State of Alaska

DEPARTMENT OF ENVIRONMENTAL CONSERVATION

DIVISION OF SPILL PREVENTION AND RESPONSE

CONTAMINATED SITES PROGRAM

RISK ASSESSMENT PROCEDURES MANUAL

FEBRUARY 1, 2018

RISK ASSESSMENT PROCEDURES MANUAL
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ACRONYMS

AAC	Alaska Administrative Code
ACL	Alternative Cleanup Levels
ADF&G	Alaska Department of Fish and Game
ADEC	Alaska Department of Environmental Conservation
ADHSS	Alaska Department of Health and Social Services
ALM	Adult Lead Model
ARARs	Applicable or Relevant and Appropriate Requirements
ATSDR	Agency of Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BERA	Baseline Ecological Risk Assessment
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
COC	Contaminant of Concern
COPC	Contaminant of Potential Concern
COPEC	Compounds of Potential Ecological Concern
CSM	Conceptual Site Model
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
IUR	Inhalation Unit Risk Factor
L/day	Liters per Day
LD_{50}	Lethal Dose, 50% of the Population
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
m^3/day	Cubic Meters Per Day
MF	Modifying Factor
mg/m^3	Milligrams Per Cubic Meter
MRLs	Minimal Risk Levels
NPL	National Priorities List
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
OSHA	Occupational Safety and Health Administration
OSWER	Office of Solid Waste and Emergency Response
PbBs	Blood-Lead Concentrations
PPRTVs	Provisional Peer-Reviewed Toxicity Values
PRGs	Preliminary Remediation Goals
QAPP	Quality Assurance Project Plan
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RfC	Reference Concentration
RfD	Reference Dose
RfD_i	Inhalation Reference Dose
RME	Reasonable Maximum Exposure
RP	Responsible Person(s)
RPF	Relative Potency Factor
RRO	Residual-Range Organics
RSL	Regional Screening Levels
SF	Slope Factor
SF_d	Dermal Slope Factors
SF_i	Inhalation Slope Factors
SF_o	Oral Slope Factors
SLERA	Screening Level Ecological Risk Assessment
SQL	Sample Quantitation Limit
TAL	Target Analyte List
TCCR	Transparency, clarity, consistency, and reasonableness
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
WOE	Weight of Evidence

1.0 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 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).
- ✓ Provide the basis for preparation of alternative cleanup levels (ACLs).
- ✓ Assist in the site remediation decision-making process.
- ✓ Identify when the Alaska Department of Environmental Conservation (ADEC) and other stakeholders must 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 (USEPA) must be used where guidance is not provided by ADEC. 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 Pollutant 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 must 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 ADEC.

1.3 The Risk Assessment Process

In general, risk assessments prepared for the ADEC Contaminated Sites Program assess risk to current and future receptors at or near the site based on current conditions. These assessments do not consider either current/future remediation or institutional controls. Figure 1 (see Appendix B) 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 a soil or groundwater cleanup level (18 AAC 75.341 and 18 AAC 75.345, respectively) as result of a risk assessment may potentially be considered an ACL. ADEC'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, Appendix B). 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.

For both assessments ADEC requires the use of reasonable maximum exposures (RMEs) for all risk characterization calculations. RME is defined as the highest exposure that is reasonably expected to occur at a site. The intent of the RME is to estimate a conservative exposure scenario that is within range of possible exposures (yet well above the average case) and to avoid estimates that are beyond the true distribution.

1.3.1 When to do a Risk Assessment

Once site characterization data gaps are adequately addressed, 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 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 also 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, exposure to fugitive dusts, or exposure to aquatic or terrestrial ecological receptors that 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 *Policy Guidance on Developing Conceptual Site Models* (ADEC 2017) indicates exposure pathways used to develop clean up levels.

1.3.2 Risk Assessment Requirements

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

- Human exposure assessment scoping and human health preliminary Conceptual Site Models (CSMs).
- Ecological scoping evaluation and ecological health preliminary CSMs.
- Risk Assessment Work Plan.
- Risk Assessment.

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

A draft version of each document must be submitted to ADEC for review and approval before submittal of the final version.

1.3.3 Risk Assessment Reviews

Draft and final CSMs, work plans, risk assessments, and other deliverables must be reviewed by ADEC risk assessment staff or a contracted third party selected by ADEC. Taking into account the technical comments on the risk assessment document, ADEC will either approve the document, return it to the RP for comment resolution, revision, and resubmittal, or reject the document. In most cases, ADEC 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. ADEC risk assessment staff must be consulted on the appropriate report needs.

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

1.4 Public Participation

ADEC will seek public participation regarding activities conducted under the site cleanup rules, using methods that ADEC determines to be appropriate for seeking public participation, per 18 AAC 75.325(j). This may include public comment when ACLs are proposed based on a site-

specific risk assessment (18 AAC 75.340(f)(1) and 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 ADEC is seeking comments. The minimum requirement is that the public notice must be published in local newspapers and on the State of Alaska website.
- Establishing a public comment period during which ADEC 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.
- 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(g)).

2.0 PLANNING

Planning for the risk assessment must 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 on CSMs is given in ADEC's *Policy Guidance on Developing Conceptual Site Models* (ADEC 2017). The risk assessment scoping meeting exercise allows for the development of the CSMs in consultation with ADEC and therefore lends greater efficiency to the work plan review process. 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 must be completed during planning and scoping. Fundamental components of problem formulation must 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 identify management goals, key issues such as current and future land use, and policies needing to be addressed.
- To share current knowledge of the site.
- To identify exposure and assessment areas.
- To discuss key exposure and toxicity assumptions.
- To develop preliminary CSMs.
- To identify and evaluate the adequacy of available data.
- To discuss work plan requirements for the human health and ecological section of the risk assessment.

A checklist of items that must 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 must 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 must focus on ADEC concurrence with assumptions, CSMs, proposed process, and schedule. Communication between ADEC and the RP is essential throughout the risk assessment process. The scoping meeting establishes lines of communication as well as determines the document deliverable schedule.

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 must consider all potential exposure media including soil, groundwater, sediments, surface water, air, and biota as applicable, and describe how risk from exposure to each media will be assessed.

Human health risk assessment work plans shall include the following:

- Site description, figures, and data summaries from site investigation(s).
- Description of land use and exposure areas.
- Data evaluation to include review of adequacy of detection limits.
- Evaluation of contaminant fate and transport.
- All proposed exposure assumptions or citations.
- Human health CSMs.
- All proposed toxicity data or citations.
- Human health risk screening levels.
- Data evaluation and an initial list of contaminants of potential concern (COPCs).
- Discussion of data gaps and a plan for data collection, if necessary.
- Descriptions and justification for all proposed modeling.
- Methods for calculating risk and ACLs.

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 scoping evaluation documentation.
- Ecological health risk screening evaluation.
- Identification of assessment endpoints – commonly derived from management goals.
- Ecological CSM.
- Data evaluation to include review of adequacy of detection limits.
- Initial list of Contaminants of Potential Ecological Concern (COPECs).
- Discussion of data gaps and plans for data collection, if necessary.
- Analysis approach – including criteria for measurement of effects, ecological benchmarks, and testable hypotheses.
- 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.

- Description and justification for all proposed modeling.

All exposure assumptions and parameters must be provided in the work plan. If parameter values are not available, detailed descriptions of the methodology and literature citations that will be used to develop the exposure parameters must be included. For instance, if the site-specific fish ingestion rate is not known at the time of the work plan, it must explain whether interviews, community surveys, literature values, or other data will be used to estimate fish ingestion rate and give a detailed description of how this is to be done. ADEC in coordination with the responsible person will consult with the Alaska Department of Health and Social Services (ADHSS) and/or the Agency for Toxic Substances and Disease Registry for the appropriate evaluation of the subsistence food pathway. 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 ADEC project manager for human health risk assessments:

- CSM (one electronic copy in portable data file (pdf) format) to include scoping forms. (see Policy Guidance on Developing Conceptual Site Models (ADEC, 2017))
- Risk Assessment Work Plan (one electronic copy in pdf format)
    - numerical data and screening levels in Microsoft Excel.
    - table of all default and site-specific exposure assumptions.
    - table of all toxicity data for COPCs.
    - all model inputs and assumptions as appropriate.
- Risk Assessment (one electronic copy in pdf format)
    - numerical data in Microsoft Excel.
    - risk screening evaluation tables in Microsoft Excel.
    - Reasonable Maximum Exposure (RME) calculations in Microsoft Excel or as ProUCL output (note: all summary and data input pages must be included).
    - risk calculations tables in Microsoft Excel.
    - all modeling inputs and outputs.
    - ACL calculations in Microsoft Excel.

For ecological risk assessments, the first submittal must be the scoping evaluation, with preliminary screening. If warranted based on site conditions, a Screening Level Ecological Risk Assessment (SLERA) may be required, and a Baseline Ecological Risk Assessment Work Plan and Baseline Ecological Risk Assessment (BERA) as warranted.

Project-specific submittal requirements need to be determined with the ADEC project manager and ADEC risk assessor.

2.4 Deterministic and Probabilistic Evaluations

Deterministic risk assessments express risk as a single numerical value which must represent the RME. 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.

ADEC 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 must 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 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 USEPA's Exposure Factors Handbook (2011. For guidance on performing a probabilistic risk assessment, please consult, *Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies* (EPA, 2014a).

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

3.0 HUMAN HEALTH RISK ASSESSMENT

The human health risk assessment (HHRA) methodology in this section integrates federal and state requirements with site-specific information to provide a framework for performing an HHRA at an Alaska contaminated site. *Risk Assessment Guidance for Superfund* (USEPA, 1989) or other USEPA guidance must be consulted if ADEC does not provide guidance for aspects of the HHRA process. Additional guidance and information on risk assessment can be obtained from Interstate Technology Regulatory Council.

EPA Guidance: Data Evaluation

- ❒ *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A) – Interim Final* (USEPA, 1989a)
- ❒ *Guidance for Data Usability in Risk Assessment (Part A) – Final* (USEPA, 1992b)
- ❒ *Data Quality Objectives Process for Hazardous Waste Site Investigations* (USEPA, 2000c)
- ❒ *Guidance for Data Quality Assessment: Practical Methods for Data Analysis* (USEPA, 2000d)

3.1 Data Evaluation

Data evaluation is the process for identifying if data is of sufficient quality and quantity 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. In general, field-monitoring tests do not provide data of sufficient quality to be used for risk assessment purposes. Consultation with the ADEC project manager and technical staff in developing the sampling plan for the site investigation is recommended to assure data are collected that are appropriate for risk assessment purposes.

The available sampling data, including any historical 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:

- Analytical data sufficient for adequate site characterization must be available.
- Data must have been collected consistent with ADEC and USEPA guidance.
- Sampling and analytical procedures must give accurate chemical-specific concentrations.
- Validated analytical laboratory data is required.
- Method detection limits and sample quantitation limits to the extent practicable should be below screening criteria.

- Qualified data must be appropriately used and explained in the uncertainty section (i.e., discussion on potential bias from qualified data and how it might result in the over or under estimation of risk).
- Rejected data **shall not** be used for risk assessment purposes. The risk assessment data usability criteria listed below must be assessed during scoping for the risk assessment. Mitigation for inadequate data must be agreed upon with ADEC.
- **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* (USEPA, 2000c) 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 is **not** recommended. A full data quality review is required.
- **Reports** – A data review report that includes evaluation of the adequacy of the analytical quantitation limits, demonstration that DQOs have been met as described above, and a narrative discussing any qualified data and potential impacts resulting in uncertainties in the risk estimates must be provided.

3.1.2 Consistency with Conceptual Site Models

Sampling plans must be consistent with the site-specific conceptual site model and must 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. The following recommendations are given to assure that data will support a risk assessment and must 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 or groundwater 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 generally 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 must be used to develop the initial list of potential contaminants. Attention must 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. USEPA 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, must be used when developing field sampling plans to address data gaps for the HHRA.

3.1.4 Selection of Contaminants 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 must be selected based on the exposure pathways and media identified in the CSM. Refer to ADEC's *Procedures for Calculating Cumulative Risk* (ADEC, 2018b) for special instructions regarding petroleum hydrocarbons, PCBs, dioxins, and lead.

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. Compounds that do not exceed ADEC-approved background concentrations are eliminated from risk characterization but may be retained for discussion in the uncertainty section if they exceed risk based screening values.
6. Identify compounds not eliminated as COPCs and carry-through for qualitative evaluation.

Note that special attention must be paid to any potential data bias when comparing sample results to screening values. For instance, if a result is qualified and considered biased low, then it may not be eliminated as a COPC even though the result is lower than the risk screening level.

If contaminants were not detected, evaluate if detection levels were greater than the screening values. If adequate detection limits are not technically feasible, then conservative alternative concentrations must be considered for the screening process to ensure that no compounds are inappropriately screened out of the HHRA.

Risk based screening levels can be obtained from the most current Regional Screening Levels (RSL) table for Chemical Contaminants based on ADEC screening requirements of a Hazard Quotient (HQ) = 0.1 and cancer risk 1×10^{-6} (see: http://www.epa.gov/region9/superfund/prg/). If compounds are not listed in the RSL table, then the RSL equations can be utilized, incorporating toxicity information from sources discussed in section 3.3.1., along with appropriate chemical specific parameters, applicable climate zone, and a residential exposure scenario. This information can be then be used to develop a screening level corresponding to the non-carcinogenic risk HQ of 0.1 and carcinogenic risk level of 1×10^{-6} for the for the respective media. Initial screening for all sites must be against residential chronic exposure scenarios using a toxicity source derived from the toxicity hierarchy discussed in section 3.3.1. If required information is unavailable for developing a screening value with RSL equations, the compound must be retained for qualitative or an approved quantitative approach evaluation in the HHRA. Consult with the ADEC risk assessment staff in this event.

If additional exposure pathways or media exist, such as ingestion of subsistence foods, inhalation of indoor air, or breast milk, other screening criteria may need to be proposed. The screening criteria must correspond to a HQ = 0.1 or a cancer risk of 1×10^{-6} when default residential exposure assumptions are used. Details for evaluating some of these additional exposure pathways and media are discussed below.

Subsistence Foods: Appropriate risk screening criteria for biota used as subsistence foods must be developed on a site-specific basis and in coordination with ADEC risk assessment staff and the Alaska Department of Health and Social Services (ADHSS) and/or the Agency for Toxic Substances and Disease Registry (ATSDR). Evaluation of the ingestion of subsistence foods exposure pathway is discussed later in Section 3.2.2.3.

Vapor Intrusion: For the evaluation of the vapor intrusion pathway (i.e., inhalation of indoor air) ADEC recommends the use of its *Vapor Intrusion Guidance* (ADEC, 2017).

Contaminants in Breast Milk: Infant consumption of contaminated breast milk shall be considered a potential exposure pathway on a chemical- and site-specific basis.

Fugitive Dust: In general, ingestion of fugitive dust is deemed a protected exposure route under the direct contact to soil pathway. This may not be the case where dust is generated by human activity or where specific fugitive dust compounds of potential concern are present at the site. A list of contaminants commonly considered for fugitive dust concern is presented in the ADEC's *Procedures for Calculating Cumulative Risk* (ADEC, 2018b).

Surface Water Consumption: If ingestion of surface water is a pathway of concern, the groundwater screening levels should be used as risk-based screening levels for surface water. However, water quality standards for surface water (18 AAC 70) must be considered when evaluating a site with surface water contamination to address ecological concerns (see ecological risk assessment section). Water quality standards for applicable fresh and marine water classes must be used. Water quality standards are to be considered ARARs and, therefore, must also be used as screening levels.

Sediment Exposure: If human 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.

Bioaccumulation in Wild Foods: 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 must be retained as COPCs. Bioaccumulation is defined as the accumulation of chemicals in the tissue of organisms through any route, including respiration, ingestion, or direct contact with contaminated water, sediment, and pore water in the sediment (EPA, 2000b). Bioaccumulative compounds are classified by ADEC as having a bioconcentration factor (BCF) equal to or greater than 1,000 (EPA, 2004d) for organic compounds or log K_{ow} greater than 3.5, or that are identified by USEPA (USEPA, 2000a) as bioaccumulative inorganic compounds. A list of bioaccumulative compounds commonly found

at contaminated sites in Alaska is provided in Appendix C, *Policy Guidance on Developing Conceptual Site Models* (ADEC, 2017).

Natural Background Contamination: Distinguishing site contamination from naturally occurring background concentrations in HHRA is an important part of screening. For further information, see USEPA's guidance *Role of Background in the CERCLA Cleanup Program* (USEPA, 2002d) and *Guidance for Comparing Background and Chemical Concentration in Soil for CERCLA Sites* (USEPA, 2002c). If inorganic contaminant concentrations are less than or equal to the naturally occurring background for the site, then the compound may not need to be retained as a COPC for remedial consideration, but still may yet be considered for its contribution to cumulative risks and risk management decisions. Hence, although naturally occurring compounds may be excluded from the baseline risk assessment, at some sites the risk from naturally occurring background compounds may be included in the baseline risk assessment, presented separately in the uncertainty section from the site-related risks, at the option of the ADEC.

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

ADEC requires the HHRA to consider both current and future exposure scenarios. The default exposure scenario for which risk assessments shall be performed is an unrestricted residential land use scenario. Prior approval with appropriate justification is required from ADEC to exclude a residential land use scenario along with the consent of each landowner who is affected. All exposure assumptions must be documented and referenced accordingly.

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 must be part of the site characterization work plan 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 and potentially complete exposure pathways, see *Policy Guidance on Developing Conceptual Site Models* (ADEC, 2017).

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, and second, exposure concentrations at the exposure point are estimated.

3.2.2.1 Pathway-Specific Intakes

The generic ingestion 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 (e.g., 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 will need adjustment based on the oral, dermal, or inhalation exposure route 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 must be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure (RME) for the pathway. All specific exposure assumptions must be defined in a table in the work plan and HHRA and their source referenced as appropriate. Table 1 provides exposure factors for common exposure pathways in Alaska. These values may be adjusted with ADEC approval to meet site conditions, as appropriate. There are several sources of information about human activity and behavior patterns, such as USEPA's Exposure Factors Handbooks, the National Human Activity Patterns Study, and published scientific literature. These must be used as a resource when site-specific exposure scenarios are developed. Deviations from information in such resources may be appropriate, but must be defensible and conservative and must be made in consultation with ADEC.

Site-specific application of quantitative bioavailability adjustments in risk assessments is not recommended. A default value of 100% is recommended for all chemicals except arsenic and lead in soil for the baseline risk assessment. A default of 60% for arsenic (EPA, 2012) and the default value used in the Integrated Exposure Uptake Biokinetic (IEUBK) model (EPA, 2009a) for lead in soil is recommended.

Table 1 Summary of Default Exposure Factors

Exposure Parameter	Resident		Commercial/Industrial Worker		Subsistence User[1]		
	Soil	Groundwater	Soil	Groundwater	Soil	Groundwater	Wild Food
Exposure Frequency (d/yr)	330/270/200[4]	350	250/200[4]	350	330/270/200[4]	350	365
Exposure Duration (yr)	20 (adult) 6 (child) 26 (combined)	20 (adult) 6 (child) 26 (combined)	25	25	20 (adult) 6 (child) 26 (combined)	20 (adult) 6 (child) 26 (combined)	20 (adult) 6 (child) 26 (combined)
Soil Ingestion Rate (mg/d)	100 (adult) 200 (child)	-	100 (outdoor worker) 50 (indoor worker)	-	100 (adult) 200 (child)	-	-
Groundwater Ingestion Rate (L/d)	-	2.5 (adult) 0.78 (child)	-	2.5	-	2.5 (adult) 0.78 (child)	-
Food Ingestion Rate (mg/kg)	-	-	-	-	-	-	Site-specific[2]
Skin Surface Area Exposed (cm^2) [3]	6,032 (adult) 2,373 (child)	20,900 (adult) 6,378 (child)	3,527	-	6,032 (adult) 2,373 (child)	-20,900 (adult) 6,378 (child)	-
Adherence Factor (mg/ cm^2)	0.07 (adult) 0.2 (child)	-	0.12	-	0.07 (adult) 0.2 (child)	-	-
Body Weight (kg)	80 (adult) 15 (child)	-	80	-	80 (adult) 15 (child)	-	80 (adult) 15 (child)
Lifetime (yr)	70	70	70	70	70	70	70

1 – All values are recommended default values. Each parameter may be adjusted, as needed, based on site and/or exposure specific information.

2 – Value can be obtained from ADF&G *Community Subsistence Information System* and must be verified or adjusted, as needed, based on input from the community potentially affected by the site contamination. Ingestion rates obtained from the *Community Subsistence Information System* 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 ADEC's *Procedures for Calculating Cleanup Levels* (ADEC, 2018a). 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* (USEPA, 2011)
*Child-Specific Exposure Factors Handbook (*USEPA, 2018a)
Procedures for Calculating Cleanup Levels (ADEC, 2018a)
Dermal Assessment (USEPA, 2004c)
Supplemental Soil Screening Guidance (USEPA, 2002g)

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 USEPA. 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 wild food resources, based on survey information. The use rates are found in the *Community Subsistence Information System* or CSIS (ADF&G, 2013). If available, the high-end user rate for the community of interest must be used to estimate ingestion rates for specific resources. Median user values are appropriate if high-end rates are not available. Values from the CSIS must only be used in consultation with the community potentially affected by site contamination. If more appropriate studies or values are available, these values must 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 recommended sources for exposure assessment. Though not mandatory, consultation with the Alaska Department of Health and Social Services (ADHSS) or the Agency for Toxic Substances and Disease Registry (ATSDR) is highly recommended for the appropriate evaluation of the subsistence food pathway. ADEC advises the responsible party to consult with ADHSS and ATSDR during the scoping phase of the risk assessment to discuss their involvement and the level of assistance required to evaluate the subsistence pathway.

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 Area

For the purposes of risk assessment, the source area is the exposure area. The source area is defined as an evident volume of soil and/or groundwater containing elevated or potentially elevated concentrations of contaminant (horizontal and vertical extent) in comparison to surrounding media. The source area includes the following:

- Area with visible stains, known contamination, and/or obvious releases.
- Area where contaminants have leaked, spilled, migrated, and been disposed.
- Area where sufficient laboratory data indicates elevated concentrations relative to surrounding media.

In addition, contamination from other nearby source areas that have comingled with those from the source area being address must be considered in the exposure assessment; however, the exposure area should not be expanded to include the nearby source area unless specifically approved by ADEC. Source area consideration takes into account not only the direct contact pathway, but also potential migration of contaminants resulting in the completed inhalation and migration to groundwater pathways. This approach provides a conservative means of protecting current and future receptors regardless of future land use. ADEC takes into

consideration volatilization and migration of contaminants in the inhalation and migration to groundwater cleanup levels and therefore any sampling approach must consider them accordingly and demonstrate these pathways are being adequately protected. The Risk Assessment Guidance Part A (RAGS A) discusses contaminant distribution and exposure considerations:

> *In some cases, contamination may be unevenly distributed across the site, resulting in hot spots (areas of high contamination relative to other areas of the site). If a hot spot is located near an area which, because of site or population characteristics, is visited or used more frequently, exposure to the hot spot must be assessed separately. The area over which the activity is expected to occur must be considered when averaging the monitoring data for a hot spot. For example, averaging soil data over an area the size of a residential back yard (e.g., an eighth of an acre) may be most appropriate for evaluating residential soils pathways* (USEPA, 1989a).

However, current, let alone future, land use may not be readily defined at most contaminated sites and this determination is further complicated with the remoteness of sites, subsistence use, and historic or cultural considerations unique to Alaska. Therefore, application of a default exposure unit is **not** appropriate for site characterization or risk assessment.

Each groundwater well must be considered the exposure area for groundwater assessment, whereby the maximum detected concentration in groundwater within the source area shall be used as the EPC.

Exposure Point Concentration

The EPC must be a conservative estimate of the average concentration to which a receptor is exposed over time. The EPC is **not** to be used for COPC screening for soils. In addition, high concentrations within an area must not be "diluted out" by averaging with several lower concentrations over a larger area or outer boundary sampling. Site characterization data is typically focused on identifying and delineating the source area. However, a data set generated solely from characterization data does not exhibit a defined distribution and has a high degree of bias to the lower concentrations (i.e., delineation and extent of boundary), which generally will not produce a 95% UCL that is representative of the source area. A visual and/or geospatial assessment is required to decrease the bias of the representation.

For groundwater, the maximum concentration is used both for screening and risk assessment. See section 3.1.4 for guidance on COPC screening. The EPC is used to assess risk and must be estimated using a 95% upper confidence limit (UCL) on the mean of the contaminant concentrations in soil. 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 the maximum value is less 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 necessarily appropriate for the statistical methods and assumptions employed in a risk assessment.

The distribution of the data set can be determined and the 95% UCL calculated using EPA's ProUCL 5.0 software (USEPA, 2013b). Alternative statistical methods for calculating the 95% UCL will be considered on a project-specific basis and must be approved by ADEC prior to their use.

The maximum detected concentration in groundwater shall be used as the EPC for the assessment of risk posed due to exposure to groundwater (i.e., ingestion, dermal contact, inhalation of volatiles from water). Considering the dynamic nature of groundwater, it is not deemed appropriate to average concentrations over an aquifer. This is recognized in 18 AAC 75.345(e) regarding the point of compliance where groundwater cleanup levels must be met throughout the aquifer. Using the maximum detected concentration provides a conservative approach to assess risks from this pathway, since it assumes the individual well is utilized as a residential drinking water source. This is also consistent with ADEC's compliance determination in 18 AAC 75.380(c)(2), requiring the use of the maximum concentration in groundwater.

Handling of Non-Detects

In cases where measurement data are described as non-detects (NDs), the concentration of the chemical is unknown; although it lies somewhere between zero and the detection limit. Data that includes both detected and non-detected results are called censored data in the statistical literature. There are a variety of ways (e.g., Kaplan Meyer (KM) method, bootstrap methods) to evaluate data that includes values below the detection limit. Some of these parametric and nonparametric methods are available in ProUCL 5.0. ADEC generally recommends the use of the ProUCL 5.0 recommended method of evaluating NDs. However, there are no general procedures that are applicable in all cases and consultation with ADEC is recommended.

Data reduction and field duplicate samples

ADEC regulates based on the maximum result or statistically valid 95% upper confidence limit (UCL) per 18 AAC 75.380(c)(1). Therefore, ADEC requires that the most conservative detectable sample result of the primary and duplicate results be used for management decision-making purposes.

In the event that more than one contaminant result is reported due to multiple analyses by a single method, the highest detected value will be used. If more than one result is reported from alternate analytical method(s) for a single contaminant, the highest detected value **OR** the result from the confirmatory method shall be used. This determination is made on a compound-specific basis. Any method-specific reporting requirements must also be adhered to. If results are reported as ND by multiple analyses or methods, the undetected result with the lowest detection limit (DL) may be selected for reporting.

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 must be discussed in the HHRA work plan and must be approved by ADEC. Models must be chosen on a site-specific basis. All model assumptions/inputs must be provided in the risk assessment work plan and approved by ADEC prior to use of the model. The following criteria must be considered when selecting models

for use in the HHRA:

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

For general guidance on the application of models, consult ADEC's *Fate and Transport Modeling Guidance* (ADEC, 2017).

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

For all exposure routes, there are generally two approaches for deriving toxicity values. One involves the derivation of a chronic reference value (e.g., RfC or RfD_o), while the other involves derivation of a predictive cancer risk estimate (e.g., SF_o or IUR). USEPA uses a weight of evidence approach to classify the likelihood that the agent in question is a human carcinogen. The chronic reference value 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.

Consistent with the USEPA directive (USEPA, 2003c), ADEC relies upon the following hierarchy of sources for toxicity values:

Tier 1: USEPA's Integrated Risk Information System (IRIS).

Tier 2: USEPA's Provisional Peer Reviewed Toxicity Values (PPRTVs).

Tier 3: Other resources as needed and as approved by ADEC on a case-by-case basis. Other resources that may be considered are CalEPA, ATSDR MRLs, or USEPA's HEAST values.

In selecting values using Tier 3 sources, priority shall be given to sources of information that meet the criteria described below. These criteria are consistent with The Environmental Council of the States and EPA white paper on Tier 3 toxicity values. (ECOS, 2007 and USEPA, 2013a).

1. Transparent assessment that clearly provides the information used and how it was used.
2. Externally and independently peer reviewed, where reviewers and affiliations are identified.
3. Established and publicly available methodology with the current best scientific information and practices.

4. Consideration of higher quality studies used.
5. Publicly available or accessible.

Consultation with ADEC is recommended when using toxicity values other than those from IRIS or PPRTVs to ensure appropriate values are used. The USEPA 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) with the coordination of ADEC risk assessment staff. Important chemicals with an insufficient toxicity database may be referred to bodies such as the EPA or the National Toxicology Program for consideration for future testing.

Neither IRIS nor the PPRTV databases contain radionuclide slope factors. USEPA's Office of Radiation and Indoor Air (ORIA) obtains peer review on the radionuclide slope factors contained in the Radionuclide Table of HEAST. In consultation with USEPA, ADEC shall follow this protocol for radionuclides.

3.3.2 Exposure Route Toxicity Values

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 slope factor (SF_o) for carcinogens, and as the oral reference dose (RfD_o) for non-carcinogens. Chronic oral reference doses and ATSDR chronic oral MRLs are expressed in units of (mg/kg-day). Oral slope factors are toxicity values for evaluating the probability of an individual developing cancer from oral exposure to contaminant levels over a lifetime. Oral slope factors are expressed in units of $(mg/kg\text{-}day)^{-1}$. This conversion is shown below:

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

For the inhalation route, a reference concentration (RfC) is an estimate of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. USEPA chronic inhalation reference concentrations are expressed in units of (mg/m^3). The inhalation unit risk factor (IUR) is defined as the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air. Inhalation unit risk toxicity values are expressed in units of $(mg/m^3)^{-1}$. Additional guidance regarding inhalation risk can be consulted from Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment (USEPA, 2009)).

USEPA 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 (USEPA, 2004). This route-to-route extrapolation has a scientific basis; 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:

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

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

3.3.3 Toxicity Equivalence Factors for Dioxins, Furans, and PCBs and Relative Potency Factors for cPAHs

Some chemicals are members of the same family and exhibit similar toxicological properties; however, they differ in the degree of toxicity. Therefore, a toxicity equivalence factor (TEF) must first be applied to adjust the measured concentrations to a toxicity equivalent concentration. ADEC recommends the use of the World Health Organization 2005 values for dioxin-like toxicity equivalency factors for Dioxins, Furans, and PCBs (USEPA, 2010; van den Berg *et al.,* 2006).

EPA's current approach to assessing cancer risk for polycyclic aromatic hydrocarbon (PAH) mixtures uses the relative potency factor (RPF) approach, which estimates the cancer risk of individual PAHs relative to benzo[a]pyrene (BaP). When assessing the risks posed by carcinogenic polycyclic aromatic hydrocarbons (cPAHs), the responsible party shall use the RPFs presented in *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons* (USEPA, 1993a). The RPFs should be applied to either the concentrations of cPAHs found in environmental samples or to adjust the available toxicity values for the cPAHs, but not to both. If the adjusted toxicity values are used, the user will need to sum the risks from all cPAHs as part of the risk assessment to derive a total risk from all cPAHs. A total risk from all cPAHs is what is derived when the RPFs are applied to the environmental concentrations of cPAHs and not to the toxicity values.

3.3.4 Special considerations

Some contaminants such as cadmium and manganese have toxicity values specific to a particular media corresponding to the dosing route used in the toxicity study. Other contaminants such as vanadium and thallium compounds have toxicity values that are based upon ionic forms (vanadium peroxide and thallium sulfate). For other contaminants such as the aminodinitrotoluenes, a surrogate approach is used whereby the oral RfD for 2,4-dinitrotoluene is used as a surrogate for 2-amino-4,6-dinitrotoluene and 4-amino-2,6-dinitrotoluene. In all such cases, these special considerations must be clearly noted in the risk assessment.

3.3.4.1 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) must 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 must 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 must be used in this instance.

Resources to Assess Exposure to Lead

- ❒ *Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children* (USEPA, 1994a) and IEUBK model (USEPA, 2009a)
- ❒ *Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil* (USEPA, 2003d) and ALM Spreadsheet (USEPA, 2003a)

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.

USEPA has 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 with the IEUBK model. Accordingly, USEPA 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 could be used to assess exposure to lead in a residential setting and to develop alternative cleanup levels. However, it must be noted that ADEC will **not** approve an alternative residential lead cleanup level greater than the default residential cleanup level of 400 mg/kg in soil.

The ALM must 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.

The default bioavailability parameter incorporated in the IEUBK Model for Children and the default bioavailability parameter incorporated in the *Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in*

Soil (USEPA, 2003d), or the most current version must be used. If alternate bioavailability values are proposed (based either on *in vivo* studies, blood lead studies, or other studies) for use in the IEUBK model or the Adult model, the proposed values must be submitted to ADEC and the Technical Review Workgroup (TRW) for Lead for review. The proposed values must be compared to current guidance regarding use of the IEUBK, blood lead studies, and other studies.

Note that neither the ALM nor the IEUBK are recommended for acute exposure scenarios (i.e., less than 1 day per week for 90 days in duration). Consideration of the use of alternative models must be done in consultation with ADEC risk assessment staff.

Note that given that lead risks are calculated separately from other contaminants, the cumulative risk estimate calculated for a site with lead and other contaminants (including naturally occurring background compounds) may underestimate actual risks. This important issue must be acknowledged and included as a source of uncertainty. Critical effects for each contaminant and any potential additive, synergistic, or antagonistic effects must be carefully considered. Several studies have shown that the effects of other metals with lead are greater than additive (i.e., arsenic-lead and cadmium-lead). Although no specific data exist to quantify the joint risks of the mixtures, endpoints of potential concern for the mixtures include critical effects of the individual metals as well as the common targets of toxicity that might become significant due to additivity (considering secondary effects) or certain interactions.

3.3.4.2 Risk from Bulk Hydrocarbons

Cumulative risks from summation of petroleum fractions must be calculated and presented in the HHRA; however, they are not included in the cumulative risk calculation with other chemicals in the tables. Individual risks from each petroleum fuel fraction (i.e., total GRO, DRO, and RRO) must be calculated and presented in the HHRA as follows:

GRO aliphatic risk + GRO aromatic risk = total GRO risk
DRO aliphatic risk + DRO aromatic risk = total DRO risk
RRO aliphatic risk + RRO aromatic risk = total RRO risk

Each petroleum fraction is a mixture of many different chemicals. As stated in ADEC's *Procedures for Calculating Cumulative Risk* (ADEC, 2018b), the Total Petroleum Hydrocarbon Criteria Working Group identified indicator contaminants within petroleum that can be evaluated individually. Toxicological information is available for each indicator compound and must be used to calculate risks due to petroleum. Differences in calculated risk from bulk hydrocarbons versus petroleum constituents must be discussed in the uncertainty section.

3.3.5 Types of Exposures: Chronic, Subchronic, and Acute

An HHRA must consider carcinogenic and non-carcinogenic effects of chronic and subchronic exposure for appropriate scenarios. Chronic exposures are repeated exposure by the oral, dermal, or inhalation route for more than approximately 10% of the life span in humans. For a residential scenario, a 6-year old child with chronic toxicity values should be assessed separately due to the inherent difference in exposure from that of an adult. Subchronic exposures are repeated exposure by the oral, dermal, or inhalation route for

more than 30 days up to approximately 10% of the life span in humans. For subchronic effects, USEPA-developed subchronic toxicity values must be used, if available. Subchronic toxicity values may not be derived from chronic toxicity values using additional uncertainty factors based on the study used to develop the chronic toxicity value. Use of subchronic toxicity values must be approved by the ADEC risk assessor prior to use in the risk assessment.

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

3.3.6 Toxicity Profiles

The final HHRA must 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 must 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 must include the following elements in the final discussion:

- Confidence that key site-related contaminants have been identified and their nature and extent fully characterized.
- 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 and noncancer risks relative to the site-remediation goals.
- Major factors driving the risks including contaminants, pathways, and scenarios.

The risk characterization must be conducted in a manner that is consistent with the principles of transparency, clarity, consistency, and reasonableness (TCCR) outlined in USEPA's Risk Characterization Policy (EPA, 2000g).

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. Carcinogenic risk is defined as the incremental risk of cancer due to exposure from site-related contaminants, averaged over a lifetime and calculated by multiplying intake of contaminants by the cancer slope factor. This will represent risk-per-unit dose.

$$Carcinogenic\ Risk_{(oral)} = Intake \times Slope\ Factor$$

$$Carcinogenic\ Risk_{(inhalation)} = Exposure\ Concentration\ X\ Inhalation\ Unit\ Risk$$

Incremental cancer risks must be estimated separately for each exposure scenario and for each subpopulation. The individual chemical cancer risk is rounded and presented to two significant figures and the incremental lifetime cancer risk is presented using one significant figure. USEPA's *Guidelines for Carcinogen Risk Assessment* (or *Cancer Guidelines*) (2005a) emphasizes using mode of action (MOA) information in interpreting and quantifying the potential cancer risk to humans. USEPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (or *Supplemental Guidance*) (2005c) also relies on assessing the MOA. In particular, the *Supplemental Guidance* advises that age-dependent adjustment factors (ADAFs) be used with the cancer slope factors and age-specific estimates of exposure in the development of risk estimates, if the weight of evidence (WOE) supports a mutagenic MOA for carcinogenicity. This default approach is used only when appropriate chemical-specific data are not available on susceptibility from early-life exposures. 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. Understanding of mode of action can be a key to identifying processes that may cause chemical exposures to differentially affect a particular population segment or lifestage. Some modes of action are anticipated to be mutagenic and are assessed with a linear approach.

Evaluating Risks from Childhood Exposures

The National Research Council (NRC) recommended that USEPA must assess risks to infants and children whenever it appears that their risks might be greater than those of adults (NRC, 1994). Executive Order 13045 (1997) requires that each Federal Agency shall make it a high priority to identify and assess environmental health and safety risks that may disproportionately affect children, and shall ensure that their policies, programs, and standards address disproportionate risks that result from environmental health risks or safety risks. In assessing risks to children, USEPA considers both effects manifest during childhood and early-life exposures that can contribute to effects at any time later in life. These cancer guidelines view childhood as a sequence of lifestages rather than viewing children as a subpopulation; the distinction being that a subpopulation refers to a portion of the population, whereas a lifestage is inclusive of the entire population. Exposures that are of concern extend from conception through adolescence and also include pre-conception exposures of both parents. The USEPA's *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a) uses the term childhood in this more inclusive sense. At this time, there is some evidence of higher cancer risks following early- life exposure. To evaluate risks from early-life exposure, these cancer guidelines emphasize the role of toxicokinetic information to estimate levels of the active agent in children and toxicodynamic information to identify whether any key events of the mode of action are of increased concern early in life. In the dose-response assessment, the potential for

susceptibility during childhood warrants explicit consideration in each assessment. The USEPA's cancer guidelines encourage developing separate risk estimates for children according to a tiered approach that considers what pertinent data are available. Childhood may be a susceptible period; moreover, exposures during childhood generally are not equivalent to exposures at other times and may be treated differently from exposures occurring later in life. In addition, adjustment of unit risk estimates may be warranted when used to estimate risks from childhood exposure. USEPA developed, in conjunction with the 2005 cancer guidelines, the *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (or *Supplemental Guidance*) (2005c). The *Supplemental Guidance* addresses a number of issues pertaining to cancer risks associated with early-life exposures generally, but provides specific guidance on procedures for adjusting cancer potency estimates only for carcinogens acting through a mutagenic mode of action. The *Supplemental Guidance* recommends, for such chemicals when no chemical-specific data exist, a default approach using estimates from chronic studies (i.e., cancer slope factors) with appropriate modifications to address the potential for differential risk of early-lifestage exposure.

3.4.2 Noncarcinogenic Risk

For non-carcinogens, the HQ is calculated as the intake or exposure concentration of the compound divided by the reference value. Hazard indices (HIs), the sum of multiple HQs, must be calculated separately for each scenario and for each exposed population. The HQ must be presented using two significant figures.

$$Hazard\ Quotient_{(oral)} = \frac{Intake}{RfD}$$

$$Hazard\ Quotient_{(inhalation)} = \frac{Exposure\ Concentration}{RfC}$$

Non-carcinogenic compounds affect different target organs or systems by different mechanisms of toxicity. To accurately assess the cumulative risk of possible effects for non-carcinogenic compounds, the HI can be further segregated by target organ or system endpoint and mechanism of toxicity consistent with USEPA's *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A) – Interim Final* (USEPA, 1989a), *Guidelines for the Health Risk Assessment of Chemical Mixtures* (USEPA, 1986), and *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000f). Since the mechanism of toxicity is not well understood for many compounds, the department will evaluate segregation of the HI by target organ or system endpoint." The HI must be presented using one significant figure.

3.4.3 Cumulative Risk

Initially, risks and HQs are calculated for individual COPCs; however, at most sites, there are multiple COPCs. To assess the overall potential for cancer and non-cancer effects posed by exposure to multiple chemicals, risk from multiple COPCs and multiple exposure pathways must

be summed. The process for calculating cumulative risk is provided in ADEC's *Procedures for Calculating Cumulative Risk* (ADEC, 2018b), adopted by reference in 18 AAC 75.325(g) and should incorporate the most updated toxicity values from the hierarchy discussed in section 3.3.1 at the time of the risk assessment. Contaminants are generally divided into two basic groups; those that have a carcinogenic effect and those that have a non-carcinogenic effect. Cumulative carcinogenic risk and non-carcinogenic hazard index are calculated separately. However, some compounds can cause both effects and therefore must be included in both cumulative risk calculations.

3.4.4 Development of Alternative Cleanup Levels

An HHRA and Ecological Risk Assessment (ERA) provide details about what COPCs in each media contribute to risk. Ultimately the goal of many HHRAs and ERAs 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 the reasonable maximum exposure expected to occur under current and future site conditions, including land use. ACLs can be calculated by setting the total carcinogenic risk or HI at the standard approved by ADEC and solving for the concentration term for each chemical in a particular medium. ADEC 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 of 1.

The ACL should also be protective of the potential for the COPC to migrate to other media and cause risk to exceed the required standard. Although risks from groundwater ingestion must be considered for the commercial/industrial (or other) exposure scenarios, it is not appropriate to calculate alternative cleanup levels for groundwater based upon such scenarios. Groundwater cleanup levels are to be considered ARARs as determined under 18 AAC 75.345. Even if a site is located in an industrial area, the groundwater underlying a site in an industrial area may be used as a drinking water source for residents several miles away due to complex geological interconnections. As noted in **RAGS B Exhibit 2-1** footnote **d** in regard to drinking water at commercial/industrial sites: "*Because the NCP encourages protection of ground water to maximize its beneficial use, risk-based PRGs generally must be based on residential exposures once groundwater is determined to be suitable for drinking water. Similarly, when surface water will be used for drinking water, general standards (e.g., ARARs) are to be achieved that define levels protective for the population at large, not simply worker populations. Residential exposure scenarios must guide risk-based PRG development for ingestion and other uses of potable water.*"

Please also note that ADEC *18 AAC 70 Water Quality Standards* are to be considered ARARs for surface water (and groundwater in connection with surface water per 18 AAC 75.345 (g) regardless of risk calculated for this media.

3.4.5 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 ADEC.

Sources of uncertainty include natural variability, measurement error, sampling error, human error, extrapolation mandated by an incomplete knowledge base and/or 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 must be presented in the uncertainty section. All uncertainty factors must be identified and discussed quantitatively and or qualitatively with respect to their overall impact on the HHRA. Specific uncertainty factors to be considered in an HHRA are included below (see EPA 1989a, Sections 6.8, 7.6, and 8.4 for details).

3.4.6 Uncertainty in Data Evaluation

Several topics associated with data used in the selection of compounds of concern need to be discussed in the uncertainty section of the HHRA. These include the data collection, data evaluation, and data reduction techniques. Furthermore, any other factors that are associated with the data and which can influence selection of compounds of concerns for the HHRA must be also be discussed. These include data gaps, detection limits, and other relevant issues.

3.4.7 Uncertainty in the Exposure Assessment

Multiple assumptions in the exposure assessment can significantly impact the HHRA results and introduce bias. Consider the level of uncertainty when using default and site-specific exposure factors to calculate RMEs for receptors and exposure pathways that are both currently occurring and that could reasonably occur in the future. In addition, there is a level of uncertainty with estimating the exposure point concentration from measurements (rather than if it is a calculated UCL or maximum detection) or from results of modeling.

3.4.8 Uncertainty in the Toxicity Assessment

The weight of evidence and the confidence in the database supporting non-carcinogenic effects must be identified and included. It is also important to identify uncertainty as a result of 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 must also be evaluated. Page 8-24 of the USEPA guidance (USEPA, 1989a) provides a checklist of the uncertainties that apply to most toxicity assessments.

4.0 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: *Guidelines for Ecological Risk Assessment* (USEPA, 1998); *EPA Region 10 Supplemental Ecological Risk Assessment Guidance for Superfund* (USEPA, 1997b). ADEC resources include: *Ecoscoping Guidance* (ADEC, 2014); *User's Guide for Selection and Application of Default Assessment Endpoints and Indicator Species in Alaskan Ecoregions* (ADEC, 1999a); *Technical Background Document for Selection and Application of Default Assessment Endpoints and Indicator Species in Alaskan Ecoregions with figures and tables updated in September of 2008* (ADEC, 1999b).

4.1 ERA Process in Alaska

ADEC's *Ecoscoping Guidance* (ADEC, 2014) helps delineate 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 must 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 must continue.
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 must be qualitatively described (USEPA, 1998).

The four main steps in ADEC's ERA process are described below. The overall process is summarized in the flowchart shown as Figure 2 (see Appendix B). As shown in Figure 2, ADEC requests that a scoping 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 – Step 1

ADEC has developed a scoping document (ADEC, 2014) designed to quickly eliminate sites that are unlikely to pose a risk to the environment. Such sites exit the ERA process without further evaluation. The scoping evaluation cannot 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 are also necessary.

4.1.2 Preliminary Screening Evaluation – Step 2

If ecological receptors are likely to be exposed to site-related contaminants, chemical concentrations in environmental media that are identified during the scoping evaluation are then compared to conservative screening benchmarks as part of the preliminary screening evaluation within the scoping document. Acceptable conservative screening values are provided in the Risk Assessment Information System (available at: http://rais.ornl.gov/). These values generally represent the lowest benchmark available for a given media. If site concentrations in media exceed these conservative benchmarks, but benchmarks exist that may be more appropriate to the receptors at the site, a screening level risk assessment may be performed. In this instance, further detail on the site and rationale for selection of specific benchmarks must be provided. The screening level risk assessment is described in the next section.

The scoping results must be submitted to ADEC for review in additional to preliminary screening when likely exposure to site-related contamination is determined. After reviewing the results, ADEC will determine whether further ERA work is warranted, or whether ecological risks are negligible and the site can exit the ERA process.

4.1.3 Screening-Level ERA – Step 3

Step 3 in the Alaska ERA process is analogous to the screening-level ERA in federal guidance (USEPA, 1997a). 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 (see Appendix B). An uncertainty evaluation also must be included in the screening-level ERA. Subsections 4.2 to 4.5 provide recommendations for implementing these activities. It must 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. ADEC review and approval of the screening-level ERA is required (see Figure 2).

4.1.4 Baseline ERA – Step 4

A baseline ERA is required when sites are complex or when scoping and screening has indicated a potential ecological risk. ADEC requires that an ERA work plan (WP) and a sampling and analysis plan (SAP) be developed prior to development of the baseline ERA. The ERA work plan must 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. The methodology recommended for use in developing the BERA is described in the *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments – Interim Final* (USEPA, 1997a). Additional guidance for ecological risk assessment can be found in the following USEPA publications*: Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual* (USEPA, 1989b), and the *Guidelines for Ecological Risk Assessment* (USEPA, 1998). Subsection 2.2 provides additional recommendations for the ERA work plan. When developing the ecological investigation, WP and SAP content should be similar to that described by USEPA (1988a and 1989b). After ADEC approval of the work plan, the baseline ERA must be completed and submitted to ADEC 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 ADEC'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 SLERA 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 (USEPA, 1998).

4.2.1 Components of Problem Formulation

The fundamental components necessary for problem formulation are:

- Environmental setting and site history.
- Documentation of site visits.
- Contaminants known or suspected to be at the site.
- Information about which receptors are most likely to be present at this site. *The Technical Background Document for Selection and Application of Default Assessment Endpoints and Indicator Species in Alaskan Ecoregions with figures and tables updated in September of 2008* (ADEC, 1999b) 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.
- 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.
3. **Measures (previously called *measurement endpoints*)** – are used to evaluate potential effects on the assessment endpoints.

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

4.2.2 Ecological Conceptual Site Models

To develop a CSM for the ecosystem, there must be at least rudimentary knowledge of the environmental setting, the presence of potentially hazardous substances, and physical and biological stressors at the site. For guidance on developing ecological CSMs, see ADEC's *Policy Guidance on Developing Conceptual Site Models* (ADEC, 2017).

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 must 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 must not be management goals or values and they must 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 (USEPA, 1998). 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 Alaskan Ecoregions* (ADEC, 1999). Additional information on establishing assessment endpoints can be found in *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment* (USEPA, 2003b).

ADEC requires that threatened and endangered species be identified in the ecological risk assessment. Where applicable, threatened and endangered species shall be used as assessment endpoints in accordance with state and federal laws. An indicator species from the same trophic level must 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(35). Examples of state and federal sensitive environments are provided in Table 2.

Table 2 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		Critical areas identified under the clean lakes program

State		Federal
animals		
		National monuments
		National seashore recreation areas
		National Lakeshore recreational areas
		National preserves
		National wildlife refuges
		Units of coastal barrier resources systems
		Coastal barriers
		Federal land designated for the protection of natural ecosystems
		Administratively proposed federal wilderness areas
		National river reaches designated as recreational
		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 a measure of dose from co-occurrence of or contact between a stressor and an ecological component. Examples include (1) the amount of a chemical ingested, (2) the amount of a chemical absorbed, and (3) the product of ambient exposure concentration and the duration of exposure.

Measures of effects are measurable changes in an attribute of an assessment endpoint associated with exposure to a stressor (USEPA, 1998). 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 are measures that influence either the behavior and location of entities selected as the assessment endpoint or the distribution of a stressor and life-history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor (USEPA, 1998). 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 carnivorous 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 USEPA's *Guidelines for Ecological Risk Assessment* (USEPA, 1998) and EPA *Region 10 Supplemental Ecological Risk Assessment Guidance for Superfund* (USEPA, 1997b) to assist in establishing measures. If additional data are needed, sampling plans must 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

One method for evaluating ecological risks from environmental contaminants is to predict the potential for adverse effects by comparing estimated levels of exposure of various environmental receptors to appropriate Toxicity Reference Values (TRVs). This section covers the process and alternative approaches.

4.3.1.1 Selection of Indicator Species and Communities

Indicator species and communities must 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 the 2008 tables and figures referenced in ADEC, 1999b for recommendations on selecting indicator species and communities for Alaskan ecoregions.

4.3.1.2 Selection of Compounds of Potential Ecological Concern

Soil screening benchmarks are available from Oak Ridge National Labs (Efroymson *et al.,* 1997a and 1997b), USEPA (2013a), and published sources such as Alloway (1990). Sediment screening benchmarks are available from NOAA (Buchman, 2008), Oak Ridge National Labs (Jones *et al.,* 1997), and ADEC (2013). Surface water screening benchmarks are available from NOAA (Buchman, 2008), 18 AAC 70, Oak Ridge National Labs (Suter & 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 maximum chemical concentrations in environmental media must be compared with these benchmarks to identify compounds of potential ecological concern (COPECs). As outlined in USEPA's *Framework for Metals Risk Assessment* (2007b), special attention must be paid to metal specific principles such as the influence of environmental chemistry on metal speciation, bioavailability, background levels of metals in the environment, and the ubiquitous presence of metal mixtures (USEPA, 2004b).

For wildlife, screening-level HQs must be calculated as described in USEPA (1997a) using exposure parameters from USEPA (1993b), Sample and Suter (1994), and other reputable sources. Subsection 4.2.1.3.1 provides additional guidance on selecting exposure parameters. ADEC 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.

Bioaccumulative 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 or log K_{ow} greater than 3.5 and inorganics identified by USEPA (2000a). A list of bioaccumulative compounds commonly found at contaminated sites in Alaska is provided in Table A-1, in Appendix A of *Policy Guidance on Developing Conceptual Site Models* (ADEC, 2017).

After ecological screening benchmarks and TRVs are selected, the screening for COPECs 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.
2. For wildlife receptors, use the maximum concentration to calculate a screening- level HQ.
3. 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.
4. Retain compounds that have a potential to bioaccumulate or bioconcentrate.
5. Identify all compounds not eliminated as COPECs and carry these through the remainder of the risk assessment process.
6. All compounds without risk-based benchmarks must 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 COPECs 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 must 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 ADEC 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.
5. Ingestion rate = maximum ingestion rate.

Alteration of default exposure assumptions may be appropriate in a baseline risk assessment with ADEC approval. Species-specific exposure parameters can be obtained from the *Wildlife Exposure Factors Handbook* (USEPA, 1993b). Other sources of species-specific wildlife exposure

parameters include Sample *et al.* (1996 and 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 (1998b) and Baes III *et al.* (1984) for plants, in Bechtel Jacobs (1998a) for benthic invertebrates, in Sample *et al.* (1998b) for earthworms, and in Sample *et al.* (1998a) 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 must 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 must 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 must 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 must be conducted as described in Sample and Arenal (1999).

4.3.1.4.1 Ecological Uncertainty Factors

For compounds with TRVs, ADEC will accept the uncertainty factors (UFs) listed in Table 3 for appropriate extrapolation to indicator species. 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 3 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

Species-Specific Data		Non-species specific data		
Toxicological data	**UF**	**Effect**	**Difference**	**UF**
Chronic Lowest Observed Effect Level (LOEL)	5	Biochemical Effects	Toxic intermediate data	4
Subchronic NOEL	5	Phylogenic 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 & 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 must 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 must 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, USEPA. However, ADEC risk assessment staff must be consulted before contacting USEPA 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 (USEPA, 1997a). 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.
- 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. USEPA (1999) describes field assessment methods for fish, benthic invertebrates, and periphyton in wadeable streams and rivers. USEPA (1991a) 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 (USEPA, 2002e), freshwater benthic invertebrates (USEPA, 2000e), marine and estuarine fish and plankton (USEPA, 2002f), and marine and estuarine benthic invertebrates (USEPA, 2001a). 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 (USEPA, 1997a). Standardized tests also are available for terrestrial plants and soil invertebrates (USEPA, 1988b). For additional information on using toxicity tests in risk assessments, please see USEPA (1994a, 1994b, and 1997a).

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 may consider such studies for estimating site-specific BAFs, they are not required or even recommended. The biota samples taken must 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 must be taken with biota samples. Organisms that are sessile or have limited mobility (i.e., plants, mussels, fish fry, and small mammals) 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 must be recorded. Methods for assessing bioaccumulation in aquatic environments can be found in USEPA (2000b and 2000e). 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 must 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; all of the above guidelines have application to such studies, even though the endpoint is different. The most critical issue is that the biota samples taken represent what predators are eating. It is also worth noting that for an ecological risk assessment, whole body contaminant load may be the appropriate determination, whereas for subsistence foods, it is often more appropriate to analyze the tissues and/or organs that are frequently consumed.

4.4 Risk Characterization

Risk characterization must 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 must 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 must 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 must 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 must be described. The discussion must 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 (USEPA, 1997a). 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 must be evaluated in the risk assessment are listed below:

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

ADEC may require calculation of ecological risk-based cleanup levels based off of the SLERA or to proceed directly to a BERA.

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 must be retained for further ecological evaluation and possible development of site-specific, risk-based, ecological cleanup levels. Quotient calculations are presented below:

$$HQ = \frac{Dose}{TRV} \qquad \text{OR} \qquad HQ = \frac{MEC}{Benchmark}$$

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 ADEC as a level at which a potential adverse ecological effect may occur in the SLERA. These contaminants must be retained for further evaluation in a BERA or development of site-specific, risk-based, ecological cleanup levels to meet regulatory requirements.

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 must be calculated, and all HQs contributing to the HI must 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 must 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 must be retained for further evaluation in the risk assessment during the SLERA.

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 must be statistically compared to these endpoints in the laboratory control and site-specific background samples to quantify adverse effects. The results must be summarized in the ERA report, and the complete laboratory bioassay report must be attached as an appendix. Whether the test results agree with risk predictions based on benchmark comparisons must 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 must 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. USEPA (1997a and 1998 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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6.0 GLOSSARY

The glossary for the ADEC 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 USEPA'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. Repeated exposure by the oral, dermal, or inhalation route for more than approximately 10% of the life span in humans. 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: The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism.

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 zone of saturation, also known as the zone below the water table, where permanently or seasonally all interstices are filled with water, 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.

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 non-carcinogenic 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.

LC_{50}: 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.

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

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, K_{ow} is a key variable used in the estimation of other properties.

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

onsite: The same or geographically contiguous property that may be divided by public or private right-of-way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right-of-way. 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 ADEC 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 contaminant 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: One of several, generally 10-fold default factors used in operationally deriving the RfD or RfC from experimental data. The factors are intended to account for (1) variation in susceptibility among the members of the human population; (2) uncertainty in extrapolating animal data to humans; (3) uncertainty in extrapolating from data obtained in a study with less than lifetime exposure; (4) uncertainty in extrapolating from a LOAEL rather than from NOAEL; and (5) uncertainty associated with extrapolation when a database is incomplete.

APPENDIX A -- SCOPING CHECKLISTS AND EXAMPLE TABLE

SCOPING MEETING CHECKLIST/SAMPLE AGENDA

✓ **Discussion Points**

❒ **GENERAL SITE INFORMATION**
- History of use
- Current and potential future 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 ADEC GUIDANCE OR USEPA PROTOCOL**

❒ **LINES OF COMMUNICATION**
- ADEC/RP roles and responsibilities
- Role of other programs/departments/agencies
- RP and ADEC team members and contact information

❒ **PUBLIC INVOLVEMENT**
- Meetings needed and schedule
- Public notices

❒ **SCHEDULE**
- Document deliverable schedule
- ADEC review
- Interim reports expected
- Fieldwork (if needed)
- Public review (if needed)

ADEC RISK ASSESSMENT CHECKLIST

✓	TASK*	DATE
	RISK ASSESSMENT SCOPING MEETING See Scoping Meeting Checklist (ADEC Project Manager; ADEC Risk Assessment Staff; Responsible Party (RP); RP consultants and other stakeholders)	_____
	SUBMIT CONCEPTUAL SITE MODELS (CSMs) identifying all potential pathways to ADEC project manager	_____
	ADEC APPROVES CONCEPTUAL SITE MODELS	_____
	SUBMIT RISK ASSESSMENT WORK PLAN including CSMs identifying all completed pathways and all items listed in subsection 2.2	_____
	ADEC REVIEWS RISK ASSESSMENT WORK PLAN comments provided to RP	_____
	SUBMIT RESPONSE TO ADEC WORK PLAN COMMENTS to ADEC project manager	_____
	COMMENT RESOLUTION MEETING for the risk assessment work plan	_____
	SUBMIT HUMAN HEALTH & ECOLOGICAL RISK ASSESSMENT to ADEC project manager	_____
	ADEC REVIEWS RISK ASSESSMENT comments provided to RP	_____
	SUBMIT RESPONSE TO ADEC RISK ASSESSMENT COMMENTS to ADEC project manager	_____
	COMMENT RESOLUTION MEETING for the risk assessment	_____
	ADEC APPROVES THE RISK ASSESSMENT	_____
	ADEC 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

Rationale Codes:

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

Deletion Reasons - Below Screening Level (BSL)

APPENDIX B -- FIGURES

FIGURE 1
HUMAN HEALTH RISK ASSESSMENT PROCESS

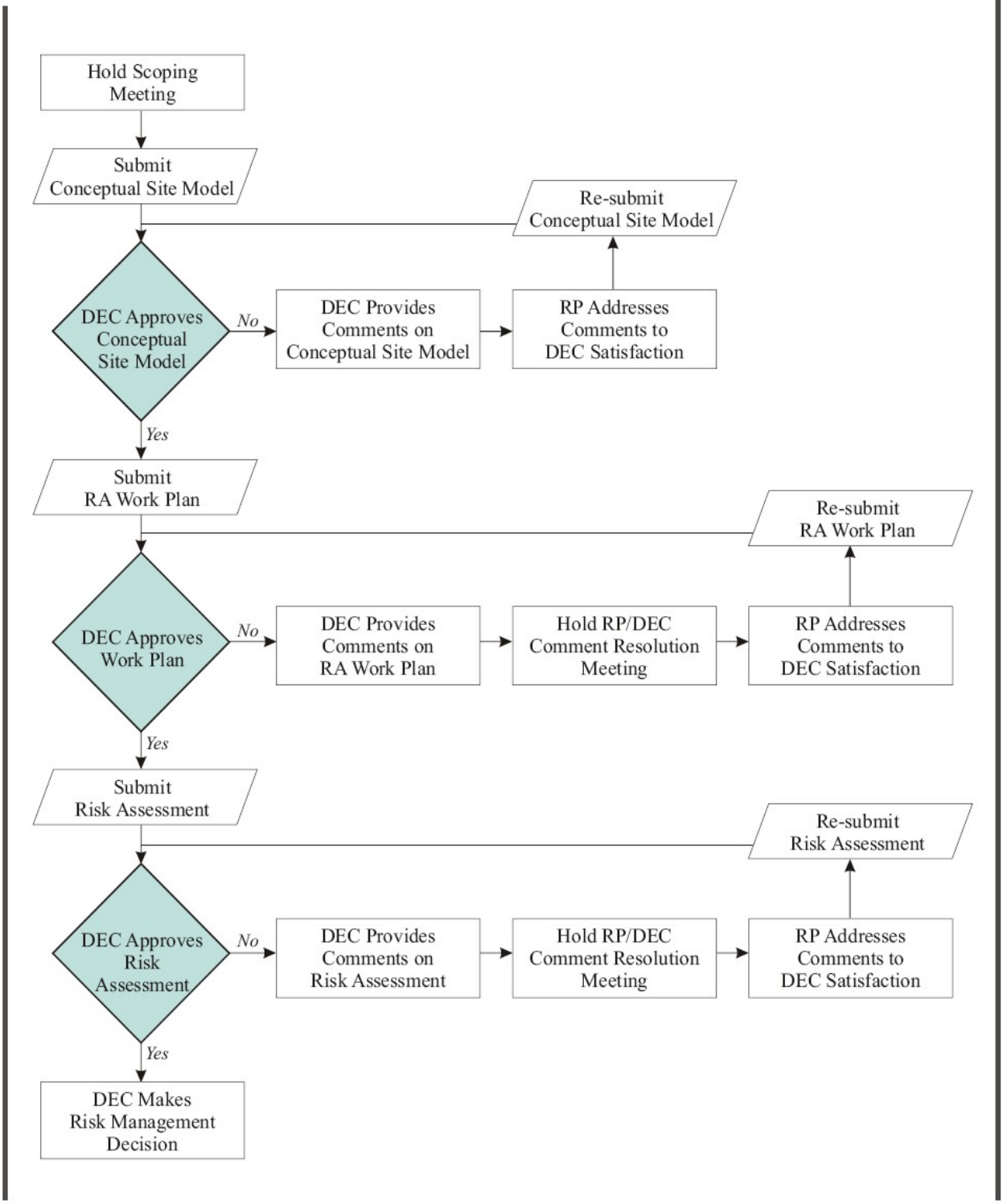


FIGURE 2

ECOLOGICAL RISK ASSESSMENT PROCESS IN ALASKA*

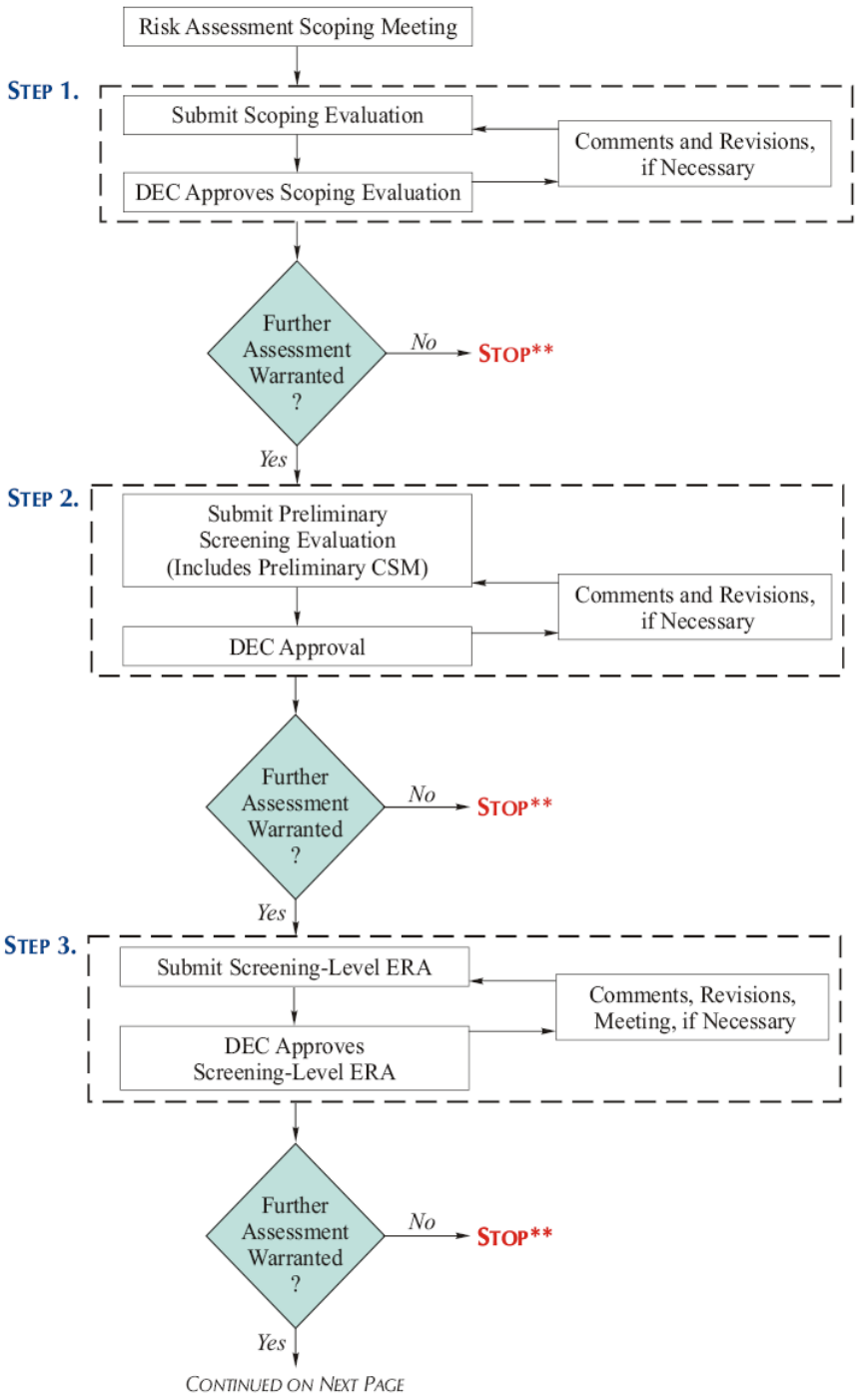
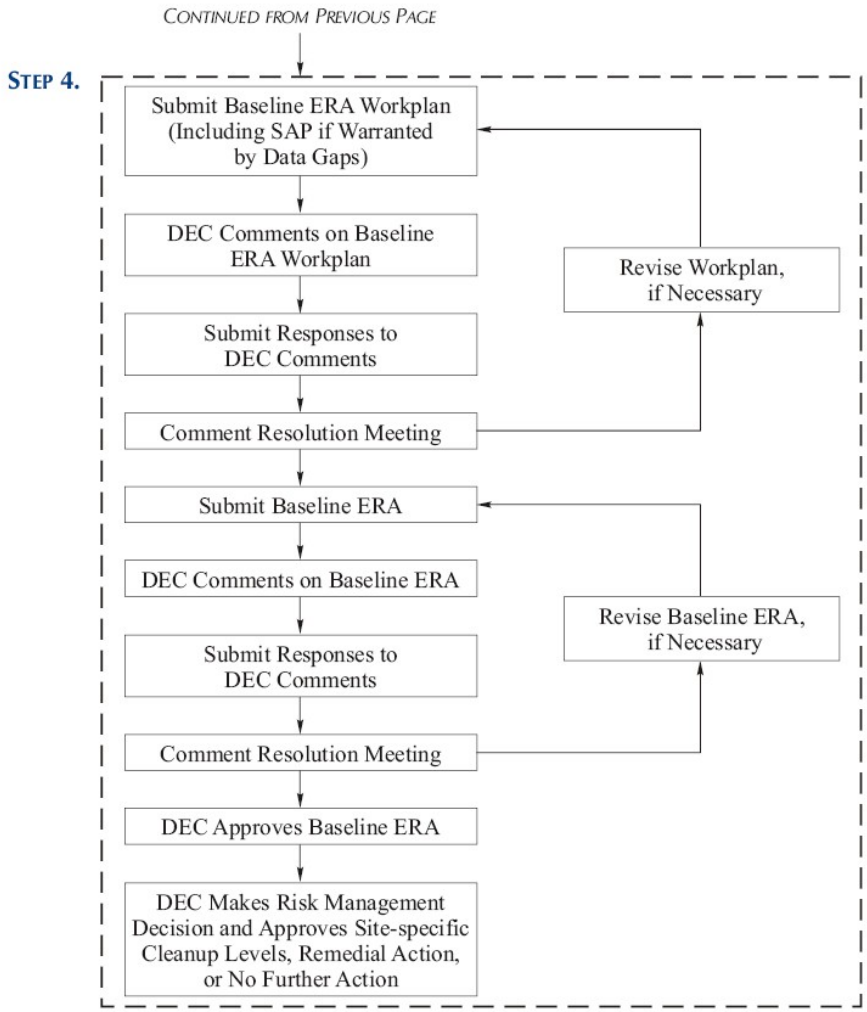


FIGURE 2
ECOLOGICAL RISK ASSESSMENT PROCESS IN ALASKA* (CONT.)



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.

FIGURE 3

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT (EPA 1998b)