State of Alaska

DEPARTMENT OF ENVIRONMENTAL CONSERVATION

DIVISION OF SPILL PREVENTION AND RESPONSE

CONTAMINATED SITES PROGRAM

DRAFT Risk Assessment Procedures Manual

November, 2005

DRAFT

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ACRONYMS

AAC	Alaska Administrative Code
ACL	alternative cleanup levels
ADF&G	Alaska Department of Fish and Game
ALM	Adult Lead Model
ARARs	Applicable or Relevant and Appropriate Requirements
ATSDR	Agency of Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
COPC	compound of potential concern
CSM	conceptual site model
DEC	Alaska Department of Environmental Conservation
DQO	data quality objective
DRO	diesel-range organics
ECAO	Environmental Criteria and Assessment Office
EEC	estimated environmental concentration
EPA	Unites States Environmental Protection Agency
EPC	exposure point concentration
ERA	ecological risk assessment
GRO	gasoline-range organics
HEAST	Health Effects Assessment Summary Tables
HHRA	human health risk assessment
HI	hazard index
HQ	hazard quotient
IEUBK	integrated exposure uptake biokinetic
IRIS	Integrated Risk Information System
L/day	liters per day
LD50	lethal dose, 50% of the population
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m^3/day	cubic meters per day
MCL	maximum contaminant level
mg/m^3	milligrams per cubic meter
MRLs	minimal risk levels
NOAA	National Oceanic and Atmospheric Administration
NOAEL	no observed adverse effect level
NOEL	no observed effect level
NPDES	National Pollutant Discharge Elimination System
ORIA	Office of Radiation and Indoor Air
OSWER	Office of Solid Waste and Emergency Response
PbBs	blood-lead concentrations
PPRTVs	Provisional Peer-Reviewed Toxicity Values
PRGs	preliminary remediation goals

RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RfC	reference concentration
RfD	reference dose
RfDi	inhalation reference dose
RME	reasonable maximum exposure
RP	responsible person(s)
RRO	residual-range organics
SF	slope factor
SFd	dermal slope factors
SFi	inhalation slope factors
SFo	oral slope factors
SQL	sample quantitation limit
TAL	Target Analyte List
TCL	Target Compound List
TRV	toxicity reference value
µg Pb/dL	micrograms of lead per deciliter of blood
$\mu g/m^3$	micrograms per cubic meter
UCL	upper confidence limit
UF	uncertainty factor
URFs	unit risk factors

1 INTRODUCTION

1.1 Development of Guidelines

This manual provides risk assessment procedures for use in preparing human health and ecological risk assessments under the Oil and Other Hazardous Substances Pollution Control site cleanup rules, 18 Alaska Administrative Code (AAC) 75.300 – 18 AAC 75.390, and the Underground Storage Tank regulations, 18 AAC 78. The purpose of performing site-specific risk assessments in accordance with this guidance is to:

- Determine the baseline risk posed by contamination;
- Provide the basis for preparation of alternative cleanup levels (ACLs);
- Allow comparison of one site to another by fostering a consistent and technically defensible approach for all sites;
- Expedite review of risk assessments;
- Minimize revision and resubmittal of risk assessment documents, thereby reducing time and costs to responsible person(s) (RP);
- Assist in the site remediation decision-making process; and
- Identify when the Alaska Department of Environmental Conservation (DEC) should be consulted.

This manual provides risk assessment procedures for use in the remediation and cleanup of contaminated sites in Alaska. It also provides users with a single resource point for requirements and technical resources necessary to complete risk assessments. Regional or national risk assessment guidance from the United States Environmental Protection Agency (EPA) should be used where guidance is not provided by DEC. However, the remoteness of many Alaska sites, the seasonal extremes of Alaska's climate, the diverse geography, and the unique subsistence lifestyles of many Alaskans combine to make Alaska risk assessments different than risk assessments prepared for typical sites in the continental United States.

The lead agency responsible for approving or directing the risk assessment must be consulted before developing a risk assessment. Risk assessments performed for other purposes than those stated above or prepared under the auspices of other state or federal regulations will likely have different requirements and guidance. 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), 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 or department with final approval authority over the risk assessment should be contacted to determine if a risk assessment under 18 AAC 75 will also satisfy that program's requirements.

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 decision makers. 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. The process relies on available, reputable scientific information, and conservative judgments in the case of uncertainty.

Risk management is the process by which risk assessment results are combined with other site information to make decisions about risk reduction. In addition to considering the human health and ecological risk assessment data, risk management takes into consideration technical feasibility, cost, political and social acceptability, and the impact of proposed alternative remedial actions. This manual does not provide guidance on the risk management decisions that must be made by DEC.

1.3 The Risk Assessment Process

In general, risk assessments prepared for the DEC Contaminated Sites Program assess risk to current and future receptors at or near the site based on current conditions. These assessments do not consider conditions either during or after remediation, including institutional controls not already in place.

Figure 1 outlines the steps of the risk assessment from the initial scoping meeting to risk management decisions, including development of ACLs. Risk assessment is a tool used to assist risk managers in determining ACLs based on site-specific factors. Any level of contamination left on site above clean up levels (18 AAC 75.341) as result of a risk assessment may potentially be considered an ACL. DEC's review of deliverables and required approvals are both highlighted in Figure 1.

The ecological risk assessment process includes additional steps and deliverables (see Figure 2). The additional steps are intended to quickly identify sites with little or no potential for ecological impacts, so that unneeded and costly evaluation is avoided. It is possible that an ecological risk assessment may not be needed at every site where a human health risk assessment is conducted. Subsection 4.1 describes the four main steps in the ecological risk assessment process.

1.3.1 When to do a Risk Assessment

A risk assessment can be used to identify potential risks at a site, communicate those risks, and/or develop ACLs at a site based on site-specific factors. A risk assessment must be

FIGURE 1
HUMAN HEALTH RISK ASSESSMENT PROCESS

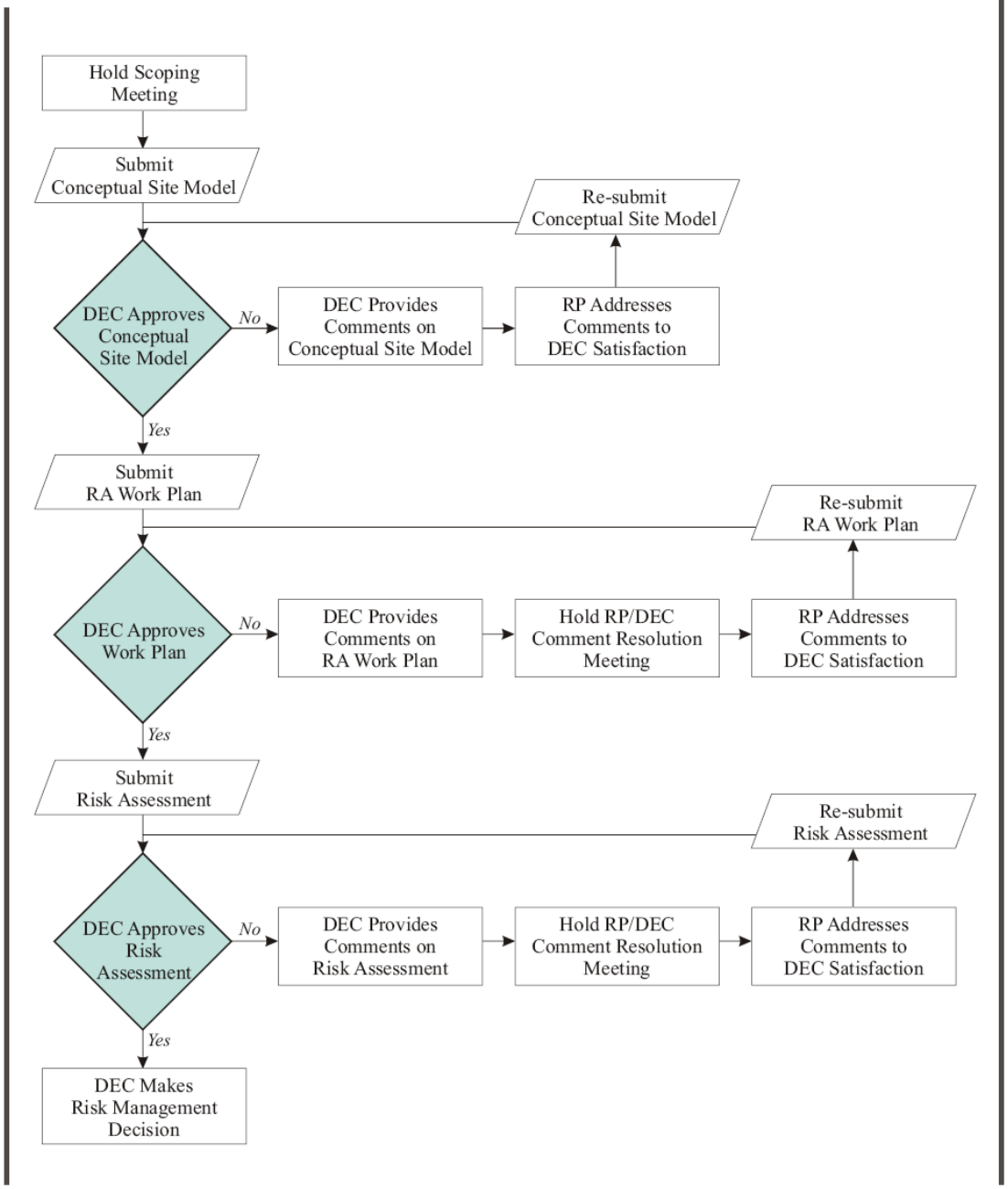


FIGURE 2
ECOLOGICAL RISK ASSESSMENT PROCESS IN ALASKA*

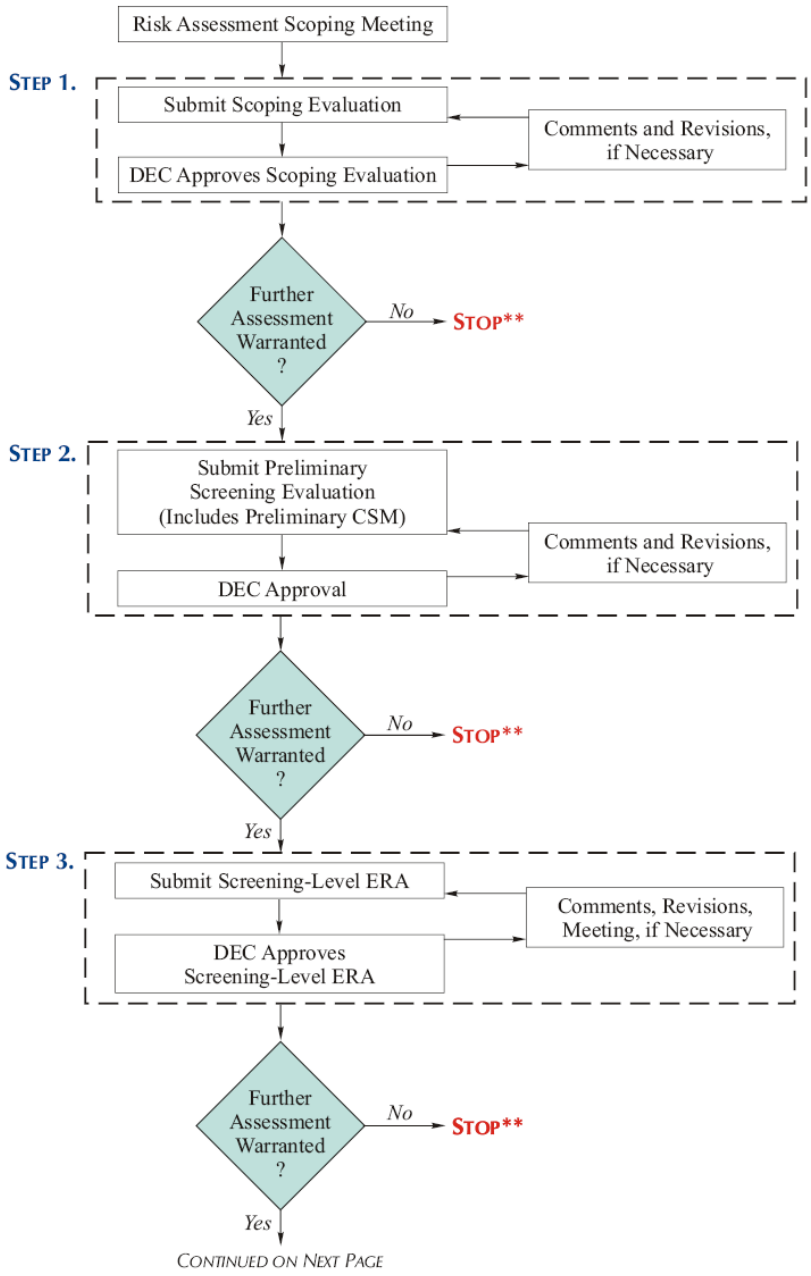
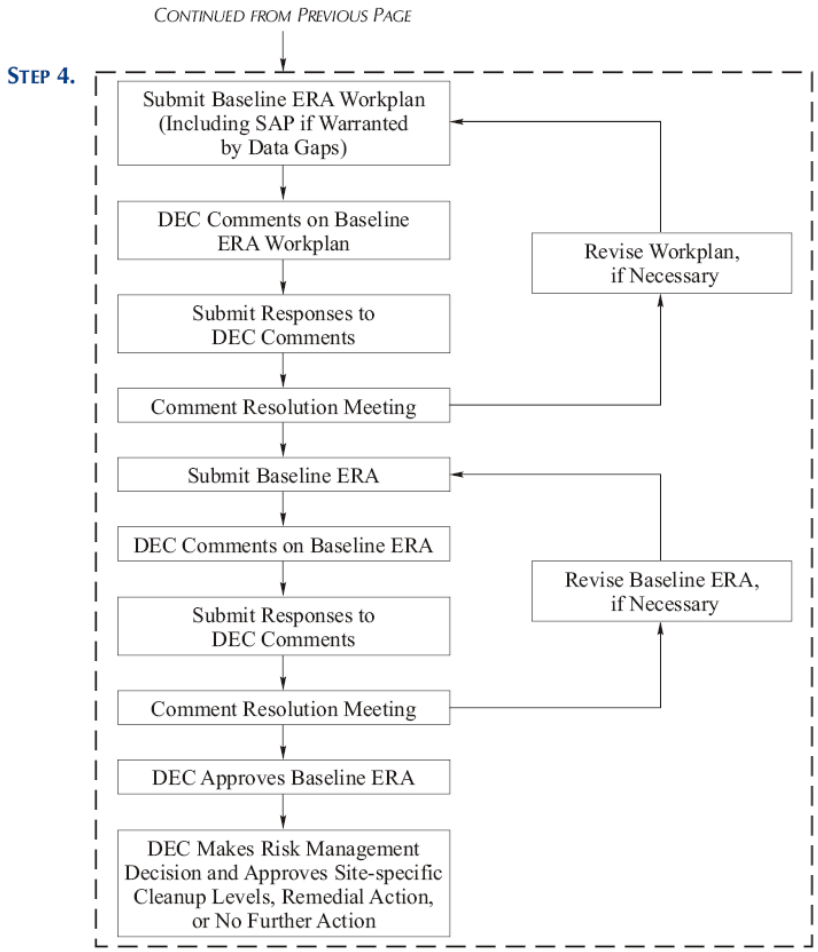


FIGURE 2
ECOLOGICAL RISK ASSESSMENT PROCESS IN ALASKA* (CONT.)



Key:

DEC	Alaska Department of Environmental Conservation
ERA	Ecological Risk Assessment
SAP	Sampling and Analysis Plan

Notes:

* Some tasks may occur concurrently.

** DEC makes risk-management decision regarding need for remedial action.

performed when the RP wishes to develop ACLs by substituting site-specific exposure factors for the defaults used to develop the cleanup levels in the 18 AAC 75 tables, or using any site-specific physical factors or models. A risk assessment may be necessary if additional complete pathways are identified other than those protected by the cleanup levels in the 18 AAC 75 tables. For instance, inhalation of volatile contaminants in indoor air, ingestion of wild foods, or exposure to aquatic or terrestrial ecological receptors are not protected under the cleanup levels in the 18 AAC 75 tables. Therefore, if one of these pathways is complete at a site, a risk assessment may be warranted. Subsection 3.5 of ADEC's *Guidance for Developing Conceptual Site Models* indicated exposure pathways used to develop clean up levels.

Risk Assessment Requirements

Risk assessment should be conducted by individuals experienced in the technical and regulatory aspects of risk assessment and in consultation with DEC's risk assessment staff. At a minimum, for human health risk assessments, the RP must submit the following documents to DEC for review and approval:

- Human health preliminary CSMs, as appropriate;
- Risk Assessment Work Plan; and
- Risk Assessment.

For ecological risk assessments, a brief scoping evaluation is the first deliverable that should be submitted by the RP. Additional deliverables may or may not be necessary based on the results of the scoping evaluation. Further details are provided in subsection 4.1.

In many cases, a draft version of each document should be submitted to DEC for review before submittal of the final version.

1.3.2 Risk Assessment Reviews

Draft and final CSMs, work plans, risk assessments, and other deliverables must be reviewed by DEC risk assessment staff or a contracted third party selected by DEC. Taking into account the technical comments on the risk assessment document, DEC will either approve the document or return it to the RP for comment resolution and revision. In most cases, DEC will request a written response to comments and a final version of the document, incorporating the agreed upon changes.

In some cases, draft documents and an addendum documenting changes will suffice to make a document final. DEC risk assessment staff should be consulted on the appropriate report needs.

At DEC's discretion, the risk assessment review process may include a public advisory committee, a technical assistance group, EPA staff, and other state and federal agencies. All interested and affected parties should be identified in the initial scoping meeting for the risk assessment.

1.4 Public Participation

DEC will seek public participation regarding activities conducted under the site cleanup rules, using methods that DEC determines to be appropriate for seeking public participation, per 18 AAC 75.325(j).

Public comment is required when ACLs are proposed for soil or groundwater based on a site-specific risk assessment (18 AAC 75.345(b)(2)). Public comment is a formal process, which includes the following:

- Providing public notice to the people of an affected area that DEC is seeking comments. The minimum requirement is that the public notice should be published in local newspapers and on the State of Alaska Website;
- Establishing a public comment period during which DEC will accept comments. The public comment period usually lasts 15 or 30 days. Comments can be received in writing, by fax, or via e-mail; and
- Completing a responsiveness summary of written responses to the received comments.

Consultation with the public is required when making a commercial/industrial land use designation for developing ACLs (18 AAC 75.340(e)(3)(A), and when alternative points of compliance are established for groundwater hydrologically connected to surface water (18 AAC 75.345(f)).

2 PLANNING

Planning for the risk assessment should begin as early as possible in the site investigation stage. Early planning for a risk assessment will save money and resources during the site investigation and reduce the potential need for collection of additional data.

The planning stage for a risk assessment involves creation of preliminary CSMs and assessing data usability. CSMs characterize the distribution of contaminant concentrations across the site and identify all potential exposure pathways, migration routes, and potential receptors at a site. Information of CSM is given in ADECs *Guidance on Developing Conceptual Site Models* Data usability is discussed in the data evaluation subsection (subsection 3.1). These components of the risk assessment are discussed during the scoping meeting and completed in the work plan.

The problem formulation phase (subsection 4.2) of the ecological risk assessment should be completed during planning and scoping. Fundamental components of problem formulation should be discussed during the planning of an ecological risk assessment. These components are discussed in subsection 4.2.1.

2.1 Scoping Meeting

The purpose of a scoping meeting is:

- To define the purpose and limitations of the risk assessment;
- To assess and fine-tune preliminary CSMs;
- To identify key issues, such as current and future land use;
- To identify exposure and assessment areas;
- To discuss key exposure and toxicity assumptions;
- To discuss work plan requirements for the human health and ecological section of the risk assessment; and
- To identify and evaluate the adequacy of available data.

A checklist of items that should be discussed during the scoping meeting, as applicable, is included in Appendix A. This checklist can also be used to develop an agenda for the meeting. Risk assessors should come to the scoping meeting prepared to discuss each of the topics listed above and in the checklist, as appropriate for the site. The meeting should focus on DEC concurrence with assumptions, CSMs, proposed process, and schedule. Communication between DEC 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.

2.2 Risk Assessment Work Plan

The risk assessment work plan describes the tasks and methods that will be used to assess risk to human health and the environment. It should consider soil, groundwater, sediments, surface water, air, and biota if each of these is applicable, and describe how risk from exposure to each media will be assessed.

Human health risk assessment work plans shall include following:

- Site description, figures and data summaries from site investigation(s);
- Evaluation of contaminant fate and transport;
- Description of land use and exposure areas;
- CSMs for each decision unit;
- Data evaluation and an initial list of compounds of potential concern (COPCs);
- All proposed exposure assumptions or citations;
- All proposed toxicity data or citations;
- Methods for calculating risk and ACLs;
- Discussion of data gaps and a plan for data collection, if necessary; and
- Descriptions and justification for all proposed modeling.

Ecological risk assessment work plans shall include the following:

- Site description, maps, figures, methods of data collection, and data summaries from site investigation(s);
- Identification of potential exposure pathways, ecological endpoints, and receptors or receptor groups;
- Evaluation of contaminant fate and transport;
- Ecological CSM;

- Identification of assessment endpoints – commonly derived from management goals;
- Analysis approach - including criteria for measurement of effects, ecological benchmarks, and testable hypotheses;
- Data evaluation - initial list of COPCs following confirmation of contaminant background levels present at site;
- Methods for determining risk-based concentrations and calculating toxicity reference values (TRVs);
- Explanation of proposed exposure assumptions or citations;
- References for proposed toxicity data or citations;
- Evaluation of adequacy of detection limits;
- Discussion of data gaps and plans for data collection, if necessary; and
- Description and justification for all proposed modeling.

To the greatest extent possible, exposure assumptions and parameters should be provided in the work plan. If parameter values are not available, detailed description of the methodology and literature citations that will be used to develop the exposure parameters should be included. For instance, if the site-specific fish ingestion rate is not known at the time of the work plan, it should explain whether interviews, literature values, or other data will be used to estimate fish ingestion and give a detailed description of how this is to be done. It may be necessary for the risk assessor to refine the CSM, list of COPCs, exposure pathways, and/or receptors presented in the work plan as additional information is obtained.

2.3 Submittal Requirements

The following list details the deliverables required to be submitted to the DEC project manager for human health risk assessments:

- CSM (one electronic copy in portable data file (pdf) format);
- Risk Assessment Work Plan (one electronic copy in pdf format, numerical data in Microsoft Excel); and
- Risk Assessment (one electronic copy in pdf format, numerical data in Microsoft Excel).

For ecological risk assessments, the first submittal should be the scoping evaluation, with preliminary screening. If warranted based on site conditions, a screening-level Ecological Risk Assessment, baseline Risk Assessment Work Plan, and baseline Risk Assessment may be required.

Project specific submittal requirements need to be determined with the DEC project manager.

2.4 Deterministic and Probabilistic Evaluations

Deterministic risk assessments express risk as a single numerical value which should represent the Reasonable Maximum Exposure. As such, uncertainty and variability in

deterministic risk assessments are discussed in a qualitative manner. In general, deterministic risk assessments are adequate for the purpose of determining risk and providing a basis for calculating ACLs.

DEC will also consider the use of probabilistic risk assessment techniques for human health and ecological risk assessments. Probabilistic risk assessments assign a distribution to exposure factors. This results in risk being expressed as a probabilistic distribution.. This approach allows uncertainty and variability to be expressed quantitatively. Probabilistic risk assessment is data intensive, and it should not be done unless there is high quality data available to characterize the distribution of contaminants in exposure media and the behavior patterns of receptors at or near the site. Data would constitute at a minimum sufficient contaminant samples (minimum 30-50), in each media, appropriate to statistically characterize the distribution of contamination. It would also require a source of information about activity patterns near the site that was comparable in quality to studies in EPA's Exposure Factors Handbook. Rarely will sufficient data be available for ecological risk assessments.

Risk assessment planning should be a tiered approach that progresses from simpler (e.g., deterministic) to more complex (e.g., probabilistic) analyses as the situation requires. Use of probabilistic risk assessment for human health or ecological evaluation should be discussed with DEC on a case-by-case basis during the scoping meeting.

3 HUMAN HEALTH RISK ASSESSMENT

The human health risk assessment (HHRA) methodology in this section integrates federal, state, and regional requirements with site-specific information to provide a framework for performing an HHRA at an Alaska contaminated site. *Risk Assessment Guidance for Superfund* (RAGS; EPA 1989a) or other EPA guidance should be consulted if DEC does not provide guidance for aspects of the HHRA process.

EPA Guidance: Data Evaluation

- *Risk Assessment Guidance for Superfund (RAGS): Volume 1 – Human Health Evaluation Manual Part A* (EPA 1989a)
- *Guidance for Data Usability in Risk Assessment (Part A)* (EPA 1992)
- *Data Quality Objectives Process for Hazardous Waste Site Investigations* (EPA 2000d)
- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis* (EPA 1998a)

3.1 Data Evaluation

Data evaluation is the process for identifying if data is of sufficient quality to determine concentrations of COPCs in a risk assessment. This must be done before screening for COPCs.

3.1.1 Data Usability

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. In general, field-monitoring tests do not provided data of sufficient quality to be used for risk assessment purposes. Collection of data not useful for risk assessment may be prevented by early involvement of the DEC project manager and technical staff in developing the sampling plan for the site investigation. 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.

The available sampling data must be evaluated to assess the type, quantity, and quality of data in order to verify that the planning objectives, Quality Assurance Project Plan (QAPP) components, and sample collection procedures were satisfied and that the data are suitable for its intended purpose.

For data to be considered adequate for a risk assessment the following criteria must be met:

- Sampling and analytical procedures must give accurate chemical specific concentrations.
- Validated analytical laboratory data is required.
- Method detection limits and sample quantitation limits must be below screening criteria.
- Qualified data must be appropriately used and explained in the uncertainty section.
- Data must have been collected consistent with guidance from EPA.

The risk assessment data usability criteria listed below should be assessed during scoping for the risk assessment. Mitigation for inadequate data must be agreed upon with DEC.

- **Data Sources -** Data must be from comparable sources (i.e., analytical methods, areas of concern, sampling methodologies).
- **Documentation** – Deviations from the sampling analysis plan (SAP) and standard operating procedures (SOPs) must be documented so that risk assessors are aware of any potential limitations in the data.
- **Analytical Methods** – The method chosen must test for the compounds at detection limits that are at or below applicable screening levels or applicable or relevant and appropriate requirements (ARARs).
- **Data Quality Objectives** – Data quality objectives (DQOs) according to the *Data Quality Objectives Process for Hazardous Waste Site Investigations* (EPA 2000d) for analytical data must be met. Components of DQOs are listed below:

    - Precision – if the reported result is near the concentration of concern, it is necessary to be as precise as possible in order to quantify the likelihood of false negatives and false positives.
    - Accuracy – inaccurate data caused by contamination or uncalibrated instruments will bias results of the risk assessment.
    - Representativeness – sample data must accurately reflect the site characteristics to effectively represent the site's risk to human health and the environment. Hot spots and exposure area media must have representative data.
    - Completeness – completeness for critical samples must be 100%
    - Comparability – risk levels generated in a quantitative risk assessment may be questionable if incompatible data sets are used together.

- **Data Review** – Use of preliminary or partially reviewed data can conserve time and resources by allowing modification of the sampling plan if the site investigation is still in progress. Critical analytes and samples require a full review.
- **Reports** – A data review that includes sample quantitation limits (SQLs), a narrative and qualifiers that are fully explained must be part of the data provided to the risk assessors.

3.1.2 Consistency with Conceptual Site Models

Sampling plans should be consistent with the site specific conceptual site model and should give adequate coverage to exposure media of concern.

Sometimes it is difficult or expensive to obtain samples of exposure media, (subsistence foods), or it is difficult to distinguish contaminant concentrations from background (volatiles in air). The following recommendations are given to assure that data will support a risk assessment and should be discussed by responsible party, project managers and risk assessors prior to completion of the work plan:

- If vapor intrusion into indoor air from soil is a potential pathway, soil gas measurements are typically the easiest to interpret.
- If migration to surface water is a potential concern, pore water data and sediment data may be necessary to determine to what extent contaminants are migrating
- Mobile organisms used as subsistence foods are problematic to sample. It is difficult to obtain sufficient samples to make conclusions in the face of the typically high variability of contaminant concentrations. Some guidance is provided in the document for sampling subsistence resources, but it is not recommended by ADEC. Additional lines of evidence, such as bioaccumulation modeling, may still be required even if tissue data is available.

3.1.3 Potential Contaminants

Potential contaminants are those compounds that were likely used or spilled at the site. Site history and previous site characterization studies should be used to develop the initial list of potential contaminants. Attention should be paid to possible breakdown products of compounds as well. For instance, if DDT is a potential contaminant at a site, it may also be necessary to include its breakdown products, DDD and DDE, as potential contaminants. The list will be further refined based on the steps provided below.

3.1.3.1 Target Analyte List/Target Compound List

At any contaminated site there is the potential for a large number of contaminants to be present. EPA 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 substances that are manufactured and used in the greatest amounts and that are the most toxic.

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 not likely to be present in any significant quantities. This list of contaminants, coupled with the site-specific CSM, should be used when developing field sampling plans to address data gaps for the HHRA.

3.1.4 Selection of Compounds of Potential Concern

Screening of site COPCs using commonly agreed upon screening concentrations and protocol is used to identify compounds at a site that need further analysis in the HHRA. Those compounds that exceed screening levels are carried through the HHRA process. A well-developed CSM is needed to properly screen for COPCs. Screening levels should be selected based on the exposure pathways and media identified in the CSM.

The general steps used to screen for human health COPCs are summarized below and described in detail in the following text:

1. Tabulate the **maximum** concentration of each contaminant detected in each environmental medium.
2. Determine contaminant-specific human health screening level.
3. Compare the **maximum** site concentration to screening level.
4. Eliminate compounds that do not exceed the screening level.
5. Eliminate compounds that do not exceed DEC-approved background concentrations.
6. Identify compounds not eliminated as COPCs and carry through for qualitative evaluation.

If contaminants were not detected, evaluate if detection levels were greater than the screening values. If so, consider ½ the detection level to be the concentration for the screening process. Although this is a conservative approach, it will ensure that no compounds are inappropriately screened out of the HHRA.

For each site contaminant, a risk-based screening level needs to be determined. For soil and groundwater screening levels, use the $1/10^{th}$ of levels listed in Table B.1 of Appendix B for the applicable climate zone.

If compounds that are not listed in Appendix B are detected in soil or groundwater, screening levels can be obtained from Region 9's Preliminary Remediation Goals (PRGs; EPA 2004a) or Region 3's RBC tables adjusted to a carcinogenic risks of 1×10^{-6} and an HQ of 0.1. Initial screening for all sites should be against residential exposure scenarios. If no screening criteria can be obtained from Appendix B or EPA's PRG or RBC tables, the compound should be retained for qualitative evaluation in the HHRA. Please note that if a federal or state maximum contaminant level exists for a compound, one-tenth of that value should be used for groundwater screening.

If additional exposure pathways or media exist than those protected in the cleanup level tables in 18 AAC 75, such as ingestion of subsistence foods or inhalation of indoor air,

other screening criteria may need to be proposed. The screening criteria should correspond to a HQ = 0.1 or a cancer risk of 1×10^{-6} when default residential exposure assumptions are used.

Screening levels for media other than soil and groundwater should be developed based on the complete pathways identified in the site-specific CSM. If ingestion of surface water is a pathway of concern, the groundwater screening levels can be used as risk-based screening levels for surface water, as well. Water quality standards for surface water (18 AAC 70) should be considered when evaluating a site with surface water contamination. Water quality standards may be considered ARARs and, therefore, should also be used as screening levels. Water quality standards for applicable fresh and marine water classes should be used.

If ingestion or dermal contact of sediment is a complete pathway based on the site-specific CSM, the soil screening levels can be used as risk-based screening levels for sediment as well.

Bioaccumulative contaminants may be of special concern if people hunt, fish or gather food on or near the site. If the ingestion of wild foods is a complete pathway at the site, bioaccumulative compounds should be retained as COPCs. Bioaccumulative compounds are defined by DEC as having a bioconcentration factor (BCF) equal to or greater than 1,000 for organic compounds or identified by EPA (2000b) as bioaccumulative inorganic compounds. A list of bioaccumulative compounds commonly found at contaminated sites in Alaska is provided in Table A-1 in Appendix A of Attachment 1, *Guidance on Developing Conceptual Site Models*. Please note that if ingestion of aquatic wild foods is a complete pathway at the site but ingestion of terrestrial wild foods is not a complete pathway, only bioaccumulative contaminants in sediment and surface water need to be retained as COPCs.

Distinguishing site contamination from naturally occurring or anthropogenic background concentrations in HHRA is an important part of screening. If inorganic contaminant concentrations are less than or equal to the background for the site, see DEC's *Determination of Background Concentrations* (DEC 2003a), then the compound need not be retained as a COPC. Background concentrations may also be obtained for organic constituents such as persistent organic pollutants on a case-by-case basis.

Compounds not eliminated after completing Steps 1 through 5 are retained as COPCs and must be carried through the HHRA for further evaluation.

Compounds detected in less than 5% of on-site samples for a given media need not be selected as COPCs if detection limits for all samples are below screening levels and adequate sampling has occurred. However, if there is reason to suppose a hot spot exists (i.e. irregularly high concentrations, clusters of detection, visible staining) this hot spot must be dealt with appropriately.

An example of a data summary table is provided as Table A.1 in Appendix A.

3.2 Exposure Assessment

Exposure assessment is the process of determining magnitude, frequency, duration, and route of exposure to chemical or physical agent. The results of the exposure assessment are detailed CSMs and a set of exposure assumptions that, combined with chemical-specific toxicity information, characterize potential risks at the site.

DEC requires the HHRA to consider both current and future exposure scenarios.

3.2.1 Developing a Conceptual Site Model

Developing a CSM is a critical step in properly evaluating contaminated sites and properly identifying data quality objectives (DQOs). A preliminary CSM should be part of the site characterization workplan and acts as a guide for data collection. The CSM is a comprehensive representation of the site that documents current site conditions. It characterizes the distribution of contaminant concentrations across the site and identifies all potential exposure pathways, migration routes, and potential receptors for further analysis. To properly develop a CSM that indicates complete exposure pathways please see ADEC's, *Guidance on Developing Conceptual Site Models*.

3.2.2 Calculating Chemical Intake

After the CSM is complete, the next step in the exposure assessment is to quantify the magnitude, frequency, and duration of exposure for the populations potentially at risk for each exposure pathway selected for quantitative evaluation. This step is conducted in two stages; first, pathway-specific intakes are quantified followed by estimation of exposure concentrations at the exposure point.

3.2.2.1 Pathway-Specific Intakes

The generic equation and variables for calculating chemical intakes are described below.

$$I = C \times \frac{CR \times EF \times ED}{BW \times AT}$$

Where:

I = intake; the amount of chemical at the exchange boundary (mg/kg body weight/day)
C = exposure point concentration in specific media (e.g., milligrams per liter of water)
CR = contact rate: the amount of contaminated medium contracted per unit time or event (e.g., liters/day)
EF = exposure frequency: describes how often exposure occurs (days/year)
ED = exposure duration: describes how long exposure occurs (years)
BW = body weight: the average body weight over the exposure period (kg)
AT = averaging time: period over which exposure is averaged (days)

The intake equation may have to be adjusted based on the exposure pathway investigated.

3.2.2.2 Exposure Assumptions

Each intake variable in the equation can have a range of values. Intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure (RME) for the pathway. Specific exposure assumptions must be defined in a table in the work plan and HHRA. Table 1 provides exposure factors for common exposure pathways in Alaska. These values may be adjusted to meet site conditions, as appropriate. There are several sources of information about human activity and behavior patterns, such as EPA's Exposure Factors Handbooks, the National Human Activity Patterns Study and published scientific literature. These should be used as a resource when site specific exposure scenarios are developed. Deviations from information in such resources may be appropriate, but should be defensible and conservative.

Table 1 Summary of Default Exposure Factors

Exposure Parameter	Resident		Commercial/Industrial Worker		Subsistence User[1]		
	Soil	Ground-water	Soil	Groundwater	Soil	Ground-water	Wild Food
Exposure Frequency (d/yr)	330/270/200[4]	350	250/200[4]	350	330/270/200[4]	350	365
Exposure Duration (yr)	30 (adult) 6 (child)	30 (adult) 6 (child)	25	25	30 (adult) 6 (child)	30 (adult) 6 (child)	30 (adult) 6 (child)
Soil Ingestion Rate (mg/d)	100 (adult) 200 (child)		100 (outdoor worker) 50 (indoor worker)		100 (adult) 200 (child)		
Groundwater Ingestion rate (L/d)		2		2		2	
Food Ingestion Rate (mg/kg)							Site-specific[2]
Inhalation Rate (m^3/d)	20 (adult) 12 (child)		20		20 (adult) 12 (child)		
Surface Area Exposed (cm^2)[3]	5,700 (adult) 2,800 (child)		3,300		5,700 (adult) 2,800 (child)		
Adherence Factor (mg/cm^2)	0.07 (adult) 0.2 (child)		0.2		0.07 (adult) 0.2 (child)		
Body Weight (kg)	70 (adult) 15 (child)		70		70 (adult) 15 (child)		70 (adult) 15 (child)
Lifetime (yr)	70	70	70	70	70	70	70

1 – All values are recommended default values. Each parameter should be adjusted, as needed, based on specific information for the community potentially affected by the site contamination.

2 – Value can be obtained from ADF&G *Community Profile Database* (ADF&G 2002) and should be verified or adjusted, as needed, based on input from the community potentially affected by the site contamination. Ingestion rates obtained from the *Community Profile Database* are developed by averaging harvest and use rates over a year; therefore, if this value is used an exposure frequency of 365 days must also be used.

3 – Exposed skin surface area may be reduced based on site-specific climate information. For instance, reduction in surface area exposed may be justified in areas that have temperatures below freezing in the winter months. The assumption is that less skin would be exposed during this time period.

4 – Soil exposure frequency is based on the climate zone in which the site is located, consistent with DEC's *Cleanup Level Guidance* (DEC 2004b). Residential and subsistence user soil exposure frequency is 330 d/yr for the over 40-inch zone, 270 d/yr for the under 40-inch zone, and 200 d/yr for the arctic zone. For commercial/industrial workers the soil exposure frequency is 250 d/yr for the over and under 40-inch zones, and 200 d/yr for the arctic zone.

Reference: *Exposure Factors Handbook* (EPA 1997a)
Cleanup Level Guidance (DEC 2004b)
Dermal Assessment (EPA 2004d)
Supplemental Soil Screening Level Guidance (EPA 2002b)

3.2.2.3 Alaska Specific Exposure Scenarios

Communities that use wild food on a subsistence basis in some instances have ingestion rates of specific wild food resources significantly different than the default rates recommended by EPA. The Alaska Department of Fish and Game (ADF&G) developed wild food consumption rates by resource for many communities throughout Alaska. These rates were developed from information on harvest and use of a wild food resources based on survey information. The use rates are found in ADF&G's *Community Profile Database* (ADF&G 2002). If available, the high end user rate for the community of interest should be used to estimate ingestion rates for specific resources. Median user values are appropriate if high-end rates are not available. Values from the *Community Profile Database* should only be used in consultation with the community potentially affected by site contamination. If more appropriate studies or values are available, these values should be used instead.
Studies done for the lower 48 states or studies that average subsistence food consumption across vast regions or the state of Alaska are not preferred sources for exposure assessment.

3.2.3 Calculating Exposure Point Concentration

Estimation of the concentration of COPC is a key element of the HHRA process for contaminated sites. The exposure point concentration (EPC) represents a conservative estimate of the chemical concentration available across a route of exposure. The EPC is determined for each individual exposure unit within a site. An exposure unit is the area throughout which a receptor comes in contact with an environmental medium for the duration of the exposure. Exposure units should be selected so that the receptor can be assumed to be equally exposure to all portions of them. The EPC is **not** to be used for COPC screening.

The EPC should be estimated using a 95% upper confidence limit (UCL) on the mean of the contaminant concentrations. If data quality objectives are established and followed, and exposure units are chosen to minimize variability in the data, then using the 95% UCL will rarely pose a problem. There is a great deal of uncertainty associated with substituting the maximum value for the 95% UCL. If maximum value is greater than the 95% UCL it typically means that variability is high and/or data quality is poor. If the maximum value is greater than the 95% UCL, and there is a weight of evidence suggesting that the maximum value is truly a conservative value, ADEC will consider it as a substitute for the UCL. Weight of evidence may include extensive field sampling or extensive documentation of site history. In general, judgmental samples constitute poor data and are not really appropriate for the statistical methods and assumptions employed in a risk assessment.

Groundwater samples from a single well should be used to calculate the 95% UCL average concentration for each sample point. If adequate groundwater data are available, trends in groundwater concentrations may be considered in establishing the EPC.

The distribution of the data set can be determined and the 95% UCL calculated using the *Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites* (EPA 2002a) or EPA (2004c) ProUCL software. Alternative statistical

methods for calculating the 95% UCL will be considered on a project-specific basis and must be approved by DEC.

3.2.3.1 Fate and Transport Models

Fate and transport models and exposure models may be used to estimate exposure concentrations in media that have not been sampled. Use of all proposed models should be discussed in the HHRA work plan and must be approved by DEC. Models should be chosen on a site-specific basis. The following criteria should be considered when selecting models for use in the HHRA:

- The model should provide conservative predictions;
- The model should be technically sound and legally defensible;
- The model is within the public domain;
- Model information and reviews are published in reputable technical journals; and
- The model has received adequate peer review.

For general guidance for the application of models, consult DEC's *Fate and Transport Modeling Guidance* (1998).

3.3 Toxicity Assessment

The toxicity assessment identifies the potential adverse effects associated with COPCs 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 values or dose-response relationships.

3.3.1 Toxicity Hierarchy

The methodologies used to develop health-based toxicity criteria vary and depend upon whether a compound is a carcinogen or a noncarcinogen.

Cancer slope factors (SFs) or unit risk values are used to estimate upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

EPA uses a weight-of-evidence approach to classify the likelihood that 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 five categories described in Table 2.

Toxicity Assessment Resources

- *Integrated Risk Information System (IRIS)* (EPA 2004e)
- *Provisional Peer-Reviewed Toxicity Values* (EPA 2004f)
- *Health Effects Assessment Summary Tables* (EPA 1997b)
- ATSDR's *Minimal Risk Levels* (ATSDR 2004)
- California EPA's *Toxicity Criteria Database* (CAL EPA 2004)

Table 2 EPA Carcinogen Classification System

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

Reference doses (RfDs) are derived for noncarcinogens. An RfD is an estimate of a daily exposure level for humans, including sensitive subpopulations that are likely to be without an appreciable risk of deleterious effects during a lifetime.

In some instances, a compound may have multiple health-based toxicity criteria. The hierarchy of sources for toxicity criteria is listed below and is consistent with the EPA directive (EPA 2003c):

1. EPA's Integrated Risk Information System (IRIS; 2004e);
2. EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs; 2004f);
3. Health Effects Assessment Summary Table (HEAST; 1997b);
4. Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels (MRLs; ATSDR 2004);
5. California EPA (2004) toxicity values; and
6. Other professionally peer reviewed documents as needed and as approved by DEC on a case-by-case basis.

Consultation with DEC is recommended when using toxicity values from sources 3 through 6 to ensure appropriate values are used. The 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, DEC risk assessment staff should be consulted before contacting the ECAO because similar derivations may be readily available from other risk assessments conducted in Alaska.

Neither IRIS nor the PPRTV databases contain radionuclide slope factors. Because EPA's Office of Radiation and Indoor Air (ORIA) obtains peer review on the radionuclide slope

factors contained in Table 4 of HEAST, routine consultation with DEC is generally not necessary when using these values.

3.3.2 Toxicity Value Conversions

Toxicity values are provided for the three main routes of exposure: ingestion, inhalation, and dermal exposure. Toxicity values for the ingestion pathway are usually provided as the oral SFs (SF_o) or, for noncarcinogens, as the oral reference dose (RfD_o). The SF_o may be derived from drinking water unit risks, if needed. This conversion is shown below:

$$SF_o\ (\text{mg/kg-day})^{-1} = \frac{\text{Water Unit Risk}\ (\mu\text{g/L})^{-1} \times 70\ \text{kg} \times 10^3\ \mu\text{g/mg}}{2\ \text{L/day}}$$

As of January 1991, IRIS and National Center for Environmental Assessment databases no longer present RfDs or SFs for the inhalation route. These criteria have been replaced with a reference concentration (RfC) for noncarcinogenic effects and a unit risk factor (URF) for carcinogenic effects. However, for the purpose of estimating risk, the inhalation reference doses (RfDi) and inhalation slope factors (SFi) may still be used. The RfDi and SFi are easily converted from the RfC and URF, respectively. The following equations show these conversions:

$$SF_i\ (\text{mg/kg-day})^{-1} = \frac{\text{URF}\ (\mu\text{g/m}^3)^{-1} \times 70\ \text{kg} \times 10^3\ \mu\text{g/mg}}{20\ \text{m}^3\text{/day}}$$

$$RfD_i\ (\text{mg/kg-day}) = \frac{\text{RfC}\ (\text{mg/m}^3) \times 20\ \text{mg/d}}{70\ \text{kg}}$$

EPA has not developed SFs or RfDs for dermal exposure to all chemicals, but has provided a method for extrapolating dermal toxicity values from oral toxicity values. This route-to-route extrapolation has a scientific basis because once a chemical is absorbed, its distribution, metabolism, and elimination patterns are usually similar, regardless of exposure route. However, dermal toxicity values typically are based on absorbed dose, whereas oral exposures usually are expressed in terms of administered dose. Consequently, if adequate data regarding the gastrointestinal absorption of a COPC are available, then the dermal toxicity values may be derived by applying a gastrointestinal absorbance factor (ABS_{GI}), the percentage of contaminant absorbed in the gastrointestinal tract, to the oral toxicity value. For chemicals lacking a gastrointestinal absorbance value, the ABS_{GI} is assumed to be 100% and the RfD_o or SF_o will be used to estimate toxicity via dermal absorption. The equations used to calculate the dermal slope factor and dermal reference dose from the ingestion toxicity values are shown below:

$$SF_d\ (\text{mg/kg-day})^{-1} = \frac{SF_o\ (\text{mg/kg-day})^{-1}}{ABS_{GI}}$$

$$RfD_d\ (\text{mg/kg-day}) = RfD_O\ (\text{mg/kg-day}) \times ABS_{GI}$$

3.3.3 Types of Exposures: Chronic, Subchronic, and Acute

An HHRA must consider carcinogenic and noncarcinogenic effects of chronic and subchronic exposure. Chronic exposures are considered seven years to lifetime and subchronic exposure are considered from two weeks to seven years. For subchronic effects, EPA-developed subchronic toxicity values should be used, if available. Subchronic toxicity values may be derived from chronic toxicity values using additional uncertainty factors based on the study used to develop the chronic toxicity value; however, derived values must be approved by DEC as needed.

Acute exposures (less than two weeks) may be of concern in hot spot areas and should be addressed immediately and in conjunction with the state or federal health department.

3.3.4 Toxicity Profiles

The final HHRA should provide toxicity information for each COPC. A brief discussion of the toxicity of the COPCs in the text or a short toxicity profile in the appendix will suffice. At a minimum, toxicity information should be discussed for COPCs that contribute significantly to the overall risk at the site.

3.4 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.

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

- Confidence that key site-related contaminants have been identified;
- Description of known or predicted health risks;
- Confidence in the toxicity information supporting the risk estimates;
- Confidence in the exposure assessment estimates;
- Magnitude of the cancer risks relative to the site-remediation goals;
- Major factors driving the risks including contaminants, pathways, and scenarios; and
- Uncertainty associated with the results.

3.4.1 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. The incremental risk of cancer due to exposure to site related contaminants averaged over a lifetime, depicted as carcinogenic risk, and is obtained by multiplying intake by the cancer slope factor. This will represent risk-per-unit dose.

$$Carcinogenic\ Risk = Intake \times Slope\ Factor$$

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

3.4.2 Noncarcinogenic Risk

For noncarcinogens, the HQ is calculated as the intake of the compound divided by the RfD. Hazard indices (HIs), the sum of multiple HQs, should be calculated separately for each scenario and for each exposed population. The HQ should be presented using two significant figures.

$$Hazard\ Quotient = \frac{Intake}{RfD}$$

3.4.3 Cumulative Risk

Initially, risks and HIs are calculated for individual COPCs; however, at most sites, there are multiple COPCs. To assess the overall potential for cancer and noncancer effects posed by exposure to multiple chemicals, risk from multiple COPCs and multiple exposure pathways should be summed. The process for calculating cumulative risk is provided in DEC's *Cumulative Risk Guidance* (DEC 2004a), adopted by reference in 18 AAC 75.325(g).

3.4.4 Lead

If lead is found to be a COPC, site-specific risk models such as the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) and the Adult Lead Model (ALM) should be used to determine lead cleanup levels. In a residential scenario the most sensitive receptor is a child exposed to lead and, therefore, the IEUBK should be used to determine appropriate cleanup levels. In a non-residential setting, such as a commercial or industrial scenario, the most sensitive receptor is the fetus of a worker who develops a body burden as a result of non-residential exposure to lead. The ALM should be used in this instance.

Resources to Assess Exposure to Lead

- *Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children* (EPA 1994a) and IEUBK model (EPA 2004b)
- *Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil* (EPA 2003b) and ALM Spreadsheet (EPA 2003a)
- *NHANES III Report* (EPA 2002e)

The IEUBK attempts to predict blood-lead (PbB) concentrations for children exposed to lead in their environment. The model allows the user to input relevant absorption parameters (e.g., the fraction of lead absorbed from water) as well as intake and exposure rates. Using these inputs, the IEUBK model rapidly calculates and recalculates a complex set of equations to estimate the potential concentration of lead in the blood for a

hypothetical child (6 months to 7 years of age). Measured lead concentration is not only an indication of exposure, but also a widely used index for discerning future health problems.

EPA and the Centers for Disease Control and Prevention (CDC) have determined that childhood PbB concentrations at or above 10 micrograms of lead per deciliter of blood (µg Pb/dL) present risks to children's health. Accordingly, EPA management actions seek to limit the risk that children will have lead concentrations above 10 µg Pb/dL. The IEUBK model calculates the probability that children's PbB concentrations will exceed 10 µg Pb/dL. By varying the data entered into the model, the user can evaluate how changes in environmental conditions may affect PbB levels in potentially exposed children. The IEUBK should be used to assess exposure to lead in a residential setting and develop alternative cleanup levels.

The ALM should be used to assess exposure to lead in a non-residential setting. The ALM assesses non-residential adult risks utilizing a methodology that relates soil lead intake to blood lead concentrations in women of childbearing age. The ALM estimates the soil lead concentration at which the probability of blood lead concentrations exceeding 10 µg Pb/dL in fetuses of women exposed to environmental lead is no greater than 5%. By varying data entered into the model such as environmental conditions (i.e. concentration of lead in soil, dust, food, etc.) or exposure parameters, alternative cleanup levels for lead can be developed.

3.4.4.1 Risk from Bulk Hydrocarbons

Reference doses and other accepted values for GRO, DRO, and RRO can be found in the DEC's *Cleanup Level Guidance* (DEC 2004b), adopted by reference in 18 AAC 75.340(e)(1). Toxicity and chemical parameters are available for the aliphatic and aromatic fractions. These values can be used to calculate risks from the total petroleum ranges (GRO, DRO, and RRO).

Risk calculated from petroleum constituents is considered adequate to account for risk from petroleum in cumulative risk calculations. Risk from exposure to bulk hydrocarbons (DRO, GRO, RRO) across all relevant pathways should be calculated and presented in the HHRA but should not be included in cumulative risk calculations with other compounds. Differences in calculated risk from bulk hydrocarbons versus petroleum constituents should be discussed in the uncertainty section.

3.4.5 Development of Alternative Cleanup Levels

An HHRA provides details about what COPCs in each media contribute to risk. Ultimately the goal of many HHRAs is to derive ACLs.

Risk based equations were derived in order to reflect the potential risk from exposure to a chemical, given a specific pathway, medium, and land-use combination. ACLs can be calculated by setting the total carcinogenic risk or HI at the standard approved by DEC and solving for the concentration term for each chemical in a particular medium. DEC requires that the risk and HIs at a site do not exceed the standards listed below:

- Target cancer risk level at or below 1 in 100,000
- HI at or below 1.0

DEC may consider a risk range of 1 in 10,000 and 1 in 1,000,000 acceptable under 40 CFR 300.430, revised as of July 1, 2002, (CFR 2002) adopted by reference in 18 AAC 75.340(h). This determination will be based on the following: site-specific conditions; land use; hazardous substance characteristics; statutory compliance; protection of human health, safety, and welfare, and the environment; ability of cleanup to be implemented; long-term and short-term effectiveness; use of treatment technologies; public comment; and cost.

3.5 Uncertainty Assessment

The risks presented in an HHRA 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 HHRAs performed for DEC.

Sources of uncertainty include natural variability, measurement error, sampling error, human error, extrapolation mandated by an incomplete knowledge base and incorrect assumptions and oversimplification. Each contributor to the uncertainty of a value or decision must be documented in the HHRA at the point where the data are introduced and all uncertainty associated with data presented in the risk characterization should be presented in the uncertainty section. Specific uncertainty factors to be considered in an HHRA are included below.

3.5.1 Uncertainty in Selection of Compounds of Concern

The following topics associated with selection of compounds of concern need to be discussed: data collection and evaluation, data and reduction techniques, and modeling uncertainties. Any other factors that can influence results of the HHRA must be discussed as well. Uncertainties in modeling must be discussed.

3.5.2 Uncertainty in the Exposure Assessment

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

3.5.3 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 HHRA 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.

4 ECOLOGICAL RISK ASSESSMENT

Ecological risk assessment (ERA) 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. Because every site is unique, the scope and complexity of an ERA will vary from site to site. Subsection 4.1 presents a general overview of the ERA process in Alaska. Specific recommendations for implementing problem formulation, evaluating ecological exposure and effects, characterizing risk, and evaluating uncertainty are presented in subsections 4.2 to 4.5, respectively. Other useful resources include: *Guidance for Ecological Risk Assessment* (EPA 1998b); EPA, Region 10, *Supplemental Ecological Risk Assessment Guidance for Superfund* (EPA 1997d). ADEC resources include; *User's Guide for Selection and Application of Default Assessment Endpoints and Indicator Species in Alaska Ecoregions* (ADEC, 1999); *Technical Background Document for Selection and Application of Default Assessment Endpoints and Indicator Species in Alaskan Ecoregions* (ADEC, 1999).

4.1 ERA Process in Alaska

ADEC's Ecological Scoping Guidance Document helps delineates information to gather at every site and how to determine if further assessment is required at a particular site. If a risk assessment is required, the information gathered as part of the scoping process will aid in the risk assessment problem formulation.

The ERA process is iterative, with results of early steps used to focus subsequent efforts on important chemicals, pathways, and issues. Each step in the process should result in a decision point where one of the following three decisions is made:

1. There are adequate data to conclude that ecological risks are negligible and there is no need for remediation based on ecological risk;
2. The information is not adequate to make a decision at this point and the ERA process should continue; or
3. The information indicates potential for adverse ecological effects, and either a more thorough assessment or remediation based on ecological risk is warranted.

Although risk assessments often include quantitative risk estimates, quantitation of risks is not always possible. In such cases, potential risks and associated uncertainties should be qualitatively described (EPA 1998b).

The four main steps in DEC's ERA process are described below. The overall process is summarized in the flowchart shown as Figure 2 (see section 1). As shown in Figure 2, DEC requests that a scooping meeting be conducted at the onset of process. Subjects to be discussed at the scoping meeting are detailed in the *Scoping Meeting Checklist/Sample Agenda* provided in Appendix A.

4.1.1 Ecological Scoping Evaluation

ADEC has developed a scoping document designed to quickly eliminate site that are unlikely to pose a risk to the environment Such sites would exit the ERA process without further evaluation. The scoping evaluation can not be performed at a site unless there is information about the following; contaminant toxicity, quantity and potential for bioaccumulation, quality and extent of habitat, presence of receptors and a record of observed direct impacts from contamination. Site maps and other descriptive information may be necessary.

Preliminary Screening Evaluation

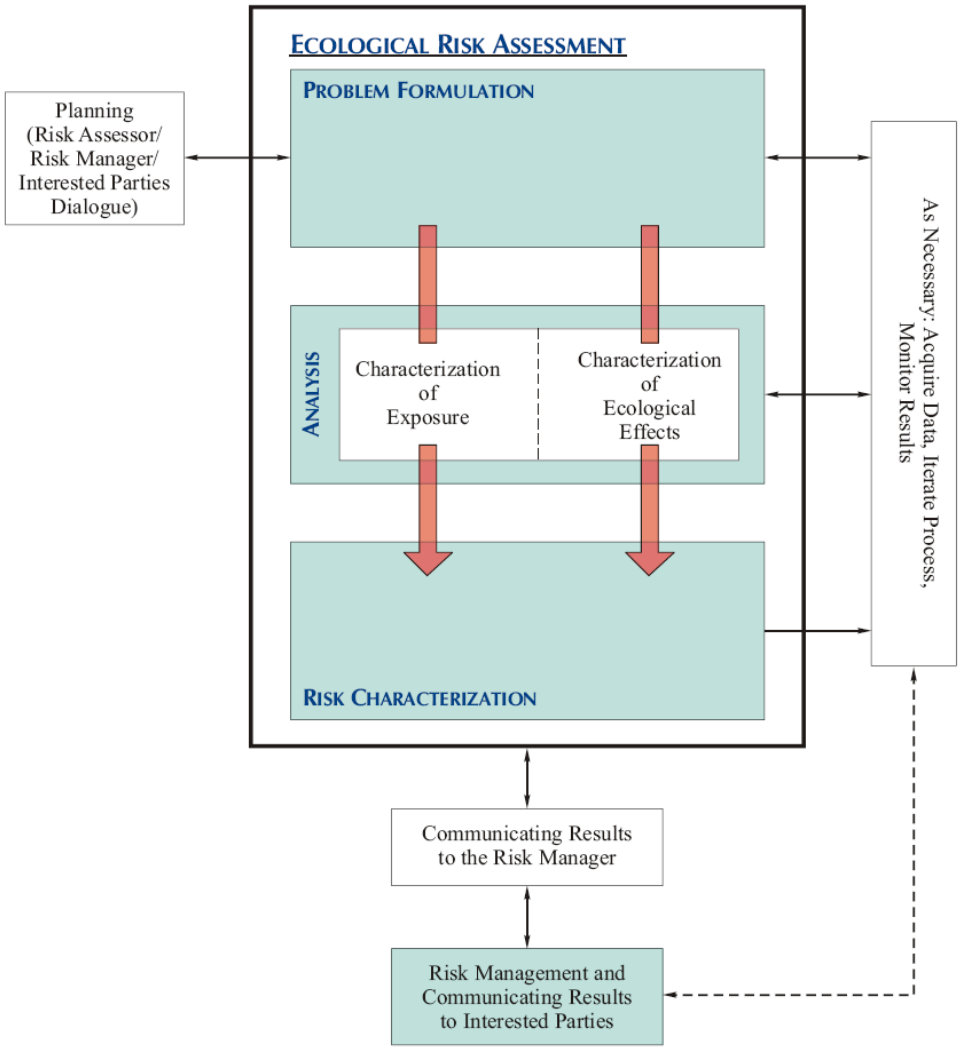
If ecological receptors are likely to be exposed to site-related contaminants, chemical concentrations in environmental media are compared to conservative screening benchmarks. Acceptable conservative screening values are attached to the Ecological Scoping Evaluation Guidance. These values represent the lowest benchmark available for a given media. If concentration in media exceed these very conservative benchmarks, but benchmarks exist that may be more appropriate to the receptors at the site, a screening level risk assessment may be performed. This provide further detail on the site and rational for selection of specific benchmarks. The screening level risk assessment is described below.

The scoping results should be submitted to DEC for review. After reviewing the results, DEC will determine whether further ERA work is warranted, or whether ecological risks are negligible and the site can exit the ERA process.

4.1.2 Screening-Level ERA

Step 3 in the Alaska ERA process is analogous to the screening-level ERA in federal guidance (EPA 1997c). This step incorporates the three basic elements of risk assessment—problem formulation, analysis of exposure and effects, and risk characterization—in an abbreviated form. The three main elements of the risk assessment process are related, as shown in Figure 3. An uncertainty evaluation also should be included in the screening-level ERA. Subsections 4.2 to 4.5 provide recommendations for implementing these activities. It should be noted that Step 3 includes several activities that are not included in the preliminary screening evaluation conducted in Step 2. Most importantly, Step 3 includes a screening-level problem formulation(in which assessment endpoints and measures of effect are described), presents screening-level HQs for wildlife receptors, and identifies data gaps. DEC review and approval of the screening-level ERA is required (see Figure 2).

FIGURE 3
FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT (EPA 1998b)



4.1.3 Baseline ERA

Baseline ERA are required when sites are complex or when scoping and screening has indicated a potential risk. DEC requests that an ERA workplan and a sampling and analysis plan (SAP) be developed prior to development of the baseline ERA. The ERA work plan should summarize the screening-level ERA, list data gaps, describe additional studies needed to fill the data gaps, and describe methods to be used to quantify exposure and characterize risk for all receptor groups being evaluated. Subsection 2.2 provides additional recommendations for the ERA work plan. The SAP should describe in detail the field and laboratory methods that will be used to guide collection of additional site data for the baseline ERA. After DEC approval of the work plan, the baseline ERA should be completed and submitted to DEC for review (see Figure 2). The baseline ERA includes the same basic elements found in the screening-level ERA—problem formulation, analysis of exposure and effects, and risk characterization—in a more developed form.

The information presented in subsections 4.2 to 4.5 is most applicable to Steps 3 and 4 in DEC's overall ERA process. These two steps will result in ERA reports with major sections for problem formulation, ecological exposure and effects, risk characterization, and uncertainty analysis. Nonetheless, some material in the following subsections also is relevant to Steps 1 and 2, especially the material relevant to CSM development, which begins in these early steps.

4.2 Problem Formulation

The first stage of ecological risk assessment is problem formulation. Problem formulation is the process for generating and evaluating preliminary hypotheses about why ecological effects have occurred or may occur from human activities (EPA 1998b).

4.2.1 Components of Problem Formulation

The fundamental components necessary for problem formulation are:

- Environmental setting and site history;
- Documentation of site visits
- Information about which receptors are most likely to be present at this site. *The Technical Background Document for Selection and Application of Default Asssessment Endpoints and Indicator Species in Alaskan Ecoregions* would be useful in accomplishing this.
- Contaminant fate and transport evaluation emphasizing site-related chemicals, gradients of contamination, and identification of all potentially affected media;
- Preliminary ecotoxicity evaluation focusing on probable site-specific toxicity mechanisms to species or habitats of concern; and
- Preliminary exposure pathway analysis showing the potential for completed pathways to species or habitats of concern. This information goes into the CSM.

Problem formulation activities generate three products:

1. **Conceptual site models** – are developed from site information and knowledge of

habitats and life histories of receptors;

2. **Assessment endpoints –** detailed species or communities to protect in order to reach broader management goals; and
3. **Measures (previously called *measurement endpoints*) –** are used to evaluate potential effects on the assessment endpoints.

Site management goals and objectives should be identified or developed prior to the selection of assessment endpoints.

4.2.2 Ecological Conceptual Site Models

While the human health CSM relies on default 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, the potential hazardous substances, and physical and biological stressors at the site. For guidance on developing ecological CSMs, see *Guidance on Developing Conceptual Site Models*.

4.2.3 Selection of Assessment Endpoints

Assessment endpoints are parts of the ecosystem identified as important to its overall health or to a particular component of the ecosystem that is particularly of value. They explicitly state what function of a community or species is to be protected and how protecting that part of the ecosystem fits in with larger management goals. Assessment endpoints should be specific and clear enough to provide risk assessors and risk managers with sufficient direction and detail for determining measurable outcomes. Measures are selected and evaluated to determine whether the assessment endpoints are being adversely affected (see subsection 4.2.4 for explanation of measures).

Assessment endpoints can be identified at the individual, population, or community level of biological organization. Examples of these levels of assessment endpoints are provided below:

Individual Level	Threatened or Endangered species
	Changes in top predator activity
Population Level	Survival and reproduction of native Brook trout
	Survival and reproduction of Eastern Bluebirds
	Survival and reproduction of meadow voles (prey base)
Community Level	Estuarine communities
	Wetland plant communities
	Grassland communities
	Sensitive habitat communities
	Sensitive environments

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 should not be management goals or values and they should not be vague.

The three principal criteria used to select ecological values that may be appropriate for assessment endpoints are ecological relevance, susceptibility to known or potential stressors, and relevance to management goals (EPA 1998b). For species and communities that are not threatened or endangered usually it is appropriate to protect them at the population or community level. Guidance for selecting assessment endpoints in Alaska can be found in *User's Guide for Selection and Application of Default Assessment Endpoints and Indicator Species in Alaska Ecoregions* (DEC 1999). Additional information on establishing assessment endpoints can be found in *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment* (EPA 2003d).

DEC requires that threatened and endangered species be identified in the ecological risk assessment. DEC also recommends that, where applicable, threatened and endangered species be used as assessment endpoints, but not as measures. An indicator species from the same trophic level be selected as a surrogate to assess ecological risk to the endangered species.

Alaska sensitive environments are defined in 18 AAC 75.610; 18 AAC 75.620, 18 AAC 75.630, and 18 AAC 75.990. Examples of state and federal sensitive environments are provided in Table 3.

Table 3 Sensitive Environments

State		Federal
State wildlife refuges		Critical habitat for federal-designated endangered or threatened species
State land designated for wildlife or game management		Marine sanctuaries
State-designated scenic or wild rivers		National parks
State-designated natural areas		Designated federal wilderness areas
State-designated areas for protection or maintenance of aquatic life		Areas identified under the Coastal Zone Management Act
Spawning areas critical for the maintenance of fish or shellfish species within rivers, lakes, or coastal tidal waters		Sensitive areas identified under the national estuary program
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		Sensitive areas identified under the near coastal waters program
Terrestrial areas used for breeding by large or dense aggregations of animals		Critical areas identified under the clean lakes program
		National monuments
		National seashore recreation areas
		National Lakeshore recreational areas
		National preserves

State		Federal
		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
		Federal-designated scenic or wild rivers

4.2.4 Measures

There are three categories of measures: (1) measures of exposure; (2) measures of effect; and (3) measures of ecosystem and receptor characteristics. Each of these measures is defined below.

Measures of exposure are chemical-specific values used to determine exposure. Examples include concentrations of specific chemicals in soil, surface water, sediment, or food. Concentrations in media can either be modeled or measured. Often exposure is based on estimate intake of a media, but for certain receptors (such as invertebrates) it can be media specific (units of mg substance/kg body weight of receptor).

Measures of effect are measurable changes in an attribute of an assessment endpoint associated with exposure to a stressor (EPA 1998b). For example, site sediment samples may be used in a toxicity test with laboratory-reared benthic organisms (i.e., a surrogate for benthic fauna at the site) under controlled conditions to evaluate effects on survival, growth, and reproduction (i.e., attributes) from chemicals in sediment. The most appropriate measures of effect depend on the number and types of lines of evidence that are needed to support risk-management decisions at the site in question.

Measures of ecosystem and receptor characteristics that influence either the behavior and location of species selected as assessment endpoint, or the distribution of a stressor. Life history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor (EPA 1998b). For example, population characteristics such as density, relative abundance, and reproductive performance can be evaluated to determine the risk from exposure to the chemical(s).

An example of a management goal, an assessment endpoint, and potential measures is outlined below:

Goal: Sustain adequate prey for carnivores mammals

Assessment Endpoint

- Potential for adverse effects on the survival and reproduction of the terrestrial mammalian insectivores

Measures of Effects:

- Analysis of adverse health effects to shrews
- Reproductive success of female shrews
- Density of shrews in a specified area
- Species community analysis

Measures of Ecosystem and Receptor Characteristics

- Quality and extent habitat (e.g. vegetative cover, preferred habitat structure)
- Abundance and distribution of juvenile and adult food sources
- Presence of burrows and runways in appropriate habitat
- Environmental conditions (e.g. temperature, rainfall)

Measures of Exposure

- Chemical concentrations in soil and food items
- Modeled intake of chemicals from soil and food

Use EPA *Guidelines for Ecological Risk Assessment* (EPA 1998b) and *Region 10 Supplemental Guidance for Ecological Risk Assessment* (EPA 1997d) to assist in establishing measures. If additional data are needed, sampling plans should be designed around the selected measures. Modeling is also acceptable at this point.

4.3 Analysis (Ecological Effects Evaluation)

In the analysis phase measures of exposure and measures of effect are used to estimate the impacts of contamination in environmental media. This relies on the concept of dose response. Different contaminants are toxic to different species in different amounts. The intake of contaminant can be related to an actual or anticipated effect. For example if a measure of effect such as reproductive success is chosen, the exposure estimate can be compared to published literature values describing the relationship between the contaminants and reproductive effect.

Some primary methods for evaluating potential adverse effects to ecological receptors are; 1) hazard quotient method, 2) population/community evaluations, 3) toxicity tests, and 4) bioaccumulation and field tissue residue studies. The hazard quotient method is the most commonly utilized method. Site-specific methods are used when the assumptions employed in the screening level and baseline risk assessment are overly conservative or when there is insufficient published information to perform an adequate analysis. More than one method may be necessary to sufficiently characterize risk to support valid risk management decisions.

4.3.1 Hazard Quotient Method

4.3.1.1 Selection of Indicator Species and Communities

Indicator species and communities should be chosen based on the assessment endpoints, CSMs, food web analysis, and other available site-specific information. Indicator communities typically selected for evaluation at hazardous waste sites include benthic fauna, soil invertebrates, terrestrial plants, and/or wetland plants, depending on the habitats affected by site-related contamination. When assessing wildlife risk, indicator species are species from the same trophic level and feeding guild as assessment endpoints, for which exposure parameters are available. See DEC 1999 for recommendations on selecting indicator species and communities for Alaskan ecoregions.

4.3.1.2 Selection of Compounds of Potential Concern

Soil screening benchmarks are available from Oak Ridge National Labs (Efroymson et al. [1997a, 1997b]), EPA (2000), and published sources such as and Alloway (1990). Sediment screening benchmarks are available from NOAA (Buchman, [1999]), Oak Ridge National Labs (Jones et al. [1997]), and DEC (2001, 2004c). Surface water screening benchmarks are available from NOAA (Buchman [1999]), 18 AAC 70, Oak Ridge National Labs (Suter and Tsao [1996]), and Suter (1996). Other screening values from government sources or published literature can be used as needed and appropriate in consultation with ADEC. Measured chemical concentrations in environmental media should be compared with these benchmarks to identify COPCs. For metals and some organic chemicals in soil and sediment, it is important to consider background concentrations when selecting COPCs. Guidance on background screening is provided by DEC (2003a).

For wildlife, screening-level HQs should be calculated as described in EPA 1997c using exposure parameters from EPA (1993), Sample and Suter (1994), and other reputable sources. Subsection 4.2.1.3.1 provides additional guidance on selecting exposure parameters. DEC prefers that TRVs be based on no observed adverse effect levels (NOAELs) for initial screening estimates for wildlife to ensure that risk is not underestimated. Subsection 4.3.1.4 discusses the selection and use of TRVs for evaluating wildlife risks.

<u>Bioaccumulative</u> compounds may not be screened out without accounting for their accumulation in the food chain. ADEC defines bioaccumulative compounds as organics with a BCF equal to or greater than 1,000, and inorganics identified by EPA (2000b). A list of bioaccumulative compounds commonly found at contaminated sites in Alaska is provided in Table A-1 in Appendix A of, *Guidance on Developing Conceptual Site Models*.

After ecological screening benchmarks and TRVs are selected, the screening for ecological COPCs is conducted similarly to human health risk screening, namely:

1. For community-level receptors, compare the maximum concentration to the ecological risk-based benchmark or other appropriate benchmark in tabular format. For wildlife receptors, use the maximum concentration to calculate a screening-level HQ.

2. Eliminate compounds if they do not exceed any of their respective risk-based benchmarks and if the screening-level wildlife HQ is less than 1.
3. Retain compounds that have a potential to bioaccumulate or bioconcentrate.
4. Identify all compounds not eliminated as COPCs 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 in the uncertainty section.

4.3.1.3 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. For receptor groups such as plants, soil invertebrates, and benthic life, exposure is defined in terms of contact of a chemical with the outer boundary of the organism and subsequent uptake. For these receptor groups, risk is typically assessed by comparing measured media concentrations to risk-based benchmarks. Exposure via specific pathways is not generally estimated.

For wildlife, exposure is defined in terms of the amount of the compound of concern ingested, inhaled, or absorbed through dermal and internal absorption. It is rare that sufficient data exist to characterize exposure through dermal absorption or through inhalation. Exposure assessment for a wildlife 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.

4.3.1.3.1 Ecological Exposure Assumptions

When calculating screening-level ecological risks, conservative estimates should be used to estimate exposures in the absence of sound, site-specific information. Conservative assumptions can be replaced with site-specific information for the purpose of calculating ecological risk based cleanup levels. For a screening level risk assessment acceptable DEC exposure assumptions are listed below:

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

Alteration of default exposure assumptions is appropriate in a baseline risk assessment. Species-specific exposure parameters can be obtained from the *Wildlife Exposure Factors Handbook* (EPA 1993). Other sources of species-specific wildlife exposure parameters include Sample et al. (1996, 1997) and Sample and Suter (1994).

During a screening-level ERA (Step 3), it may be necessary to model COPC levels in wildlife food. Bioaccumulation factors (BAFs) and/or equations for such modeling can be

found in Bechtel Jacobs 1998a and Beas et al. 1984 for plants, in Bechtel Jacobs 1998b for benthic invertebrates, in Sample et al. 1998a for earthworms, and in Sample et al. 1998b for small mammals.

4.3.1.4 Selecting and Scaling Toxicity Reference Values

TRVs are analogous to reference doses in human health risk assessment. They are used for wildlife risk characterization and should be based on toxicity studies from the literature. In many cases, uncertainty factors are applied to published toxicity data to make them relevant to indicator species.

In general, the endpoints that ecological risk assessments address for non-endangered species include reproduction, growth, maintenance, and critical developmental processes. Cancer is not usually selected as a chronic ecological endpoint.

Currently, the most extensive compilation of TRVs for wildlife is found in Sample et al. 1996. Original papers from the peer-reviewed literature should be consulted for toxicity data for chemicals not included in Sample et al. 1996. If a TRV is not available from Sample et al. 1996, and suitable data for developing a TRV cannot be found in the peer-reviewed literature, the approaches described in subsection 4.3.1.4.2 should be considered.

Most animal toxicity studies reported in the literature are conducted with small animals (e.g., mice, rats, and chickens) that are adaptable to living in confined spaces. Toxicity data are not available for all wildlife species and chemicals that may be considered in an ERA. Hence, extrapolation of toxic responses observed in test species to wildlife receptors is necessary. Allometric scaling is one commonly used extrapolation approach. Allometric scaling of TRVs should be conducted as described in Sample and Arenal 1999.

4.3.1.4.1 Ecological Uncertainty Factors

DEC will accept the uncertainty factors (UFs) for calculating TRVs that are listed in Table 4. The UFs for phylogenic effects need not be applied if allometric scaling of TRVs is conducted as described in subsection 4.3.1.4.

Table 4 Uncertainty Factors

Species Specific Data		Non-species specific data		
Toxicological data	**UF**	**Effect**	**Difference**	**UF**
Chronic No Observed Effect Level (NOEL)	1	Population Effects	Different Trophic level	2
Chronic NOAEL	1-2		Different Exposure media	2
Chronic Lowest Observed Effect Level (LOEL)	5	Biochemical Effects	Toxic intermediate data	4
Subchronic NOEL	5	Phylogency Effects	Species sensitive to toxic endpoint	½
Subchronic NOAEL	5-10		Different Genus	2
Subchronic LOEL	25		Different Order/Family	4
Subchronic Lowest Observed Adverse Effect Level (LOAEL)	25-50		Different Class	Cannot use data
Acute NOEL	20			
Acute NOAEL	20-40			
Acute LOEL	100			
Acute LOAEL	100-200			
Lethal Dose at 50% (LD50)	250			

For more detailed procedures for deriving TRVs for wildlife receptors, 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.

4.3.1.4.2 Alternative Approaches for Developing TRVs

For some contaminants, ecological screening benchmarks and/or TRVs are not available. In such cases, the use of surrogates should be considered. For example, wildlife TRVs for polynuclear aromatic hydrocarbons (PAHs) are limited, but the TRV for benzo(a)pyrene may be used as a surrogate for other PAHs. In addition, quantitative structural activity relationships (QSARs) can be developed. A QSAR is a mathematical relationship between a property of a chemical, either bioconcentration potential or toxicity, and its chemical and/or physical characteristics (Walker 2004). The ecological criteria databases should be used to determine bioconcentration and toxicity data needed to establish a mathematical relationship between the defined property and the descriptor (Hickey *et al*., 1993). The QSAR can then be used to predict the bioconcentration or toxicity potential of untested chemicals based on their chemical and/or physical characteristics. QSARs may be developed by, or in consultation with, EPA. However, DEC risk assessment staff should

be consulted before contacting EPA because similar derivations may be readily available from other risk assessments conducted in Alaska.

4.3.2 Ecological Field Studies

A well-conducted field study can provide a valuable link between site contaminants and potential ecological effects (EPA 1997d). The field study will help determine the conditions of organisms at the site. Several endpoints are considered evidence of adverse toxic effects, including:

- Reduction in species population;
- Absence of species known to inhabit the area;
- Presence of plant or animal species associated with "stressed" habitats;
- Changes in community balance or trophic structure; and
- Frequency of lesions, tumors or other pathological conditions in individuals.

Field studies must be designed and conducted by experienced wildlife biologists and be based on published methodology. EPA 1999 describes field assessment methods for fish, benthic invertebrates, and periphyton in wadeable streams and rivers. EPA 1989b describes field assessment methods for terrestrial plants, vertebrates, and invertebrates at hazardous waste sites. Lastly, a good example of the use of field studies as part of an ERA can be found in Menzie et al. 1992.

4.3.3 Toxicity Tests

The bioavailability and toxicity of site contaminants can be tested with toxicity tests or bioassays. As with other methods, it is critical that the media tested are in exposure pathways relevant to the assessment endpoint. Testing methods are available for evaluating the toxicity of chemicals in sediment, surface water, and soil. Standardized test methods have been developed for freshwater fish and plankton (EPA 2002c), freshwater benthic invertebrates (EPA 2000a), marine and estuarine fish and plankton (EPA 2002d), and marine and estuarine benthic invertebrates (EPA 1994b). Some 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 1997d). Standardized tests also are available for terrestrial plants and soil invertebrates (EPA 1988). For additional information on using toxicity tests in risk assessments, please see EPA 1997d, 1994c, and 1994d.

4.3.4 Bioaccumulation and Field Tissue Residue Studies

Field tissue residue studies may be done in cases where there is potential to overestimate risk by using conservative BAFs from the literature. Although ADEC with consider such studies for estimating site specific BAFs, they are not required or even recommended. The biota samples taken should be in the exposure pathway of the assessment endpoint and not the endpoint itself, as toxicity data are rarely available to determine effects from tissue concentrations. Co-located samples of contaminated media should be taken with biota samples. Organisms that are sessile or have limited mobility(i.e., plants, mussels, fish fry, small mammals) are likely represent the site better than animals with a large home range, provided they are a key element in the food chain. It may also be important to consider the

season that samples are taken. Sample gender, size and age should be recorded. Methods for assessing bioaccumulation in aquatic environments can be found in EPA 2000a and 2000c.
It is extremely difficult to obtain sufficient samples to perform a valid background determination in the face of the inevitable high variability typically encountered when sampling biota. For this reason, biota samples should not be taken with the intention of eliminating compounds from the COPC list.

In Alaska, field residue studies are often performed for biota that are subsistence food items and all of the above guideline have application to such studies, even though the endpoint is different. The most critical issue is that the biota samples taken represent what people are eating. The most appropriate season to take samples would be the season that is typically used for hunting and harvesting. It is also worth noting that for an ecological risk assessment, whole body contaminant load may be the appropriate determination, where as for subsistence foods, it is often more appropriate to analyze the tissues and or organs that are frequently consumed. Local subsistence users should be conferred with when taking samples for subsistence exposure.

4.4 Risk Characterization

Risk characterization should answer the following basic question:

> Are ecological receptors at the site expected to be exposed to levels of contaminants that could harm a community or population important to the functioning of the ecosystem, or to particular valued species within that ecosystem, now or in the future?

Risk estimates should integrate exposure and toxicity information in a way that supplies a measurement of adverse risks. Such a measurement may be a qualitative description, or it may be a quantitative value or set of values such as a quotient or range. Discussion of risk estimates, such as the hazard quotient should identify the strengths and limitations of the assessment in such a way as to provide complete and useful information for decision makers.

To fully characterize the potential risks at a contaminated site, all data should be presented clearly, and in the context of the associated endpoints from the CSM. Toxicity and exposure parameters, any professional judgments, any inferences applied to the data, and all sources should be described. The discussion should also consider the following; whether NOAEL or LOAEL were used to develop TRVs; whether the intake represented a receptor with average exposure or RME; whether information was site specific or default values were used; whether field data is available.

The conclusion of a risk assessment may be authenticated by using lines of evidence to interpret risk (EPA 1997d). Lines of evidence may be derived from several sources or by different techniques such as hazard quotient estimates, modeling results, field experiments,

and observations. Some of the factors that should be evaluated in the risk assessment are listed below:

- The relevance of evidence to assessment endpoints,
- The relevance of evidence to the CSM,
- The sufficiency and data quality and study design used in the key studies,
- The strength of the cause and effect relationships, and
- The relative uncertainties associated with the lines of evidence and their direction.

DEC may require calculation of ecological risk-based cleanup levels.

4.4.1 Hazard Quotient Risk Calculations

To characterize wildlife risks, conservative intake estimates are compared to TRVs using the HQ method. To assess risks to receptor groups, like plants, soil invertebrates, and benthic life, measured chemical concentrations in soil, sediment, and water are compared to ecological risk-based benchmarks; the ratio of the media concentration to the benchmark may also be thought of as an HQ. Compounds that exceed an HQ of 1 should be retained for further ecological evaluation and possible development of site-specific, risk-based, ecological cleanup levels. Quotient calculations are presented below:

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

Where:

HQ	=	hazard quotient (no units)
Dose	=	estimated contaminant intake as determined in the exposure estimate (mg/kg-day)
MEC	=	measured environmental concentration (e.g., mg/kg)
TRV	=	toxicity reference value (see subsection 4.3.1.4)
Benchmark	=	ecological screening benchmark (see subsection 4.3.1.2)

An HQ greater than 1 for a compound is interpreted by DEC as a level at which a potential adverse ecological effect may occur. These contaminants should be retained for further evaluation and discussed in the Uncertainty Assessment section.

Chemicals with HQs less than 1 generally need only be retained for uncertainty assessment. However, when a cumulative effect is suspected or known, the 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 HI calculation is described below:

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

If the HI is less than 1, yet the chemical has potential to bioaccumulate, it should be retained for further evaluation in the risk assessment.

4.4.2 Toxicity Testing Results

Toxicity tests provide direct evidence as to whether chemicals in environmental media have potential to adversely affect living organisms. The effects typically evaluated include survival, growth, and reproduction. If toxicity tests are conducted for the ERA at a site, test organism survival, growth, and reproduction in site samples should be statistically compared to these endpoints in the laboratory control and site-specific background samples to quantify adverse effects. The results should be summarized in the ERA report, and the complete laboratory bioassay report should be attached as an appendix. Whether the test results agree with risk predictions based on benchmark comparisons should be evaluated and discussed.

4.5 Uncertainty Assessment

Uncertainty can be associated with: (1) exposure parameters, BAFs, and other information taken from the literature; (2) extrapolations used in developing a screening-level benchmark or TRV; (3) site data, or the lack thereof; and (4) elements of the CSM, such as chemical fate and transport and wildlife use of the site. In the uncertainty assessment section of the ERA, the risk assessor should list important sources of uncertainty and describe whether they result in an underestimate or overestimate of ecological risk at the site. Highly uncertain parameters and assumptions that, if better understood, could alter the conclusions of the assessment are the most important to identify. Such sources of uncertainty may require collection of additional site-specific data before a risk management decision can be made. EPA (1997d, 1998b) and Warren-Hicks and Moore (1998) provide additional information regarding identifying, assessing, and limiting sources of uncertainty, and discuss the difference between uncertainty and variability in ERAs.

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6 GLOSSARY

The glossary for the DEC Risk Assessment Procedures Manual defines some commonly used terms in risk assessment.

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

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 concentration: The concentration of a hazardous substance that is consistently present in the environment or in the vicinity of a site and that is naturally present or is the result of human activities unrelated to a discharge or release at the site. See also, definition in 18 AAC 75.990(6).

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.

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 is expected to cause cancer in nonhuman life; or for human health purposes, a substance that meets the criteria of a Group A or Group B carcinogen according to EPA's *Guidelines for Carcinogen Risk Assessment*. See also, definition in 18 AAC 75.990(12).

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.

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.

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 the 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.

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.

groundwater: Water in the saturated zone, for purposes of evaluating whether the groundwater is a drinking water source under 18 AAC 75.350; or water beneath the surface of the soil, for purposes of evaluating whether the water will act as a transport medium for hazardous substance migration;
See also, definition in 18 AAC 75.990(46).

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. See also, definition in 18 AAC 75.990(47).

hazard quotient (HQ): The ratio of the exposure point value to the reference dose for hazardous substances. See also, definition in 18 AAC 75.990(50).

hazardous substance: An element or compound that, when it enters into the atmosphere or in or upon the water or surface or subsurface land of the state, presents an imminent and substantial danger to the public health or welfare, including but not limited to fish, animals,

vegetation, or any part of the natural habitat in which they are found. See also, definition in AS 46.03.826(5).

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. Hazardous waste means waste within the scope of 18 AAC 62.020. See also definition in 18 AAC 75.990(49).

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.

institutional control: A measure taken to limit, prohibit, or protect against an activity that could interfere with the integrity of contaminated site cleanup activities or improvements designed to encapsulate or control residual contamination or result in human or environmental exposure to a hazardous substance. See also definition in 18 AAC 75.990(54).

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.

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, Kow 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. Noncontiguous 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: A visible or measurable discharge or release of a hazardous substance from a given point of origin. See also definition in 18 AAC 75.990(91).

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 DEC decision-making process.

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

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: Determination of potential health effects including effects of containment exposure through inhalation, ingestion, dermal absorption, and other means, and the assessment of risk to human health and the environment from contaminants remaining in the land, air, or water as a result of a release; See also definition 18 AAC 75.990(109) and AS 46.03.450.

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.

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 that is contaminated, including areas contaminated by the migration of hazardous substances from a source area, regardless of property ownership. See also, definition in 18 AAC 75.990(115).

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.

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.”

APPENDIX A
SCOPING CHECKLISTS AND EXAMPLE TABLE

SCOPING MEETING CHECKLIST/SAMPLE AGENDA

✔ Discussion Points

- **GENERAL SITE INFORMATION**
  - History of use
  - Current land use
  - Map of site
  - Currently available relevant documents
- **PURPOSE OF ASSESSMENT**
  - Determine risk posed by site
  - Public concern over hazardous substances associated with a contaminated site
  - Develop ACLs
  - Develop preliminary remediation goals
- **USE OF DETERMINISTIC VS. PROBABILISTIC RA TECHNIQUES**
- **STUDY AREA**
  - Boundary of study area
  - Use of operable units
- **PRELIMINARY CSM**
  - Human health
  - Ecological
  - Sensitive populations or environments
- **COPCS**
  - Preliminary identification of COPCs
  - ARARs
  - Screening criteria reference for each media of concern
- **DATA GAPS**
  - Quality and quantity of available data
  - Additional sampling needs
  - Upcoming sampling and analysis plans
- **DEVIATIONS FROM DEC GUIDANCE OR EPA PROTOCOL**
- **LINES OF COMMUNICATION**
  - DEC/RP roles and responsibilities
  - Role of other programs/departments/agencies
  - RP and DEC team members and contact information
- **PUBLIC INVOLVEMENT**
  - Meetings needed and schedule
  - Public notices
- **SCHEDULE**
  - Document deliverable schedule
  - DEC review
  - Interim reports expected
  - Fieldwork (if needed)
  - Public review (if needed)

DEC RISK ASSESSMENT CHECKLIST

✔	TASK*	DATE
❒	**RISK ASSESSMENT SCOPING MEETING** See Scoping Meeting Checklist **(**DEC Project Manager; DEC Risk Assessment Staff; Responsible Party (RP); and RP consultants)	_____
❒	**SUBMIT CONCEPTUAL SITE MODELS** (CSMs) identifying all potential pathways to DEC project manager	_____
❒	**DEC APPROVES CONCEPTUAL SITE MODELS**	_____
❒	**SUBMIT RISK ASSESSMENT WORK PLAN** including CSMs identifying all completed pathways and all items listed in subsection 2.2	_____
❒	**DEC REVIEWS RISK ASSESSMENT WORK PLAN** comments provided to RP	_____
❒	**SUBMIT RESPONSE TO DEC WORK PLAN COMMENTS** to DEC project manager	_____
❒	**COMMENT RESOLUTION MEETING** for the risk assessment work plan	_____
❒	**SUBMIT HUMAN HEALTH & ECOLOGICAL RISK ASSESSMENT** to DEC project manager	_____
❒	**DEC REVIEWS RISK ASSESSMENT** comments provided to RP	_____
❒	**SUBMIT RESPONSE TO DEC RISK ASSESSMENT COMMENTS** to DEC project manager	_____
❒	**COMMENT RESOLUTION MEETING** for the risk assessment	_____
❒	**DEC APPROVES THE RISK ASSESSMENT**	_____
❒	**DEC MAKES RISK MANAGEMENT DECISION AND APPROVES ALTERNATIVE CLEANUP LEVELS, REMEDIAL ACTION, OR NO FURTHER ACTION**	_____

*some tasks may occur concurrently

Table A.1 Human Health Compounds of Potential Concern Data Presentation

Media	Compound	Maximum Concentration (Qualifier)	Units	Frequency of Detection	Range of Detection Limits	Background Concentration	Screening Concentration (C/NC)	Source	COPC Flag	Rationale for Selection or Deletion[1]
Soil	Benzene	0.06	mg/kg	5/15	0.01 – 0.02	N/A	0.002	DEC	Yes	ASL
	Arsenic	5.8	mg/kg	8/8	0.04	7.2	0.2	DEC	Yes	BBC

1 – Rationale Codes:

Selection Reasons - Above Screening Level (ASL)
No Screening Criteria (NSC)

Deletion Reasons - Below Screening Level (BSL)
Below Background Concentration (BBC)
Infrequently Detected (IFD)

APPENDIX B
HUMAN HEALTH SCREENING LEVELS

**CURRENTLY ADEC IS UPDATING CLEAN UP LEVELS.
A REVISED SCREENING LEVEL TABLE WILL BE PROVIDED
WHEN UPDATES ARE COMPLETED.**