mean of a set of sampling results, however, bears no logical connection to the cumulative intake that would result from long-term contact with site contaminants, and it may differ appreciably from — and be much lower than — the arithmetic mean. Although the geometric mean is a convenient parameter for describing central tendencies of lognormal distributions, it is not an appropriate basis for estimating the concentration term used in Superfund exposure assessments. The following simple example may help clarify the difference between the arithmetic and geometric mean when used for an exposure assessment:

> Assume the daily exposure for a trespasser subject to random exposure at a site is 1.0, 0.01, 1.0, 0.01, 1.0, 0.01, 1.0, and 0.01 units/day over an 8-day period. Given these values, the cumulative exposure is simply their summation, or 4.04 units. Dividing this by 8 days of exposure results in an arithmetic mean of 0.505 units/day. This is the value we would want to use in a risk assessment for this individual, not the geometric mean of 0.1 units/day. Viewed another way, multiplication of the geometric mean by the number of days equals 0.8 units, considerably lower than the known cumulative exposure of 4.04 units.

UCL AS AN ESTIMATE OF THE AVERAGE CONCENTRATION

What is a 95 percent UCL?

The 95 percent UCL of a mean is defined as a value that, when calculated repeatedly for randomly drawn subsets of site data, equals or exceeds the true mean 95 percent of the time. Although the 95 percent UCL of the mean provides a conservative estimate of the average (or mean) concentration, it should not be confused with a 95th percentile of site concentration data (as shown in **Highlight 2**).

Why use the UCL as the average concentration?

Statistical confidence limits are the classical tool for addressing uncertainties of a distribution average. The 95 percent UCL of the arithmetic mean concentration is used as the average concentration because it is not possible to know the true mean. The 95 percent UCL therefore accounts for uncertainties due to limited sampling data at Superfund sites. As sampling data become less limited at a site, uncertainties decrease, the UCL moves closer to the true mean, and exposure evaluations using either the mean or the UCL produce similar results. This concept is illustrated in **Highlight 2**.

Should a value other than the 95 percent UCL be used for the concentration?

A value other than the 95 percent UCL can be used provided the risk assessor can document that high coverage of the true population mean occurs (i.e., the value equals or exceeds the true population mean with high probability). For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the UCL can be greater than the highest measured or modeled concentration. In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value could be used as the concentration term. Note, however, that the true mean still may be higher than this maximum value (i.e., the 95 percent UCL indicates a higher mean is possible), especially if the most contaminated portion of the site has not been sampled.

CALCULATING THE UCL

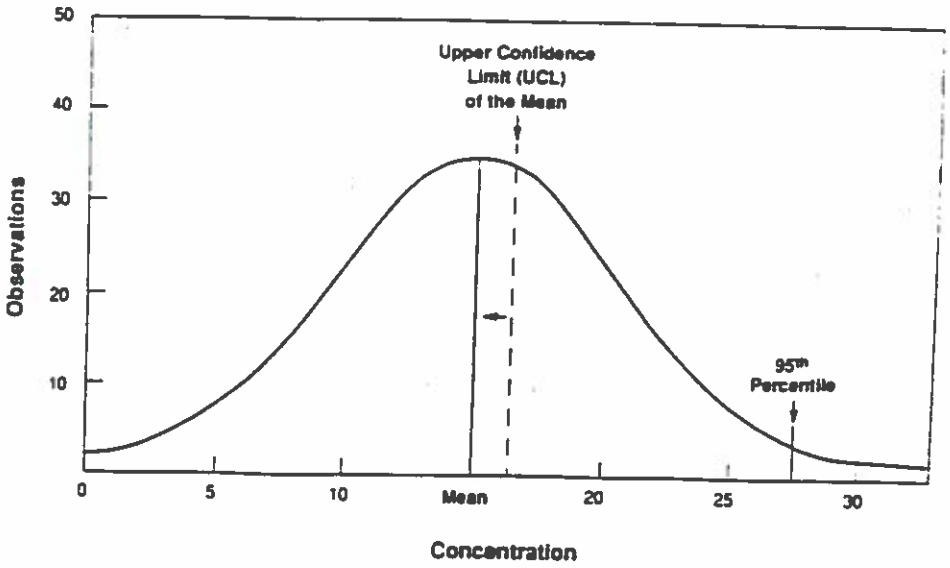
How many samples are necessary to calculate the 95 percent UCL?

Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95 percent UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95 percent UCL is close to the sample mean). Remember that, in general, the UCL approaches the true mean as more samples are included in the calculation.

Should the data be transformed?

EPA's experience shows that most large or "complete" environmental contaminant data sets

Highlight 2
COMPARISON OF UCL AND 95th PERCENTILE



As sample size increases, the UCL of the mean moves closer to the true mean, while the 95th percentile of the distribution remains at the upper end of the distribution.

from soil sampling are lognormally distributed rather than normally distributed (see **Highlights** 3 and 4 for illustrations of lognormal and normal distributions). In most cases, it is reasonable to assume that Superfund soil sampling data are lognormally distributed. Because transformation is a necessary step in calculating the UCL of the arithmetic mean for a lognormal distribution, the data should be transformed by using the natural logarithm function (i.e., calculate ln(x), where x is the value from the data set). However, in cases where there is a question about the distribution of the data set, a statistical test should be used to identify the best distributional assumption for the data set. The W-test (Gilbert 1987) is one statistical method that can be used to determine if a data set is consistent with a normal or lognormal distribution. In all cases, it is valuable to plot the data to better understand the contaminant distribution at the site.

How do you calculate the UCL for a lognormal distribution?

To calculate the 95 percent UCL of the arithmetic mean for a lognormally distributed data set, first transform the data using the natural logarithm function as discussed previously (i.e., calculate ln(x)). After transforming the data, determine the 95 percent UCL for the data set by completing the following four steps:

(1) Calculate the arithmetic mean of the transformed data (which is also the log of the geometric mean);

(2) Calculate the standard deviation of the transformed data;

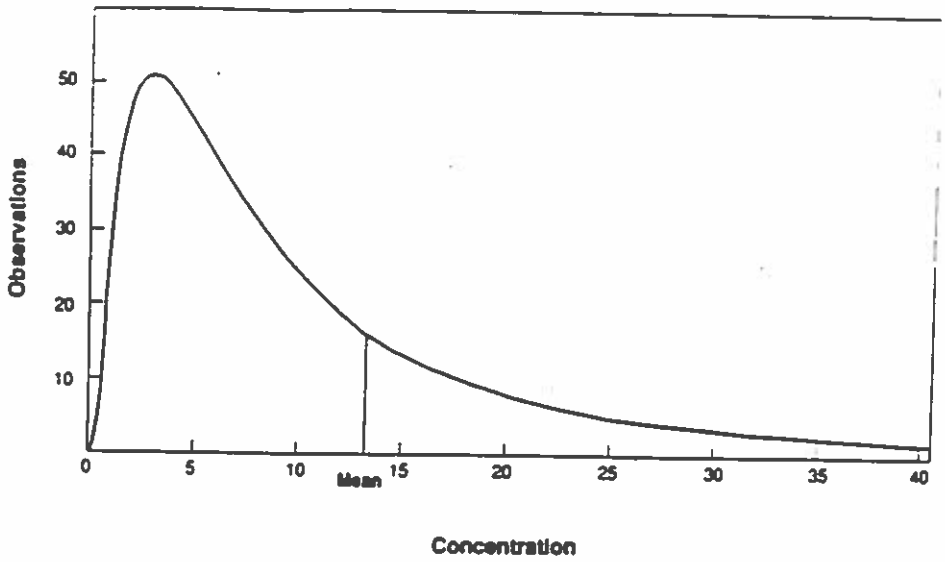
(3) Determine the H-statistic (e.g., see Gilbert 1987); and

(4) Calculate the UCL using the equation shown in **Highlight** 5.

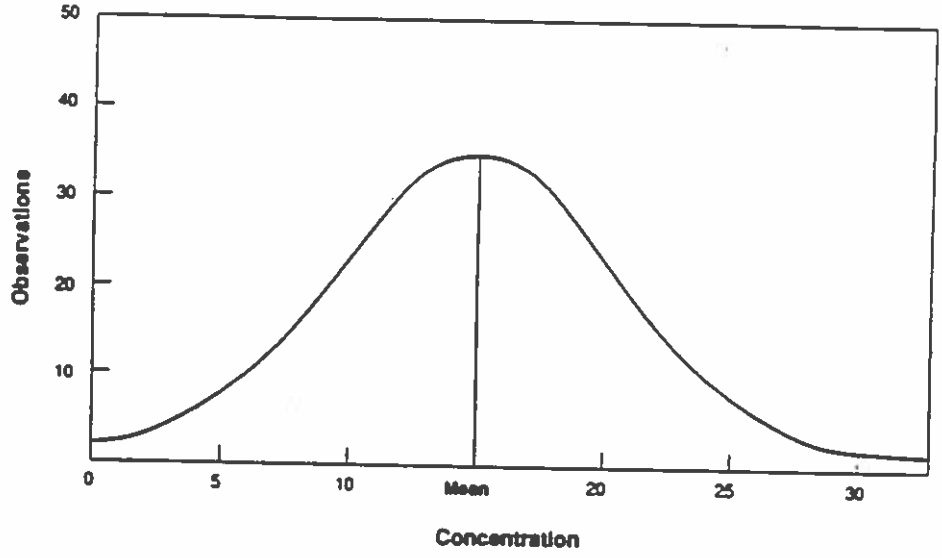
How do you calculate the UCL for a normal distribution?

If a statistical test supports the assumption that the data set is normally distributed, calculate the 95 percent UCL by completing the following four steps:

Highlight 3
EXAMPLE OF A LOGNORMAL DISTRIBUTION



Highlight 4
EXAMPLE OF A NORMAL DISTRIBUTION



Highlight 5
CALCULATING THE UCL OF THE ARITHMETIC MEAN FOR A LOGNORMAL DISTRIBUTION

$$UCL = e^{(\bar{x} + 0.5s^2 + sH/\sqrt{n-1})}$$

where:

UCL	=	upper confidence limit
e	=	constant (base of the natural log, equal to 2.718)
$\bar{x}$	=	mean of the transformed data
s	=	standard deviation of the transformed data
H	=	H-statistic (e.g., from table published in Gilbert 1987)
n	=	number of samples

Highlight 6
CALCULATING THE UCL OF THE ARITHMETIC MEAN FOR A NORMAL DISTRIBUTION

$$UCL = \bar{x} + t(s/\sqrt{n})$$

where:

UCL	=	upper confidence limit
$\bar{x}$	=	mean of the untransformed data
s	=	standard deviation of the untransformed data
t	=	Student-t statistic (e.g., from table published in Gilbert 1987)
n	=	number of samples

(1) Calculate the arithmetic mean of the untransformed data;

(2) Calculate the standard deviation of the untransformed data;

(3) Determine the one-tailed t-statistic (e.g., see Gilbert 1987); and

(4) Calculate the UCL using the equation presented in **Highlight 6**.

Use caution when applying normal distribution calculations if there is a possibility that heavily contaminated portions of the site have not been adequately sampled. In such cases, a UCL from normal distribution calculations could fall below the true mean, even if a limited data set at a site appears normally distributed.

EXAMPLES

The examples shown in **Highlights 7** and **8** address the exposure scenario where an individual at a Superfund site has equal opportunity to contact soil in any sector of the contaminated area over time. Even though the examples address only soil exposures, the UCL approach is applicable to all exposure pathways. Guidance and examples for other exposure pathways will be presented in forthcoming bulletins.

Highlight 7 presents a simple data set and provides a stepwise demonstration of transforming the data — assuming a lognormal distribution — and calculating the UCL. **Highlight 8** uses the same data set to show the difference between the UCLs that would result from assuming normal and lognormal distribution of the data. These

examples demonstrate the importance of using the correct assumptions.

WHERE CAN I GET MORE HELP?

Additional information on Superfund's policy and approach to calculating the concentration term and estimating exposures at waste sites can be obtained in:

- U.S. EPA, *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (Part A)*, EPA/540/1-89/002, December 1989.
- U.S. EPA, *Guidance for Data Useability in Risk Assessment*, EPA/540/G-90/008 (OSWER Directive 9285.7-05), October 1990.
- U.S. EPA, *Risk Assessment Guidance for Superfund (Part A — Baseline Risk Assessment) Supplemental Guidance/ Standard Exposure Factors*, OSWER Directive 9285.6-03, May 1991.

Useful statistical guidance can be found in many standard textbooks, including:

- Gilbert, R.O., *Statistical Methods for Environmental Pollution Monitoring*, Van Nostrand Reinhold, New York, New York, 1987.

Questions or comments concerning the concentration term can be directed to:

- Toxics Integration Branch
  Office of Emergency and Remedial Response
  401 M Street SW
  Washington, DC 20460
  Phone: 202-260-9486

EPA staff can obtain additional copies of this bulletin by calling EPA's Center for Environmental Research Information at FTS 684-7562 (513-569-7652). Others can obtain copies by contacting NTIS at 800-336-4700 (703-487-4650 in the Washington, DC area).

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Highlight 7
EXAMPLE OF DATA TRANSFORMATION AND CALCULATION OF UCL

This example shows the calculation of a 95 percent UCL of the arithmetic mean concentration for chromium in soil at a Superfund site. This example is applicable only to a scenario in which a spatially random exposure pattern is assumed. The concentrations of chromium obtained from random sampling in soil at this site (in mg/kg) are 10, 13, 20, 36, 41, 59, 67, 110, 110, 136, 140, 160, 200, 230, and 1300. Using these data, the following steps are taken to calculate a concentration term for the intake equation:

(1) Plot the data and inspect the graph. (You may need the help of a statistician for this part [as well as other parts] of the calculation of the UCL.) The plot (not shown, but similar to Highlight 3) shows a skew to the right, consistent with a lognormal distribution.

(2) Transform the data by taking the natural log of the values (i.e., determine ln(x)). For this data set, the transformed values are: 2.30, 2.56, 3.00, 3.58, 3.71, 4.08, 4.20, 4.70, 4.70, 4.91, 4.94, 5.08, 5.30, 5.44, and 7.17.

(3) Apply the UCL equation in Highlight 5, where:

$\bar{x} = 4.38$
$s = 1.25$
$H = 3.163$ (based on 95 percent)
$n = 15$

The resulting 95 percent UCL of the arithmetic mean is thus found to equal $e^{(6.218)}$, or 502 mg/kg.

Highlight 8
COMPARING UCLS OF THE ARITHMETIC MEAN ASSUMING DIFFERENT DISTRIBUTIONS

In this example, the data presented in Highlight 7 are used to demonstrate the difference in the UCL that is seen if the normal distribution approach were inappropriately applied to this data set (i.e., if, in this example, a normal distribution is assumed).

ASSUMED DISTRIBUTION:	Normal	Lognormal
TEST STATISTIC:	Student-t	H-statistic
95 PERCENT UCL (mg/kg):	325	502

Environmental Protection Agency | Emergency Response Washington, D.C. 20460 | December 1993

Supplemental Guidance to RAGS: Estimating Risk from Groundwater Contamination

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division

Intermittent Bulletin
Volume X Number X

The Toxics Integration Branch and Regional risk assessors have formed a Total Quality Management (TQM) Quality Action Team (QAT), known as the Concentration Term workgroup, to address the broad goal of improving the quality of data used in baseline risk assessments.

For this fact sheet, the Concentration Term workgroup consulted with representatives of the Groundwater Forum to address the risk assessment challenges posed by groundwater, in particular.

Calculating Risk

Risk at Superfund sites generally is calculated by comparing estimates of human exposure with Agency-verified toxicity criteria. Exposure is calculated by combining concentration with other parameters, such as the contact rate, exposure frequency and duration, and body weight. Current Agency guidance (U.S. EPA, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, February 26, 1993) requires risk assessments to present multiple descriptors of risk, including estimates for both average and high-end exposure scenarios. The Superfund site manager uses the calculated risk value to help determine the need for and extent of contaminant cleanup. Since risk and exposure are linearly related, the pollutant's concentration has a significant influence on the risk analysis, and, consequently, the remedial decision at a given site. The calculation of the concentration term is crucial; miscalculation could result in a false estimate of risk and, ultimately, result in inappropriate cleanup decisions and misdirected Superfund actions.

The Superfund program uses a reasonable maximum exposure (RME) or high-end risk calculation as the basis for remedial decisions. RME is intended to estimate a conservative case that is both protective of human health and the environment, while remaining within the range of potential exposure levels.

Because groundwater is a very complex and dynamic medium with characteristics that can change seasonally, it is likely that concentration of a given contaminant in each well will vary over time. Therefore, the concentration term is best described by an arithmetic average, regardless of whether the overall exposure estimate is high-end or average. Time and resource considerations generally preclude collecting enough data to calculate a true average; therefore, Superfund has relied on an upper-confidence limit on the arithmetic mean (UCL_{95}) to represent the average concentration.

The Challenge of Groundwater Risk Assessment

When determining the need for action, there are both policy and technical issues that set groundwater apart from other media, such as soil. EPA's policy is to consider the maximum beneficial use of groundwater and to protect it against future contamination. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (U.S. EPA Publication 9200.2-14, January 1992) states that groundwater is an inherently valuable natural resource to be protected and restored where necessary and practieal, as groundwater that is not currently used may be a drinking water supply in the future. An example of this practice is where a deeper, uncontaminated aquifer is hydraulically connected to a shallow, contaminated aquifer.

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Although the shallow aquifer may not currently be a drinking water resource, EPA may choose to remediate it to protect the deeper aquifer. In addition, few states have designated aquifers as unpotable, resulting in most aquifers being considered drinking water sources that must be addressed in the risk assessment.

These policies are sometimes at odds with Superfund's attempts to reasonably assess potential risks to human health. Risk assessment should be based upon the likelihood that a person will be continuously exposed to the contaminants present at the site over time. In a true assessment of risk, the usability of the aquifer must be considered. This includes such factors as the quality of the water (pH, redox potential, salinity, etc.), the size of the aquifer, the hydraulic characteristics, the community's water needs, and the availability of other drinking water sources.

Technical issues center around the characteristics of groundwater and make estimating long-term exposures particulary difficult. Most groundwater plumes move over time. The rate at which the plume moves, both horizontally and vertically, can greatly affect the concentration of contaminants at the same well. Seasonal variations in precipitation can cause low-to-high shifts in the groundwater table, flushing some contaminants out of the sample area.

The complexity of groundwater as a medium has a very definite impact on the ability to calculate a reliable concentration term. Because the concentration term is key to determining risk, it is imperative that the risk assessor has enough information to properly calculate the concentration term. Analysis has shown that as the number of samples increases, the degree of uncertainty and inherent conservatism is reduced. Preliminary results with soil analyses have shown that data from 10 to 20 samples per exposure area can support the calculation of a UCL_{95} that is reasonably close to the true mean.

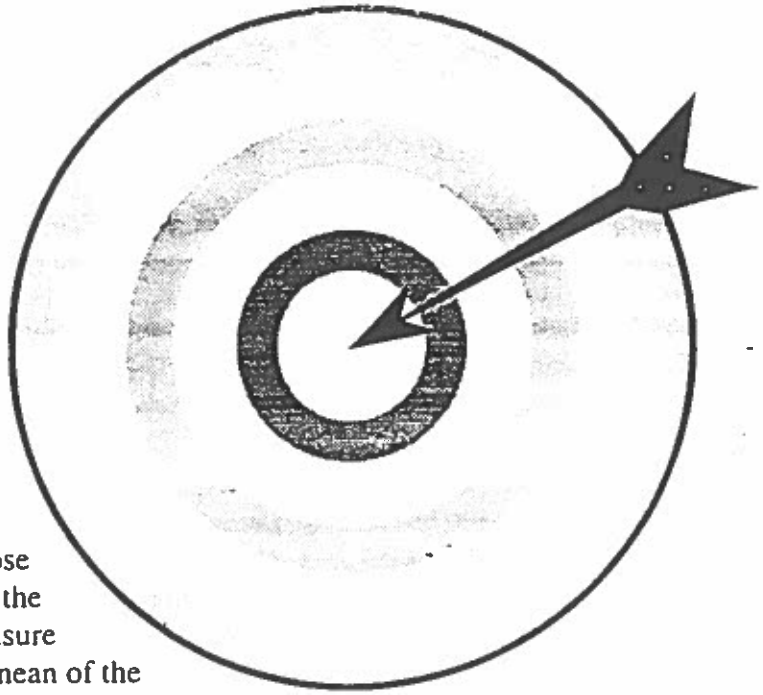
Risk assessors have found that groundwater pollutant concentration data collected during the remedial investigation often are insufficient to support a statistically meaningful average. For groundwater, the exposure area is difficult to define, and due to the expense and labor required to install monitoring wells, adequate data may not be available for risk analysis use. If the available data cannot support statistical calculation of a pollutant's average concentration, the risk assessor is forced to calculate risk values from a single concentration measurement, usually relying on a maximum value. This approach provides very low scientific confidence, as a single measurement cannot represent the contamination present in the entire plume. Thus, the risk assessors and site managers must reach a compromise between the desire for the optimum amount of data and the cost of installing and sampling wells.

For More Information

Additional information on Superfund's policy and approach to calculating risk at groundwater sites can be obtained in:

- U.S. EPA, *Risk Assessment Guidance for Superfund (RAGS): Volume I—Human Health Evaluation Manual (Part A)*, EPA/540/1-89/002, December 1989.
- U.S. EPA, *Supplemental Guidance to RAGS: Calculating the Concentration Term*, Publication 9285.7-081, March 1992.
- U.S. EPA, *Guidance for Data Usability in Risk Assessment*, EPA/540/G-90/008 (OSWER Directive 9285.7OS), October 1990.
- U.S. EPA, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, memorandum from F. Henry Habicht II to Assistant and Regional Administrators, February 26, 1993. (Available from the Office of the Administrator.)
- U.S. EPA, *Guidance Document for Providing Alternate Water Supplies*, EPA/540/G-87/006 (OSWER Directive 9355.3-03), February 1988. (Available from the Superfund Document Center at 202/260-9760.)
- U.S. EPA, *National Oil and Hazardous Substances Pollution Contingency Plan (The NCP)*, Publication 9200.2-14, January 1992.

Targeting Groundwater Risk



Members of the Groundwater Forum provided the following description of a groundwater site investigation. First, they stated that it is common practice in the initial phases of a groundwater site investigation to install between five to six wells across the site, targeting source areas and potential downgradient migration. Second, around wells with high hits, one or two additional wells may be installed to further define the "center of the plume." Finally, once the "center" has been located, future efforts focus on defining the extent of contamination downgradient of the "center." The number of sampling rounds varies from site to site, but four quarters' worth of data will provide a very good picture of the influence of seasonal changes on the level of the water table.

Although other exposure estimates are made, the NCP directs that the risk assessment focus on estimating an RME. Therefore, it is appropriate for the assessor to target data from wells in the "center" of the plume. As stated above, the assessor may have data from only two or three wells, and calculation of a meaningful UCL_{95} requires 10 to 20 samples. The primary purpose of calculating the UCL_{95} is to ensure that the true mean of the entire site would not be underestimated, as is common with limited data sets. However, in this case, we are targeting data from the more highly contaminated area of the plume, and it is unlikely that the site-wide average will be underestimated. Thus, for the concentration term in groundwater risk assessments, it is sufficient to take the simple arithmetic average of sample data obtained from two to three wells in the "center" of the plume. Again, to account for the impact of seasonal variations, data from at least two quarters is required, and data from four quarters is preferred.

This guidance is most applicable to sites where groundwater is not currently used for drinking water. For residential wells that are currently in use, action may be taken where "Removal Action Levels" are exceeded. This action can be taken based on one round of sampling with confirmation analyses.

Issues to Consider Jointly at Each Site

Our discussions with the Groundwater Forum produced the following list of issues that Regional risk assessors and hydrogeologists should explore together on a site-specific basis.

Speed of Plume Movement

- Plumes move at different rates, but few are static. This fact underscores the indefensibility of using one data point to represent a long-term exposure point concentration.
- Also, speed of plume movement can affect duration of exposure to contaminants, leading to either acute or chronic exposure.

Hydraulic Forces in the Aquifer

- Contaminants in a plume are subject to a variety of forces that can retard migration or attenuate the concentration over time. Even quarterly sample data over a year's time represents only a "snapshot" of contaminant levels that may not be representative of the true long-term exposure point concentration.

Width/Size of Capture Zone

- The true exposure area for groundwater is the area "captured" by a residential pumping well. The area defined as the "center" of the plume may be different.

Type of Well

Residential, municipal, or monitoring

- Residential wells usually pump on the order of 1 to 5 gallons per minute, and data obtained from monitoring wells may not reflect the type of exposure in a residential setting. A more representative estimate of exposure point concentration may be achieved by modeling the impact of a pumping well in the "center" of the plume.
- Municipal wells or well fields can differ substantially in construction and pumping capacity from monitoring wells.

ATTACHMENT N

A BIBLIOGRAPHY RELATED TO ECOLOGICAL RISK ASSESSMENT

This bibliography is based on a limited literature search and review and is not a complete list of documents related to ecological risk assessment.

U.S. ENVIRONMENTAL PROTECTION AGENCY GUIDANCE

U.S. Environmental Protection Agency. 1994. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.* Environmental Response Team. Edison, New Jersey. September.

This proposed agency-wide guidance document describes an accepted process for designing and conducting ecological risk assessments under the Superfund program, including methods for calculating risk-based cleanup levels. The final version of this guidance document will supersede *Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual*, which still can be used as a basic tutorial on Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) ecological risk assessment.

EPA. 1993 and 1994. *A Review of Ecological Assessment Case Studies From a Risk Assessment Perspective.* Volumes 1 and 2. Risk Assessment Forum. Washington, D.C.

EPA scientists present a cross section of ecological assessment case studies. The case studies present a variety of work scopes, ecosystems, ecological endpoints, chemical and nonchemical stressors, and programmatic requirements within EPA. The approaches used in the case studies are generally consistent with some, but not all, of the principles in the *Framework for Ecological Risk Assessment* (EPA 1992). While these case studies are useful examples of the "state-of-the-practice," they should not be regarded models to be followed.

EPA. 1992. *Framework for Ecological Risk Assessment.* EPA/630/R-92/001. Risk Assessment Forum. Washington, D.C. February.

This reference should be used in conjunction with other technical guidelines since it is only a conceptual framework and is not considered a "stand alone" guidance document. The framework provides a format that facilitates consistent ecological risk assessment formulation at regulated facilities, including Resource Conservation and Recovery Act (RCRA) hazardous waste facilities.

EPA. 1989. *The Nature and Extent of Ecological Risks at Superfund Sites and RCRA Facilities.* EPA-230-03-89-043. Office of Policy Analysis. Washington, D.C. June.

This report presents the results of a study of ecological risks posed by Superfund sites and RCRA facilities. The report includes discussions of methods used in the identification of sites and review of reports, the nature and extent of ecological threats, and summaries of key findings.

EPA. 1989. *Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual.* Interim Final. EPA/540/1-89/001. Office of Solid Waste and Emergency Response. Washington, D.C. March.

Risk Assessment Guidance for Superfund (RAGS) Volume II provides conceptual guidance in planning studies to evaluate the ecology of a site, including RCRA facilities. The draft *Ecological Risk Assessment Guidance for Superfund* supersedes RAGS Volume II as guidance on how to design and conduct

ecological risk assessments. RAGS Volume II does include useful information on the regulatory and statutory bases of ecological risk assessment, basic ecological concepts, and other background information that are not presented in RAGS Volume II.

EPA. 1989. ***Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference.*** **EPA/600/3-89/013. Office of Research and Development. Washington, D.C. March.**

This document provides introductory discussions on various techniques in ecological risk assessment that may be appropriate for RCRA facilities.

The following ***ECO Updates*** are ecological risk assessment bulletins intermittently issued by the EPA that supplement RAGS Volume II. These bulletins are used to provide technical information that pertains to various aspects of ecological risk assessment. The bulletins do not constitute rule making by the EPA. There are currently three volumes of ***ECO Updates*** containing specific topics as follows:

Volume 1:

EPA. 1991. ***The Role of BTAGs in Ecological Assessment.*** **Volume 1. Number 1. Office of Solid Waste and Emergency Response. Washington, D.C. September.**

This bulletin summarizes the Biological Technical Assistance Group (BTAG) structure and function in the CERCLA process. It explains how the BTAG can assist project managers in evaluating ecological risks.

EPA. 1991. ***Ecological Assessment of Superfund Sites: An Overview.*** **Volume 1. Number 2. Office of Solid Waste and Emergency Response. Washington, D.C. December.**

This bulletin provides an updated framework for ecological assessment in the Superfund (or CERCLA) program. It describes ecological assessment components and how they fit into the remedial investigation and feasibility study (RI/FS) process.

EPA. 1992. ***The Role of Natural Resource Trustees in the Superfund Process.*** **Volume 1. Number 3. Office of Solid Waste and Emergency Response. Washington, D.C. March.**

This bulletin facilitates the working relationship between project managers involved in site cleanup and natural resource trustees. It also helps ensure compliance with applicable or relevant and appropriate requirements (ARAR) and increases understanding of trustee issues relevant to the CERCLA process.

EPA. 1992. ***Developing a Work Scope for Ecological Assessments.*** **1992. Volume 1. Number 4. Office of Solid Waste and Emergency Response. Washington, D.C. May.**

This bulletin helps project managers involved in site cleanup to plan and manage ecological assessments as part of the RI/FS process under CERCLA. It includes information on project scoping, preparing statements of work, and work plan development.

EPA. 1992. ***Briefing the BTAG: Initial Description of Setting, History, and Ecology of a Site.*** **Volume 1. Number 5. Office of Solid Waste and Emergency Response. Washington, D.C. August.**

This bulletin focuses on the first opportunity (usually in the early RI planning stage) that a project manager has for conferring with the BTAG about possible ecological effects at a site. Pertinent information to present to the BTAG includes the site's setting and history, constituents expected, and ecological characteristics.

Volume 2:

EPA. 1994. *Using Toxicity Tests in Ecological Risk Assessment.* Volume 2. Number 1. Office of Solid Waste and Emergency Response. Washington, D.C. September.

This bulletin presents measurement endpoints in toxicity testing, elements in a toxicity assessment, and general guidelines for selecting toxicity tests. These tests may help to determine whether concentrations of COPECs detected in site media are high enough to cause adverse effects in organisms; demonstrate whether constituents are bioavailable; evaluate the aggregate toxic effects of all hazardous constituents in a medium; and evaluate the toxicity of substances whose biological effects are not well understood.

EPA. 1994. *Catalogue of Standard Toxicity Tests for Ecological Risk Assessment.* 1994. Volume 2. Number 2. Office of Solid Waste and Emergency Response. Washington, D.C. September.

This bulletin consists of a list of standardized aquatic, sediment, terrestrial, and microbial toxicity tests used at CERCLA sites. It indicates source documents that more fully describe test protocols.

EPA. 1994. *Field Studies for Ecological Risk Assessment.* Volume 2. Number 3. Office of Solid Waste and Emergency Response. Washington, D.C. September.

This bulletin addresses ecological field studies as part of the ecological risk assessment that occur in the area of ecological concern at a site. It covers important considerations such as the organisms to be evaluated in the field study and elements in the design of a field study. A catalogue of field methods is also presented.

EPA. 1994. *Selecting and Using Reference Information in Superfund Ecological Risk Assessments.* Volume 2. Number 4. Office of Solid Waste and Emergency Response. Washington, D.C. September.

This bulletin summarizes methods for identifying and using reference information sources such as existing relevant data, mathematical models, and new data collected from unimpacted or reference sites.

Volume 3:

EPA. 1996. *Ecological Significance and Selection of Candidate Assessment Endpoints.* Volume 3. Number 1. Office of Solid Waste and Emergency Response. Washington, D.C. January.

This bulletin helps project managers identify ecological elements at a site, estimate their relative value and significance in the ecosystem, and identify potential assessment endpoints.

EPA. 1996. *Ecotox Thresholds.* Volume 3. Number 2. Office of Solid Waste and Emergency Response. Washington, D.C. January.

This bulletin describes how ecotoxicological values are to be used for screening purposes in the Superfund ecological risk assessment process. It summarizes the methodologies used to calculate ecotox thresholds for each medium and discusses limitations of using ecotox thresholds.

REGION-SPECIFIC U.S. ENVIRONMENTAL PROTECTION AGENCY GUIDANCE

Region 1

EPA. 1989. *Supplemental Risk Assessment Guidance for the Superfund Program - Part 2: Guidance for Ecological Risk Assessments.* EPA/901/5-69/01. Risk Assessment Work Group. Boston, Massachusetts.

This manual reviews elements of the ecological risk assessment process and the types of data needed to evaluate risks to ecological receptors.

Region 3

EPA. 1994. *Interim Ecological Risk Assessment Guidelines.* 9107-4431. Hazardous Waste Management Division. Philadelphia, Pennsylvania.

This draft document briefly summarizes three levels of ecological risk assessment: the screening level, the semiquantitative level, and the quantitative level.

Region 4

EPA. 1995. *Supplemental Guidance to RAGS: Region 4 Bulletins - Ecological Risk Assessment.* Draft. Office of Health Assessment. Atlanta, Georgia. November.

This draft document includes bulletins that discuss preliminary risk evaluation or screening-level ecological risk assessment, ecological screening values used to identify COPECs in the screening-level ecological risk assessment, assessment and measurement endpoint selection based on the results of the screening-level ecological risk assessment, and inclusion of natural resource trustees in the CERCLA process.

Region 5

EPA. 1992. *Regional Guidance for Conducting Ecological Assessments.* Draft final. Chicago, Illinois. April.

This reference supplements existing CERCLA guidelines; it outlines a framework for conducting ecological assessments at Superfund sites.

EPA. 1994. *Ecological Risk Assessment Guidance for RCRA Corrective Action.* Interim draft. Waste Management Division. Chicago, Illinois. July.

This is a draft document that discusses ecological risk assessment and how to effectively integrate risk assessment and corrective action processes.

Region 7

EPA. 1995. ***Assessing Ecological Risk at RCRA Hazardous Waste Treatment, Storage, and Disposal Facilities: A Project Manager's Guide.*** **Kansas City, Kansas. June.**

This guide is design to help project managers and risk managers that are unfamiliar with ecological concepts used in ecological risk assessment. The focus is on evaluating ecological risks posed by RCRA treatment, storage, and disposal (TSD) facilities in Region 7. The guide relies primarily on CERCLA guidance to provide the framework for ecological risk assessment at RCRA TSD facilities in Region 7.

Region 8

EPA. 1994. ***Operation of the Ecological Technical Assistance Group (ETAG) for EPA Region VIII Ecological Risk Assessments.*** **ER-01. Hazardous Waste Management Division. September.**

This technical guidance describes the goals of the ETAG (or BTAG) for CERCLA ecological risk assessments in Region 8. ETAGs and BTAGs help EPA achieve better and more consistent ecological risk assessments at CERCLA sites.

Region 10

EPA. 1995. ***Supplemental Risk Assessment Guidance for Superfund.*** **Draft. Seattle, Washington. December.**

This draft guidance incorporates CERCLA human health and ecological risk assessment guidance. It summarizes important concepts for the agency-wide guidance, highlights steps of the CERCLA RI/FS process in which risk assessors need to be involved, and identifies specific deliverables required by EPA Region 10 during the development of baseline risk assessments.

DEPARTMENT OF ENERGY GUIDANCE

U.S. Department of Energy (DOE). 1996. ***Screening Benchmarks for Ecological Risk Assessment.*** **Version 1.5 (computer database program). Oak Ridge National Laboratory. Oak Ridge, Tennessee. January.**

Note: Screening benchmarks approved for use at some DOE facilities are formatted in a computer database format. The database provides screening values for aquatic biota, wildlife, terrestrial plants, sediment-associated organisms, and soil and litter organisms. The sources and derivation of these screening values are presented in the following DOE documents.

Suter II, G.W. and J.B. Mabrey. 1994. *Toxicological Benchmarks for Screening of Potential Contaminants of Concern for Effects on Aquatic Biota on Oak Ridge Reservation: 1994 Revision.* ES/ER/TM-96. Oak Ridge National Laboratory. Oak Ridge, Tennessee.

Opresko, D.M., B.E. Sample, and G.W. Suter II. 1995. *Toxicological Benchmarks for Wildlife: 1995 Revision.* ES/ER/TM-86/R2. Oak Ridge National Laboratory. Oak Ridge, Tennessee.

Will, M.E. and G.W. Suter II. 1995. *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants: 1995 Revision.* ES/ER/TM-85-R2. Oak Ridge National Laboratory. Oak Ridge, Tennessee.

Suter II, G.W., and R.N. Hull. 1994. *Toxicological Benchmarks for Screening Contaminants of Potential Concern for Effects on Sediment-Associated Biota: 1994 Revision.* ES/ER/TM-95/R1. Oak Ridge National Laboratory. Oak Ridge, Tennessee.

Will, M.E. and G.W. Suter II. 1995. *Toxicological Benchmarks for Potential Contaminants of Concern for Effects on Soil and Litter Invertebrates and Heterotrophic Process.* ES/ER/TM-126/R1. Oak Ridge National Laboratory. Oak Ridge, Tennessee.

Barnthouse, L.W., et al. 1992. *Survey of Ecological Risk Assessment at DOE Facilities.* NTIS Accession Number: DE93000972/XAB. Oak Ridge National Laboratory. Oak Ridge, Tennessee.

This document is a survey of ecological risk assessment procedures at a subset of major DOE facilities. The survey identifies ecological risk assessment approaches used by DOE and its contractors. It documents lessons learned with these approaches. The survey identifies new technical developments and approaches that may apply to DOE facilities. The report also identifies major data needs, data resources, and methodological deficiencies.

Suter II, G.W. 1994. *Approach and Strategy for Performing Ecological Risk Assessments for the U.S. Department of Energy's Oak Ridge Reservation.* ES/ER/TM-33/R1. Oak Ridge National Laboratory. Oak Ridge, Tennessee. August.

This document includes guidelines on developing conceptual models for the ecological risk assessment process, selecting assessment and measurement endpoints, specific data requirements, and risk characterization.

DEPARTMENT OF DEFENSE GUIDANCE

LaPoint, T.W., M. Simini, J.D. Florian, Jr., and R.S. Wentsel. 1995. *Procedural Guidelines for Ecological Risk Assessments at U.S. Army Sites - Volume 2: Research and Biomonitoring Methods for the Characterization of Ecological Effects.* Report Number: ERDEC-TR-221. Aberdeen Proving Ground, Maryland. February.

Volume 2 contains information about more than 100 environmental models and test methods used in ecological risk assessment. The methodologies are designed to assist risk assessors in selecting appropriate models and tests that are relevant to ecological hypotheses and goals of RIs and FSs.

Wentsel, R.S., T.W. LaPoint, M. Simini, D. Ludwig, and L. Brewer. 1994. *Procedural Guidelines for Ecological Risk Assessments at U.S. Army Sites - Volume 1.* Report Number: ERDEC-TR-221. Aberdeen Proving Ground, Maryland. December.

Volume 1 provides ecological risk assessment guidance for U.S. Army National Priority sites and sites listed under the Base Realignment and Closure program. This report provides an enhanced understanding of CERCLA guidance, cost-effective and tiered procedures, and a conceptual framework to standardize

ecological risk assessments at U.S. Army facilities. The conceptual framework is based on EPA's agency-wide framework.

NATIONAL OCEANIC and ATMOSPHERIC ADMINISTRATION GUIDANCE

Long, E.R. and L.G. Morgan. 1990. *The Potential for Biological Effects of Sediment-Sorbed Contaminants Tested in the National Status and Trends Program.* Technical memorandum NOS OMA 52. March.

This report assesses the potential for adverse biological effects through exposure of biota to hazardous constituents in sediments sampled and analyzed under the National Status and Trends Program. Guidelines for assessing potential effects are included and were developed from data assembled for a variety of approaches and many geographic areas.

Long, E.R. 1992. *Ranges in chemical concentrations in Sediments Associated with Adverse Biological Effects.* Marine Pollution Bulletin 24. Volume 1. Pages 38-45.

Data derived from many geographic regions, methods, and approaches are evaluated in this paper to identify the ranges in chemical concentrations associated with adverse biological effects. Data from three basic approaches to determining health-based criteria were evaluated: the equilibrium partitioning approach, the spiked-sediment bioassay approach, and various methods of evaluating biological and chemical data collected during field surveys.

Long, E.R. et al. 1995. "Incidence of Adverse Biological Effects Within Ranges of Chemical Concentrations in Marine and Estuarine Sediments." *Environmental Management.* 19(1): 81-97.

This paper presents effects range-low (ER-L) and effects range-median (ER-M) guideline values for selected chemicals, based on biological and chemical data compiled from numerous modeling, laboratory, and field studies performed in marine and estuarine sediments. The incidence of adverse effects was quantified within 3 separate concentration ranges for the selected chemicals.

AMERICAN SOCIETY for TESTING and MATERIALS GUIDANCE

American Society for Testing and Materials (ASTM). 1996. *Standard Guide for Selecting and Using Ecological Endpoints for Contaminated Sites.* Draft. ASTM subcommittee E-47.13. January.

This guide presents an approach to identifying, selecting, and using assessment and measurement endpoints that may be affected by direct or indirect chemical and nonchemical stressors associated with wastes and contaminated media at specific sites under current and future land uses. **NOTE:** According to ASTM, this document is a draft and not an ASTM standard. As such, it has not been approved by ASTM. The final approved version of this draft may or may not include the same information as it appears in this draft. For more information on this draft, contact ASTM at 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428.

ASTM. 1995. *Standard Guide for Developing Conceptual Site Models for Contaminated Sites.* STP E-1689. ASTM. Philadelphia, Pennsylvania.

This guide assists in the development of conceptual site models used to integrate technical information, support sampling design elements such as identifying data needs and data collection activities, and evaluate risk to human health and the environment posed by a contaminated site.

Gorsuch, J.W., J. Dwyer, C. Ingersoll, and T.W. LaPoint, editors. 1993. *Environmental Toxicology and Risk Assessment - Volume 2.* ASTM STP 1216. ISBN 0-8031-1485-0. Philadelphia, Pennsylvania.

This document presents 48 papers on new research techniques, findings concerning various environmental stressors, and the application of techniques and processes of environmental assessment. Specific topics include aquatic toxicology and the use of experimental ecosystems, plants for toxicity assessments, and sediment toxicology.

Hughes, J.S., G.R. Biddinger, and E. Mones, editors. 1995. *Environmental Toxicology and Risk Assessment - Volume 3.* ASTM STP 1218. ISBN 0-8031-1485-0. Philadelphia, Pennsylvania.

This text provides a comprehensive overview of the current status of ecological risk assessment and suggested advances. Also, 22 papers are presented on topics such as models in ecological risk assessment, ecotoxicology and the measurement of ecological effects at various sites, fate and effects of chemicals, and the development and refinement of new methods to evaluate exposure and toxicity.

Landis, W.G., J.S. Hughes, and M.A. Lewis, editors. 1993. *Environmental Toxicology and Risk Assessment.* ASTM STP 1179. ISBN 0-8931-1860-0. ASTM. Philadelphia, Pennsylvania.

This document presents 28 papers addressing such topics as evaluating ecological impacts at the population and community levels, biomarkers, and marine toxicity test methods and methods development. Other topics include evaluating regulatory concerns, basic research, risk and hazard assessment, and methods development in environmental toxicology.

CANADIAN GUIDANCE

Canadian Council of Ministers of the Environment (CCME). 1996. *A Framework for Ecological Risk Assessment-General Guidance.* National Contaminated Sites Remediation Program. March.

This document provides general guidance for using the framework for ecological risk assessment at contaminated sites in Canada. Topics include planning ecological risk assessments, screening-level assessments, and preliminary and detailed quantitative ecological risk assessments.

CCME. 1996. *A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines.* National Contaminated Sites Remediation Program. March.

This document includes rationale and guidance for developing environmental and human health soil quality guidelines for contaminated sites in Canada. Topics include derivation of environmental soil quality guidelines, relevant endpoints for deriving soil quality guidelines, potential ecological receptors and exposure pathways of soil contamination, and uncertainties in guidelines derivation.

CCME. 1995. *Protocol for the Derivation of Canadian Sediment Quality Guidelines for the Protection of Aquatic Life.* CCME EPC-98E. Environment Canada. Ottawa, Canada. March.

These guidelines can be used to assess sediment quality, help set goals for sediment quality that will sustain aquatic system health for the long term, and develop site-specific objectives. The document outlines procedures for deriving scientifically defensible sediment quality guidelines for the protection of aquatic life. The document also discusses the use of sediment quality guidelines as benchmarks, the National Status and Trends Program (NSTP) approach, the spiked-sediment toxicity approach, and derivation of safety factors.

Gaudet, C. 1994. *A Framework for Ecological Risk Assessment at Contaminated Sites in Canada: Review and Recommendations*. Scientific Series Number 199. Environment Canada. Ottawa, Canada.

This document presents the ecological risk assessment framework for the National Contaminated Sites Remediation Program. The framework includes a tiered approach to ecological risk assessment. The document discusses ecological risk assessment components such as problem definition, exposure assessment, receptor characterization, hazard assessment, and risk characterization.

Jaagumagi, R. 1993. *Development of the Ontario Provincial Sediment Quality Guidelines for Arsenic, Cadmium, Chromium, Copper, Iron, Lead, Manganese, Mercury, Nickel, and Zinc*. ISBN 0-7729-9249-5. Ontario Ministry of the Environment. Canada. August.

This document describes the derivation of the metals guidelines and summarizes data used to derive the values listed in the guidelines. The document also summarizes properties and fate of the metals, describes the forms in which metals can exist in sediments, and provides details of the calculations used to arrive at the sediment quality guidelines.

Jaagumagi, R. 1994. *Development of the Ontario Provincial Sediment Quality Guidelines for Polycyclic Aromatic Hydrocarbons*. ISBN 0-7778-1710-1. Ontario Ministry of the Environment. Canada. January.

This document describes the derivation of the guidelines for 12 individual polycyclic aromatic hydrocarbons (PAH) as well as total PAH and summarizes data used to derive these values. The document also summarizes the fate of PAHs in sediments, and provides details of the calculations of the sediment quality guidelines.

Keddy, C., J.C. Greene, and M.A. Bonnell. 1994. *A Review of Whole Organism Bioassays for Assessing the Quality of Soil, Freshwater Sediment, and Freshwater in Canada*. Scientific Series Number 198. Ecosystem Conservation Directorate. Ontario, Canada.

This report addresses application of recommended bioassays to site assessment and remediation. The report identifies potentially suitable test methods, assesses their applicability, and recommends tests for soil, freshwater sediment, and fresh water. The report also evaluates the future for hazardous constituent assessment using biological organisms, including alternative test endpoints, in situ tests, and assessment beyond whole organisms and fresh water, such as methods for assessing impacts to microbial processes and multispecies testing.

Persaud, D., R. Jaagumagi, and A. Hayton. 1993. *Guidelines for the Protection and Management of Aquatic Sediment Quality in Ontario*. ISBN 0-7729-9248-7. Ontario Minister of the Environment. Canada. August.

The purpose of the sediment quality guidelines is to protect aquatic systems by setting safe concentrations for metals, nutrients, and organic compounds. The guidelines help decision makers with sediment issues, including determining which sediments are contaminated and how to effectively manage the problem. The guidelines establish three levels of effect: no effect level, lowest effect level, and severe effect level.

ADDITIONAL GUIDANCE

Bartell, S.M., R.H. Gardner, and R.V. O'Neill. 1992. *Ecological Risk Estimation*. ISBN 0-873711637. Lewis Publishers. Chelsea, Michigan.

This publication presents an approach to estimating ecological risks using laboratory toxicity data to predict ecological consequences of toxic chemicals. The text includes discussions of the following subjects: toxicological and ecological data for risk analysis, modeling aquatic ecosystems, modeling sublethal toxic effects, predicting risks, evaluating predictive methodology, and comparisons of predicted and measured effects.

Burmaster, D.E. and P.D. Anderson. 1994. "Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessment." *Risk Analysis*. Volume 14. Pages 477-481.

This paper proposes 14 principles of good practice in performing and reviewing probabilistic or Monte Carlo risk assessments of toxic chemicals in the environment. Monte Carlo risk assessments that follow these principles will be easier to understand, will explicitly distinguish assumptions from data, and will consider and quantify effects that could otherwise lead to misinterpretation of the results.

Calabrese, E.J. and L.A. Baldwin. 1993. *Performing Ecological Risk Assessments*. Lewis Publishers. Chelsea, Michigan.

This text presents an extensive compilation that addresses components of an ecological risk assessment, including environmental fate modeling and pharmacokinetic factors, uncertainty factors, deriving chemical-specific and species-specific maximum acceptable tissue concentrations, and sediment quality criteria.

Cairns, J., B.R. Niederlehner, and D.R. Orvos, editors. 1992. *Predicting Ecosystem Risk*. Volume XX. Princeton Scientific Publishing Company. Princeton, New Jersey.

This text includes a series of papers on topics such as predicting ecological risks posed by changes in hydrological regime, forest management, genetically engineered microorganisms and products, highways, and radioactive materials. The use of experimental stream mesocosms in assessing risks is also discussed.

Cardwell, R., et al. 1991. *Aquatic Risk: An Assessment Report. Evaluation of the Protocols for Aquatic Ecological Risk Assessment*. Water Environment Research Foundation Order Number: D0005. Alexandria, Virginia.

This report evaluates aquatic and ecological risk models. Additional research is identified to help develop a conceptual framework to integrate, organize, and validate aquatic ecological risk assessment protocols, and to apply these protocols to water quality issues.

Clifford, P.A., D.E. Barchers, D.F. Ludwig, R.L. Sielken, J.S. Klingensmith, R.V. Graham, and M.I. Banton. 1995. "An Approach to Quantifying Spatial Components of Exposure for Ecological Risk Assessment." ***Environmental Toxicology and Chemistry.*** **Volume 14. Pages 895-906.**

This paper presents an approach to quantifying spatial components of exposure using the Geographic Information System (GIS). GIS is used to estimate spatially weighted exposure concentrations within an organism's foraging or exposure ranges. GIS is also used for comparing exposure concentrations to benchmark concentrations and presenting site-specific results in a three-dimensional format to effectively present site-specific quantified ecological risks and to provide an effective risk management decision-making tool.

International Atomic Energy Agency. 1992. ***Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards.*** **Technical Report Series Number 332. ISBN 92-0-100992-5. Vienna, Austria.**

This report addresses potential effects on plant and animal populations through chronic releases of radionuclides. The report includes reviews of available information on the effects of ionizing radiation on natural organisms and determines the doses above which there are adverse effects to plants and animals. The report also establishes whether on not plant and animal populations are adequately protected under radiation protections standards for humans.

Landis, W.G., G.B. Matthews, R.A. Matthews, and A. Sergeant. 1994. "Application of Multivariate Techniques to Endpoint Determination, Selection, and Evaluation in Ecological Risk Assessment." ***Environmental Toxicology and Chemistry.*** **Volume 13. Pages 1917 - 1927.**

The paper reviews the role of ecological endpoints and introduces and discusses the ramifications of multivariate analysis on the assessment of risk to ecological systems. Three methods are discussed in the paper: the mean strain measurement, the state-space analysis, and the nonmetric clustering method.

MacDonald, D.D. 1994. ***Approach to the Assessment of Sediment Quality in Florida Coastal Waters, Volume 1 - Development and Evaluation of Sediment Quality Assessment Guidelines.*** **MacDonald Environmental Sciences, Ltd. British Columbia, Canada. November.**

This report recommends a scientifically defensible framework for assessing the biological significance of sediment-associated hazardous constituents. Numerical sediment quality assessment guidelines (SQAG) provide the basis for assessing potential effects of sediment-associated constituents. The report reviews a variety of approaches and recommends an integrated strategy and relevant assessment tools. The SQAGs are derived from a variety of sediment quality data and are based on a weight-of-evidence approach that links constituent concentrations with adverse biological effects.

MacDonald, D.D. 1994. ***Approach to the Assessment of Sediment Quality in Florida Coastal Waters, Volume 2 - Application of the Sediment Quality Assessment Guidelines.*** **MacDonald Environmental Sciences, Ltd. British Columbia, Canada. November.**

This document assists potential users in applying SQAGs and other relevant sediment quality assessment tools. The report lists applications of SQAGs that are considered inappropriate and presents a framework for assessing the significance of sediment-associated constituents.

MacIntosh, D.L., G.W. Suter II, and F.O. Hoffman. 1994. "Use of Probabilistic Exposure Models in Ecological Risk Assessments of Contaminated Sites." *Risk Analysis.* Volume 14. Pages 405 - 419.

This paper discusses the use stochastic food web models in ecological risk assessment, particularly in estimating exposure to endpoint species as well as subsequent effects and determining cleanup levels by estimating concentrations in environmental media that will not cause significant adverse effects in endpoint species.

Maughan, J.T. 1993. *Ecological Assessment of Hazardous Waste Sites.* ISBN 0-442-01091-5. Van Nostrand Reinhold. New York, New York.

Essential technical and regulatory information necessary to plan, prepare, and implement an ecological risk assessment is presented in this text. The ecological risk assessment process is examined along with techniques for evaluating three important components of ecological risk assessments: terrestrial pathways of constituents, sediment quality and contamination, and toxicity testing.

McCarthy, J.F. and L.R. Shugart, editors. 1990. *Biomarkers of Environmental Contamination.* ISBN 0-87371-284-6. Lewis Publishers. Boca Raton, Florida.

This text provides and introduction and review of the research on biological markers in plants as well as animals and provides an approach to evaluating ecological and health effects of environmental contamination. The focus is on the development, application, and validation of biological markers as indicators of exposure to toxic chemicals or as predictors of the averse consequences of that exposure.

Peterle, T.J. 1991. *Wildlife Toxicology.* Van Nostrand Reinhold. New York, New York.

This text provides information on environmental pollution as it affects wildlife. The text covers relevant laws and regulations, materials found in environmental pollutants, transport and distribution in natural systems, accumulation in organisms, lethal and chronic effects on organisms, and effects on ecosystems.

Suter II, G.W. 1993. *Ecological Risk Assessment.* ISBN 0-87371-875-5. Lewis Publishers. Chelsea, Michigan.

This text emphasizes risks to aquatic systems because of the preponderance of data and modeling techniques for aquatic systems. There are also more ecological risk assessments that address aquatic rather than terrestrial systems. Predictive risk assessments are the main focus because the risk assessment paradigm is based on predictive assessments. A chapter in the text is dedicated to retrospective assessments. Chemical, physical, and biological stressors are discussed in the text. Effects of exposure to chemicals and fate and transport of chemicals are discussed. This text also refers to other literature concerning ecological risk assessment.

Suter II, G.W. 1990. "Endpoints for Regional Ecological Risk Assessments." *Environmental Management.* Volume 14. Pages 19 - 23.

This article distinguishes between assessment and measurement endpoints in terms of their roles in ecological risk assessment. Topics include endpoint selection criteria and regional ecosystem effects.

ATTACHMENT O

EPA GUIDANCE AND POLICY FOR PROBABILISTIC RISK ASSESSMENT

EPA | U.S. Environmental Protection Agency • Office of Research and Development

POLICY FOR USE OF PROBABILISTIC ANALYSIS IN RISK ASSESSMENT

at the U.S. Environmental Protection Agency

May 15, 1997

Guiding Principles for Monte Carlo Analysis (EPA/630/R-97/001)

INTRODUCTION

The importance of adequately characterizing variability and uncertainty in risk assessments has been emphasized in several science and policy documents. These include the 1992 U.S. Environmental Protection Agency (EPA) Exposure Assessment Guidelines, the 1992 EPA Risk Assessment Council (RAC) Guidance, the 1995 EPA Policy for Risk Characterization, the EPA Proposed Guidelines for Ecological Risk Assessment, the EPA Region 3 Technical Guidance Manual on Risk Assessment, the EPA Region 8 Superfund Technical Guidance, the 1994 National Academy of Sciences "Science and Judgment in Risk Assessment," and the report by the Commission on Risk Assessment and Risk Management. As part of the implementation of the recommendations contained in these reports, the Agency is issuing guidance on the appropriate use of an application for analyzing variability and uncertainty in Agency risk assessments.

This policy and the guiding principles attached are designed to support the use of various techniques for characterizing variability and uncertainty. Further, the policy defines a set of Conditions for Acceptance. These conditions are important for ensuring good scientific practice in quantifying uncertainty and variability. In accordance with EPA's 1995 Policy for Risk Characterization, this policy also emphasizes the importance of clarity, transparency, reasonableness, and consistency in risk assessments.

There are a variety of different methods for characterizing uncertainty and variability. These methods cover a broad range of complexity from the simple comparison of discrete points to probabilistic techniques like Monte Carlo analysis. Recently, interest in using Monte Carlo analysis for risk assessment has increased. This method has the advantage of allowing the analyst to account for relationships between input variables and of providing the flexibility to investigate the effects of different modeling assumptions. Experience has shown that to benefit fully from the advantages of such probabilistic techniques as Monte Carlo analysis, certain standards of practice are to be observed. The Agency is issuing, therefore, this policy statement and associated guiding principles. While Monte Carlo analysis is the most frequently encountered probabilistic tool for analyzing variability and uncertainty in risk assessments, the intent of this policy is not to indicate that Monte Carlo analysis is the only acceptable approach for Agency risk assessments. The spirit of this policy and the Conditions for Acceptance described herein are equally applicable to other methods for analyzing variability and uncertainty.

POLICY STATEMENT

It is the policy of the U.S. Environmental Protection Agency that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments. As such, and provided that the conditions described below are met, risk assessments using Monte Carlo analysis or other probabilistic techniques will be evaluated and utilized in a manner that is consistent with other risk assessments submitted to the Agency for review or consideration. It is not the intent of this policy to recommend that probabilistic analysis be conducted for all risk assessments supporting risk management decisions. Such analysis should be a part of a tiered approach to risk assessment that progresses from simpler (e.g., deterministic) to more complex (e.g., probabilistic) analyses as the risk management situation requires. Use of Monte Carlo or other such techniques in risk assessments shall not be cause, *per se*, for rejection of the risk assessment by the Agency. For human health risk assessments, the application of Monte Carlo and other probabilistic techniques has been limited to exposure assessments in the majority of cases. The current policy, Conditions for Acceptance and associated guiding principles are not intended to apply to dose response evaluations for human health risk assessment until this application of probabilistic analysis has been studied further. In the case of ecological risk assessment, however, this policy applies to all aspects including stressor and dose-response assessment.

CONDITIONS FOR ACCEPTANCE

When risk assessments using probabilistic analysis techniques (including Monte Carlo analysis) are submitted to the Agency for review and evaluation, the following conditions are to be satisfied to ensure high quality science. These conditions, related to the good scientific practices of transparency, reproducibility, and the use of sound methods, are summarized here and explained more fully in the Attachment, "Guiding Principles for Monte Carlo Analysis."

1. The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.
2. The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report. This documentation is to include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation is to include the names of the models and software used to generate the analysis. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced.
3. The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.
4. The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.
5. Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of the distributions (e.g., probability density function and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible.
6. The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions are to be presented and discussed.
7. Calculations of exposures and risks using deterministic (e.g., point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening level risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are

answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.

8. Since fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity metrics (e.g., Reference Doses, Reference Concentrations, unit cancer risk factors), the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.

LEGAL EFFECT

This policy and associated guidance on probabilistic analysis techniques do not establish or affect legal rights or obligations. Rather, they confirm the Agency position that probabilistic techniques can be viable statistical tools for analyzing variability and uncertainty in some risk assessments. Further, they outline relevant Conditions for Acceptance and identify factors Agency staff should consider in implementing the policy.

The policy and associated guidance do not stand alone; nor do they establish a binding norm that is finally determinative of the issues addressed. Except where otherwise provided by law, the Agency's decision on conducting a risk assessment in any particular case is within the Agency's discretion. Variations in the application of the policy and associated guidance, therefore, are not a legitimate basis for delaying action on Agency decisions.

IMPLEMENTATION

Assistant Administrators and Regional Administrators are responsible for implementation of this policy within their organizational units. The implementation strategy is divided into immediate and follow-up activities.

Immediate Activities

To assist EPA program and regional offices with this implementation, initial guidance on the use of one probabilistic analysis tool, Monte Carlo analysis, is provided in the Attachment, "Guiding Principles for Monte Carlo Analysis" (EPA/630/R-97/001). The focus of this guidance is on Monte Carlo analysis because it is the most frequently encountered technique in human health risk assessments. Additional information may be found in the "Summary Report for the Workshop on Monte Carlo Analysis" (EPA/630/R-96/010). This report summarizes discussions held during the May 1996 Risk Assessment Forum sponsored workshop that involved leading experts in Monte Carlo analysis.

Follow-Up Activities

To prepare for the use and evaluation of probabilistic analysis methods, including Monte Carlo analysis, within the next year, EPA's Risk Assessment Forum (RAF) will develop illustrative case studies for use as guidance and training tools. Further, the RAF will organize workshops or colloquia to facilitate the development of distributions for selected exposure factors. EPA's National Center for Environmental Assessment (NCEA) will develop an Agency training course on probabilistic analysis methods, including Monte Carlo analysis for both risk assessors and risk managers which will become available during Fiscal Year (FY) 1997 or FY 1998. Also, NCEA will develop detailed technical guidance for the quantitative analysis of variability and uncertainty.

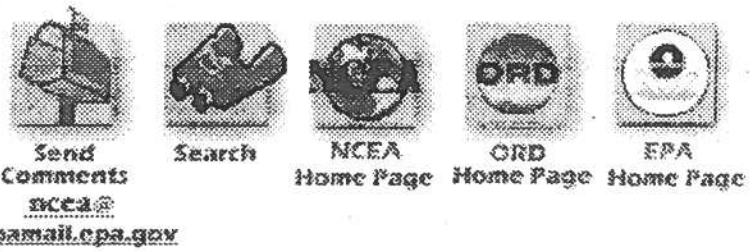
In the longer term, various Regions, Programs and the Office of Research and Development (ORD) may need to modify existing or develop new guidelines or models to facilitate use of such techniques as Monte Carlo analysis. Also, the NCEA will revise or update the Exposure Factors Handbook to include distributional

information. ORD's National Exposure Research Laboratory

(NERL) has formed a modeling group that may provide assessment and analysis advice to Program and Regional Offices. The issue of using probabilistic techniques, including Monte Carlo analysis in the dose response portion of human health risk assessments requires further study. NCEA will conduct research in this area and additional guidance will be provided if necessary.

Fred Hansen

Deputy Administrator



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EPA/630/R-97/001
March 1997

Guiding Principles for Monte Carlo Analysis

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DISCLAIMER

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TABLE OF CONTENTS

PREFACE

The U.S. Environmental Protection Agency (EPA) Risk Assessment Forum was established to promote scientific consensus on risk assessment issues and to ensure that this consensus is incorporated into appropriate risk assessment guidance. To accomplish this, the Risk Assessment Forum assembles experts throughout EPA in a formal process to study and report on these issues from an Agency-wide perspective. For major risk assessment activities, the Risk Assessment Forum has established Technical Panels to conduct scientific reviews and analyses. Members are chosen to assure that necessary technical expertise is available.

This report is part of a continuing effort to develop guidance covering the use of probabilistic techniques in Agency risk assessments. This report draws heavily on the recommendations from a May 1996 workshop organized by the Risk Assessment Forum that convened experts and practitioners in the use of Monte Carlo analysis, internal as well as external to EPA, to discuss the issues and advance the development of guiding principles concerning how to prepare or review an assessment based on use of Monte Carlo analysis. The conclusions and recommendations that emerged from these discussions are summarized in the report "Summary Report for the Workshop on Monte Carlo Analysis" (EPA/630/R-96/010). Subsequent to the workshop, the Risk Assessment Forum organized a Technical Panel to consider the workshop recommendations and to develop an initial set of principles to guide Agency risk assessors in the use of probabilistic analysis tools including Monte Carlo analysis. It is anticipated that there will be need for further expansion and revision of these guiding principles as Agency risk assessors gain experience in their application.

Introduction

The importance of adequately characterizing variability and uncertainty in fate, transport, exposure, and dose-response assessments for human health and ecological risk assessments has been emphasized in several U.S. Environmental Protection Agency (EPA) documents and activities. These include:

- the 1986 Risk Assessment Guidelines;
- the 1992 Risk Assessment Council (RAC) Guidance (the *Habicht memorandum*);
- the 1992 Exposure Assessment Guidelines; and
- the 1995 Policy for Risk Characterization (the *Browner memorandum*).

As a follow up to these activities EPA is issuing this policy and preliminary guidance on using probabilistic analysis. The policy documents the EPA's position "that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments." The policy establishes conditions that are to be satisfied by risk assessments that use probabilistic techniques. These conditions relate to the good scientific practices of clarity, consistency, transparency, reproducibility, and the use of sound methods.

The EPA policy lists the following conditions for an acceptable risk assessment that uses probabilistic analysis techniques. These conditions were derived from principles that are presented later in this document and its Appendix. Therefore, after each condition, the relevant principles are noted.

1. The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly, etc.). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.

2. The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report. This documentation is

to include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation is to include the names of the models and software used to generate the analysis. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced. (Principles 4, 5, 6, and 11)

3. The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment. (Principles 1 and 2)

4. The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution. (Principles 1 and 14)

5. Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of the distributions (e.g., probability density function and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible. (Principles 3, 7, 8, 10, 12, and 13)

6. The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions are to be presented and discussed. (Principle 9)

7. Calculations of exposures and risks using deterministic (e.g., point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening level risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models. (Principle 15).

8. Since fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity metrics (e.g., Reference Doses, Reference Concentrations, unit cancer risk factors), the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.

The following sections present a general framework and broad set of principles important for ensuring good scientific practices in the use of Monte Carlo analysis (a frequently encountered tool for evaluating uncertainty and variability). Many of the principles apply generally to the various techniques for conducting quantitative analyses of variability and uncertainty; however, the focus of the following principles is on Monte Carlo analysis. EPA recognizes that quantitative risk assessment methods and quantitative variability and uncertainty analysis are undergoing rapid development. These guiding principles are intended to serve as a minimum set of principles and are not intended to constrain or prevent the use of new or innovative improvements where scientifically defensible.

Fundamental Goals and Challenges

In the context of this policy, the basic goal of a Monte Carlo analysis is to chatacterize, quantitatively, the uncertainty and variability in estimates of exposure or risk. A secondary goal is to identify key sources of variability and uncertainty and to quantify the relative contribution of these sources to the overall variance and range of model results.

Consistent with EPA principles and policies, an analysis of variability and uncertainty should provide its audience with clear and concise information on the variability in individual exposures and risks; it should provide information on population risk (extent of harm in the exposed population); it should provide information on the distribution of exposures and risks to highly exposed or highly susceptible populations; it should describe qualitatively and quantitatively the scientific uncertainty in the models applied, the data utilized, and the specific risk estimates that are used.

Ultimately, the most important aspect of a quantitative variability and uncertainty analysis may well be the process of interaction between the risk assessor, risk manager and other interested parties that makes risk assessment into a dynamic rather than a static process. Questions for the risk assessor and risk manager to consider at the initiation of a quantitative variability and uncertainty analysis include:

- *Will the quantitative analysis of uncertainty and variability improve the risk assessment?*

- *What are the major sources of variability and uncertainty? How will variability and uncertainty be kept separate in the analysis?*

- *Are there time and resources to complete a complex analysis?*

- *Does the project warrant this level of effort?*

- *Will a quantitative estimate of uncertainty improve the decision? How will the regulatory decision be affected by this variability and uncertainty analysis?*

- *What types of skills and experience are needed to perform the analysis?*

- *Have the weaknesses and strengths of the methods been evaluated?*

- *How will the variability and uncertainty analysis be communicated to the public and decision makers?*

One of the most important challenges facing the risk assessor is to communicate, effectively, the insights an analysis of variability and uncertainty provides. It is important for the risk assessor to remember that insights will generally be qualitative in nature even though the models they derive from are quantitative. Insights can include:

- *An appreciation of the overall degree of variability and uncertainty and the confidence that can be placed in the analysis and its findings.*

- *An understanding of the key sources of variability and key sources of uncertainty and their impacts on the analysis.*

- *An understanding of the critical assumptions and their importance to the analysis and findings.*

- *An understanding of the unimportant assumptions and why they are unimportant.*

- *An understanding of the extent to which plausible alternative assumptions or models could affect any conclusions.*

- *An understanding of key scientific controversies related to the assessment and a sense of what difference they might make regarding the conclusions.*

The risk assessor should strive to present quantitative results in a manner that will clearly communicate the information they contain.

When a Monte Carlo Analysis Might Add Value to a Quantitative Risk Assessment

Not every assessment requires or warrants a quantitative characterization of variability and uncertainty. For example, it may be unnecessary to perform a Monte Carlo analysis when screening calculations show exposures or risks to be clearly below levels of concern (and the screening technique is known to significantly over-estimate exposure). As another example, it may be unnecessary to perform a Monte Carlo analysis when the costs of remediation are low.

On the other hand, there may be a number of situations in which a Monte Carlo analysis may be useful. For example, a Monte Carlo analysis may be useful when screening calculations using conservative point estimates fall above the levels of concern. Other situations could include when it is necessary to disclose the degree of bias associated with point estimates of exposure; when it is necessary to rank exposures, exposure pathways, sites or contaminants; when the cost of regulatory or remedial action is high and the exposures are marginal; or when the consequences of simplistic exposure estimates are unacceptable.

Often, a "tiered approach" may be helpful in deciding whether or not a Monte Carlo analysis can add value to the assessment and decision. In a tiered approach, one begins with a fairly simple screening level model and progresses to more sophisticated and realistic (and usually more complex) models only as warranted by the findings and value added to the decision. Throughout each of the steps in a tiered approach, soliciting input from each of the interested parties is recommended. Ultimately, whether or not a Monte Carlo analysis should be conducted is a matter of judgment, based on consideration of the intended use, the importance of the exposure assessment and the value and insights it provides to the risk assessor, risk manager, and other affected individuals or groups.

Key Terms and Their Definitions

The following section presents definitions for a number of key terms which are used throughout this document.

Bayesian

The Bayesian or subjective view is that the probability of an event is the degree of belief that a person has, given some state of knowledge, that the event will occur. In the classical or frequentist view, the probability of an event is the frequency with which an event occurs given a long sequence of identical and independent trials. In exposure assessment situations, directly representative and complete data sets are rarely available; inferences in these situations are inherently subjective. The decision as to the appropriateness of either approach (Bayesian or Classical) is based on the available data and the extent of subjectivity deemed appropriate.

Correlation, Correlation Analysis

Correlation analysis is an investigation of the measure of statistical association among random variables based on samples. Widely used measures include the *linear correlation coefficient* (also called the *product-moment correlation coefficient* or *Pearson's correlation coefficient*), and such non-parametric measures as *Spearman rank-order correlation coefficient*, and *Kendall's tau*. When the data are nonlinear, non-parametric correlation is generally considered to be more robust than linear correlation.

Cumulative Distribution Function (CDF)

The CDF is alternatively referred to in the literature as the *distribution function*, *cumulative frequency function*, or the *cumulative probability function*. The cumulative distribution function, F(x), expresses the probability the random variable X assumes a value less than or equal to some value x, $F(x) = \text{Prob}(X \leq x)$. For continuous random variables, the cumulative distribution function is obtained from the probability density function by integration, or by summation in the case of discrete random variables.

Latin Hypercube Sampling

In Monte Carlo analysis, one of two sampling schemes are generally employed: simple random sampling or Latin Hypercube sampling. Latin hypercube sampling may be viewed as a stratified sampling scheme designed to ensure that the upper or lower ends of the distributions

used in the analysis are well represented. Latin hypercube sampling is considered to be more efficient than simple random sampling, that is, it requires fewer simulations to produce the same level of precision. Latin hypercube sampling is generally recommended over simple random sampling when the model is complex or when time and resource constraints are an issue.

Monte Carlo Analysis, Monte Carlo Simulation

Monte Carlo Analysis is a computer-based method of analysis developed in the 1940's that uses statistical sampling techniques in obtaining a probabilistic approximation to the solution of a mathematical equation or model.

Parameter

Two distinct, but often confusing, definitions for parameter are used. In the first usage (preferred), parameter refers to the constants characterizing the probability density function or cumulative distribution function of a random variable. For example, if the random variable W is known to be normally distributed with mean μ and standard deviation σ, the characterizing constants μ and σ are called parameters. In the second usage, parameter is defined as the constants and independent variables which define a mathematical equation or model. For example, in the equation $Z = \alpha X + \beta Y$, the independent variables (X,Y) and the constants (α,β) are all parameters.

Probability Density Function (PDF)

The PDF is alternatively referred to in the literature as the *probability function* or the *frequency function*. For continuous random variables, that is, the random variables which can assume any value within some defined range (either finite or infinite), the probability density function expresses the probability that the random variable falls within some very small interval. For discrete random variables, that is, random variables which can only assume certain isolated or fixed values, the term *probability mass function* (PMF) is preferred over the term probability density function. PMF expresses the probability that the random variable takes on a specific value.

Random Variable

A random variable is a quantity which can take on any number of values but whose exact value cannot be known before a direct observation is made. For example, the outcome of the toss

of a pair of dice is a random variable, as is the height or weight of a person selected at random from the New York City phone book.

Representativeness

Representativeness is the degree to which a sample is characteristic of the population for which the samples are being used to make inferences.

Sensitivity, Sensitivity Analysis

Sensitivity generally refers to the variation in output of a mathematical model with respect to changes in the values of the model's input. A sensitivity analysis attempts to provide a ranking of the model's input assumptions with respect to their contribution to model output variability or uncertainty. The difficulty of a sensitivity analysis increases when the underlying model is nonlinear, nonmonotonic or when the input parameters range over several orders of magnitude. Many measures of sensitivity have been proposed. For example, the partial rank correlation coefficient and standardized rank regression coefficient have been found to be useful. Scatter plots of the output against each of the model inputs can be a very effective tool for identifying sensitivities, especially when the relationships are nonlinear. For simple models or for screening purposes, the sensitivity index can be helpful.

In a broader sense, sensitivity can refer to how conclusions may change if models, data, or assessment assumptions are changed.

Simulation

In the context of Monte Carlo analysis, simulation is the process of approximating the output of a model through repetitive random application of a model's algorithm.

Uncertainty

Uncertainty refers to *lack of knowledge* about specific factors, parameters, or models. For example, we may be uncertain about the mean concentration of a specific pollutant at a contaminated site or we may be uncertain about a specific measure of uptake (e.g., 95th percentile fish consumption rate among all adult males in the United States). Uncertainty includes *parameter uncertainty* (measurement errors, sampling errors, systematic errors), *model uncertainty* (uncertainty due to necessary simplification of real-world processes, mis-specification of the model structure, model misuse, use of inappropriate surrogate variables), and *scenario uncertainty* (descriptive errors, aggregation errors, errors in professional judgment, incomplete analysis).

Variability

Variability refers to observed differences attributable to *true heterogeneity* or diversity in a population or exposure parameter. Sources of variability are the result of natural random processes and stem from environmental, lifestyle, and genetic differences among humans. Examples include human physiological variation (e.g., natural variation in bodyweight, height, breathing rates, drinking water intake rates), weather variability, variation in soil types and differences in contaminant concentrations in the environment. Variability is usually not reducible by further measurement or study (but can be better characterized).

Preliminary Issues and Considerations

Defining the Assessment Questions

The critical first step in any exposure assessment is to develop a clear and unambiguous statement of the purpose and scope of the assessment. A clear understanding of the purpose will help to define and bound the analysis. Generally, the exposure assessment should be made as simple as possible while still including all important sources of risk. Finding the optimum match between the sophistication of the analysis and the assessment problem may be best achieved using a "tiered approach" to the analysis, that is, starting as simply as possible and sequentially employing increasingly sophisticated analyses, but only as warranted by the value added to the analysis and decision process.

Selection and Development of the Conceptual and Mathematical Models

Some Considerations in the Selection of Models

- appropriateness of the model's assumptions *vis-à-vis* the analysis objectives
- compatibility of the model input/output and linkages to other models used in the analysis
- the theoretical basis for the model
- level of aggregation, spatial and temporal scales
- resolution limits
- sensitivity to input variability and input uncertainty
- reliability of the model and code, including peer review of the theory and computer code
- verification studies, relevant field tests
- degree of acceptance by the user community
- friendliness, speed and accuracy
- staff and computer resources required

To help identify and select plausible models, the risk assessor should develop selection criteria tailored to each assessment question. The application of these criteria may dictate that different models be used for different subpopulations under study (e.g., highly exposed individuals vs. the general population). In developing these criteria, the risk assessor should consider all significant assumptions, be explicit about the uncertainties, including technical and scientific uncertainties about specific quantities, modeling uncertainties, uncertainties about functional forms, and should identify significant scientific issues about which there is uncertainty.

At any step in the analysis, the risk assessor should be aware of the manner in which alternative selections might influence the conclusions reached.

Selection and Evaluation of Available Data

After the assessment questions have been defined and conceptual models have been developed, it is necessary to compile and evaluate existing data (e.g., site specific or surrogate data) on variables important to the assessment. It is important to evaluate data quality and the extent to which the data are representative of the population under study.

Guiding Principles for Monte Carlo Analysis

This section presents a discussion of principles of good practice for Monte Carlo simulation as it may be applied to environmental assessments. It is not intended to serve as detailed technical guidance on how to conduct or evaluate an analysis of variability and uncertainty.

Selecting Input Data and Distributions for Use in Monte Carlo Analysis

1. **Conduct preliminary sensitivity analyses or numerical experiments to identify model structures, exposure pathways, and model input assumptions and parameters that make important contributions to the assessment endpoint and its overall variability and/or uncertainty.**

The capabilities of current desktop computers allow for a number of "what if" scenarios to be examined to provide insight into the effects on the analysis of selecting a particular model, including or excluding specific exposure pathways, and making certain assumptions with respect to model input parameters. The output of an analysis may be sensitive to the structure of the exposure model. Alternative plausible models should be examined to determine if structural differences have important effects on the output distribution (in both the region of central tendency and in the tails).

Numerical experiments or sensitivity analysis also should be used to identify exposure pathways that contribute significantly to or even dominate total exposure. Resources might be saved by excluding unimportant exposure pathways (e.g., those that do not contribute appreciably to the total exposure) from full probabilistic analyses or from further analyses altogether. For important pathways, the model input parameters that contribute the most to overall variability and uncertainty should be identified. Again, unimportant parameters may be excluded from full probabilistic treatment. For important parameters, empirical distributions or parametric distributions may be used. Once again, numerical experiments should be conducted to determine the sensitivity of the output to different assumptions with respect to the distributional forms of the input parameters. Identifying important pathways and parameters where assumptions about distributional form contribute significantly to overall uncertainty may aid in focusing data gathering efforts.

Dependencies or correlations between model parameters also may have a significant influence on the outcome of the analysis. The sensitivity of the analysis to various assumptions about known or suspected dependencies should be examined. Those dependencies or correlations identified as having a significant effect must be accounted for in later analyses.

Conducting a systematic sensitivity study may not be a trivial undertaking, involving significant effort on the part of the risk assessor. Risk assessors should exercise great care not to prematurely or unjustifiably eliminate pathways or parameters from full probabilistic treatment. Any parameter or pathway eliminated from full probabilistic treatment should be identified and the reasons for its elimination thoroughly discussed.

2. Restrict the use of probabilistic assessment to significant pathways and parameters.

Although specifying distributions for all or most variables in a Monte Carlo analysis is useful for exploring and characterizing the full range of variability and uncertainty, it is often unnecessary and not cost effective. If a systematic preliminary sensitivity analysis (that includes examining the effects of various assumptions about distributions) was undertaken and documented, and exposure pathways and parameters that contribute little to the assessment endpoint and its overall uncertainty and variability were identified, the risk assessor may simplify the Monte Carlo analysis by focusing on those pathways and parameters identified as significant. From a computational standpoint, a Monte Carlo analysis can include a mix of point estimates and distributions for the input parameters to the exposure model. However, the risk assessor and risk manager should continually review the basis for "fixing" certain parameters as point values to avoid the perception that these are indeed constants that are not subject to change.

3. Use data to inform the choice of input distributions for model parameters .

The choice of input distribution should always be based on all information (both qualitative and quantitative) available for a parameter. In selecting a distributional form, the risk assessor should consider the quality of the information in the database and ask a series of questions including (but not limited to):

- *Is there any mechanistic basis for choosing a distributional family?*
- *Is the shape of the distribution likely to be dictated by physical or biological properties or other mechanisms?*
- *Is the variable discrete or continuous?*

- *What are the bounds of the variable?*
- *Is the distribution skewed or symmetric?*
- *If the distribution is thought to be skewed, in which direction?*
- *What other aspects of the shape of the distribution are known?*

When data for an important parameter are limited, it may be useful to define plausible alternative scenarios to incorporate some information on the impact of that variable in the overall assessment (as done in the sensitivity analysis). In doing this, the risk assessor should select the widest distributional family consistent with the state of knowledge and should, for important parameters, test the sensitivity of the findings and conclusions to changes in distributional shape.

4. **Surrogate data can be used to develop distributions when they can be appropriately justified.**

The risk assessor should always seek representative data of the highest quality available. However, the question of how representative the available data are is often a serious issue. Many times, the available data do not represent conditions (e.g., temporal and spatial scales) in the population being assessed. The assessor should identify and evaluate the factors that introduce uncertainty into the assessment. In particular, attention should be given to potential biases that may exist in surrogate data and their implications for the representativeness of the fitted distributions.

When alternative surrogate data sets are available, care must be taken when selecting or combining sets. The risk assessor should use accepted statistical practices and techniques when combining data, consulting with the appropriate experts as needed.

Whenever possible, collect site or case specific data (even in limited quantities) to help justify the use of the distribution based on surrogate data. The use of surrogate data to develop distributions can be made more defensible when case-specific data are obtained to check the reasonableness of the distribution.

5. **When obtaining empirical data to develop input distributions for exposure model parameters, the basic tenets of environmental sampling should be followed. Further,**

particular attention should be given to the quality of information at the tails of the distribution.

As a general rule, the development of data for use in distributions should be carried out using the basic principles employed for exposure assessments. For example,

- *Receptor-based sampling in which data are obtained on the receptor or on the exposure fields relative to the receptor;*
- *Sampling at appropriate spatial or temporal scales using an appropriate stratified random sampling methodology;*
- *Using two-stage sampling to determine and evaluate the degree of error, statistical power, and subsequent sampling needs; and*
- *Establishing data quality objectives.*

In addition, the quality of information at the tails of input distributions often is not as good as the central values. The assessor should pay particular attention to this issue when devising data collection strategies.

6. **Depending on the objectives of the assessment, expert [1] judgment can be included either within the computational analysis by developing distributions using various methods or by using judgments to select and separately analyze alternate, but plausible, scenarios. When expert judgment is employed, the analyst should be very explicit about its use.**

Expert judgment is used, to some extent, throughout all exposure assessments. However, debatable issues arise when applying expert opinions to input distributions for Monte Carlo analyses. Using expert judgment to derive a distribution for an input parameter can reflect bounds on the state of knowledge and provide insights into the overall uncertainty. This may be particularly useful during the sensitivity analysis to help identify important variables for which additional data may be needed. However, distributions based exclusively or primarily on expert judgment reflect the opinion of individuals or groups and, therefore, may be subject to considerable bias. Further, without explicit documentation of the use of expert opinions, the

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[1] According to NCRP (1996), an expert has (1) training and experience in the subject area resulting in superior knowledge in the field, (2) access to relevant information, (3) an ability to process and effectively use the information, and (4) is recognized by his or her peers or those conducting the study as qualified to provide judgments about assumptions, models, and model parameters at the level of detail required.

distributions based on these judgments might be erroneously viewed as equivalent to those based on hard data. When distributions based on expert judgement have an appreciable effect on the outcome of an analysis, it is critical to highlight this in the uncertainty characterization.

Evaluating Variability and Uncertainty

7. **The concepts of variability and uncertainty are distinct. They can be tracked and evaluated separately during an analysis, or they can be analyzed within the same computational framework. Separating variability and uncertainty is necessary to provide greater accountability and transparency. The decision about how to track them separately must be made on a case-by-case basis for each variable.**

Variability represents the true heterogeneity or diversity inherent in a well-characterized population. As such, it is not reducible through further study. Uncertainty represents a lack of knowledge about the population. It is sometimes reducible through further study. Therefore, separating variability and uncertainty during the analysis is necessary to identify parameters for which additional data are needed. There can be uncertainty about the variability within a population. For example, if only a subset of the population is measured or if the population is otherwise under-sampled, the resulting measure of variability may differ from the true population variability. This situation may also indicate the need for additional data collection.

8. **There are methodological differences regarding how variability and uncertainty are addressed in a Monte Carlo analysis.**

There are formal approaches for distinguishing between and evaluating variability and uncertainty. When deciding on methods for evaluating variability and uncertainty, the assessor should consider the following issues.

- *Variability depends on the averaging time, averaging space, or other dimensions in which the data are aggregated.*
- *Standard data analysis tends to understate uncertainty by focusing solely on random error within a data set. Conversely, standard data analysis tends to overstate variability by implicitly including measurement errors.*
- *Various types of model errors can represent important sources of uncertainty. Alternative conceptual or mathematical models are a potentially important source of uncertainty. A major threat to the accuracy of a variability analysis is a lack of representativeness of the data.*

9. **Methods should investigate the numerical stability of the moments and the tails of the distributions.**

For the purposes of these principles, numerical stability refers to observed numerical changes in the characteristics (i.e., mean, variance, percentiles) of the Monte Carlo simulation output distribution as the number of simulations increases. Depending on the algebraic structure of the model and the exact distributional forms used to characterize the input parameters, some outputs will stabilize quickly, that is, the output mean and variance tend to reach more or less constant values after relatively few sampling iterations and exhibit only relatively minor fluctuations as the number of simulations increases. On the other hand, some model outputs may take longer to stabilize. The risk assessor should take care to be aware of these behaviors. Risk assessors should always use more simulations than they think necessary. Ideally, Monte Carlo simulations should be repeated using several non-overlapping subsequences to check for stability and repeatability. Random number seeds should always be recorded. In cases where the tails of the output distribution do not stabilize, the assessor should consider the quality of information in the tails of the input distributions. Typically, the analyst has the least information about the input tails. This suggest two points.

- *Data gathering efforts should be structured to provide adequate coverage at the tails of the input distributions.*
- *The assessment should include a narrative and qualitative discussion of the quality of information at the tails of the input distributions.*

10. **There are limits to the assessor's ability to account for and characterize all sources of uncertainty. The analyst should identify areas of uncertainty and include them in the analysis, either quantitatively or qualitatively.**

Accounting for the important sources of uncertainty should be a key objective in Monte Carlo analysis. However, it is not possible to characterize all the uncertainties associated with the models and data. The analyst should attempt to identify the full range of types of uncertainty impinging on an analysis and clearly disclose what set of uncertainties the analysis attempts to represent and what it does not. Qualitative evaluations of uncertainty including relative ranking of the sources of uncertainty may be an acceptable approach to uncertainty evaluation, especially when objective quantitative measures are not available. Bayesian methods may sometimes be

useful for incorporating subjective information into variability and uncertainty analyses in a manner that is consistent with distinguishing variability from uncertainty.

Presenting the Results of a Monte Carlo Analysis

11. Provide a complete and thorough description of the exposure model and its equations (including a discussion of the limitations of the methods and the results).

Consistent with the Exposure Assessment Guidelines, Model Selection Guidance, and other relevant Agency guidance, provide a detailed discussion of the exposure model(s) and pathways selected to address specific assessment endpoints. Show all the formulas used. Define all terms. Provide complete references. If external modeling was necessary (e.g., fate and transport modeling used to provide estimates of the distribution of environmental concentrations), identify the model (including version) and its input parameters. Qualitatively describe the major advantages and limitations of the models used.

The objectives are transparency and reproducibility - to provide a complete enough description so that the assessment might be independently duplicated and verified.

12. Provide detailed information on the input distributions selected. This information should identify whether the input represents largely variability, largely uncertainty, or some combination of both. Further, information on goodness-of-fit statistics should be discussed.

It is important to document thoroughly and convey critical data and methods that provide an important context for understanding and interpreting the results of the assessment. This detailed information should distinguish between variability and uncertainty and should include graphs and charts to visually convey written information.

The probability density function (PDF) and cumulative distribution function (CDF) graphs provide different, but equally important insights. A plot of a PDF shows possible values of a random variable on the horizontal axis and their respective probabilities (technically, their densities) on the vertical axis. This plot is useful for displaying:

- *the relative probability of values;*
- *the most likely values (e.g., modes);*
- *the shape of the distribution (e.g., skewness, kurtosis); and*

- *small changes in probability density.*

A plot of the cumulative distribution function shows the probability that the value of a random variable is less than a specific value. These plots are good for displaying:

- *fractiles, including the median;*
- *probability intervals, including confidence intervals;*
- *stochastic dominance; and*
- *mixed, continuous, and discrete distributions.*

Goodness-of-fit tests are formal statistical tests of the hypothesis that a specific set of sampled observations are an independent sample from the assumed distribution. Common tests include the chi-square test, the Kolmogorov-Smirnov test, and the Anderson-Darling test. Goodness-of-fit tests for normality and lognormality include Lilliefors' test, the Shapiro-Wilks' test, and D'Agostino's test.

Risk assessors should never depend solely on the results of goodness-of-fit tests to select the analytic form for a distribution. Goodness-of-fit tests have low discriminatory power and are generally best for rejecting poor distribution fits rather than for identifying good fits. For small to medium sample sizes, goodness-of-fit tests are not very sensitive to small differences between the observed and fitted distributions. On the other hand, for large data sets, even small and unimportant differences between the observed and fitted distributions may lead to rejection of the null hypothesis. For small to medium sample sizes, goodness-of-fit tests should best be viewed as a systematic approach to detecting gross differences. The risk assessor should never let differences in goodness-of-fit test results be the sole factor for determining the analytic form of a distribution.

Graphical methods for assessing fit provide visual comparisons between the experimental data and the fitted distribution. Despite the fact that they are non-quantitative, graphical methods often can be most persuasive in supporting the selection of a particular distribution or in rejecting the fit of a distribution. This persuasive power derives from the inherent weaknesses in numerical goodness-of-fit tests. Such graphical methods as probability-probability (P-P) and quantile-quantile (Q-Q) plots can provide clear and intuitive indications of goodness-of-fit.

Having selected and justified the selection of specific distributions, the assessor should provide plots of both the PDF and CDF, with one above the other on the same page and using identical horizontal scales. The location of the mean should be clearly indicated on both curves [See Figure 1]. These graphs should be accompanied by a summary table of the relevant data.

13. Provide detailed information and graphs for each output distribution.

In a fashion similar to that for the input distributions, the risk assessor should provide plots of both the PDF and CDF for each output distribution, with one above the other on the same page, using identical horizontal scales. The location of the mean should clearly be indicated on both curves. Graphs should be accompanied by a summary table of the relevant data.

14. Discuss the presence or absence of dependencies and correlations.

Covariance among the input variables can significantly affect the analysis output. It is important to consider covariance among the model's most sensitive variables. It is particularly important to consider covariance when the focus of the analysis is on the high end (i.e., upper end) of the distribution.

When covariance among specific parameters is suspected but cannot be determined due to lack of data, the sensitivity of the findings to a range of different assumed dependencies should be evaluated and reported.

15. Calculate and present point estimates.

Traditional deterministic (point) estimates should be calculated using established protocols. Clearly identify the mathematical model used as well as the values used for each input parameter in this calculation. Indicate in the discussion (and graphically) where the point estimate falls on the distribution generated by the Monte Carlo analysis. Discuss the model and parameter assumptions that have the most influence on the point estimate's position in the distribution. The most important issue in comparing point estimates and Monte Carlo results is whether the data and exposure methods employed in the two are comparable. Usually, when a major difference between point estimates and Monte Carlo results is observed, there has been a fundamental change in data or methods. Comparisons need to call attention to such differences and determine their impact.

In some cases, additional point estimates could be calculated to address specific risk management questions or to meet the information needs of the audience for the assessment. Point estimates can often assist in communicating assessment results to certain groups by providing a

scenario-based perspective. For example, if point estimates are prepared for scenarios with which the audience can identify, the significance of presented distributions may become clearer. This may also be a way to help the audience identify important risks.

16. A tiered presentation style, in which briefing materials are assembled at various levels of detail, may be helpful. Presentations should be tailored to address the questions and information needs of the audience.

Entirely different types of reports are needed for scientific and nonscientific audiences. Scientists generally will want more detail than non-scientists. Risk managers may need more detail than the public. Reports for the scientific community are usually very detailed. Descriptive, less detailed summary presentations and key statistics with their uncertainty intervals (e.g., box and whisker plots) are generally more appropriate for non-scientists.

To handle the different levels of sophistication and detail needed for different audiences, it may be useful to design a presentation in a tiered format where the level of detail increases with each successive tier. For example, the first tier could be a one-page summary that might include a graph or other numerical presentation as well as a couple of paragraphs outlining what was done. This tier alone might be sufficient for some audiences. The next tier could be an executive summary, and the third tier could be a full detailed report. For further information consult Bloom et al., 1993.

Graphical techniques can play an indispensable role in communicating the findings from a Monte Carlo analysis. It is important that the risk assessor select a clear and uncluttered graphical style in an easily understood format. Equally important is deciding which information to display. Displaying too much data or inappropriate data will weaken the effectiveness of the effort. Having decided which information to display, the risk assessor should carefully tailor a graphical presentation to the informational needs and sophistication of specific audiences. The performance of a graphical display of quantitative information depends on the information the risk assessor is trying to convey to the audience and on how well the graph is constructed (Cleveland, 1994). The following are some recommendations that may prove useful for effective graphic presentation:

- Avoid excessively complicated graphs. Keep graphs intended for a glance (e.g., overhead or slide presentations) relatively simple and uncluttered. Graphs intended for publication can include more complexity.

- Avoid pie charts, perspective charts (3-dimensional bar and pie charts, ribbon charts), pseudo-perspective charts (2-dimensional bar or line charts).

- Color and shading can create visual biases and are very difficult to use effectively. Use color or shading only when necessary and then, only very carefully. Consult references on the use of color and shading in graphics.

- When possible in publications and reports, graphs should be accompanied by a table of the relevant data.

- If probability density or cumulative probability plots are presented, present both, with one above the other on the same page, with identical horizontal scales and with the location of the mean clearly indicated on both curves with a solid point.

- Do not depend on the audience to correctly interpret any visual display of data. Always provide a narrative in the report interpreting the important aspects of the graph.

- Descriptive statistics and box plots generally serve the less technically-oriented audience well. Probability density and cumulative probability plots are generally more meaningful to risk assessors and uncertainty analysts.

Appendix: Probability Distribution Selection Issues

Surrogate Data, Fitting Distributions, Default Distributions Subjective Distributions

Identification of relevant and valid data to represent an exposure variable is prerequisite to selecting a probability distribution However, often the data available are not a direct measure of the exposure variable of interest. The risk assessor is often faced with using data taken in spatial or temporal scales that are significantly different from the scale of the problem under consideration. The question becomes whether or not or how to use marginally representative or surrogate data to represent a particular exposure variable. While there can be no hard and fast rules on how to make that judgment, there are a number of questions risk assessors need to ask when the surrogate data are the only data available.

Is there Prior Knowledge about Mechanisms? Ideally, the selection of candidate probability distributions should be based on consideration of the underlying physical processes or mechanisms thought to be key in giving rise to the observed variability. For example, if the exposure variable is the result of the product of a large number of other random variables, it would make sense to select a lognormal distribution for testing. As another example, the exponential distribution would be a reasonable candidate if the stochastic variable represents a process akin to inter-arrival times of events that occur at a constant rate. As a final example, a gamma distribution would be a reasonable candidate if the random variable of interest was the sum of independent exponential random variables.

Threshold Question - Are the surrogate data of acceptable quality and representativeness to support reliable exposure estimates?

What uncertainties and biases are likely to be introduced by using surrogate data? For example, if the data have been collected in a different geographic region, the contribution of factors such as soil type, rainfall, ambient temperature, growing season, natural sources of exposure, population density, and local industry may have a significant effect on the exposure concentrations and activity patterns. If the data are collected from volunteers or from hot spots, they will probably not represent the distribution of values in the population of interest. Each difference between the survey data and the population being assessed should be noted. The effects of these differences on the desired distribution should be discussed if possible.

How are the biases likely to affect the analysis and can the biases be corrected? The risk assessor may be able to state with a high degree of certainty that the available data over-estimates or under-estimates the parameter of interest. Use of ambient air data on arsenic collected near smelters will almost certainly over-estimate average arsenic exposures in the United States. However, the smelter data can probably be used to produce an estimate of inhalation exposures that falls within the high end. In other cases, the assessor may be unsure how unrepresentative data will affect the estimate as in the case when data collected by a particular State are used in a

national assessment. In most cases, correction of suspected biases will be difficult or not possible. If only hot spot data are available for example, only bounding or high end estimates may be possible. Unsupported assumptions about biases should be avoided. Information regarding the direction and extent of biases should be included in the uncertainty analysis.

How should any uncertainty introduced by the surrogate data be represented?

In identifying plausible distributions to represent variability, the risk assessor should examine the following characteristics of the variable:

1. ***Nature of the variable.***
Can the variable only take on discrete values (e.g., either on or off; either heads or tails) or is the variable continuous over some range (e.g., pollutant concentration; body weight; drinking water consumption rate)? Is the variable correlated with or dependent on another variable?

2. ***Bounds of the variable.***
What is the physical or plausible range of the variable (e.g., takes on only positive values; bounded by the interval [a,b]). Are physical measurements of the variable censored due to limits of detection or some aspect of the experimental design?

3. ***Symmetry of the Distribution.***
Is distribution of the variable known to be or thought to be skewed or symmetric? If the distribution is thought to be skewed, in which direction? What other aspects of the shape of the distribution are known? Is the shape of the distribution likely to be dictated by physical/biological properties (e.g., logistic growth rates) or other mechanisms?

4. ***Summary Statistics.***
Summary statistics can sometimes be useful in discriminating among candidate distributions. For example, frequently the range of the variable can be used to eliminate inappropriate distributions; it would not be reasonable to select a lognormal distribution for an absorption coefficient since the range of the lognormal distribution is $(0,\infty)$ while the range of the absorption coefficient is (0,1). If the coefficient of variation is near 1.0, then an exponential distribution might be appropriate. Information on skewness can also be useful. For symmetric distributions, skewness = 0; for distributions skewed to the right, skewness > 0; for distributions skewed to the left, skewness < 0.

5. ***Graphical Methods to Explore the Data.***
The risk assessor can often gain important insights by using a number of simple graphical techniques to explore the data prior to numerical analysis. A wide variety of graphical methods have been developed to aid in this exploration including frequency histograms for continuous distributions, stem and leaf plots, dot plots, line plots for discrete distributions, box and whisker plots, scatter plots, star representations, glyphs, Chernoff faces, etc. [Tukey (1977); Conover (1980); du Toit *et al.* (1986); Morgan and Henrion, (1990)]. These graphical methods are all

intended to permit visual inspection of the density function corresponding to the distribution of the data. They can assist the assessor in examining the data for skewness, behavior in the tails, rounding biases, presence of multi-modal behavior, and data outliers.

Frequency histograms can be compared to the fundamental shapes associated with standard analytic distributions (e.g., normal, lognormal, gamma, Weibull). Law and Kelton (1991) and Evans et al. (1993) have prepared a useful set of figures which plot many of the standard analytic distributions for a range of parameter values. Frequency histograms should be plotted on both linear and logarithmic scales and plotted over a range of frequency bin widths (class intervals) to avoid too much jaggedness or too much smoothing (i.e., too little or too much data aggregation). The data can be sorted and plotted on probability paper to check for normality (or log-normality). Most of the statistical packages available for personal computers include histogram and probability plotting features, as do most of the spreadsheet programs. Some statistical packages include stem and leaf, and box and whisker plotting features.

After having explored the above characteristics of the variable, the risk assessor has three basic techniques for representing the data in the analysis. In the first method, the assessor can attempt to fit a theoretical or parametric distribution to the data using standard statistical techniques. As a second option, the assessor can use the data to define an empirical distribution function (EDF). Finally, the assessor can use the data directly in the analysis utilizing random resampling techniques (i.e., bootstrapping). Each of these three techniques has its own benefits. However, there is no consensus among researchers (authors) as to which method is generally superior. For example, Law and Kelton (1991) observe that EDFs may contain irregularities, especially when the data are limited and that when an EDF is used in the typical manner, values outside the range of the observed data cannot be generated. Consequently, when the data are representative of the exposure variable and the fit is good, some prefer to use parametric distributions. On the other hand, some authors prefer EDFs (Bratley, Fox and Schrage, 1987) arguing that the smoothing which necessarily takes place in the fitting process distorts real information. In addition, when data are limited, accurate estimation of the upper end (tail) is difficult. Ultimately, the technique selected will be a matter of the risk assessor's comfort with the techniques and the quality and quantity of the data under evaluation.

The following discussion focuses primarily on parametric techniques. For a discussion of the other methods, the reader is referred to Efron and Tibshirani (1993), Law & Kelton (1991), and Bratley *et al (1987)*.

Having selected parametric distributions, it is necessary to estimate numerical values for the intrinsic parameters which characterize each of the analytic distributions and assess the quality of the resulting fit.

Parameter Estimation. Parameter estimation is generally accomplished using conventional statistical methods, the most popular of which include the method of maximum likelihood, method of least squares, and the method of moments. See Johnson and Kotz (1970), Law and

Kelton (1991), Kendall and Stewart (1979), Evans et al. (1993), Ang and Tang (1975), Gilbert (1987), and Meyer (1975).

Assessing the Representativeness of the Fitted Distribution. Having estimated the parameters of the candidate distributions, it is necessary to evaluate the "quality of the fit" and, if more than one distribution was selected, to select the "best" distribution from among the candidates. Unfortunately, there is no single, unambiguous measure of what constitutes best fit. Ultimately, the risk assessor must judge whether or not the fit is acceptable.

Graphical Methods for Assessing Fit. Graphical methods provide visual comparisons between the experimental data and the fitted distribution. Despite the fact that they are non-quantitative, graphical methods often can be most persuasive in supporting the selection of a particular distribution or in rejecting the fit of a distribution. This persuasive power derives from the inherent weaknesses in numerical goodness-of-fit tests. Commonly used graphical methods include: *frequency comparisons* which compare a histogram of the experimental data with the density function of the fitted data; *probability plots* compare the observed cumulative density function with the fitted cumulative density function. Probability plots are often based on graphical transformations such that the plotted cumulative density function results in a straight line; *probability-probability plots* (P-P plots) compare the observed probability with the fitted probability. P-P plots tend to emphasize differences in the middle of the predicted and observed cumulative distributions; *quantile-quantile plots* (Q-Q plots) graph the *ith-quantile* of the fitted distribution against the *ith quantile* data. Q-Q plots tend to emphasize differences in the tails of the fitted and observed cumulative distributions; and *box plots* compare a box plot of the observed data with a box plot of the fitted distribution.

Goodness-of-Fit Tests. Goodness-of-fit tests are formal statistical tests of the hypothesis that the set of sampled observations are an independent sample from the assumed distribution. The null hypothesis is that the randomly sampled set of observations are independent, identically distributed random variables with distribution function F. Commonly used goodness-of-fit tests include the chi-square test, Kolmogorov-Smirnov test, and Anderson-Darling test. The chi-square test is based on the difference between the square of the observed and expected frequencies. It is highly dependent on the width and number of intervals chosen and is considered to have low power. It is best used to reject poor fits. The Kolmogorov-Smirnov Test is a non-parametric test based on the maximum absolute difference between the theoretical and sample Cumulative Distribution Functions (CDFs). The Kolmogorov-Smirnov test is most sensitive around the median and less sensitive in the tails and is best at detecting shifts in the empirical CDF relative to the known CDF. It is less proficient at detecting spread but is considered to be more powerful than the chi-square test. The Anderson-Darling test is designed to test goodness-of-fit in the tails of a Probability Density Function (PDF) based on a weighted-average of the squared difference between the observed and expected cumulative densities.

Care must be taken not to over-interpret or over-rely on the findings of goodness-of-fit tests. It is far too tempting to use the power and speed of computers to run goodness-of-fit tests against a generous list of candidate distributions, pick the distribution with the "best" goodness-of-fit statistic, and claim that the distribution that fit "best" was not rejected at some specific level of significance. This practice is statistically incorrect and should be avoided [Bratley *et al.*, 1987, page 134]. Goodness-of-fit tests have notoriously low power and are generally best for rejecting poor distribution fits rather than for identifying good fits. For small to medium sample sizes, goodness-of-fit tests are not very sensitive to small differences between the observed and fitted distributions. On the other hand, for large data sets, even minute differences between the observed and fitted distributions may lead to rejection of the null hypothesis. For small to medium sample sizes, goodness-of-fit tests should best be viewed as a systematic approach to detecting gross differences.

Tests of Choice for Normality and Lognormality. Several tests for normality (and lognormality when log-transformed data are used) which are considered more powerful than either the chi-square or Komolgarov-Smirnoff (K-S) tests have been developed: Lilliefors' test which is based on the K-S test but with "normalized" data values, Shapiro-Wilks test (for sample sizes $\leq$ 50), and D'Agostino's test (for sample sizes $\geq$ 50). The Shapiro-Wilks and D'Agostino tests are the tests of choice when testing for normality or lognormality.

If the data are not well-fit by a theoretical distribution, the risk assessor should consider the Empirical Distribution Function or bootstrapping techniques mentioned above.

For those situations in which the data are not adequately representative of the exposure variable or where the quality or quantity of the data are questionable the following approaches may be considered.

Distributions Based on Surrogate Data. Production of an exposure assessment often requires that dozens of factors be evaluated, including exposure concentrations, intake rates, exposure times, and frequencies. A combination of monitoring, survey, and experimental data, fate and transport modeling, and professional judgment is used to evaluate these factors. Often the only available data are not completely representative of the population being assessed. Some examples are the use of activity pattern data collected in one geographic region to evaluate the duration of activities at a Superfund site in another region; use of national intake data on consumption of a particular food item to estimate regional intake; and use of data collected from volunteers to represent the general population.

In each such case, the question of whether to use the unrepresentative data to estimate the distribution of a variable should be carefully evaluated. Considerations include how to express the possible bias and uncertainty introduced by the unrepresentativeness of the data and alternatives to using the data. In these situations, the risk assessor should carefully evaluate the basis of the distribution (e.g., data used, method) before choosing a particular surrogate or before picking among alternative distributions for the same exposure parameter. The

following table indicates exposure parameters for which surrogate distributions may be reasonable and useful.

Table 1 Examples of exposure parameters for which distributions based on surrogate data might be reasonable

Receptor Physiological Parameters		body weight height total skin surface area exposed skin - hands, forearms, head, upper body
Behavioral	Receptor Time-Activity Patterns	residency periods - age, residency type weekly work hours time since last job change showering duration
	Receptor Contact Rates	soil ingestion rates soil adherence food ingestion - vegetables, freshwater finfish, saltwater finfish, shellfish, beef water intake - total water, tapwater inhalation rates

Rough Characterizations of Ranges and Distributional Forms. In the absence of acceptable representative data or if the study is to be used primarily for screening, crude characterizations of the ranges and distributions of the exposure variable may be adequate. For example, physical plausibility arguments may be used to establish ranges for the parameters. Then, assuming such distributions as the uniform, log-uniform, triangular and log-triangular distributions can be helpful in establishing which input variables have the greatest influence on the output variable. However, the risk assessor should be aware that there is some controversy concerning the use of these types of distributions in the absence of data. Generally, the range of the model output is more dependant on the ranges of the input variables than it is on the actual shapes of the input distributions. Therefore, the risk assessor should be careful to avoid assigning overly-restrictive ranges or unreasonably large ranges to variables. Distributional assumptions can have a large influence on the shapes of the output distribution. When the shape of the output distribution must be estimated accurately, care and attention should be devoted to developing the input distributions.

Distributions Based on Expert Judgment. One method that has seen increasing usage in environmental risk assessment is the method of subjective probabilities in which an expert or experts are asked to estimate various behaviors and likelihoods regarding specific model variables or scenarios. Expert elicitation is divided into two categories: (1) informal elicitation, and (2) formal elicitation. Informal elicitation methods include self assessment, brainstorming, causal elicitation (without structured efforts to control biases), and taped group discussions between the project staff and selected experts.

Formal elicitation methods generally follow the steps identified by the U.S. Nuclear Regulatory Commission (USNRC, 1989; Oritz, 1991; also see Morgan and Henrion, 1990; IAEA, 1989; Helton, 1993; Taylor and Burmaster; 1993) and are considerably more elaborate and expensive than informal methods.

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Figure 1a. Example Monte Carlo Estimate of the PDF for Lifetime Cancer Risk

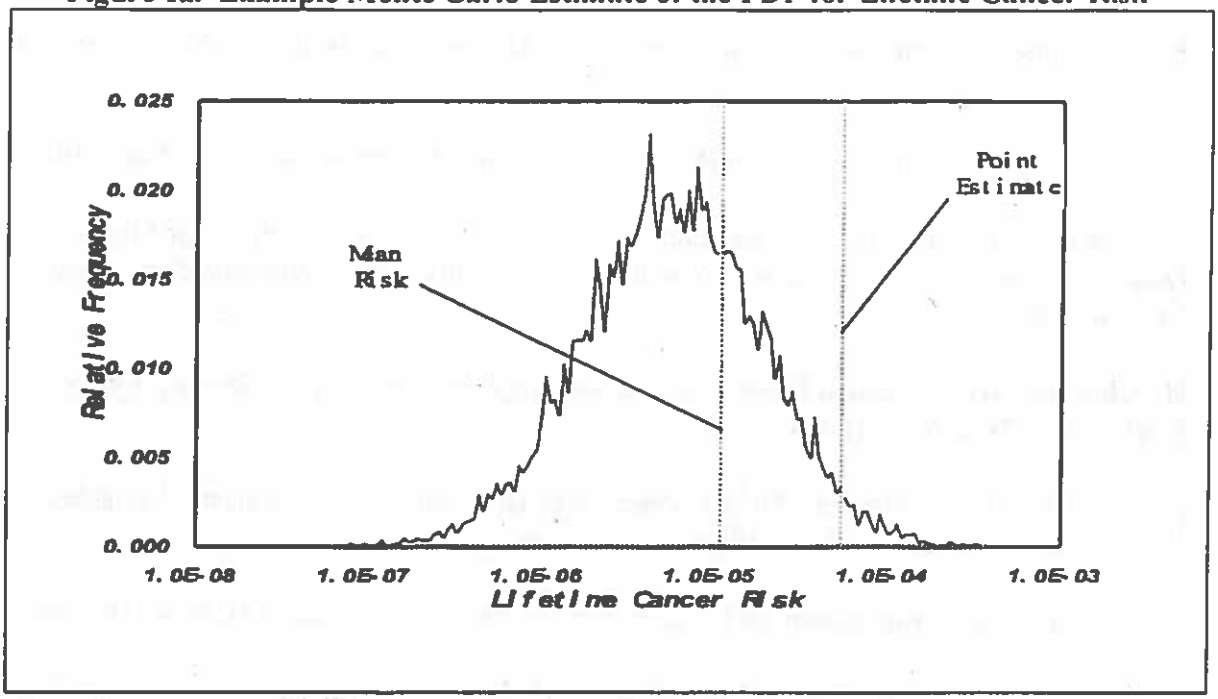


Figure 1b: Example Monte Carlo Estimate of the CDF for Lifetime Cancer Risk

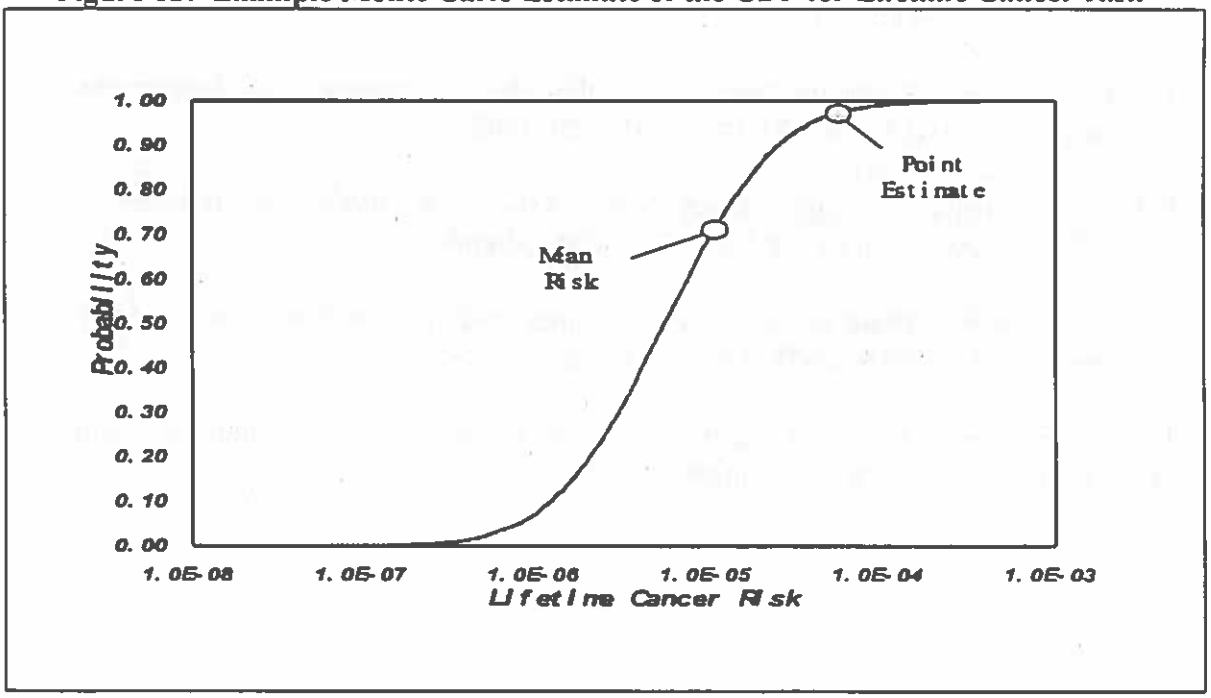
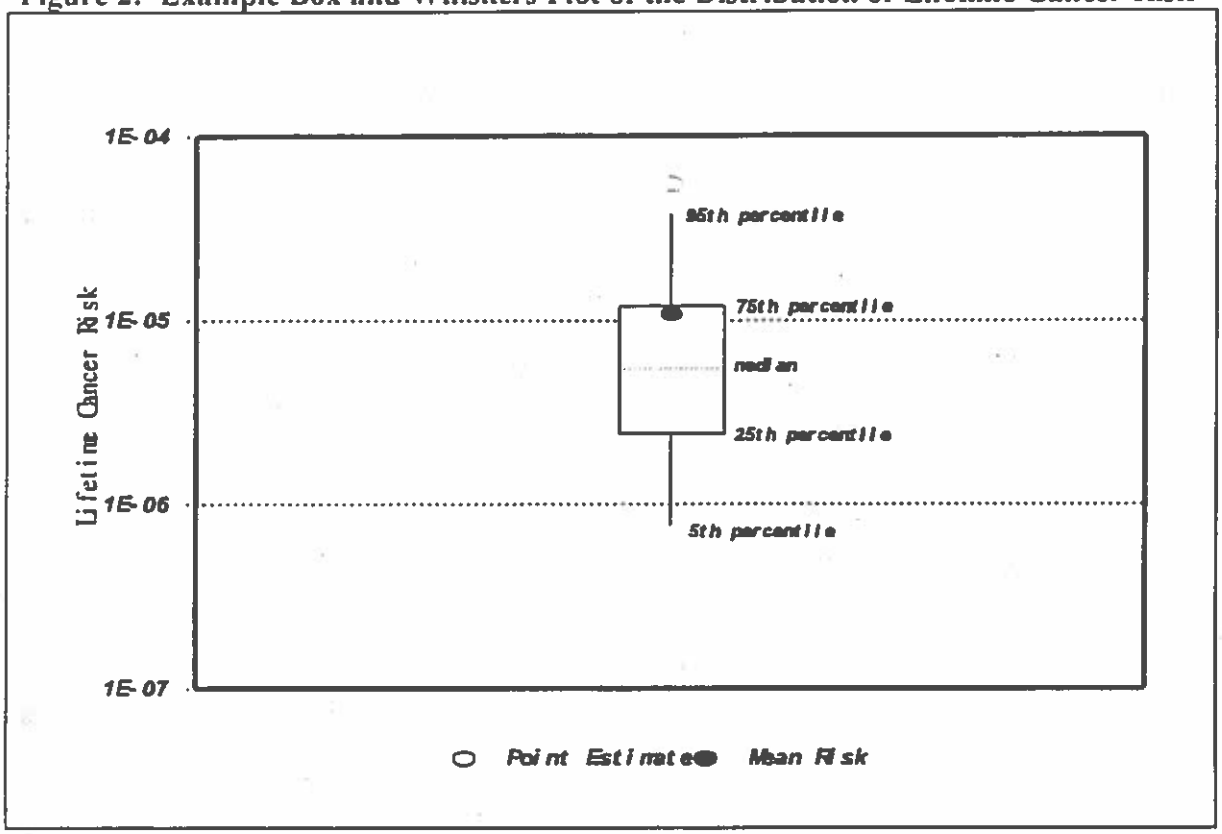


Figure 2: Example Box and Whiskers Plot of the Distribution of Lifetime Cancer Risk



ATTACHMENT P

DEALING WITH DATA BELOW DETECTION LIMITS, QUALITY ASSURANCE COURSE MODULE 492, EPA NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH AND QUALITY ASSURANCE

492: Dealing with Data Below Detection Limits

Monitoring Well Data for Gladstone Recycling Corporation

- Arsenic in ground water
- Method 606a (1987) with a detection limit of 2 μg/liter
- Intensive monitoring (almost daily) for February 1994

4.9	<2	<2	3.5	4.2	4.4	<2
2.2	2.9	2.7	3.2	2.2	2.1	2.9
4.3	3.1	2.9	<2	4.9	3.3	2.6
5.1	2.1	<2	5.3			

- 5 out of 25 readings were "less than detection"
- Problem is to estimate the mean level of arsenic

Strategies for Estimating Mean

- Strategy 1: Throw them away, ignore them
- Strategy 2: Make them all zero
- Strategy 3: Set them all at the detection limit
- Strategy 4: Use a statistical approach
- Strategy 5: Set them all at some value (e.g., DL/2)
  (Note that strategies 2 and 3 are subsets of this strategy)

Consequences of the 3 Easy Strategies

Strategy 1: Ignore them (invisible)

- Overestimates true mean (non-detects are small)
- Underestimates the variability (data set more compact)

Strategy 2: Make them all zero

- Underestimates true mean (non-detects probably greater than zero)
- Overestimates the variability (increases spread in data)

Strategy 3: Set them all at the detection limit

- Overestimates true mean (non-detects are small)
- Underestimates the variability (reduces spread in data)

Comparison of the 3 Easy Strategies

	Estimated Mean	Estimated Variance
1. Ignore them	3.440	1.143
2. Make them 0	2.752	2.877
3. Set to DL	3.152	1.250

- Real values for "<2" are 1.9, 0.9, 1.5, 1.7, 1.8
- True Mean is 3.064,
- True Variance is 1.520

Recommendations

Strategy 3: If you want to "nail them"

Strategy 2: If you want to conceal things

Strategy 1: Provided your boss does not catch you wasting resources!

Strategies 4 and 5

If there is a reasonable amount of data available:

Approximate Percentage of Non-Detects	Analysis Method
< 15 %	Replace non-detects with DL/2, DL, or a very small number
15% - 50%	Use a trimmed mean, Cohen's adjustment, or the Winsorized mean and standard deviation
50% - 90%	Use a test for proportions*
> 90%	Use a Poisson Approach*

* Consult a statistician!

Case (i): Less than 15% Non-Detects

- Set all non-detects equal to DL/2
- Resulting bias in estimating mean and variance quite small
- In the Arsenic Example:
  - Adjusted Mean = 2.952 (True Mean = 3.064)
  - Adjusted Variance = 1.897 (True Variance = 1.520)

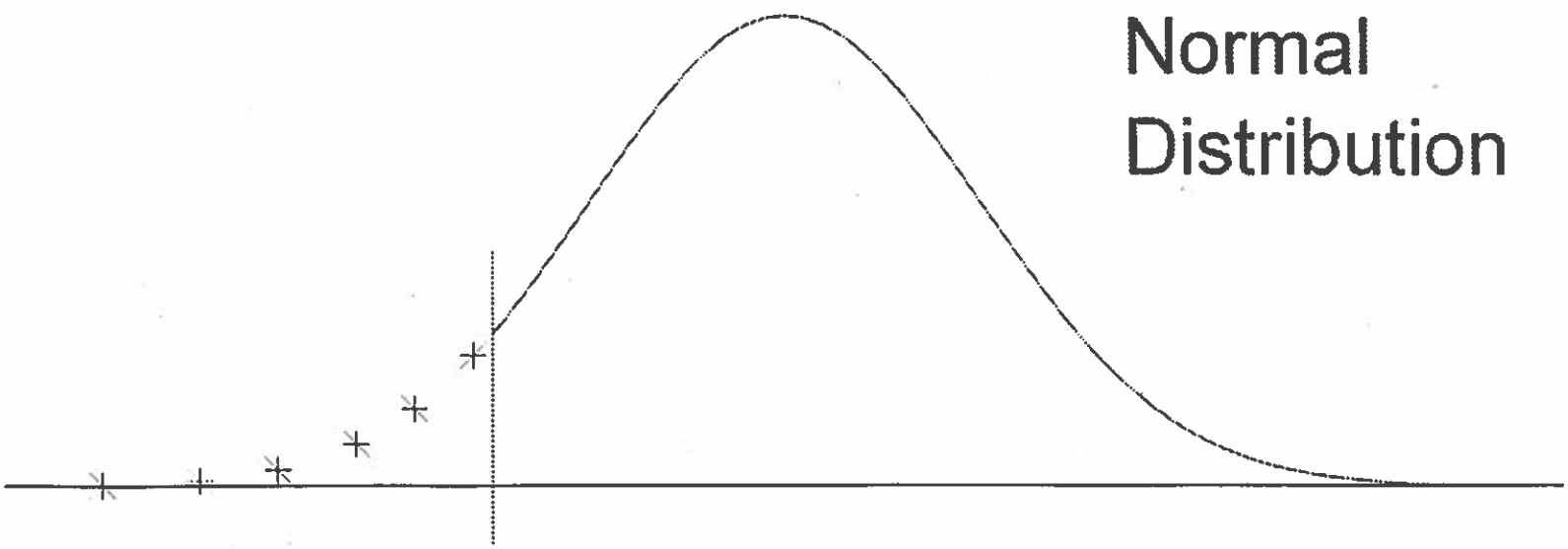
Case (ii): Between 15-50% Non-Detects

- Cohen's Method
  - Mends the Data
- Trimmed Mean
  - Discards the Data
- Winsorized Mean and Standard Deviation
  - Substitutes the Data

Cohen's Method

- "Mends" the data essentially by estimation; estimates what values should have been found
- Uses information from the values above the detection limit together with assumptions about the distribution of the data
- Calculates mean and variance from the values above the Detection Limit, then adjusts the mean down and the variance up
- Requires special tables

Why Cohen's Method Works



Cohen's method uses Normality and the principle of Maximum Likelihood to estimate what impact the below Detection Limit values (dotted) would have on the estimates calculated from the above Detection Limit values.

How Cohen's Method Works

The data look like:

x x x x x (n-m) observations below DL	DL	x x x x x x x x x x (m) observations above DL	(n) Total number of observations

1) Calculate the mean ($\bar{X}_d$) and variance (s_d^2) of the m observations above the DL.

How Cohen's Method Works - Continued

2) Then $Adjusted\ \bar{X} = \bar{X}_d - \hat{\lambda}(\bar{X}_d - DL)$

$$Adjusted\ s^2 = s_d^2 + \hat{\lambda}(\bar{X}_d - DL)^2$$

where λ is calculated from special tables.

In the Arsenic Example:

Adjusted Mean = 2.998 (True = 3.064)

Adjusted Variance = 1.780 (true = 1.520)

The Trimmed Mean

- Discards data below the DL and an equivalent amount of the largest values above the DL.
- The percentage of data discarded below the DL defines the trimmed mean percentage. For example, if 10% of the data are below the detection level (so 20% of the data are discarded), this method will compute a 10% trimmed mean.
- Although good for estimating the mean, it does not help with the variance.

How Trimming Works

1) Find the percentage (p%) of readings below the DL. (In the example, this was 5 out of 25 = 20%).

2) Determine the equivalent highest above the DL and discard these values. (In the example, 5.3, 5.1, 4.9, 4.9, 4.4 are discarded.)

3) Calculate the mean of the remaining values. This is the p% trimmed mean.

In the Arsenic Example:

20% Trimmed Mean is 2.947 (True = 3.064)

Trimmed Variance, incidently, is 0.476 (True = 1.520)

Winsorized Mean and Variance

Similar to trimming but instead of throwing data away, the ones below the DL are replaced by the value closest to the DL, and the equivalent number of highest values are replace by an equivalent high value.

How the Winsorized Mean Works

1) Rank the data from smallest to largest.

In the example,

>2, >2, >2, >2, >2 | 2.1, 2.1, 2.2, . . ., 4.3, 4.4, 4.9, 4.9, 5.1, 5.3

2) Replace those below the DL by the first value greater than the DL. Replace the same number of the largest values by the next closest value.

In the example, 2.1 is the first value greater than the DL so the 5 non-detects are replaced with 2.1.

The five largest values are 4.4, 4.9, 4.9, 5.1, and 5.3. These values are replaced by 4.3.

How the Winsorized Mean Works - Continued

3) Calculate sample mean, $\bar{X}_w$, and sample variance, s^2, as usual. Then the winsorized mean is X_w, and the winsorized variance s_w^2 is

$$s_w^2 = \left[\frac{n-1}{2m-n-1}\right]^2 s^2$$

In the Arsenic Example:

Winsorized Mean = 3.048 (True = 3.064)

Winsorized Variance = 2.344 (True = 1.520)

Comparison of Methods

	True	1 <DL = ?	2 <DL = 0	3 <DL=DL	4 - Stat Cohen	4 - Stat Trim.	4 - Stat Winsor	5 <DL=1/2DL
Mean	3.064	3.440	2.752	3.152	2.998	2.947	3.048	2.952
Var.	1.520	1.143	2.877	1.250	1.780	0.476	2.344	1.897

- Cohen's method is close for mean and variance
- Setting Less Than DL = ½DL good if only a few non-detects
- Winsorization quite good if only interested in the mean

But Why Does It Matter?

Data are likely to be used in a statistical test to determine compliance with a standard or evidence of contamination.

For example, standard Student's t-test:

$$t = \frac{\bar{X} - \mu}{\sqrt{\frac{s^2}{n}}}$$

where μ comes from the null hypothesis (e.g., the regulatory standard)

Bias

- If less than detection values are replaced by something else (i.e., some number) and $\bar{X}_{new}$ and s^2_{new} are calculated, then

$$true\ mean\ (\bar{X}) = \bar{X}_{new} + bias\ (\bar{X}_{new})$$

$$true\ variance\ (s^2) = s^2_{new} + bias\ (s^2_{new})$$

- It is impossible to eliminate these biases

- Statistical methods (Cohen or Winsorization) reduce the bias considerably where as substitution methods (½ DL, etc.) do not.

What's the Practical Effect?

Since is impossible to make the biases cancel, the simple t-test becomes:

$$t = \frac{[\bar{X}_{new} + bias\ (\bar{X}_{new})] - \mu}{\sqrt{\frac{[s^2_{new} + bias\ (s^2_{new})]}{n}}}$$

This:

- **does not have the intended false positive rate (α)**
- **does not have the intended false negative rate (β)**
- **does not have the intended statistical power**

Hypothesis Testing and Bias

It is difficult to predict what the true false positive rate and false negative rate will be as both biases are functions of the DL, amount of data, amount of data below DL, and the relative standard deviation (coefficient of variation).

What if the Data are Not Normally Distributed?

- If approximately Lognormal, transform and use Cohen's method
- If roughly Lognormal shaped and only a few data below DL, substitute ½ DL
- Trimming and Winsorization perform poorly unless data are approximately symmetric

Lognormal Example

- 10 Carbon Monoxide readings in a furnace room collected a random intervals over a 24-hour period.
- Data from smallest to largest are:

  1.53, 2.20, 2.72, 3.16, 3.76, 4.15, 4.43, 7.81, 8.42, 20.76

- Data are lognormally distributed
- Let DL = 2.00, so 9 readings are above DL

Lognormal Example - Continued

* True Mean = 5.89 *

* True Variance = 32.33 *

Winsorized: Replace < DL with 2.20, Replace 20.76 with 8.42

Winsorized Mean = 4.72

Winsorized Variance = 6.45

Substitution: Replace < DL with ½ DL (1.00)

Substitution Mean = 5.84

Substitution Variance = 32.891

Conclusions