

ALASKA DEPARTMENT OF ENVIRONMENTAL CONSERVATION

Contaminated Sites Remediation Program



Risk Assessment Procedures Manual

June 8, 2000

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Since risk assessment is a dynamic and evolving science, it is anticipated that, as needed, ADEC will update this manual through the public review process as a regulatory amendment. Updates are especially likely in ecological risk assessment, petroleum risk assessment, arsenic, PCBs, dioxin, and lead toxicity assessment for which limited, evolving guidance is available. Please ask ADEC to add your name and address to its mailing list so that you will receive a copy of any public notice announcing proposed changes to this manual and the regulations under which it has been created.

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List of Acronyms

ADEC	Alaska Department of Environmental Conservation
AQUIRE	Aquatic Toxicity Information Retrieval Database
ARAR	Applicable or Relevant and Appropriate Requirements
ASTM	American Society of Testing and Materials
ATSDR	Agency of Toxic Substances and Disease Registry
AWQC	ambient water quality criteria
BAF	bioaccumulation factor
BCF	bioconcentration factor
BTAG	biological technical assistance group
COPC	compound of potential concern
CSM	conceptual site model
ECHO	Environmental Criteria and Assessment Office
EEC	estimated environmental concentration
EPA	United States Environmental Protection Agency
HEAST	Health Effects Assessment Summary Tables
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
LD50	lethal dose, 50% of the population
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
MCL	maximum contaminant level
MCLG	maximum contaminant level goals
NOAA	National Oceanic and Atmospheric Administration
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PA	preliminary assessment
PEL	permissible exposure limits
PFD	probability density function
RfC	reference concentration
RfD	reference dose
RME	reasonable maximum exposure
RP	responsible person(s)
SA	site assessment
SF	slope factor
SI	site investigation
SQL	sample quantitation limit
TAL	target analyte list
TCL	target compound list
TLV	threshold limit values
TRV	toxicity reference value
UCL	upper confidence limit
UF	uncertainty factor
UR	unit risk
USFWS	United States Fish and Wildlife Service

Acknowledgments

This manual was developed by the Alaska Department of Environmental Conservation (ADEC), Contaminated Sites Risk Assessment WorkTeam. The WorkTeam consisted of team leader Linda Himmelbauer, Clint Adler, Randal Buckendorf, Renee Evans, Jim Frechione, Scott Pexton, Katarina Rutkowski, and Tamar Stephens. We thank the WorkTeam for the time, dedication, energy, and enthusiasm that they devoted to this project.

ADEC would also like to acknowledge and express sincere appreciation to the following staff who contributed valuable comments and insights on sections of this manual: Amy Crook, Judy Kitagawa, Cynthia Pring-Ham, Bill Walker, and Ron Klein.

We would also like to thank Bruce Duncan, Julius Nwosu, and Marcia Bailey from EPA Region 10 for their guidance and support during the evolution of this project.

NOTE TO RISK ASSESSMENT PROCEDURES MANUAL USERS

As you use this manual, please note on this page any suggestions you have about how ADEC could improve the manual. This might include:

1. changing the format;
2. clarifying directions;
3. expanding the glossary (list terms you'd like to see included);
4. additional data presentation tables; and
5. any other ideas you may have.

It would also be helpful to know how often you refer to the regulations in 18 AAC 75 Article 3 governing this manual, and whether further cross references would be helpful.

Please send comments and suggestions to:

Alaska Contaminated Sites Remediation Program
410 Willoughby Avenue, Suite 105
Juneau, Alaska 99801
RE: RAP Manual Comments

Your assistance in making this manual easier to use will be appreciated.

Comments:

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1.0 - INTRODUCTION

1.1 Development of Guidelines

This manual provides risk assessment procedures for use in preparing a human health and ecological risk assessment under the Oil and Other Hazardous Substances Pollution Control regulations in 18 AAC 75.300 – 18 AAC 75.397.

A risk assessment performed under another state or federal program may need to follow different guidelines. Therefore, appropriate Alaska and federal agencies should be contacted. For example, if a risk assessment is performed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Resource Conservation and Recovery Act (RCRA), the Underground Storage Tank (UST) program, a National Priority Discharge Elimination System (NPDES) permit application, an Air Quality Emissions permit application, or a Department of Transportation land transfer, the appropriate agency should be contacted to determine if a risk assessment under 18 AAC 75 will also satisfy that program's requirements.

This manual is not meant to replace regional or national guidance from the U.S. Environmental Protection Agency (EPA) on risk assessment. ADEC's intent in developing the manual is to provide supplemental risk assessment procedures for use in the remediation and cleanup of contaminated sites in Alaska.

Due to the remoteness of many Alaska sites, the seasonal extremes of Alaska's climate, the diverse geography, and the unique subsistence lifestyle of many Alaskans, a risk assessment prepared for an Alaska site may vary significantly from the standard EPA default protocol.

Use of this manual for methods and report presentation for Alaska contaminated sites will:

- allow comparison of one site to another by fostering a consistent and technically defensible approach for all sites;
- expedite ADEC's review of risk assessments;
- minimize revision and resubmittal of risk assessment documents, thus reducing time and costs to responsible persons; and
- assist in the site remediation decision-making process.

These procedures also specify when ADEC should be consulted during preparation of a risk assessment to ensure that the methodology used is as complete as possible and appropriate for the site. ADEC may agree to modify certain portions of this guidance for certain sites based on site-specific data and information from other government agencies.

1.2 Risk Assessment and Risk Management

Regulatory actions taken at Alaska contaminated sites require an integration of two distinct processes - risk assessment and risk management.

Risk assessments organize and interpret technical information for use by decisionmakers. Risk assessment is the scientific process of evaluating the toxic properties of compounds and the conditions of human and ecological exposure to determine the likelihood that an exposed population or ecosystem will be adversely affected. This manual provides instruction in preparing a site-specific risk assessment for ADEC. While risk assessment is firmly based on scientific considerations, it also requires judgments to be made when information is incomplete. Such judgments inevitably draw on both scientific and policy considerations.

Risk management is the process by which risk assessment results are integrated with other site information to make decisions about the need for, method of, and extent of risk reduction. For example, risk management determines the most appropriate means to control or eliminate a significant risk. In addition to considering the human health and ecological risk assessment data, risk management also includes examining issues such as technical feasibility, cost, political and social acceptability, and impact of proposed alternative remedial actions. This manual does not provide guidance on the risk management decisions that must be made by ADEC. ADEC may, however, require a potentially responsible person to perform calculations useful to the risk management process.

In general, the types of risk management actions ADEC considers are:

- **Removal** - moving waste or contaminated media away to another location for storage, processing, or disposal;
- **Decontamination** - applying treatment processes to eliminate a present or future threat to human health or the environment; and
- **Institutional Controls and Engineering Measures** - such as fencing, capping, signs, deed notices or deed restrictions, and legal measures.

1.3 Risk Assessment Requirements

A risk assessment is the written document in which pertinent scientific information regarding toxicology, human and ecological experience, environmental fate and transport, and exposure are assembled, critiqued, and interpreted. The risk assessment evaluates existing and future potential risks to human health and the environment from hazardous substances detected in soil, groundwater, sediments, surface waters, and (in some cases) air and biota, that are at the site and that have or have the potential to migrate off site. The results of the risk assessment provide a basis for determining whether, and to what extent, remediation of impacted media is warranted. DEC's risk assessment procedures include, at a minimum, the steps in *Figure 1.3 ADEC Risk Assessment Checklist* and *Figure 1.4 Scoping Meeting Checklist*.

Figure 1.3**ADEC RISK ASSESSMENT CHECKLIST**

✓	TASK*	DATE
<input type="checkbox"/>	RISK ASSESSMENT SCOPING MEETING See Figure 1.4 Scoping Meeting Checklist (ADEC Project Manager; ADEC Risk Assessment Staff; Responsible Person (RP); and RP consultants)	_____
<input type="checkbox"/>	SUBMIT CONCEPTUAL SITE MODELS (CSMs) identifying all potential pathways to ADEC project manager	_____
<input type="checkbox"/>	ADEC APPROVES CONCEPTUAL SITE MODELS	_____
<input type="checkbox"/>	SUBMIT RISK ASSESSMENT WORKPLAN including CSM identifying all completed pathways to ADEC project manager	_____
<input type="checkbox"/>	ADEC REVIEWS RISK ASSESSMENT WORKPLAN comments provided to RP	_____
<input type="checkbox"/>	SUBMIT RESPONSE TO ADEC WORKPLAN COMMENTS to ADEC project manager	_____
<input type="checkbox"/>	COMMENT RESOLUTION MEETING for the risk assessment workplan	_____
<input type="checkbox"/>	SUBMIT HUMAN HEALTH & ECOLOGICAL RISK ASSESSMENT to ADEC project manager	_____
<input type="checkbox"/>	ADEC REVIEWS RISK ASSESSMENT comments provided to RP	_____
<input type="checkbox"/>	SUBMIT RESPONSE TO ADEC RISK ASSESSMENT COMMENTS to ADEC project manager	_____
<input type="checkbox"/>	COMMENT RESOLUTION MEETING for the risk assessment	_____
<input type="checkbox"/>	ADEC APPROVES THE RISK ASSESSMENT	_____
<input type="checkbox"/>	ADEC MAKES RISK MANAGEMENT DECISION AND APPROVES ALTERNATIVE CLEANUP LEVELS, REMEDIAL ACTION, OR NO FURTHER ACTION	_____

*some tasks may occur concurrently

1.4 The Risk Assessment Process

In addition to following these guidelines, it is recommended that risk assessments prepared for ADEC generally follow the basic procedures outlined in EPA's *Risk Assessment Guidance Manual for Superfund: Volume I - Human Health Evaluation Manual* (EPA, 1989), *Framework for Ecological Risk Assessment* (EPA, 1992), *Region 10 Supplemental Risk Assessment Guidance for Superfund* (EPA, 1997a), interim final *Ecological Risk Assessment Guidance for Superfund: Processes for Designing and Conducting Ecological Risk Assessments* (EPA, 1997b), and *Proposed Guidelines for Ecological Risk Assessment* (EPA, 1996).

Since risk assessment is a dynamic and evolving science, it is anticipated that, as needed, ADEC will update this manual through the public review process as a regulatory amendment. Updates are especially likely in ecological risk assessment, petroleum risk assessment, arsenic, PCBs, dioxin, and lead toxicity assessment for which limited, evolving guidance is available. Please ask ADEC to add your name and address to its mailing list so that you will receive a copy of any public notice announcing proposed changes to this manual and the regulations under which it has been created.

Figure 1.4

SCOPING MEETING CHECKLIST

- ✓ **Discussion Points**
- HUMAN HEALTH MANAGEMENT GOALS**
- ECOLOGICAL MANAGEMENT GOALS**
- DOCUMENT DELIVERABLE SCHEDULE**
- COST RECOVERY**
- CHEMICALS OF POTENTIAL CONCERN**
- POTENTIALLY EXPOSED POPULATIONS**
- POTENTIALLY EXPOSED ECOLOGICAL RECEPTORS**
- IDENTIFICATION OF SENSITIVE POPULATIONS AND ENVIRONMENTS**
- STUDY AREA FOR RISK ASSESSMENT**
- DISCUSS SITE CHEMISTRY FROM SITE INVESTIGATION/SITE ASSESSMENT**
- IDENTIFY ADDITIONAL SAMPLING NEEDED**
- COMMUNICATION LINES BETWEEN ADEC AND RP**
- COORDINATION TIME BETWEEN COMMENT RESOLUTION MEETING AND SUBMITTAL OF RISK ASSESSMENT**
- CHANGES IN THE RISK ASSESSMENT PROCEDURES MANUAL EXPECTED TO OCCUR BETWEEN SUBMITTAL OF THE WORKPLAN AND THE RISK ASSESSMENT DOCUMENT**
- PRELIMINARY PROBLEM FORMULATION FOR ECOLOGICAL RISK (See Section 3.3.1)**

SUBMIT THE FOLLOWING ECOLOGICAL CHECKLISTS:

- Figure B.1 Ecological Checklist #1: General**
- Figure B.2 Ecological Checklist #2: Terrestrial**
- Figure B.3 Ecological Checklist #3: Aquatic Flowing Systems**
- Figure B.4 Ecological Checklist #4: Aquatic Non-Flowing Systems**
- Figure B.5 Ecological Checklist #5: Wetlands**

- OTHER**

1.5 Risk Assessment Reviews

Draft and final conceptual site models, risk assessment work plans, and risk assessments prepared for ADEC are reviewed by ADEC risk assessment staff or ADEC third-party contractors with an ADEC audit. Staff and contractor comments on the risk assessment documents are provided to the ADEC project manager for the site. Taking into account the technical comments on the risk assessment document, ADEC will either approve the document or return it to the responsible person for revision and comment resolution. In many cases, draft documents and a document addendum from the risk assessment comment resolution meeting will suffice to make a document final. Based on the approved risk assessment document, ADEC will determine if there is a risk associated with contamination from the site and the appropriate risk management action to be taken.

If ADEC determines that impacted media at a site requires remediation to protect human health and the environment under specific land use conditions, levels of risk will indicate the extent that the concentration of compounds of potential concern should be reduced to achieve an acceptable risk.

If ADEC determines that the site poses a significant health risk, the responsible person must provide notice to all exposed individuals regarding the results of the risk assessment in a manner approved by ADEC on a site-specific basis.

At ADEC's discretion, the risk assessment review process may include a public advisory committee, a Biological Technical Assistance Group (BTAG), EPA staff, and other state and federal agencies as they are able to participate. All interested and affected parties (such as stakeholders) should be identified in the initial scoping meeting for the risk assessment.

1.6 Scoping Meeting

Communication between ADEC and the RP is essential throughout the risk assessment process. The scoping meeting establishes lines of communication as well as determines the document deliverable schedule.

At the scoping meeting, sensitive populations (Section 4.2.4.2) and environments (Section 4.2.4.3) are identified. Completion of the Appendix B ecological checklists and the conceptual site models may also aid in determining whether an ecological risk assessment is needed for the site. Please see *Figure 1.4 Scoping Meeting Checklist*.

2.0 - CONCEPTUAL SITE MODELS

The human health and ecological conceptual site models (CSMs) are the first documents that must be submitted to the ADEC project manager for review. The CSMs are flow charts or diagrams used as document planning tools to evaluate completed exposure pathways for human health and ecological receptors. Risk to human health and the environment cannot exist unless the contamination at a site has the ability to cause an adverse effect AND comes in contact with a human or environmental receptor. CSMs establish whether contamination that is at a site or that has migrated offsite will come in contact with human and ecological receptors.

Two types of CSMs are to be submitted to ADEC:

1. **Potential** exposure pathways for current and future land use (one for human exposure pathways, one for ecological pathways) submitted during or after the scoping meeting, before developing the Risk Assessment Workplan.
2. **Actual** exposure pathways for current and future land use (one for human health, one for ecological pathways) submitted with the Risk Assessment Workplan

A risk assessment need only evaluate completed exposure pathways. An exposure pathway is complete when a contaminant can be tracked from its source to a human health or ecological receptor. CSMs must be provided and approved by ADEC before a risk assessment workplan can be submitted.

2.1 Human Health Conceptual Site Models

All human health CSMs must consider potential subsistence pathways. A general human health CSM is depicted in Figure 2.1. This can be used as a starting point or reference for the development of a site-specific CSM. CSMs for human health must consider graphical flow chart representations of the following:

2.1.1 Historical contamination sources

1. Tanks
2. Drums
3. Unknown sources

2.1.2 Release mechanisms

1. Spills
2. Leaks
3. Direct discharge
4. Burning
5. Other

2.1.3 Impacted media

1. Soil
2. Sediments
3. Groundwater
4. Surface Water
5. Air

2.1.4 Migration pathways and media transfers, including

- a. uptake by plants
- b. uptake by animals/fish
 - i. ingestion
 - ii. water column exposure
 - iii. sediment exposure
- c. volatilization
 - i. to atmosphere
 - ii. to enclosed space
- d. excavation
- e. fugitive dust via contaminant dispersion
- f. groundwater

2.1.5 Exposure routes

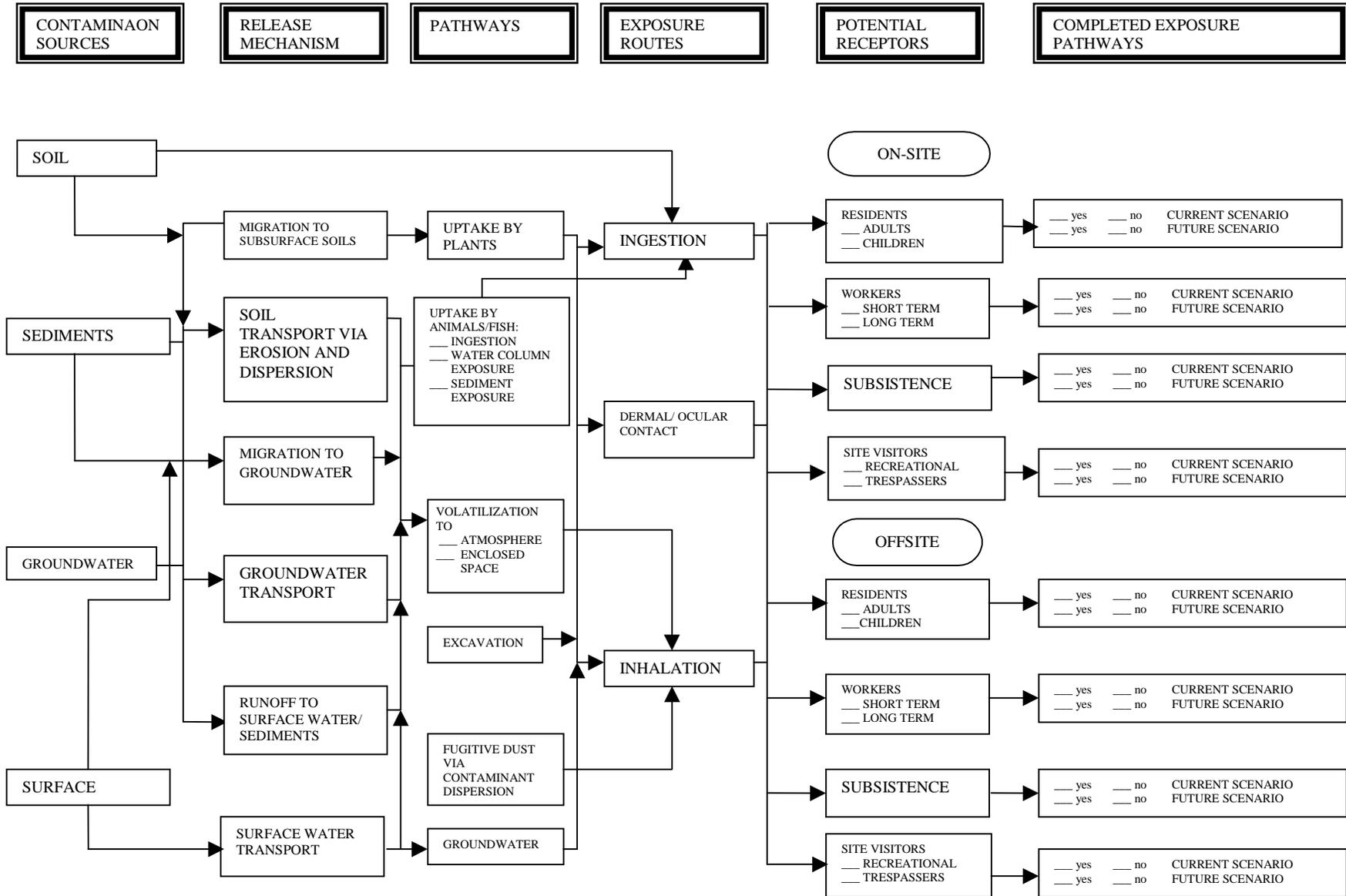
- a. ingestion
- b. dermal
- c. inhalation

2.1.6 Potential human receptors

- a. onsite
 - i. residents
 - (1) adults
 - (2) children
 - ii. workers
 - (1) short term
 - (3) long term
 - iii. subsistence
 - iv. site visitors
 - (1) recreationalists
 - (2) trespassers

- b. offsite
 - i residents
 - (1) adults
 - (2) children
 - ii. workers
 - (1) short term
 - (2) long term
 - iii. subsistence
 - iv. site visitors
 - (1) recreationalists
 - (2) trespassers

Figure 2.1 EXAMPLE HUMAN HEALTH CONCEPTUAL SITE MODEL



2.2 Ecological Conceptual Site Models

EPA's *Ecological Risk Assessment Guidance for Superfund* (1997a) defines an ecological risk assessment as a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. Stressors are defined as any physical, chemical, or biological entity that can induce an adverse ecological response. Risk cannot exist unless a stressor contacts an ecological entity.

While the human health CSM relies on conservative exposure assumptions, the ecological CSM requires more site-specific information. To develop a CSM for the ecosystem, there must be at least rudimentary knowledge of the environmental setting and the potential hazardous substances, and physical and biological stressors at the site. This information may be compiled from reports from the site including the preliminary assessment (PA), site inspection (SI), and site assessment (SA). To ascertain the level of effort needed to assess ecological risk at a particular site, ADEC has modified various EPA checklists (see Appendix B). If additional data are needed to confirm and document the completed exposure pathways, an additional site visit by ADEC staff may be needed. A general ecological CSM is depicted in Figure 2.2. This can be used as a starting point or reference for the development of a site-specific CSM.

The CSM is one component of ecological problem formulation (Section 3.3). If planning permits, actual assessment endpoints should be used in the CSM for the potential pathways. However, if the assessment endpoints are not known, best professional judgment should be used.

CSMs can then be refined for the risk assessment workplan once assessment endpoints are established. The CSMs for ecological systems should include separate graphical flow chart representations for terrestrial and aquatic food chains to include the following:

2.2.1 Historical contamination sources

1. Tanks
2. Drums
3. Unknown sources

2.2.2 Release mechanisms

1. Spills
2. Leaks
3. Direct discharge
4. Burning
5. Other

2.2.3 Impacted Media

1. Soil
2. Sediments
3. Groundwater
4. Surface water
5. Air

2.2.4 Migration pathways and media transfers to the various trophic levels

- a. Plant uptake

- b. Volatilization
- c. groundwater

2.2.5 Exposure routes for various trophic levels

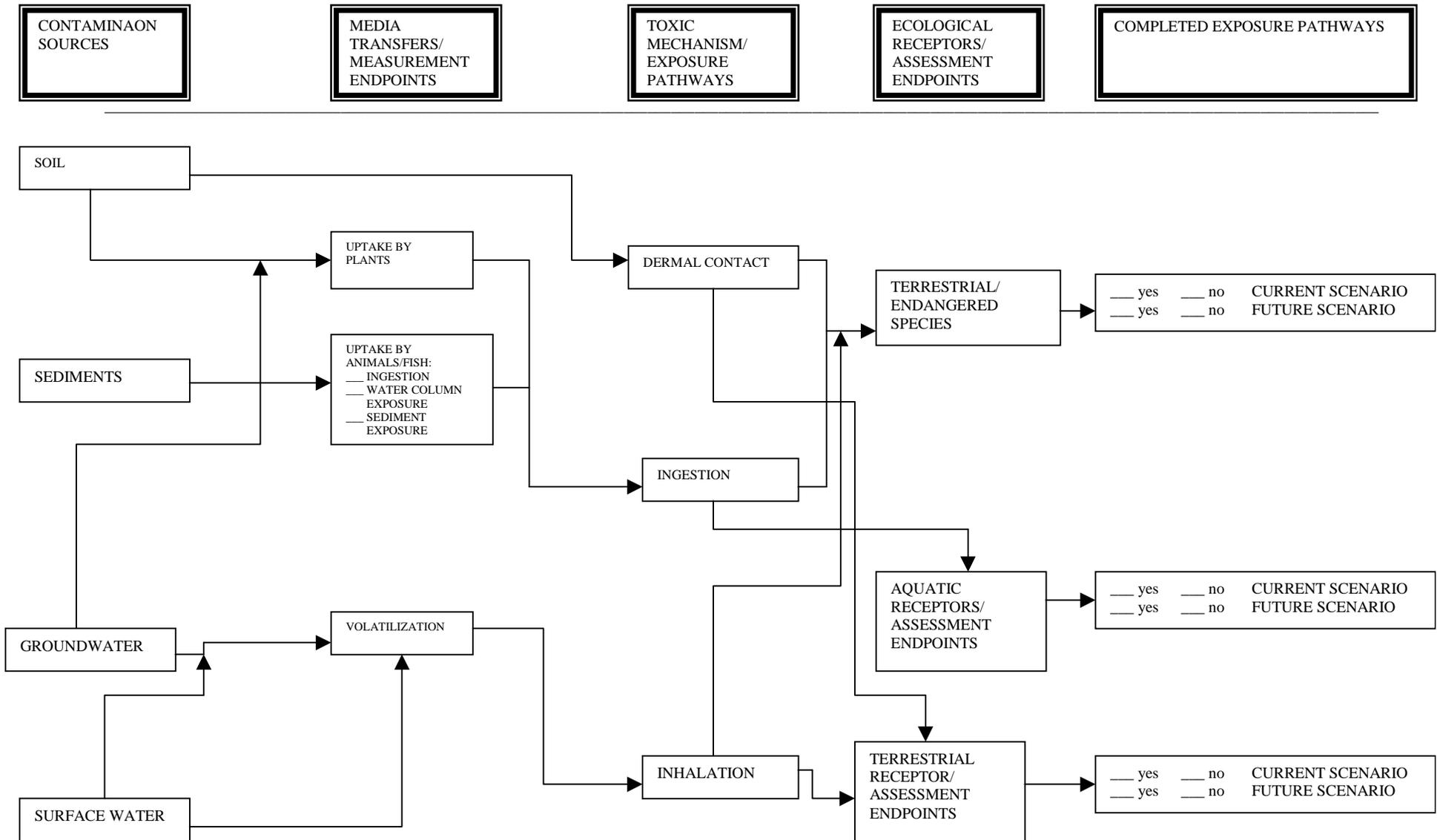
- a. ingestion
- b. dermal
- c. inhalation

2.2.6 Ecological Receptors / Assessment Endpoints

- a. ecological communities
- b. indicator species selection criteria
 - i. functional group
 - ii. abundance
 - iii. status
 - iv. habitat
- c. trophic level
- d. diet
- e. representativeness
- f. availability of toxicological data
- g. threatened and endangered species

While ADEC requires threatened and endangered species to also be identified in the ecological risk assessment, ADEC recommends that, where applicable, threatened and endangered species be used as assessment endpoints and not as measurement endpoints. Instead, it is recommended that an indicator species from the same trophic level be selected as a measurement endpoint to assess ecological risk to the endangered species if present.

Figure 2.2 EXAMPLE ECOLOGICAL CONCEPTUAL SITE MODEL



3.0 - THE RISK ASSESSMENT WORKPLAN

After ADEC approves the Conceptual Site Models, the risk assessment workplan may be developed and submitted to the ADEC project manager. The risk assessment workplan describes the methodologies for developing the human health and ecological risk assessment for the site. The workplan identifies the tasks necessary to define the magnitude and probability of threats to human health and the environment posed by contaminants in soil, groundwater, sediments, surface water, and (in some cases) air and biota at the site. The workplan must also identify the activities required to accomplish these tasks.

3.1 Selection of Compounds of Concern

It is recognized that sampling and analysis data may not all be available for the risk assessment workplan. However, the risk assessment should detail the methods of data evaluation and the selection of compounds of potential concern. Site characterization maps should be included.

Sampling and analysis activities undertaken during site characterization should provide adequate data for the risk assessment. However, the workplan must demonstrate that there is adequate data to evaluate each exposure pathway. Additional samples may be needed or required and should be identified in the workplan.

In the absence of laboratory data, based on past site activities, a list of potential contaminants at the site must be provided.

3.2 Human Health

The human health portion of the risk assessment workplan must include the items in sections 3.2.1 through 3.2.5 (please see section 4.3 for specific topical discussions):

3.2.1 Toxicity Criteria

The preparation of the toxicity assessment relies primarily on existing toxicity information and does not usually involve development of new toxicity information or dose-response relationships. Toxicity criteria should be selected from the following hierarchy (See Table 3.2.1 for toxicity criteria contacts):

1. the Integrated Risk Information System (IRIS);
2. the Health Effects Assessment Summary Table (HEAST);
3. EPA ECAO Office Criteria Documents; and
4. other professionally peer-reviewed documents such as ATSDR minimum risk levels (MRLs) as needed and as approved by ADEC on a case-by-case basis.

Table 3.2.1**HUMAN HEALTH TOXICITY CRITERIA CONTACTS**

Toxicity Criteria	Contact Agency	Phone/Email
To verify most recent cancer slope, RfD, or RfC	EPA Risk Information Hotline	(513) 569-7254
IRIS	For government agencies and government contractors, access is free via EPA	(513) 569-7254
	Online access via TOXNET, National Library of Medicine	(301) 469-6531
	Floppy disks via NTIS	(800) 553-6847
	RTK Net (The Right to Know Network)	http://rtk.net/
HEAST	To order table via National Technical Information Service (NTIS)	(800) 553-6847
EPA Criteria Documents	EPA Publications	(513) 569-7980
	Center for Environmental research Information (CERI)	(513) 569-7562
ATSDR Toxicological Profiles	ATSDR	http://www/atsdrhome.htm
Other peer reviewed documents		

3.2.2 Exposure Assessment

The overall goal of the exposure assessment is to estimate the nature and magnitude of actual or potential exposures to compounds of potential concern (COPC) present at the site. Both current and future hypothetical exposure pathways should be identified. The methods by which exposure point concentrations will be calculated should be outlined. Methods used to estimate actual or assumed exposures (intakes) of COPCs should be identified. The CSM should be refined in the workplan, and exposure pathways for receptors of concern should be identified. All models for environmental fate and transport must be submitted for approval. Initial modeling data should be identified in the workplan.

3.2.2.1 Land Uses

Current and reasonably anticipated future land use scenarios should be identified in the

workplan. In calculating risk, estimations are made of the future exposure of people living or working on or near the site as well as their current exposure. Estimating future exposure requires an assumption about how the site and surrounding land will be used in the future. It is one of the most important steps in the exposure assessment because assumptions about the future use of land are a major determinant in calculating risk-based cleanup levels. Risk-based cleanup levels can vary depending on whether the site will be used for residential or commercial/industrial purposes. For alternative cleanup level determinations, a land use assumption requires ADEC concurrence. The current land use is to be determined by comparison of actual land use to the following definitions:

- **Residential Land** - Property used for one or more dwellings such as single-family houses and multi-family apartments, children's homes, and nursing homes. Because of the similarity of exposure potential and the sensitive nature of the potentially exposed population, day-care facilities, educational facilities, hospitals, playgrounds and similar facilities are considered residential. Properties restricted to residential use by legally enforceable zoning ordinance or specific deed restriction also meet this definition.
- **Commercial/Industrial Land** - Any real property or portions of a property not used for human habitation or for other purposes with a similar potential for human exposure. Examples include manufacturing, industrial research and development, utilities, commercial warehouse operations, lumber yards, retail gas stations, auto service stations, auto dealerships, equipment repair and service stations, professional offices (lawyers, architects, engineers, real estate, insurance, etc.), medical/dental offices and clinics (excluding hospitals), financial institutions, publicly owned office buildings, a retail business where the principal activity is the sale of food or merchandise, personal service establishments (health clubs, barber/beauty salons, mortuaries, photographic studios, etc.), churches (excluding churches providing day-care or school services other than during normal worship services), and motels/hotels (excluding those that allow residence). Also, properties restricted to commercial or industrial use by a legally enforceable zoning ordinance or specific deed restriction meet this definition.
- **Other Land Uses** - Other land uses such as recreational areas, aquaculture or silvicultural areas, hunting and fishing areas, pipelines, remote fuel depots, transfer stations, waste disposal units, and military target ranges will be evaluated on a case-by-case basis for each site.

- **Future Land Use** - Generally, can best be predicted by the landowner. A residential receptor will generally be assumed at the property boundary. However, zoning of the property, the adjoining neighboring property, and any municipal comprehensive plan may also be the deciding factor for purposes of establishing risk-based cleanup levels. The responsible person may propose the future land use only for property owned by that person.

If the planned future use is less sensitive than the current use, the current land use must be used to develop protective risk-based cleanup levels unless the current use is stopped. If the planned future land use is more sensitive than the current use, then the future use must be used to develop protective risk-based cleanup levels. Also, if land use changes, alternative risk-based cleanup levels must be recalculated. In proposing nonresidential land use for the site in the risk assessment workplan, the following information must be provided:

1. current ownership or lease information;
2. disclosures on subleasing;
3. population and economic trends;
4. zoning ordinances or comprehensive plans;
5. other land use restrictions;
6. use of adjacent land;
7. use of groundwater;
8. availability of municipal water or other public water systems; and
9. water resource protection plans such as wellhead protection, aquifer vulnerability, and watershed protection goals.

3.2.2.2 Groundwater Considerations

The risk assessment workplan should also verify groundwater use based on 18 AAC 70.050(2).

3.2.2.3 Reasonable Maximum Exposure

ADEC requires the use of Reasonable Maximum Exposures (RMEs) for all risk characterization calculations. RME is defined as the highest exposure that is reasonably expected to occur at a site. RME is a high-end estimate - 95th percentile of the actual distribution (EPA, 1989) - that focuses on exposure to the actual population. The intent of the RME is to estimate a conservative exposure scenario that is within range of possible exposures (yet well above the average case) and to avoid estimates that are beyond the true distribution.

3.2.2.4 Deterministic Versus Probabilistic Risk Assessment

ADEC accepts only deterministic risk assessments for ecological risk assessment, but will, on a case-by-case basis, also consider the use of distributional simulation techniques in performing probabilistic risk assessments for human health. Probabilistic risk assessment techniques characterize uncertainties in risk estimates by allowing for distributions of values (probability density function or PDFs) in one or more of the input variables in a statistical analysis. ADEC is developing guidelines for probabilistic risk assessment techniques.

3.2.2.5 Soil Exposure Areas

The risk assessment workplan should identify soil exposure areas for the various land uses. For all land uses, ADEC will generally use a default value of two feet to define surface soil and 15 feet to define subsurface soil to which residents will have a reasonable potential to be exposed (ingestion, dermal contact, and inhalation). Fifteen feet is the depth above which it is reasonably likely for affected soils to be excavated and brought to the surface during the installation of septic systems, utilities, construction of basements, etc. These defaults may be increased or decreased on a site-specific basis. A default of two cm will be used for inhalation of particulates exposure areas.

3.2.3 Risk Characterization

The quantitative estimate of the risk is of principal interest to ADEC in making risk management decisions. ADEC considers the results of the risk characterization when evaluating the economics, societal aspects, and various benefits of the risk assessment. All risk characterization procedures should be detailed in the risk assessment workplan. Both carcinogenic and noncarcinogenic contaminants should be addressed in risk characterization calculations.

3.2.4 Calculation of Risk-based Cleanup Levels

Equations and methodologies to be used to propose the risk-based cleanup levels must be provided in the workplan for ADEC approval. The risk assessment provides the basis for determining whether impacted media at a site require remediation to protect human health and the environment under specific land use conditions. Levels of risk will indicate the extent that the concentration of compounds of potential concern should be reduced to achieve acceptable risk levels. Site-specific risk based cleanup levels will be calculated consistent with ADEC regulations and EPA guidance.

3.2.5 Risk Levels for Carcinogens and Non-Carcinogens

The target risk level serves as a starting point in the development of scientifically defensible risk-based regulations, the establishment of mixing zones for permits, as well as in the development of alternative cleanup levels in risk assessments.

Additionally, a source or site's contribution to cumulative risk will be considered. Cumulative risk to human health is defined as the totality of risks resulting from multiple sources and pathways to which humans are exposed.

To ensure the same level of protection of human health for all land uses, single acceptable target risk levels are proposed (as opposed to a range of risks). ADEC is adopting the following risk management standards:

For method four cleanup, the HI goal will be 1.0. The cumulative carcinogenic risk goal will be 1×10^{-5} . At the department's discretion, a risk range consistent with 42 U.S.C. 9605 (National Contingency Plan) will be considered based on the following criteria:

- Site-specific conditions
- Land use
- Contaminate characteristics
- Statutory compliance
- Protection of human health and the environment
- Implementability of a cleanup
- Long and short term effectiveness
- Public comment
- Cost

3.3 Ecological

Ecological risk assessment is a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. EPA approaches to ecological risk assessments for Superfund sites are based on the human health risk assessment format, but modified for the increased complexity of organisms encountered and their interactions with the system (EPA, 1997b).

3.3.1 Preliminary (or Screening Level) Problem Formulation

Preliminary problem formulation is the first stage of the ecological risk assessment. In this phase, policy and regulatory discussions with the risk manager and the stakeholders establish the goals and focus of the risk assessment. Much of the preliminary problem formulation takes place through the deliverables required at the scoping meeting (Section 1.6) and via the submittal of the conceptual site models. The remainder of the preliminary problem formulation tasks may take place in the workplan. Upon the completion of the preliminary problem formulation, it is possible to establish an Ecological Scientific/Management Decision Point (EPA, 1997a), using Figure 3.3.1, because at this point, it will be evident whether or not a significant ecological threat may exist.

Figure 3.3.1 Ecological Scientific/Management Decision Point #1:

- are sensitive environments identified?
 - Yes? Proceed with Ecological risk Assessment
Go to 3.3.2 Effects Evaluation
 - No? End ecological risk assessment unless
the following question is answered yes

- are completed exposure pathways identified?
 - Yes? Proceed with ecological risk assessment
Go to 3.3.2 Effects Evaluation

EPA lists the following steps needed in this preliminary phase (EPA, 1997a):

1. **Environmental setting and contaminants at the site.** ADEC will accept the Appendix B ecological checklists as sufficient to characterize the site setting for this preliminary problem formulation phase. Information from the site's preliminary assessment (PA) and site investigation (SI) can be used to fill out the checklists. A list of the contaminants of concern is also required for the scoping meeting.

2. **Contaminant fate and transport.** ADEC will accept the Appendix B ecological checklists and the ecological CSM as sufficient to characterize contaminant fate and transport for the preliminary problem formulation phase.

3. **Ecotoxicity and potential receptors.** ADEC requires the development of the CSM as an initial planning tool. If more information become available regarding pathways and toxic mechanisms for the site, an updated CSM must be included in the risk assessment workplan. ADEC will accept the ecological CSM, the Appendix B ecological checklists and the ecological risk-based screening for compounds of concern described in Section 4.2.4 as sufficient to meet this step.

4. Completed exposure pathways. The ecological CSM from Section 2.1 identifying potential pathways must be refined in the workplan to include all completed exposure pathways.

5. General assessment and measurement endpoints. As per EPA guidance (EPA, 1997b), for purposes of screening, assessment endpoints will be defined as any adverse effects on the ecological receptors described in the scoping meeting. Receptors are plant and animal populations, communities, habitats as identified in the Appendix B ecological checklists or sensitive environments as identified in the scoping meeting (section 1.6) via section 4.2.4.2 (state sensitive environments) and 4.2.4.3 (federal sensitive environments).

3.3.2 Ecological Effects Evaluation

The initial analysis plan in Alaska risk assessments consists of a risk-based screening (see Section 4.2.4 for more detail). All information regarding the selection of the measurement of effects criteria and ecological benchmarks must be included in the workplan. The preparation of the analysis plan relies primarily on existing toxicity information but can involve development of new toxicity information or ecological benchmarks.

Figure 3.1.2 Ecological Scientific/Management Decision Point #2:

- are all chemical concentrations below ecological benchmarks?

No? Proceed with Ecological risk Assessment

Go to 4.4.2

**Yes? End ecological risk assessment unless
the following question is answered yes**

- do chemicals of concern have a tendency to bioaccumulate and/or biomagnify?

Yes? Proceed with ecological risk assessment

Go to 4.4.2

The following sources should be consulted for ecological benchmarks for soil, sediment, and water (see Table 3.3.2 for toxicity criteria contacts.):

1. ECOTOX thresholds listed in current EPA Eco Updates;
2. ECOTOX databases:
 - a. AQUIRE database;
 - b. TERRETOX database;
 - c. PHYTOTOX database;
3. Screening Benchmarks for Ecological Risk Assessment (Oak Ridge National Laboratory);
4. NOAA Sediment Guidelines, Long and Morgan;
5. Hazardous Substances Database (HSDB);
6. IRIS;
7. Ambient Water Quality Criteria;
- 8.. State of Washington Summary of Guidelines for Contaminated Sediments;
9. (WDOE, publication #95-308)
10. other professionally peer reviewed documents as needed and as approved by ADEC on a case-by-case basis.

Table 3.3.2

ECOLOGICAL TOXICITY CRITERIA CONTACTS

Toxicity Criteria	Agency Contact	Phone/Email
ECOTOX Thresholds	EPA Eco Updates	n/a
ECOTOX database (AQUIRE, TERRETOX, PHYTOTOX, QSAR, ASTER)	For government and government contractors, access free via EPA Scientific Research Program	(218) 720-5602 outreach@du4500.dul
ECOTOX database (AQUIRE, TERRETOX, and PHYTOTOX only)	For private sector, VAX VMS and non-VMS data tapes via National Technical Information Service (NTIS)	(703) 487-4763
NOAA Sediment Guidelines (ER-L and ER-M)	National Oceanic and Atmospheric Administration	(206) 526-6338
Oak Ridge Ecological Risk Assessment Screening Benchmarks	ORNL	http://www.hsr.d.ornl.gov/ecorisk/ecorisk.html
AQUIRE database	For government and government contractors online, access via EPA Scientific Research	(218) 720-5602 outreach@du4500.dul
	For private sector online, Chemical Information Systems, Inc.	(800) CIS-USER
	For private sector online, Technical Database Services, Inc.	(212) 245-0044
	For database files, Spectrum Research, Inc.	(218) 525-5322
	For microcomputer format, ASCI Corporation	(703) 847-0001
	For microcomputer format, Spectrum Research, Inc.	(218) 525-5322
	For VAX VMS and UNIX based software onsite, Daylight Chemical Information Systems, Inc.	(714) 476-0451
Hazardous Substances Database (HSDB)	National Library of Medicine	(301) 469-6531
Other professionally peer reviewed documents as needed and as approved by ADEC on a case-by- case basis.		

Assessment endpoints are critical to problem formulation because they link the risk assessment to risk management. Criteria for the selection of assessment endpoints must be included in the workplan. An example of an assessment endpoint can be found in federal (EPA, 1996c) and regional (EPA, 1996a) guidance. The goals of the assessment should clearly be defined in the problem formulation portion of the workplan. The workplan must also include the data requirements and existing data gaps for the assessment endpoints.

3.4 Data Usability

Sampling and analytical procedures must be appropriate to the data needs of each risk assessment. The quality of data used in the risk assessment is critical. Data usability must be discussed and approved by ADEC.

Since the human health and ecological risk assessment will estimate risk for individual chemicals, only sampling methods that give accurate, chemical-specific concentrations are useful. For example, field meters used for screens of total organic vapor do not give information on individual chemicals. Toxicity Characteristic Leaching Procedure (TCLP) analysis of soil provides information on chemical concentrations in leachate from the soil but does not provide chemical concentrations in the soil itself, so it is not useful data for risk assessment.

Unnecessary collection of data not useful for risk assessment may be prevented by early involvement of the ADEC project manager and risk assessment staff in developing the sampling plan. Professional judgment should be used to eliminate sampling data that are unsuitable for quantitative risk assessment. Rationale for all data elimination must be presented in the risk assessment report.

4.0 - RISK ASSESSMENT PROCEDURES

After ADEC approves the risk assessment workplan, the draft risk assessment document may be developed and submitted to the ADEC project manager. The human health risk assessment methodology in this section integrates federal, regional, and state requirements with site-specific information to provide a framework for performing a risk assessment at an Alaska contaminated site. The methodology provides a conservative estimate of the risks associated with a site. The risk assessment must be conducted by individuals with experience in the technical and regulatory aspects of risk assessment. All human health and ecological reporting tables in Appendices A, B, and C -- or a similar presentation -- must be submitted with the risk assessment document.

4.1 Organization of the Risk Assessment Report

The risk assessment report should follow the outline described in Figure 4.1 with minor adjustments as necessitated by site-specific conditions. General format requirements for the risk assessment report are as follows:

1. Text should be single spaced and printed double-sided.
2. Headings and subheadings should be numbered.
3. In all tables or discussions of contaminant concentrations in the body of the text, use the following concentrations of environmental media:
 - a. groundwater and surface water should be in micrograms per liter ($\mu\text{g/l}$, equivalent to parts per billion or ppb);
 - b. soil and sediments should be in milligrams per kilogram (mg/kg , equivalent to parts per million or ppm);
 - c. air concentrations and soil gas concentrations should be in milligrams per cubic meter (mg/m^3); and
 - d. fish tissue and other food concentration should be in micrograms per gram wet weight ($\mu\text{g/g}$, equivalent to parts per million or ppm).
4. Three copies of each submitted document (CSM, risk assessment workplan and risk assessment) should be submitted in the following manner:
 - a. one copy to the ADEC project manager; and
 - b. two copies to the ADEC risk assessment project manager.
5. In addition to the hard copies, for archival purposes, the document or portions of the document may be required electronically or on disc in *. pdf format. Exceptions will be considered on a case-by-case basis.

Figure 4.1

RISK ASSESSMENT REPORT FORMAT CHECKLIST



ITEMS

- I. Executive Summary**
- II. Introduction**
 - A. Site Description
 - B. Characterization of the Physical Setting
 - C. General Site Map
 - 1. Site name
 - 2. Site location
 - 3. North arrow
 - 4. Scale
 - 5. Map source
 - 6. Identify surface waterbodies and any drinking water wells
 - D. Specific Site Map 1
 - 1. Site name
 - 2. Site location
 - 3. North arrow
 - 4. Scale
 - 5. Map source
 - 6. Show land use areas including schools, residential areas, commercial areas, private and public drinking water supply wells
 - E. Specific Site Map 2
 - 1. Site name
 - 2. Site location
 - 3. North arrow
 - 4. Scale
 - 5. Map source
 - 6. Location of all structures, buried tanks, sources, impacted areas.
 - 7. Sample points including monitoring wells
 - 8. Ecological areas
 - F. Photographs
provide copies (photocopies acceptable) of any available site photographs
- III. Refined Conceptual Site Models**
 - A. Human Health
 - B. Ecological

- IV. Selection of Compounds of Potential Concern: Human Health and Ecological**
 - A. Target Analyte List/Target Compound List, modified as needed
 - B. Nondetected Parameters
 - C. Human Health Risk-based Screening Using Maximum Concentrations
 - D. Background Comparison Using Maximum Concentrations
 - E. Other Potential Human Health Standards/Criteria
 - F. Potential Sensitive Environments
 - G. Ecological Risk-Based Screening Using Maximum Concentrations
 - H. Other Potential Ecological Standards/Criteria
 - I. Data Gaps
 - J. Data Usability
 - K. Appropriate Concentration Units
 - L. Table A.1: ADEC Human Health Compounds of Potential Concern Data Presentation Table
 - M. Table C.1: ADEC Ecological Compounds of Potential Concern Data Presentation Table

- V. Human Health**
 - A. Exposure Assessment**
 - 1. Land Use
 - a. Current
 - b. Future
 - 2. Scenarios /Potentially Exposed Populations
 - 3. Pathways
 - 4. Groundwater Classification as per 18 AAC 70.050(2) or 18 AAC 70.055
 - 5. Exposure Point Concentrations
 - 6. RME Exposures
 - 7. Central Tendency Exposure
 - 8. Soil Exposure Depths
 - 9. Deterministic Risk Assessment
 - 10. Types of Exposures
 - a. Chronic
 - b. Subchronic
 - c. Acute
 - 11. Table A.2: ADEC Human Health Exposure Data Presentation Table

 - B. Toxicity Assessment**
 - 1. Published Criteria Used
 - 2. Missing Toxicity Factors
 - 3. Adjustments and Extrapolations
 - 4. Table A.3: ADEC Human Health Toxicity Data Presentation Table for Carcinogenic Data
 - 5. Table A.3: Human Health Toxicity Data Presentation Table for Noncarcinogenic Data

- C. Risk Characterization**
 - 1. Carcinogenic Risks
 - 2. Noncarcinogenic Risks
 - 3. Risk Levels
 - 4. Table A.5: ADEC Risk Characterization Data Presentation Table
 - 5. Table A.6: Risk Summary Data Presentation Table for Carcinogenic Data
 - 6. Table A.7: Risk Summary Data Presentation Table for Noncarcinogenic Data

- VI. Ecological**
 - A. Results of Preliminary Problem Formulation and Ecological Effects Evaluation
 - 1. Environmental Setting and Contaminants at the Site
 - 2. Contaminants Fate and Transport
 - 3. Ecotoxicity and Potential Receptors
 - 4. Completed Exposure Pathways
 - 5. General Assessment Endpoints and Measurement Endpoints

 - B. Problem Formulation and Analysis Phase
 - 1. Preliminary Risk Calculations
 - 2. Selection of Assessment Endpoints
 - 3. Selection of Measurement Endpoints
 - 4. Field Verification of Sampling Design

 - C. Risk Characterization

 - D. Results of Scientific/Management Decision Points

- VII. Calculations for Alternative Risk-based Cleanup Levels: Human Health and Ecological**
 - A. Comparison of Calculated Risk-based Concentrations to Regulatory Standards and Guidelines
 - B. Consideration of Effects of Leaching to Groundwater

- VIII. Uncertainty Assessment**
 - A. Human Health Uncertainty
 - 1. List of Uncertainty Factors
 - 2. Consideration of Other Studies

 - B. Ecological Uncertainty
 - 1. List of Ecological Uncertainty Factors and Sources

 - C. Endocrine Disruptor
 - 1. List of possible Human Health and Ecological Endocrine Disruptors

IX. Appendices

- A. Toxicological profiles, one page each for each major risk driver
- B. ADEC Ecological Checklists
- C. Modeling Inputs
- D. Other information as needed

4.2 Selection of Compounds of Potential Concern: Human Health and Ecological

Selecting compounds of potential concern (COPCs) for a risk assessment requires the use of numerous site-specific procedures for data collection, sampling and analysis, data evaluation and validation, and site characterization. The identification of the COPCs includes the use of conservative preliminary risk-based screening.

Identifying a process for the selection of COPCs results in a site-specific list of COPCs. These contaminants are then subject to the remainder of the data evaluation and risk assessment (exposure assessment, toxicity assessment, risk characterization, and calculation of alternative risk-based cleanup levels).

The precise procedure used to identify the applicable COPCs at a site is often an iterative site-specific process. For that reason, the following information is set out as a method for obtaining this information. The precise methodology used must be agreed upon by the person conducting the risk assessment and ADEC.

This section discusses the process for using data collected and evaluated as part of the site characterization process to identify COPCs. Organization of data should be conducted before the risk assessment in the following manner (EPA, 1989):

1. Gather all data available from the site investigation and sort by medium;
2. Evaluate the analytical methods used;
3. Evaluate the quality of data with respect to sample quantification limits;
4. Evaluate the quality of data with respect to qualifiers and codes;
5. Evaluate the quality of data with respect to spikes and blanks;
6. Evaluate tentatively identified compounds;
7. Compare potential site-related contamination with background according to ADEC guidance on background determinations;
8. Develop a set of data for use in the risk assessment; and
9. If appropriate, further limit the number of contaminants to be carried through the risk assessment.

4.2.1 Target Analyte List/Target Compound List

At any contaminated site there is the potential for a large number of contaminants to be present. It is not always feasible to analyze for all substances and, fortunately, it is not necessary to do so. Multi-variate data sets typically exhibit a phenomena described by the Pareto principle, which states that a relatively large number of problems (for example, a large proportion of site attributable risk) in a given situation will be found to be caused by only a few factors (or a few hazardous substances). EPA applied this concept when it developed a list of approximately 150 hazardous substances most commonly encountered while implementing the clean water, clean air, and hazardous substance programs. These substances, referred to as the target analyte list (TAL) and the target compound list (TCL), are those manufactured and used in the greatest amounts and that are the most toxic.

ADEC also applied the concept of the Pareto principle when developing the list of hazardous substances for the cleanup levels in 18 AAC 75.340 and 18 AAC 75.345. These lists typically form the initial set of hazardous substances considered during a site investigation. With appropriate information on the history of site operations and previous environmental investigation data, the initial set can be tailored to site conditions by adding site-specific hazardous substances and indicator parameters that could prove to be of interest and by deleting those likely to be absent in any significant quantities.

4.2.2 Nondetected Parameters

When measurements less than the level of detection are reported as nondetected, the data are referred to as “censored.” In censored data sets, the number of nondetects is known. As contaminant data sets contain considerable amounts of censored data, a process must be established for estimating tolerance limits when a given parameter is never detected or only sometimes detected in the data set. Computerized methods, such as iterative maximum likelihood calculations, are available for estimating the true means and variances of censored data sets.

4.2.3 Human Health Risk-Based Screening for Compounds of Potential Concern

Once actual compounds are attributable to a particular site, the relevant data set can be further focused through a risk-based screening. The ADEC procedure for risk-based screening is as follows:

1. Tabulate the **maximum** concentration of each contaminant in each environmental medium.
2. Determine a human health risk-based benchmark using the following hierarchy:
 - a. use one-tenth of the ADEC calculated soil and groundwater cleanup levels set out in 18 AAC 75.340 and 18 AAC 75.345;
 - b. for compounds that do not have regulatory cleanup levels or for media other than groundwater and soil, calculate one-tenth of the risk-based benchmark concentrations for residential scenario. This must be done according to ADEC guidance and any additional information as necessary. The calculation for risk-based benchmarks must consider both carcinogenic and non-carcinogenic effects;
 - c. identify compounds without any risk-based benchmark concentrations.
3. Compare the maximum concentration to the risk-based benchmark cleanup level or other appropriate benchmark in tabular format (see Appendix A for data presentation).
4. Eliminate compounds if they do not exceed any of their respective risk-based benchmarks at 1×10^{-6} risk or HQ = 0.1.
5. Identify all compounds not eliminated as contaminants of potential concern and carry these through the remainder of the human health risk assessment process.

6. All compounds without risk-based benchmarks should be retained for more detailed evaluation in the remainder of the risk assessment process.

All maximum contaminant concentrations, regulatory levels or other benchmarks, and site background levels (if applicable) must be listed in tabular form for comparative purposes.

4.2.3.1 Other Human Health Standards/Criteria as Screening Limits

In addition to one-tenth of the ADEC soil and groundwater cleanup levels in 18 AAC 75.340 and 18 AAC 75.345, ADEC will also continue to use other screening criteria, as appropriate.

ADEC will consider the following standards for risk management decisions:

- One-day and Ten-day Health Advisories;
-
- Ambient Surface Water Quality Criteria (18 AAC 70);
-
- Permissible Exposure Limits (PELs); and
-
- ACGIH Threshold Limit Values (TLVs).

Distinguishing site contamination from naturally occurring or anthropogenic background levels in risk assessment is critical. If inorganic contaminant concentrations are less than or equal to background for the site (as calculated according to ADEC's *Technical Guidance Document on Determination of Background Concentrations*) then the compound need not be retained as a COPC for human health or ecological risk assessment. Background demonstrations for organic constituents may be evaluated on a case-by-case basis as determined by ADEC when data supports the demonstration.

4.2.3.2 Soil Ingestion Risk-Based Screening

For preliminary screening procedures, the maximum contaminant detected remaining in soil must be evaluated using the soil ingestion pathway. This concentration should be used regardless of the depth of the maximum concentration.

4.2.3.3 Water Ingestion Risk-Based Screening

The water ingestion pathway, if present, must conservatively assume direct exposure to groundwater. Surface water should also be considered if a completed exposure pathway is present. At this point in the risk assessment process, conservatism outweighs the desire for realism in terms of screening for compounds of potential concern. Realism - actual exposures - can be addressed in the exposure assessment section of the risk assessment.

4.2.3.4 Air Inhalation and Particulate Inhalation Risk-Based Screening

If empirical monitoring data or soil gas data are not available, soil concentrations will need to be extrapolated to the atmosphere through simple modeling such as the EPA Soil Screening Model (EPA, 1996d) regardless of depth.

See Figure 4.2.3.4 for example of a data presentation format.

FIGURE 4.2.3.4 EXAMPLE HUMAN HEALTH COMPOUNDS OF POTENTIAL CONCERN

✓ ENVIRONMENTAL MEDIUM: Surface Water Groundwater Air
 Soil Sediment Biota

1. Compound of Potential Concern	2. Units	3. Detection Frequency	4. Minimum Concentration (above SQL)	5. Maximum Concentration (above SQL)	6. Detection Limits	7. Background Concentration	8. Risk Based Screening Level (carcinogen)	9. Detection Frequency above RBSL (carcinogen)	10. Risk Based Screening level (non- carcinogen)	11. Detection Frequency above RBSL (non-carcinogen)	12. Potential ARAR/ TBC	13. Detection Frequency above ARAR/TBC
Compound a	ug/l	6/10	2.2	40.1	1.0	16.8	x.xx	2/10	y.yy	2/10	50 (MCL)	2/10

4.2.4 Ecological Risk-based Screening for Compounds of Potential Concern

4.2.4.1 Sensitive Environments/Ecological Hazards

If a compound is eliminated based on the human health risk-based screening criteria, it may nonetheless be retained if ADEC determines there are habitats, sensitive environments, or biological species of potential concern. Alaska sensitive environments are defined in 18 AAC 75.610; 18 AAC 75.620, 18 AAC 75.630, and 18 AAC 75.990. Sensitive environments may include:

4.2.4.2 State Sensitive Environments

- State wildlife refuges;
- State land designated for wildlife or game management;
- State-designated scenic or wild rivers;
- State-designated natural areas;
- State-designated areas for protection or maintenance of aquatic life;
- Spawning areas critical for the maintenance of fish or shellfish species within rivers, lakes, or coastal tidal waters;
- Migratory pathways and feeding areas critical for maintenance of anadromous fish species within river reaches or areas in lakes or coastal tidal waters in which the fish spend extended periods; and
- Terrestrial areas used for breeding by large or dense aggregations of animals.

4.2.4.3 Federal Sensitive Environments

- Critical habitat for federal-designated endangered or threatened species;
- Marine sanctuaries;
- National parks;
- Designated federal wilderness areas;
- Areas identified under the Coastal Zone Management Act;
- Sensitive areas identified under the national estuary program;
- Sensitive areas identified under the near coastal waters program;
- Critical areas identified under the clean lakes program;
- National monuments;
- National seashore recreation areas;
- National Lakeshore recreational areas;
- National preserves;
- National wildlife refuges;
- Units of coastal barrier resources systems;
- Coastal barriers;
- Federal land designated for the protection of natural ecosystems;
- Administratively proposed federal wilderness areas;
- National river reaches designated as recreational; and
- Federal-designated scenic or wild rivers.

4.2.4.4 Ecological Benchmarks

If a compound is retained for ecological consideration based on a completed exposure pathway, an ecological risk-based benchmark should be determined using an actual site-specific receptor (as identified in the site characterizations or conceptual site model) or an actual assessment endpoint. In general, each literature source should be reviewed for the lowest exposure level shown to produce adverse effects in a potential receptor species. In addition, the highest exposure level at which no adverse effects have been demonstrated should be identified. ADEC prefers the use of no observed adverse effects levels (NOAELs) for initial screening estimates to ensure that risk is not underestimated (see Table 3.3.2 for ecological criteria contacts). The following sources should be used for ecological benchmarks (see Table 3.3.2):

1. ECOTOX thresholds listed in current EPA Eco Updates;
2. AQUIRE database;
3. TERRETOX database;
4. PHYTOTOX database;
5. Screening Benchmarks for Ecological Risk Assessment (Oak Ridge National Laboratory);
6. NOAA Screening Guidelines;
7. Hazardous Substances Database (HSDB);
8. IRIS; and
9. other professionally peer reviewed documents as needed and as approved by ADEC on a case-by-case basis.

After an ecological benchmark is determined, the screening for ecological risk applies the same process as human health risk screening, namely:

1. Compare the maximum concentration to the ecological risk-based benchmark or other appropriate benchmark in tabular format.
2. Eliminate compounds if they do not exceed any of their respective risk-based benchmarks at $HQ = 1$.
3. Retain compounds (even if the $HQ < 1$) that have a potential to bioaccumulate.
4. Identify all compounds not eliminated as contaminants of potential concern and carry these through the remainder of the risk assessment process.
5. All compounds without risk-based benchmarks should be retained for more detailed evaluation.

4.2.4.5 Calculating Toxicity Reference Values/Ecological Benchmarks

For many ecological contaminants, ecological benchmarks will not be readily available. In these cases, toxicity reference values (TRVs) need to be calculated. TRVs are the ecological equivalent of calculating a human health reference dose (RfD). TRVs are accepted as intake values on the premise that ecological risk assessments are designed to protect the population of a species and not the individual response. This may not always be the case since legislative acts can require the protection of individuals in a species. But, in general, the types of endpoints that ecological risk assessments need to address for non-endangered species include reproduction, growth, maintenance, and critical developmental processes. Cancer is not usually selected as a chronic ecological endpoint.

For more detailed procedures for calculating TRVs, refer to *Performing Ecological Risk Assessments* (Calabrese and Baldwin, 1993). In general, the derivation of TRVs must deal with various uncertainties in the extrapolation of laboratory data to site-specific conditions.

4.2.4.6 Quantitative Structural Activity Relationship

For a very few ecological contaminants, ecological benchmarks are not readily available nor are TRV calculations possible. In these instances, quantitative structural activity relationships (QSARs) must be determined. A QSAR is a mathematical relationship between a property of a chemical, either bioconcentration potential or toxicity, and its chemical or physical characteristics. The ecological criteria databases (Table 3.3.2) should be used to determine bioconcentration and toxicity data needed to establish a mathematical relationship between the defined property and the descriptor (Hickey, 1993). The QSAR can then be used to predict the bioconcentration or toxicity potential of untested chemicals for which the descriptors are known. QSARs may be developed by, or in consultation with EPA. However, ADEC risk assessment staff should be consulted before contacting EPA because similar derivations may be readily available from other risk assessments conducted in Alaska.

4.2.4.7 Ecological Uncertainty Factors

ADEC will accept the following uncertainty factors (UFs) for calculating toxicity reference values:

4.2.4.7.1 Species-specific data

- a. Chronic NOEL
UF = 1
- b. Chronic NOAEL
UF = 1-2
- c. Chronic LOEL
UF = 5
- d. Chronic LOAEL
UF = 5-10
- e. Subchronic NOEL
UF = 5
- f. Subchronic NOAEL
UF = 5-10
- g. Subchronic LOEL
UF = 25
- h. Subchronic LOAEL
UF = 25-50
- i. Acute NOEL
UF = 20
- j. Acute NOAEL
UF = 20-40
- k. Acute LOEL
UF = 100
- l. Acute LOAEL
UF = 100-200
- m. LD₅₀
UF = 250

4.2.4.7.2 Non-species specific data

- a. For population effects
 - i. Different trophic level
UF = 2
 - ii. Different exposure media
UF = 2
- b. For biochemical effects
 - i. Toxic intermediate data
UF = 4
- c. Phylogeny effects
 - i. Species sensitive to toxic endpoint
UF = ½
 - ii. Different genus
UF = 2
 - iii. Different order/family
UF = 4
 - iv. Different class

Cannot use data

As with human health tables, all ecological information must be presented in a tabular format. In addition, maximum detected levels, risk-based calculations (whether literature or calculated), frequency of samples exceeding screening benchmarks, as well as background values (if applicable) must be included in tabular format (see Figure 4.2.4.7).

FIGURE 4.2.4.7 EXAMPLE ECOLOGICAL COMPOUNDS OF POTENTIAL CONCERN

- ENVIRONMENTAL MEDIUM:
 Surface Water Groundwater Air
 Soil
 Sediment Biota

1. Compound of Potential Concern	2. Units	3. Detection Frequency	4. Minimum Concentration (above sql)	5. Maximum Concentration (above sql)	6. Detection Limits	7. Background Concentration	8. ECO Risk Based BENCHMARK	9. Detection Frequency above ECO BENCHMARK	10. Potential ARAR/ TBC	11. Detection Frequency above ARAR/TBC
Compound b	Ug/l	6/10	2.2	40.1	1.0	16.8	0.046	2/10	50 (MCL)	2/10

Human Health Risk Assessment

4.2.5 Exposure Assessment

The objective of the exposure assessment is to estimate the type and magnitude of exposures to the compounds of potential concern present, migrating from the site, or with the potential to migrate from the site. This information is integrated with the toxicity information to characterize the potential risks associated with exposure to contaminants at the site. The human health risk assessment is a “baseline” risk assessment. That is, it does not consider conditions either during or after remediation. ADEC requires the risk assessment to consider both current and future exposure scenarios at the site.

4.2.5.1 Characterization of the Physical Setting

Characterization of the physical setting of a specific site is essential in developing the exposure assessment. Section 6.2.1 of EPA Risk Assessment Guidance for Superfund (EPA, 1989) identifies important site characteristics that should be considered when preparing an exposure assessment.

4.2.5.2 Determining Potentially Exposed Populations

For the human health portion of the risk assessment, the receptor populations for a site are selected based on the location and activities of current and reasonably anticipated future populations associated with probable land use. Section 6.2.2 of EPA Risk Assessment Guidance for Superfund (EPA, 1989) provides information on identifying potentially exposed populations. To evaluate human health risk under current and future conditions, the risk assessment should include a residential scenario, or an industrial scenario. For a remote site, the risk assessment must propose a more appropriate scenario reflecting land use. The Alaska Department of Labor maintains population estimates for most Alaska communities (ADOL, 1992; ADOL, 1994).

4.2.5.3 Identification of Exposure Pathways

An exposure pathway describes a unique mechanism by which an individual or population is exposed to hazardous substances such as chemicals at or originating from a site. All exposure pathways must have been identified in the CSM. The exposure assessment, then, focuses on those completed pathways that are likely to contribute significantly to the overall risks. Only completed exposure pathways should be evaluated in the exposure assessment. A completed exposure pathway must contain the following elements:

1. a contaminant source;
2. a mechanism for hazardous substance release;
3. a transport mechanism to the various environmental media;
4. exposure media;
5. exposure route; and
6. receptors.

At Alaska sites, soil is often the primary source of contaminants that can potentially be transported to other media where human contact may occur. For example, contaminants in soil can be transported to groundwater and direct ingestion of the groundwater is then considered a completed exposure pathway for the soil and the groundwater. All completed pathways should be identified and evaluated.

Primary pathways identified in the conceptual site model are usually evaluated qualitatively to see if a completed exposure pathway exists. Primary completed exposure pathways will then be evaluated quantitatively in the risk assessment process. Primary pathways in Alaska risk assessments usually include:

1. ingestion of soil and dust;
2. inhalation of fugitive dust or volatiles;
3. ingestion of water; and
4. dermal contact with soil and water.

Secondary pathways that were also identified in the conceptual site model are usually identified only qualitatively, but may be evaluated quantitatively based on pathway specific toxicity information, frequency of detection, and likelihood of exposure. Secondary pathways in Alaska risk assessments are often associated with subsistence, hunting, and fishing and may include:

1. ingestion of game;
2. ingestion of fish and shellfish;
3. ingestion of homegrown vegetables and fruit; and
4. ingestion of wild berries, mushrooms, vegetables, and fruit.

4.2.5.4 Exposure Point Concentrations

The exposure point concentration is the concentration of the compound of concern in the environmental media at the point of human exposure. In the detailed exposure assessment of a risk assessment, the exposure point concentration is dependent on the location of the human receptor being modeled or measured. ADEC requires risk assessments to consider conservative distributions of exposures. The reasonable maximum exposed (RME) individual in each receptor group should be quantified. The choice of sampling data used to estimate exposures in each scenario should reflect actual exposure points and locations of land use.

The exposure point concentration must be estimated using a 95 percent upper confidence limit (UCL) on the arithmetic mean (or geometric mean if the values are lognormally distributed) of the contaminant concentrations. If there is a high degree of variability in contaminant concentrations, the 95% UCL on the average concentration may exceed the maximum concentration. In such a situation, the maximum contaminant concentration should be used to represent the exposure point concentration. The selection criteria for samples used to determine exposure point concentrations should be clearly defined. While actual monitoring data are preferred for current exposure point concentrations, modeled data are preferred for future scenario exposure point concentrations.

Groundwater samples from a single well should use the 95% UCL average concentration that would be contacted by the RME. If enough points do not exist for this calculation, a simple average must be used. Soil sample concentrations may vary significantly over the site. In these cases, hot spots should be separated from other source areas, and separate exposure point concentrations should be calculated. See Figure 4.3.1.6 for reporting the statistics associated with exposure point concentration.

4.2.5.5 Types of Exposures: Chronic, Subchronic, and Acute

A risk assessment must consider carcinogenic and noncarcinogenic effects of chronic exposure (seven years to lifetime). However, due to the remoteness of many Alaska contaminated sites, effects from subchronic exposure (two weeks to seven years) may need to be calculated. For subchronic effects, toxicity values should be changed from standard protocol to reflect the shorter exposure duration. Acute exposures (less than two weeks) may be of concern in hot spot areas. Emergency response actions, as needed to abate the release and mitigate impacts on public health and the environment should be sufficient to identify and control any acute hazards associated with releases of waste materials and hazardous substances, including petroleum products.

4.2.5.6 Alaska Specific Exposure Scenarios

ADEC is developing Alaska specific exposure scenarios for subsistence users by eco-region and plans to make them available for public review and comment in late 1998.

FIGURE 4.3.1.6 EXAMPLE HUMAN HEALTH EXPOSURE ASSESSMENT DATA

ENVIRONMENTAL MEDIUM:
 Surface Water
 Groundwater
 Air
 Soil
 Sediment
 Biota

1. Compound of Potential Concern	2. Units	3. Minimum Concentration (above sql)	4. Maximum Concentration (above sql)	5. Mean of Normal data	6. Standard Deviation of Normal data	7. T-statistic	8. 95% UCL of Normal Data	9. Mean of Log-transformed Data	10. H-statistic	11. 95% UCL of log-Transformed data	12. Reasonable Maximum Exposure	13. Central Tendency	14. Statistic Selected	
													RME	CT
compound	ug/l	2.2	40.1	2.3E01	NA	NA	NA	3.1E01	2.222	3.2E01	3.2E01	3.1E01	95% UCL-T	Mean-T

4.2.6 Toxicity Assessment

A toxicity assessment identifies the potential adverse effects associated with site-related substances and estimates, using numerical toxicity values, the likelihood that these adverse effects will occur based on the extent of the exposure. The preparation of a toxicity assessment relies primarily on existing toxicity information and does not usually involve development of toxicity information or dose-response relationships.

4.2.6.1 Toxicity Hierarchy

The methodologies used to develop health-based toxicity criteria vary and depend upon whether a compound is a carcinogen (produces tumors) or a noncarcinogen (produces adverse effects such as immunotoxicity, reproductive toxicity, etc.). Cancer slope factors (SFs) or unit risk values are derived for carcinogens, while oral reference doses (RfDs) or inhalation reference concentrations (RfCs) are derived for noncarcinogens. In some instances, a compound may have multiple health-based toxicity criteria. The hierarchy of sources for toxicity criteria is as follows:

1. the Integrated Risk Information System (IRIS);
2. the Health Effects Assessment Summary Table (HEAST);
3. EPA Criteria Documents;
4. ATSDR minimal risk levels (MRLs); and
5. other professionally peer reviewed documents as needed and as approved by ADEC on a case-by-case basis.

(See Table 3.3.2 for toxicity criteria contacts and Figure 4.3.2.3 for reporting toxicity assessment data.)

EPA derived toxicity values may not be available for all substances and all routes of exposure. Toxicity values may be developed by, or in consultation with, the Superfund Technical Support Center at the Environmental Criteria and Assessment Office (ECAO). However, ADEC risk assessment staff should be consulted before contacting the ECAO because similar derivations may be readily available from other risk assessments conducted in Alaska.

4.2.6.2 Toxicity Profiles

The final risk assessment must provide toxicity information for each contaminant of potential concern. A short toxicity profile will suffice but should be directed toward the nontechnical reader, and may be used in site facts sheets. The Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles are good sources for informative yet readable toxicity discussions.

FIGURE 4.3.2.3 EXAMPLE HUMAN HEALTH TOXICITY ASSESSMENT DATA

CARCINOGENIC CRITERIA

1. Compound of Potential Concern	2. Citation	3. Cancer Slope Factor /Unit Risk		4. Dermal Absorption Rate	5. Adjusted Dermal CSF	6. EPA Weight of Evidence
		Type	Value			
Compound	IRIS (1996)	CSFo	1.75E00	95%	1.84E00	A

NONCARCINOGENIC DATA

1. Compound of Potential Concern	2. Citation	3. Reference Dose		4. Dermal Absorption Rate	5. Adjusted Dermal RfD	6. Target organ	7. Uncertainty Factors
		Type	Value				
Compound	IRIS (1996)	RFD _o , chronic	3.0E04	95%	2.85E04	skin	3

4.2.7 Risk Characterization

The information from the exposure assessment and the toxicity assessment is integrated to form the basis for the characterization of human health risks. The risk characterization presents qualitative and quantitative descriptions of risks. The numerical values in the risk characterization must be accompanied by the interpretive discussion qualifying the risks. The risk characterization serves as the bridge between risk assessment and risk management.

4.2.7.1 Carcinogenic Risk

For carcinogens, risks are defined as the likelihood of an individual developing cancer over a lifetime as a result of exposure to the chemical. That is, incremental or lifetime excess risk. The incremental lifetime cancer risk is obtained by multiplying the average daily dose over a lifetime by the cancer potency factor. This will represent risk-per-unit dose.

$$\text{Carcinogenic risk} = (\text{Chronic Daily Dose}) \times (\text{Slope Factor})$$

A weight-of-evidence approach is used by the EPA to classify the likelihood the agent in question is a human carcinogen. A three-stage procedure is followed. In the first stage, the evidence is characterized separately for human studies and for animal studies. Secondly, the human and animal evidence are combined into a presumptive overall classification. In the third stage, the provisional classification is adjusted upward or downward, based on analysis of the supporting evidence. The result is that each chemical is placed into one of the following five categories in Table 4.3.3.1.

Table 4.3.3.1 EPA Carcinogen Classification System & Risk Assessment

Group	Category	Retain as Carcinogen in Risk Assessment?
A	Human Carcinogen	yes
B1	Probable Human Carcinogen (Limited Human Evidence)	yes
B2	Probable Human Carcinogen (Sufficient evidence in animals, inadequate or no evidence in humans)	yes
C	Possible Human Carcinogen	discuss in uncertainty assessment only
D	Not Classifiable as to Human Carcinogenicity	no
E	Evidence of non-carcinogenicity for humans	no

Incremental cancer risks should be estimated separately for each exposure scenario and for each subpopulation. They should be presented using only one significant figure. Only group A, B1, B2 carcinogens should have incremental cancer risks. Group C chemicals should be discussed in the uncertainty analysis. Group D and E carcinogens should not have incremental cancer risk calculations.

Summaries of all incremental cancer risks for all media and all exposure scenarios should be included in the risk assessment. Please see Figure 4.3.3.2 for reporting risk characterization and Tables A5, A6, and A7 for reporting risk summary data.

ADEC recognizes that the EPA carcinogenic classification is changing and will update this procedures manual as more information becomes available.

4.2.7.2 Noncarcinogenic Risk

For noncarcinogens, the Hazard Quotient (HQ) is calculated as the average daily dose for the chronic exposure period divided by the chronic reference dose (RfD). Hazard indices should be calculated separately for each scenario and for each exposed population. They should be presented using two significant figures.

$$\text{Hazard Quotient} = \frac{\text{Chronic Daily Intake}}{\text{RfD}}$$

The risk characterization should include the following elements in the final discussion:

1. confidence that key site-related contaminants have been identified;
2. description of known or predicted health risks;
3. confidence in the toxicity information supporting the risk estimates;
4. confidence in the exposure assessment estimates;
5. magnitude of the cancer risks relative to the site-remediation goals;
6. major factors driving the risks including contaminants, pathways, and scenarios;
7. uncertainty associated with the results; and
8. ADEC Human Health Data Presentation Tables (Appendix A).

The risk characterization provides information to aid ADEC project managers in making risk management decisions regarding the site. Risk assessments should not contain unqualified statements in interpreting results. Statements such as “insignificant risk,” “unacceptable risk,” and “not of concern” should only be used when comparing results to ADEC risk management standards. These statements represent a set of values about what is an acceptable and significant risk to a community. They also imply conclusions concerning whether remediation should take place at a site. As previously stated, risk management should not be discussed in a risk assessment.

Figure 4.3.3.2 EXAMPLE HUMAN HEALTH RISK CHARACTERIZATION DATA

- SELECTED STATISTICS:** RME CENTRAL TENDENCY
- SCENARIO:** CURRENT FUTURE
- ENVIRONMENTAL MEDIUM:** Surface Water Groundwater Air
- Soil Sediment Biota
- RECEPTOR:** ADULT CHILD
- RESIDENT MAINTENANCE WORKER
- RECREATIONAL TRESPASSER
- CONSTRUCTION WORKER

RME

1. EXPOSURE ROUTE	2. COMPOUND OF POTENTIAL CONCERN	3. CANCER INTAKE	4. CSF	5. CANCER RISK	6. CANCER RISK TOTAL	7. NON-CANCER INTAKE	8. REFERENCE DOSE	9. HAZARD QUOTIENT
ingestion	compound a	3.0E-04	1.75E00	5.6E-04	12.0E-04	9.0E-04	3.00E-04	3.0
	compound b	6.7E-04	6.0E-01	4.0E-04		1.7E-03	9.0E-03	.1
	compound c	4.0E-03	5.2E-02	2.4E-04		1.4E-02	1.00E-02	1.1

4.3 Ecological Risk Assessment

Based on new EPA guidance from federal and regional levels, ecological risk assessment methodology has changed remarkably over the last few years. While this manual was drawn from many sources, several documents were especially important in its development: EPA's *Framework for Ecological Risk Assessment* (EPA, 1992a), draft *Proposed Guidelines for Ecological Risk Assessment* (EPA, 1996), *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA, 1997a), and *EPA Region 10 Supplemental Risk Assessment Guidance for Superfund* (EPA, 1997b).

Although the concepts are the same, as set out in 4.4.1, the EPA procedure for ecological risk assessment has been modified for use in Alaska. Please note that problem formulation has been divided into discreet components.

4.3.1 Preliminary Problem Formulation and Ecological Effects Evaluation

Preliminary problem formulation and ecological effects evaluation are discussed in the risk assessment workplan section (section 3.3) since it is likely that the tasks involved for preliminary problem formulation may be completed and a baseline ecological risk assessment may not be necessary. Based on the results of the scoping meeting, the ecological CSMs, and the Appendix B ecological checklist, the following two ecological scientific management decision points may be made:

RESULTS OF THE PRELIMINARY PROBLEM FORMULATION:

Figure 4.4.0 Ecological Scientific/Management Decision Point #1

- are sensitive environments identified?
 - Yes? Proceed with Ecological risk Assessment
Go to 3.3.2 Effects Evaluation
 - No? End ecological risk assessment unless the answer to the next question is yes

- are completed exposure pathways identified?
 - Yes? Proceed with ecological risk assessment
Go to 3.3.2 Effects Evaluation

RESULTS OF THE EFFECTS EVALUATION\

Figure 4.4.1 Ecological Scientific/Management Decision Point #2

- are all chemical concentrations below ecological benchmarks?

**No? Proceed with Ecological risk Assessment
Go to 4.4.2**

Yes? End ecological risk assessment unless the answer to the next question is yes

- do chemicals of concern have a tendency to bioaccumulate and/or biomagnify?

**Yes? Proceed with ecological risk assessment
Go to 4.4.2**

4.3.2 Preliminary Risk Calculations

The preliminary risk calculation compares the exposure estimates of the compound of potential concern to the screening ecological risk-based benchmarks. The hazard quotient (previously called the toxicity quotient) compares the exposure estimate (dose) to the ecological risk-based benchmark. (Please see Section 4.2.4.4 for acceptable sources of benchmarks.)

Figure 4.4.2 Ecological Scientific/Management Decision Point #3

- is there adequate information to conclude that risks are negligible?

Yes? End ecological risk assessment.

**No? Continue ecological risk assessment
Go to 4.4.3**

Conservative exposure estimates are compared to the screening ecological risk-based benchmarks using the hazard quotient (HQ) method. Compounds that exceed a $HQ > 1$ should be retained for further ecological evaluation and the possible development of a site specific risk-based ecological cleanup level. Quotient calculations include:

$$HQ = \frac{\text{Dose}}{\text{Benchmark}} \quad \text{or} \quad HQ = \frac{\text{EEC}}{\text{Benchmark}}$$

where:

HQ	=	hazard quotient (no units)
Dose	=	estimated contaminant intake as determined in the exposure estimate (mg/kg-day)
EEC	=	estimated environmental concentration (for example, mg/l)
Benchmark	=	toxicity reference value, an approved risk based concentration or a NOAEL (units to match Dose or EEC)

A $HQ > 1$ for a compound is interpreted by ADEC as a level at which a potential adverse ecological effect may occur. That is, there is potential likelihood of risk in an $HQ > 1$. These contaminants should be retained for further study in the risk assessment especially in the Uncertainty Assessment section.

A $HQ < 1$ generally need only be retained for uncertainty assessment. However, when a cumulative effect is suspected or known, the Hazard Index (HI) should be calculated, and all HQs contributing to the HI should be retained for further evaluation in the risk assessment. The HI is the summation of all of the HQs corresponding to the particular contaminant for all pathways for each media. If the HI exceeds unity, then the individual HQs should be retained for further evaluation in the risk assessment.

The hazard index calculation is as follows:

$$HI = \Sigma HQ \text{ with similar toxicological endpoints}$$

where:

HI	=	hazard index
HQ	=	hazard quotient

If the $HQ < 1$, yet has a potential to bioaccumulate, it should be retained for further evaluation in the risk assessment.

4.3.2.1 Exposure Estimates

The characterization of ecological exposure to chemicals requires the characterization of releases into the environment, the spatial and temporal distribution within the environment, and analysis of the compounds of concern coming in contact with the ecological receptor. Exposure assessment for an individual organism is defined in terms of contact of a compound of concern with the outer boundary of the organism. Exposure is defined in terms of the amount of the compound of concern ingested, inhaled, or absorbed through dermal and internal absorption. Exposure assessment for a population can be accomplished by incorporating the variability in exposure among individuals within a population, while exposure estimates can be presented as a distribution of exposure in the population or as point estimates to the individual.

4.3.2.2 Ecological Exposure Assumptions

Conservative estimates should be used to estimate exposures for HQ comparisons in the absence of sound site-specific information. Exceedances of the HQ unity must be retained for further evaluation, in which case, conservative assumptions will be replaced with site-specific assumptions in the calculated ecological risk based cleanup levels.

Acceptable ADEC exposure assumptions include:

1. Area use factor = 100%
2. Bioavailability = 100%
3. Sensitive life stage = most sensitive life stage
4. Body weight = minimum body weight
5. Ingestion rate = maximum ingestion rate

4.3.3 Problem Formulation and the Selection of Assessment Endpoints

To recap, at this point in the process, there are completed exposure paths and exceedances of ADEC risk management levels for Hazard Quotients and Hazard Indices. During problem formulation, compounds retained for further evaluation in the risk assessment are reassessed using more detailed site-specific conditions to determine reasonable exposure estimates. Generally, compounds of potential concern retained for further evaluation are known to be of ecological concern at the site. The problem formulation also includes the selection of assessment endpoints or specific ecological values to be protected (EPA, 1992). Upon completion, enough information should be gathered to answer the following:

- is there agreement on the following:

The assessment endpoints?

The exposure pathways?

Yes? Proceed with ecological risk assessment

Go to 4.4.4

**No? Develop new assessment endpoint to represent
Stakeholders' values**

4.3.3.1 Selection of Assessment Endpoints

At this point in the risk assessment process, assessment endpoints must be selected. ADEC is developing lists of assessment endpoints by eco-region and plans to have them available for public review and comment by late 1998. These will be lists pre-approved by stakeholders and trustees and these lists should be consulted at this point. An assessment endpoint is “an explicit expression of the environmental value that is to be protected” (EPA, 1992). That is, assessment endpoints are the parts of the ecosystem that are identified as being valuable and, hence, should be assessed.

EPA Headquarters has identified three criteria to consider when selecting assessment endpoints (EPA 1996c):

1. policy goals and societal values;
2. ecological relevance; and
3. susceptibility to the stressor.

In general, there are two parts to an assessment endpoint: an ecological entity and a characteristic about the entity that is important to assess. Assessment endpoints are effective only if they can be measured, directly or indirectly. ADEC is developing an ecoregion approach to assist in selecting ecological assessment endpoints.

Assessment endpoints should be selected according to EPA procedures (EPA, 1997a and EPA, 1997b).

EPA Region 10 guidance lists the following as characteristics of good assessment endpoints as well as examples (EPA, 1997b):

Figure 4.4.3.1 Characteristics of Good Assessment Endpoints

- biological relevance
- measurable or predictable
- susceptible to the hazard
- logically related to decision
- social relevance

Examples of Good Assessment Endpoints:

- population flux of American peregrine falcons
- Coho salmon populations in a river basin
- protection of piscivorous birds from eggshell thinning

4.3.4 Study Design and Selection of Measurement Endpoints

This component establishes the measurement endpoints for the assessment endpoints (EPA, 1997a) and establishes the study design and the need for additional data or sampling and analysis to assess ecological risk. A measurement endpoint is “ a measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint and is a measure of biological effects (EPA, 1996). The relationship between measurement endpoints and assessment endpoints must be clearly defined. Use EPA guidance to assist in establishing measurement endpoints (EPA, 1997a and EPA, 1997b). If additional data is needed, sampling plans should be designed around measurement endpoints. Modeling is also acceptable at this point. Information on filed study methods can be found in *ECO Update Volume 2, Number 3* (EPA, 1994).

Figure 4.4.4 Ecological Scientific/Management Decision Point #5

- is there agreement on the following:

The measurement endpoints?

- Yes? Proceed with ecological risk assessment
Go to 4.4.5**
- No? Develop new measurement endpoints**

4.3.4.1 Use of Toxicity tests and Bioassays as Measurement Endpoints in Alaska Ecological Risk Assessments

The bioavailability and toxicity of site contaminants can be tested with toxicity tests and bioassays. As with other methods, it is critical that the media tested are in exposure pathways relevant to the assessment endpoint. There are a limited number of toxicity tests that are readily available for testing environmental media. Many of the aquatic toxicity tests were developed for the regulation of aqueous discharges to surface waters. These tests are useful, but one must consider the original purpose of the test (EPA, 1997a). For additional information on using toxicity tests in risk assessments, please see EPA *Region 10 Guidance* (1997b) and *ECO Update Volume 2, Numbers 1 and 2* (USEPA, 1994).

4.3.5 Field Verification of Sampling Design

The primary purpose of field verification of the study design for the measurement endpoints is to ensure that the samples specified can be collected. At this point, all exposure pathways must be verified, too. For further discussion of this step, see EPA, 1997a and EPA, 1997b.

Figure 4.4.5 Ecological Scientific/Management Decision Point #6

- is there agreement on sampling plan?

- Yes? Proceed with ecological risk assessment
Go to 4.4.6
- No? Develop new sampling locations

4.3.6 Risk Characterization

Risk characterization is the final stage of the risk assessment process. ADEC may require calculation of ecological risk-based cleanup levels.

Figure 4.4.6 Ecological Scientific/Management Decision Point #7

- are ecological receptors at the site expected to be exposed to contaminants at levels capable of causing harm to the overall ecosystem?
Or to a particular valued species within that eco-system?
Now or in the future?

- Yes? Calculate alternative cleanup levels or
Go to 4.4.7
- No? End of ecological risk assessment

4.3.7 Risk Management (See section 1.2 Risk Assessment and Risk Management)

4.4 Uncertainty Assessment

4.4.1 Qualitative Versus Quantitative

The risks presented in a risk assessment are conditional estimates based on multiple assumptions about exposures, toxicity, etc. Each assumption is associated with some degree of uncertainty. These uncertainties may contribute to an overestimation or underestimation of the risks at the site. Therefore, to place the risk estimates in their proper perspective, it is important that, at a minimum, a qualitative discussion of uncertainty be included in all human health and ecological risk assessments performed for ADEC. Specific uncertainty factors to be considered in a risk assessment are included below. Additional discussion on uncertainty can be found in EPA *Risk Assessment Guidance to Superfund* (EPA, 1989).

4.4.2 Uncertainty in Selection of Compounds of Concern

Data collection and data evaluation and reduction techniques that can influence a risk assessment must be discussed. Uncertainties in modeling must be discussed.

4.4.2.1 Endocrine Disruptors

ADEC is concerned about the growing body of evidence that some man-made chemicals may be interfering with normal endocrine system functioning in humans and other animals. Considerable scientific uncertainty remains, however, as to which chemicals may be involved, patterns of exposure, mechanisms of action in humans and wildlife, and the best means for testing to predict or screen for these effects. EPA is investing significant resources to resolve these uncertainties, and ADEC will closely monitor the results of this research. In risk assessments submitted to ADEC, chemicals of potential concern (as determined in Section 4.2.3 for human health and 4.2.4.4 for ecological) there may also be chemicals with hormone disrupting effects must be identified and discussed in the Uncertainty Analysis section.

4.4.3 Human Health Uncertainty

All uncertainty associated with toxicity values should be identified. Possible sources include:

1. animal-to-human extrapolations;
2. short-term to long-term extrapolations; and
3. high-dose effects to low-dose effects extrapolations.

4.4.3.1 Uncertainty in the Exposure Assessment

Multiple assumptions in the exposure assessment can significantly impact the risk assessment results. All uncertainty factors should be identified and discussed as to their overall impact the risk assessment.

4.4.3.2 Uncertainty in the Toxicity Assessment

The weight of evidence and the confidence in the database supporting noncarcinogenic effects should be identified and included. It is also important to identify uncertainty contributed by not evaluating substances in the risk assessment because of inadequate toxicity information. The possible consequences of excluding substances and impacts to the overall estimate of risk for a site should also be evaluated.

5.0 - CONSIDERATION OF OTHER HUMAN STUDIES

ADEC recommends consideration of site-specific human studies that may be available to aid in evaluating the estimates of risk associated with a site. This is especially important with regard to epidemiological studies. Any use of ongoing or past studies or results should carefully be evaluated for applicability to a specific site's risk assessment.

In general, the following guidelines should be followed to determine whether an epidemiological study is appropriate to use in a regulatory risk assessment (Federal Focus, 1996).

1. The population in the epidemiological study should be pertinent to the current and future populations outlined in the risk assessment.
2. The measures of the exposures should be relevant to the risk assessment's completed exposure pathways and properly quantified to represent dose-response relationships.
3. The dose-response assessment should include a range of reasonable dose measures.
4. Only peer-reviewed, published epidemiological studies or studies of such quality deemed publishable in a peer-reviewed scientific journal should be considered

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7.0 - APPENDICES

APPENDIX A - HUMAN HEALTH DATA PRESENTATION TABLES

APPENDIX B - ECOLOGICAL CHECKLISTS

APPENDIX C - ECOLOGICAL DATA PRESENTATION TABLES

Table A.3 HUMAN HEALTH TOXICITY ASSESSMENT CARCINOGENIC ADEC DATA PRESENTATION

CARCINOGENIC CRITERIA

1. Compound of Potential Concern	2. Citation	3. Cancer Slope Factor /Unit Risk		4. Dermal Absorption Rate	5. Adjusted Dermal CSF	6. EPA Weight of Evidence
		Type	Value			

Table A.4 HUMAN HEALTH TOXICITY ASSESSMENT NON-CARCINOGENIC ADEC DATA PRESENTATION

NON-CARCINOGENIC CRITERIA

1. Compound of Potential Concern	2. Citation	3. Reference Dose		4. Dermal Absorption Rate	5. Adjusted Dermal RfD	6. Target organ	7. Uncertainty Factors
		Type	Value				

Table A.5 HUMAN HEALTH RISK CHARACTERIZATION ADEC DATA PRESENTATION

- SELECTED STATISTICS:** RME CENTRAL TENDENCY
- SCENARIO:** CURRENT FUTURE
- ENVIRONMENTAL MEDIUM:** Surface Water Groundwater Air
 Soil Sediment Biota
- RECEPTOR:** ADULT CHILD
 RESIDENT MAINTENANCE WORKER CONSTRUCTION WORKER
 RECREATIONAL TRESPASSER

RME

1. EXPOSURE ROUTE	2. COMPOUND OF POTENTIAL CONCERN	3. CANCER INTAKE	4. CSF	5. CANCER RISK	6. CANCER RISK TOTAL	7. NON-CANCER INTAKE	8. REFERENCE DOSE	9. HAZARD QUOTIENT	10. HAZARD INDEX (HAZARD QUOTIENT TOTAL)

Table A.6 HUMAN HEALTH RISK SUMMARY CARCINOGEN ADEC DATA PRESENTATION

PRIMARY COMPOUNDS CONTRIBUTING TO HUMAN HEALTH RISK / CARCINOGEN

- SELECTED STATISTICS:** RME CENTRAL TENDENCY
SCENARIO: CURRENT FUTURE
ENVIRONMENTAL MEDIUM: Surface Water Groundwater Air Soil Sediment Biota
RECEPTOR: ADULT CHILD
 RESIDENT MAINTENANCE WORKER CONSTRUCTION WORKER
 RECREATIONAL TRESPASSER

Medium	Location	Compound of Potential Concern	Carcinogenic Risk Percent Contribution						Total by Medium	Total Exposure Routes
			Ingestion	% contribution	Inhalation	% Contribution	Dermal	% Contribution		
Total Receptor Risk = Across All Media & exposure routes										

Table A.7 HUMAN HEALTH RISK SUMMARY NON-CARCINOGEN ADEC DATA PRESENTATION

PRIMARY COMPOUNDS CONTRIBUTING TO HUMAN HEALTH RISK / NON-CARCINOGEN

- ✓ **SELECTED STATISTICS:** RME CENTRAL TENDENCY
- ✓ **SCENARIO:** CURRENT FUTURE
- ✓ **ENVIRONMENTAL MEDIUM:** Surface Water Groundwater Air Soil Sediment Biota
- ✓ **RECEPTOR:** ADULT CHILD
 RESIDENT MAINTENANCE WORKER CONSTRUCTION WORKER
 RECREATIONAL TRESPASSER

Medium	Location	Compound of Potential Concern	Noncarcinogenic Hazard Percent Contribution								Total Exposure Routes
			Target Organ	Ingestion	% contribution	Inhalation	% Contribution	Dermal	% Contribution	Total by Medium	
										Total Liver HI =	
										Total Skin HI =	
										Total CNS HI =	
										Total Proteinuria HI =	

APPENDIX B ECOLOGICAL CHECKLIST

Figure B.1 ECOLOGICAL CHECKLIST #1: GENERAL

1. **SITE NAME:** _____
ADEC LC: _____
2. **LOCATION:** _____

3. **LATITUDE:** _____
4. **LONGITUDE:** _____
5. **APPROXIMATE SITE AREA:** _____
6. **DATES OF SITE VISITS:**

- ATTACH USGS TOPOGRAPHIC MAP**
- ATTACH AVAILABLE PHOTOS**
7. **LAND USE ON THE SITE**
_____**% RESIDENTIAL**
_____**% RURAL**
_____**% URBAN**
_____**% INDUSTRIAL/COMMERCIAL**
_____**% AGRICULTURAL**
_____**% RECREATIONAL**
_____**% FOREST/WOODED**
_____**% WETLANDS**
_____**% UNDISTURBED**
_____**% OTHER**
8. **LAND USE SURROUNDING THE SITE**
_____**% RESIDENTIAL**
_____**% RURAL**
_____**% URBAN**
_____**% INDUSTRIAL/COMMERCIAL**
_____**% AGRICULTURAL**
_____**% RECREATIONAL**
_____**% FOREST/WOODED**
_____**% WETLANDS**
_____**% UNDISTURBED**
_____**% OTHER**

9. DESCRIBE MOVEMENT OF SOIL ON THE SITE

- AGRICULTURAL USE
- NATURAL EVENTS
- EROSION
- HEAVY EQUIPMENT
- MINING
- OTHER

**10. IDENTIFY SENSITIVE ENVIRONMENTS
(PLEASE SEE SECTION 4.2.4.2 State Sensitive Environments AND
4.2.4.3 Federal Sensitive Environments)**

11. POTENTIAL ROUTES OF OFFSITE MIGRATION

- SWALES
- RUNOFF
- DEPRESSIONS
- WINDBLOWN PARTICULATES
- DRAINAGE DITCHES
- VEHICULAR TRAFFIC
- OTHER _____

12. DEPTH OF WATER TABLE _____

13. IDENTIFY WATER BODIES ON THE VICINITY OF THE SITE

14. EVIDENCE OF FLOODING

- YES
- NO

Figure B.2 ECOLOGICAL CHECKLIST #2: TERRESTRIAL

A. Wooded Areas

1. ARE THERE WOODED AREAS AT THE SITE

- YES
- NO

2. PERCENTAGE OF SITE WOODED

_____ %
_____ acres

3. DOMINANT TYPE OF VEGETATION

- DECIDUOUS
- MIXED
- OTHER _____

4. DOMINANT TREE SIZE BY DIAMETER

- 0-6 INCH
- 6-12 INCH
- > 12 INCH

B. SHRUB/SCRUB

1. IS THERE SHRUB/SCRUB VEGETATION PRESENT AT THE SITE

- YES
- NO

2. PERCENTAGE OF SITE COVERED WITH SHRUB/SCRUB

_____ %
_____ acres

3. DOMINANT TYPE OF VEGETATION

-
-

4. DOMINANT HEIGHT OF SHRUB/SCRUB VEGETATION

- 0-2 FEET
- 2-5 FEET
- > 5 FEET

5. SHRUB/SCRUB DENSITY

- DENSE

- PATCHY
- SPARSE

C. OPEN AREAS

1. ARE THERE OPEN (BARE, BARREN) FIELD AREAS PRESENT AT THE SITE

- YES
- NO

2. PERCENTAGE OF SITE OPEN FIELD

_____ %
_____ acres

3. DOMINANT TYPE OF PLANT

-
-
-

4. DOMINANT HEIGHT OF DOMINANT PLANT

- 0-2 FEET
- 2-5 FEET
- > 5 FEET

5. SHRUB/SCRUB DENSITY

- DENSE
- PATCHY
- SPARSE

Figure B.3 ECOLOGICAL CHECKLIST #3: AQUATIC-FLOWING SYSTEMS

1. TYPE OF FLOWING WATER SYSTEMS PRESENT AT SITE

- RIVER
 - PERENNIAL
 - INTERMITTENT
- STREAM
 - PERENNIAL
 - INTERMITTENT
- CREEK
- BROOK
- DRY WASH
- MAN-MADE (DITCH, ETC.)
- ARROYO
- INTERMITTENT STREAM
- CHANNELING SPARSE
- LAKE OR POND
- TIDAL STREAM
 - BAY
 - ESTUARY
- OTHER

2. GENERAL COMPOSITION OF SUBSTRATE

- BEDROCK
- SAND
- SILT
- BOULDER
- COBBLE
- GRAVEL
- MARL
- CLAY
- MUCK
- DEBRIS
- CONCRETE
- OTHER

3. CONDITION OF THE BANK - HEIGHT, SLOPE, ETC.

4. FLOW INTERMITTENT

- YES
- NO

5. DISCHARGE FROM SITE TO WATER BODY

- YES
- NO

6. DISCHARGE FROM WATER BODY

- YES

NO

7. TYPE OF AQUATIC VEGETATION PRESENT

- EMERGENT
- SUBMERGENT
- FLOATING
- NONE

8. OTHER ORGANISMS PRESENT

- BENTHIC MACRO INVERTEBRATES
- FISH
- BIRDS
- MAMMALS
- OTHER
- NONE

Figure B.4 ECOLOGICAL CHECKLIST #4: AQUATIC NON-FLOWING SYSTEMS

**1. TYPE OF OPEN WATER NON-FLOWING SYSTEMS PRESENT AT SITE
FLOWING WATER SYSTEMS PRESENT AT SITE**

- NATURAL
- MAN MADE

2. KNOWN USES OF WATER BODY

- RECREATIONAL
- NAVIGATIONAL
- SUBSISTENCE
- OTHER

**3. APPROXIMATE SIZE OF WATER BODY
_____ACRES**

4. TYPE OF AQUATIC VEGETATION PRESENT

- EMERGENT
- SUBMERGENT
- FLOATING

**5. DEPTH OF WATER
_____FEET**

6. GENERAL COMPOSITION OF SUBSTRATE

- BEDROCK
- SAND
- SILT
- BOULDER
- COBBLE
- GRAVEL
- MARL
- CLAY
- MUCK
- DEBRIS
- CONCRETE
- OTHER

7. SOURCE OF WATER IN THE WATER BODY

- RIVER/STREAM/CREEK
- GROUNDWATER
- SURFACE RUNOFF
- INDUSTRIAL DISCHARGE
- OTHER

8. DISCHARGE FROM SITE TO WATER BODY

- YES
- NO

9. DISCHARGE FROM WATER BODY

- | | | |
|---------------------------------------|---------------------------------|----------------------------------|
| <input type="checkbox"/> RIVER STREAM | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |
| <input type="checkbox"/> GROUNDWATER | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |
| <input type="checkbox"/> WETLAND | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |
| <input type="checkbox"/> IMPOUNDMENT | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |

Figure B.5 ECOLOGICAL CHECKLIST #5: WETLANDS

1. ANY DESIGNATED OR KNOWN WETLANDS AT THE SITE

- YES
- NO

2. ARE WETLAND HABITATS EXPECTED

- YES
- NO

3. TYPES OF VEGETATION PRESENT

- EMERGENT
- SUBMERGENT
- SCRUB/SHRUB
- WOODED
- OTHER

4. DISCHARGE FROM SITE TO WETLANDS

- YES
- NO

5. DISCHARGE FROM WETLAND

- | | | |
|---------------------------------------|---------------------------------|----------------------------------|
| <input type="checkbox"/> RIVER STREAM | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |
| <input type="checkbox"/> GROUNDWATER | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |
| <input type="checkbox"/> LAKE/POND | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |
| <input type="checkbox"/> MARINE | <input type="checkbox"/> ONSITE | <input type="checkbox"/> OFFSITE |

APPENDIX C ECOLOGICAL DATA PRESENTATION

Table C.1 ECOLOGICAL COMPOUNDS OF POTENTIAL CONCERN ADEC DATA PRESENTATION

✓ ENVIRONMENTAL MEDIUM: Surface Water Groundwater Air
 Soil Sediment Biota

1. Compound of Potential Concern	2. units	3. Detection frequency	4. Minimum Concentration (above sql)	5. Maximum Concentration (above sql)	6. Detection Limits	7. Background Concentration	8. ECO Risk Based BENCHMARK	9. Detection Frequency above ECO BENCHMARK	10. Potential ARAR/ TBC	11. Detection Frequency above ARAR/TBC

8.0 GLOSSARY

The glossary for the ADEC Risk Assessment Procedures Manual defines the most commonly used risk terms appearing in this document.

action plan: A plan describing a specific cleanup or corrective activity.

acute effects: Effects that show up soon after exposure.

acute exposure: Exposure over a short period: up to two weeks.

additive effect: Combined effect of two or more chemicals equal to the sum of their individual effects

ambient: Naturally occurring background amounts of a substance in a particular environmental medium; may also refer to existing amounts in a medium, regardless of source.

applicable or relevant and appropriate requirements (ARARs): Requirements, including cleanup standards, standards of control, and other substantive environmental protection requirements and criteria for hazardous substances as specified under federal and state statutes and regulations, that must be met to comply with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund), 42 U.S.C. 9601 - 42 U.S.C. 9675.

background level: **Naturally occurring** ambient environmental concentration of a substance.

bias: An inadequacy in experimental design that leads to results or conclusions not representative of the population under study.

bioaccumulation: The absorption, via breathing, eating, drinking or active uptake, and concentration of a substance in plants or animals.

bioassay: Test which determines the effect of a chemical on a population of living organisms **or test organisms and results may be extrapolated to a population.**

bioconcentration: The accumulation of a chemical in tissues of an organism (such as fish) to levels that are greater than the level in the medium (such as water) in which the organism resides.

bioconcentration factor: A measure of the tendency for a chemical to accumulate. The ratio of the concentration of a substance in a living organism (mg/kg) to the concentration of that substance in the surrounding environment (mg/l for aquatic systems).

biomagnification: Process by which substances such as pesticides or heavy metals move up the food chain, becoming more concentrated with each succeeding step up the chain.

cancer: The uncontrolled, invasive growth of cells. Cancerous cells can metastasize; they can break away from the original tumor, relocate, and grow elsewhere in the body.

carcinogen: A substance that causes or induces cancer. See also, definition of “carcinogenic” in 18 AAC 75.990.

characterization: Site sampling, monitoring, and analysis to determine the extent and nature of a release.

chronic: Of long duration: Seven years - lifetime. Chronic exposure usually refers to long-term, low-level exposure. Chronic toxicity refers to the effects produced by such exposure. Chronic exposure may cause latent damage that does not appear until later.

compliance agreements: Agreements between regulatory agencies and regulated parties that are legally binding, including consent order and compliance agreements, federal facilities agreements, and federal facility compliance agreements.

compound: A substance formed by the union of two or more elements.

cumulative exposure: The summation of exposures of an organism to a chemical over a period of time.

default options: Inputs or assumptions to the risk assessment that are used absent specific data. These options may be based on generalized experience or data and are often purposely chosen as upper-bound estimates of the predictors of risk to protect against underestimation of risk. Thus this practice conserves resources by not necessarily requiring that tests be done, but it also places value on specific and detailed data for answering the questions at hand.

dose: A measure of exposure. Dose is often expressed in milligrams per kilogram **body weight per day** (mg/kg-d)

dose-response: A quantitative relationship between the dose of a chemical and the degree/severity of an effect caused by the chemical.

dose-response curve: A graphical presentation of the relationship between degree of exposure to a substance (dose) and observed biological effect or response.

dusts: Fine, dry, mechanically-produced particles.

ecosystem: The interacting system of a biological community and its nonliving environment. See, also definition of “environmentally sensitive area” in 18 AAC 75.990.

environment: Comprises air, water, food, and soil media. Regarding air, it refers to all indoor and outdoor microenvironments, including residential and occupational settings. See, also definition of “environmentally sensitive area” in 18 AAC 75.990.

environmental fate: The destiny of a substance after release to the environment. Involves considerations such as transport through air, soil, and water; bioconcentration and degradation.

environmental restoration: Cleaning up and restoring a site contaminated with hazardous substances.

expert judgment: Opinions of persons who are well informed in an area, and are incorporated into probability estimates.

epidemiology: The study of the incidence and distribution of disease and toxic effects in a population.

exposure: Contact with a chemical. Some common routes of exposure are dermal (skin), oral (by mouth) and inhalation (breathing).

exposure assessment: Involves numerous techniques to identify a contaminant, contaminant source, environmental media of exposure, transport through each medium, chemical and physical transformations, routes of entry to the body, intensity and frequency of contact, and spatial and temporal concentration patterns of the contaminant. An array of techniques can be used, ranging from estimating the number of people exposed and contaminant concentrations to sophisticated methodology employing contaminant monitoring, modeling, and human biological marker measurement.

exposure scenario: A set of conditions or assumptions about sources, exposure pathways, concentrations of toxic chemicals, and populations (numbers, characteristics, and habits) that the investigator uses to evaluate and quantify exposure in a given situation.

extrapolation: Estimation of unknown values by extending or projecting from known values.

food chain: A sequence of species in which each species serves as a food source for the next species. Food chains usually begin with species that consume detritus or plant material (herbivores) and proceed to larger and larger carnivores. Example: grasshopper eaten by snake eaten by owl.

facility: A building or other structure and its functional systems and equipment, including site development features such as landscaping, roads, walks and parking areas; outside lighting and communication systems; central utility plants; utility supply and distribution systems; and other physical plant features.

groundwater: Water in the zone of saturation, which is the zone below the water table, where all interstices are filled with water. This term has the meaning given in 18 AAC 75.990.

hazard: A source of risk that does not necessarily imply potential for occurrence. A hazard produces risk only if an exposure pathway exists and if exposure creates the possibility of adverse consequences.

hazard identification: A component of risk assessment that involves gathering and evaluating data on the types of injury or disease (for example, cancer) that might be produced by a substance and on the conditions of exposure under which injury or disease is produced.

hazard index (HI): The sum of the hazard quotients attributable to noncarcinogenic hazardous substances with similar critical endpoints;

hazard quotient (HQ): The ratio of a single substance exposure level over time to a toxicity value (i.e. LOAEL or NOAEL).

hazardous substance: An element or compound that, when it enters into the atmosphere or in or upon the water or surface or subsurface land, presents an imminent and substantial danger to the public health or welfare, including fish, animals, vegetation, or any part of the natural habitat in which they are found.

hazardous waste: As defined in RCRA, a solid waste, or combination of solid wastes, that because of its quantity, concentration, or physical, chemical, or infectious characteristics, may cause or significantly contribute to an increase in mortality or an increase in serious, irreversible, or incapacitating reversible illness or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed. Also see 18 AAC 62 and 18 AAC 75.990.

human equivalent dose: A dose that, when administered to humans, produces an effect equal to that produced by a particular dose in animals.

human health risk: The likelihood (or probability) that a given exposure or series of exposures may have damaged or will damage the health of individuals experiencing the exposures.

incidence (of disease): The number of new cases of a disease, usually expressed as an incidence rate, the number of new cases occurring in a population during a specified period divided by the number of persons exposed to the disease during that period.

inhalation: Drawing of air into the lungs.

intake: Amount of material inhaled, ingested, or absorbed dermally during a specified period of time.

inherent risk: Actual or potential risk to a worker or the environment during the implementation of environmental management activities.

institutional control: Active institutional control refers to control of sites by the authorized party, by restrictions that limit human or animal access to or use of land or resources, for example, with deeds, fences, and patrols, whereas passive institutional control refers to measures such as site markers used to warn human intruders of possible exposure to hazardous substances or conditions. See 18 AAC 75.395.

irreversible effect: Effect characterized by the inability of the body to partially or fully repair injury caused by a toxic agent.

land use planning: A decision-making process to determine the future or end use of a parcel of land, considering such factors as current land use, public expectations, cultural considerations, local ecological factors, legal rights and obligations, technical capabilities, and costs.

LC50: The concentration of toxicant necessary to kill 50 percent of the organisms being tested. It is usually expressed in parts per million (ppm).

likelihood: Statistical probability that an event such as harm or injury could occur as a result of exposure to a risk agent.

lowest observed effect level (LOEL): The lowest exposure level at which effects are observed. These effects may or may not be serious. On the other hand, a LOAEL (the A stands for adverse) makes a judgment on the significance of the effect.

LD: Lethal dose.

LD50: The amount of a chemical that is lethal to one-half (50%) of the experimental animals exposed to it. LD50s are usually expressed as the weight of the chemical per unit of body weight (mg/kg). It may be fed (oral LD50), applied to the skin (dermal LD50), or administered in the form of vapors (inhalation LD50).

LOAEL: Lowest-Observed-Adverse-Effect-Level; the lowest dose in an experiment that produced an observable adverse effect.

LOEL: Lowest-Observed-Effect-Level; the lowest dose in an experiment that produced an observable effect.

MCL: Maximum Contaminant Level. The highest amount of a contaminant allowed by EPA in water supplied by a municipal water system; also referred to as "drinking water standard."

modeling: Use of mathematical equations to simulate and predict potential events and processes.

monitoring: Measuring concentrations of substances in environmental media or in human or other biological tissues.

mortality rate: The death rate, often made explicit for a particular characteristic (for example, age, sex, or specific cause of death). A mortality rate contains three essential elements: (1) the number of people in a population group exposed to the risk of death, (2) a time factor, and (3) the number of deaths occurring in the exposed population during a certain time period.

National Priorities List (NPL): Listing of the nation's hazardous waste sites as established by CERCLA, prioritized for assessment.

NOAEL: No-Observed-Adverse-Effect Level; the highest dose in an experiment that did not produce an observable adverse effect.

NOEL: No-Observed Effect Level; the dosage or exposure level at which no toxicologically significant adverse effect can be detected.

OSHA: Occupational Safety and Health Administration, a branch of the U.S. Department of Labor.

Octanol-water partition coefficient (K_{ow}): A measurement of how a chemical is distributed at equilibrium between octanol and water. It is an important parameter and is used often in the assessment of environmental fate and transport for organic chemicals. Additionally, K_{ow} is a key variable used in the estimation of other properties.

Organic carbon partition coefficient (K_{oc}): A measure of the tendency for organics to be adsorbed by soil and sediment.

onsite: The same or geographically contiguous property that may be divided by public or private right-of-way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right-of-way. Non-contiguous properties owned by the same person but connected by a right-of-way that he/she controls and to which the public does not have access is also considered onsite property.

plume: The three-dimensional area containing measurable concentrations of a compound or element that has migrated from its source point.

population at risk: A population subgroup that is more likely to be exposed to a substance (such as a chemical), or is more sensitive than is the general population.

probability: The likelihood of an event occurring expressed as a number.

public: Anyone outside the site boundary at the time of an accident or during normal operation.

public participation: The process by which public views and concerns are identified and incorporated into the ADEC decisionmaking process.

quantitative: Numerical for measured information, such as the dose needed to produce an effect, or the number of people affected.

release site: A location at which a hazardous, radioactive, or mixed waste release has occurred or is suspected to have occurred. It is usually associated with an area where the hazardous, radioactive waste, mixed waste, or waste-contaminated substances have been used, treated, stored, migrated, and/or disposed of. See also, definitions of “release” and “site” in 18 AAC 75.990.

remedial investigation (RI): The CERCLA process of determining the extent of hazardous substance contamination and, as appropriate, conducting treatability investigations. The RI provides the site-specific information for the feasibility study.

remediation: A general term indicating overall cleanup and operations thereof, such as treatment, storage, or disposal; usually refers to contaminated media such as soils, groundwater, and buildings rather than waste contained in drums and stored in buildings.

risk: In risk assessment, the probability that something will cause injury, combined with the potential severity of that injury.

risk assessment: A qualitative or quantitative evaluation of the environmental and/or health risk resulting from exposure to a chemical or physical agent; combines exposure assessment results with toxicity assessment results to estimate risk. See also, definition of “risk assessment” in 18 AAC 75.990.

risk characterization: The final phase of the risk assessment process that involves integration of the data and analysis involved in hazard identification, source/release assessment, exposure assessment, and dose-response assessment to estimate the nature and likelihood of adverse effects.

risk estimate: A description of the probability that organisms exposed to a specified dose of a substance (such as a chemical) will develop an adverse response (for example, cancer).

risk factor: Characteristic (such as race, sex, age, or obesity) or variable (such as smoking or occupational exposure level) associated with increased probability of a toxic effect.

risk management: Uses information from risk assessment and analysis together with information about technical resources, social, economic, and political values, and control or response options to determine means of reducing or eliminating a risk.

risk perceptions: An important factor influencing both risk assessment and risk management. People perceive risks differently, depending on the likelihood of a hazard having adverse effects; whom it affects; how widespread, familiar, and dreaded the effects are; how a hazard affects the individuals personally, and whether they have voluntarily agreed to bear the risks. Perceptions of risk are also influenced by the benefits derived from accepting the risks.

route of exposure: The avenue by which a substance (such as a chemical) comes into contact with an organism; such avenues include inhalation, ingestion, and dermal contact.

subchronic: Intermediate between acute and chronic toxicities.

safety: Belief that a substance will not cause injury under careful, defined circumstances of use.

site: An area or location at which hazardous substances have been stored, treated, disposed of, placed, or otherwise come to be located. This includes land, structures, other appurtenances and improvements on the land used for treatment, storage, or disposal of hazardous substances. A site may consist of several treatment, storage, or disposal facilities (for example, impoundments, containers, buildings or equipment). See also, definition of “risk assessment” in 18 AAC 75.990.

site characterization: Technical process used to evaluate the nature and extent of environmental contamination, which is necessary for designing of remediation measures and monitoring their effectiveness.

stakeholder: An individual or institution with a stake in the outcome of the results of the action. Specific examples noted in the report include: local residents; federal, state, and local citizen groups; federal, state, and local environmental groups; Native American governments and associations; workers, unions, industry, and economic interests; federal, state, and local environmental, safety, and nuclear regulatory agencies; local, county, and state government; universities and research groups; "self regulators"; technical advisors and reviewers.

synergism: Effects from a combination of two or more events, efforts, or substances that are greater than would be expected from adding the individual effects.

threshold: The lowest dose of a substance at which a specified measurable effect is observed and below which it is not observed.

toxic: Harmful; poisonous

toxicity: The quality or degree of being poisonous or harmful to plants, animals, or humans. See also, definition of “toxicity index” in 18 AAC 75.990.

toxicity assessment: Characterization of the toxicological properties and effects of a substance including all aspects of its absorption, metabolism, excretion, and mechanism of action, with special emphasis on the establishment of dose-response characteristics.

uncertainty factor: A number (equal to or greater than one) used to divide NOAEL, LOAEL, etc., values derived from measurements in animals, humans, or ecological receptors, in order to estimate a NOAEL value for the population; also called “margin-of-safety.”