Kentucky Risk Assessment Guidance

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Natural Resources and
Environmental Protection Cabinet

Section 1. Introduction

Risk assessment is a formalized process for evaluating the potential human health and ecological impacts based on the concentration of, exposure to, and toxicity of environmental contaminants. Risk assessment has been used in environmental decision-making since the process was outlined in a publication by the National Research Council – National Academy of Sciences (1983) Red Book. The United States Environmental Protection Agency (U.S. EPA) produced several guidance documents to assist in assessing risks (U.S. EPA, 1989; 1991).

Human health risk assessment, as outlined, is a four-part process. The first step, Data Collection and Evaluation, assesses the available data and identifies chemicals of potential concern (COPCs). The next part, Exposure Assessment, identifies potential receptors and calculates their exposure to the COPCs. Toxicity Assessment, the third process, quantifies the toxicity of the COPCs for carcinogenic and noncarcinogenic effects. The final step, Risk Characterization, is the calculation of the potential effects on the receptors identified in the Exposure Assessment, based on the toxicity of the chemicals identified in the Data Collection and Evaluation step.

Risk assessment procedures are used in several stages of site assessment and closure. During site scoping Preliminary Remediation Goals may be used to determine preferred detection limits and to screen initial data to focus on areas of concern. Data from Site Characterization are often screened against target risk-based concentrations (Preliminary Remediation Goals) to identify whether a baseline risk assessment or further evaluation is needed and, if so, which chemicals should be further assessed. Risk assessment is also used in setting remedial goals, and as an exit criterion for closure of remediation activities. Risk assessment is used as part of activities related to the Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Clean Water Act, and Clean Air Act.

This document details the application of risk assessment to environmental remediation. The document can be used to determine if site conditions are protective of human health and the environment, or that risks are reduced to acceptable levels through removal of contaminants or management. The risk-based procedures for the program are based on a tiered approach allowing for screening against default risk-based screening values in lower tiers and incorporating more site-related data in the higher tiers.

This document outlines the procedures for:

1. Comparing site data against risk-based screening values.
2. Preparing a baseline risk assessment to determine protectiveness of human health and the environment.
3. Evaluating when an ecological assessment is necessary
4. Evaluating when to compare site soil data to Soil Screening Levels for protection of groundwater.
5. Selecting remedial cleanup goals.

The following sections describe the process of evaluating the site data that were collected during the site characterization. The data must be representative and complete. If statistical procedures are used, a sufficient number of samples should be collected to meet the needs of those statistical tests. Human health risk assessment is described in Section 2.0. The subsections within Section 2.0 describe the application of risk assessment to the processes of environmental assessment and remediation including: tiered risk assessment, groundwater evaluation, risk management, selection of remedial goals, and presenting the results of the two tiers of risk assessment. Section 3.0 details the ecological risk assessment procedures.

Section 2. Human Health Risk Assessment

This section provides methods for screening environmental data to identify Contaminants of Concern, performing screening and baseline risk assessment, evaluating groundwater, managing risks, and selecting remedial goals. Figures 1 and 2 outline the process for risk-based procedures for residential and commercial/industrial scenarios in environmental remediation. The remedial options listed in Figures 1 and 2 are those listed in KRS 224.01-400 (18)-(21).

Figure 1. Flowchart for Residential Cleanup Options

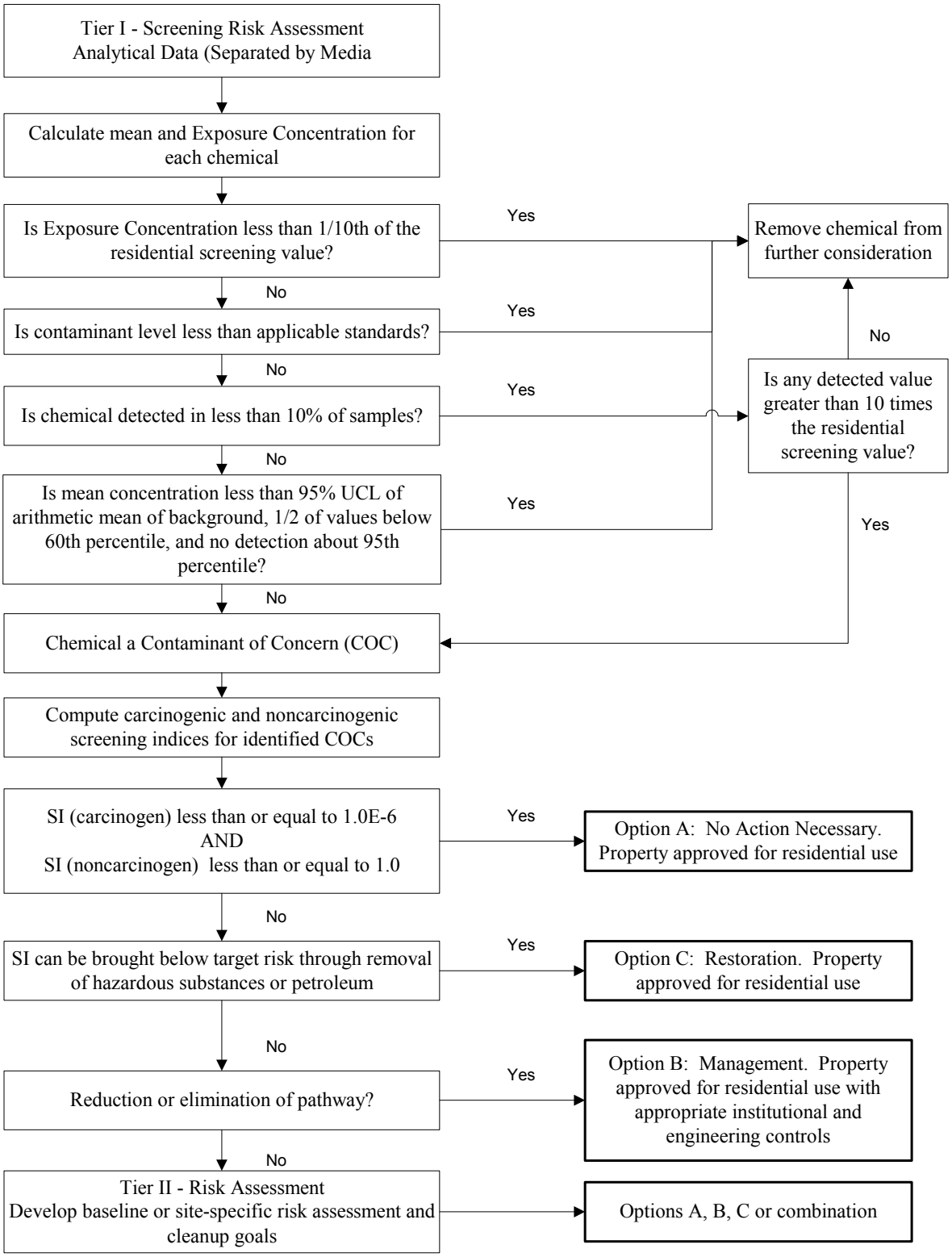
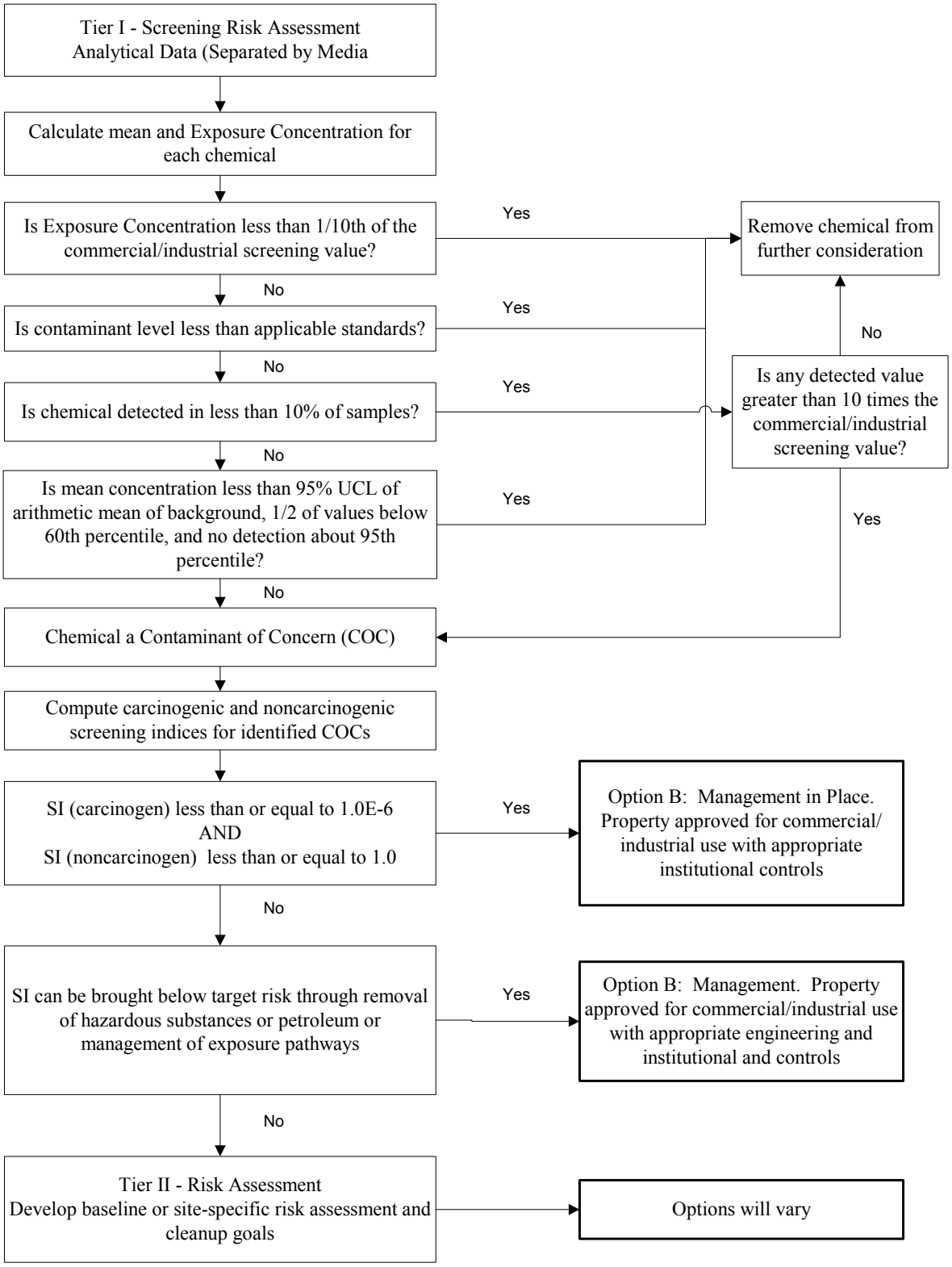


Figure 2. Flowchart for Commerical/Industrial Cleanup Options



Section 2.1. Tier I. Human Health Risk-Based Screening

This initial tier identifies which contaminants contribute significantly to the risks associated with the property and calculates the cumulative risk for all Contaminants of Concern (COCs). For this guidance, hazardous substance or petroleum shall have the meaning as defined in KRS 224.01-512. The screening-level risk assessment should be completed for residential land use as a baseline, and commercial or industrial land use if commercial or industrial use is part of the management plan. The following steps should be followed when completing a screening-level risk assessment for human health.

1. Segregate analytical data by medium. Further segregate soil data into surface (0-1 foot depth) and subsurface (greater than one foot depth).

2. Calculate 95% Upper Confidence Limit (UCL) of the arithmetic mean as described in U.S. EPA, 1992 (Supplemental Guidance to RAGS: Calculating the Concentration Term). Use all samples of the property and site(s). Use one-half of the detection limit for non-detect sample results. The Exposure Concentration shall be the lower of the 95% UCL of the arithmetic mean and the maximum detected value for that medium (and horizon, for soil). Calculate the mean of the site data for inorganic compounds in addition to the 95% UCL.

3. Compare the Exposure Concentration to $1/10^{th}$ of the residential or commercial/industrial screening value, as appropriate. When screening, use the Total Chromium value for chromium, use carcinogenic effects for arsenic, and use Toxicity Equivalency Factors (TEFs) to calculate a Toxicity Equivalency Quotient (TEQ) for dioxins. Instead of $1/10^{th}$ of the screening value for lead, use the Kentucky Lead Action Level of 50 mg/kg for soils for residential, and 400 mg/kg for commercial/industrial soils. Appendix E contains the KY Radiological Risk-Based Preliminary Remediation Goals, if applicable. Compare the Exposure Concentration to the following standards when applicable: Maximum Contaminant Levels (MCLs) for surface and ground water (401 KAR 8:250, 401 KAR 8:300, 401 KAR 8:400, 401 KAR 8:420), National Ambient Air Quality Standards (NAAQS) for air, and Surface Water Standards (401 KAR 5:031) for surface water.

4. Calculate the frequency of detection of the hazardous substance or petroleum constituent. Identify those compounds that are detected in at least 10 percent of the samples. If there is any detection above ten times the residential or commercial/industrial screening value, as

appropriate, then the hazardous substance or petroleum should remain a Contaminant of Concern (COC) regardless of the frequency of detection.

5. Compare the mean of the site data to the 95% UCL of background for inorganics. The background value shall be the generic statewide background number listed on Table G-2 in Appendix G, or site-specific background may be determined using the methods described in 401 KAR 100:100 Section 7 (6). In addition to the site mean being less that the 95% UCL of background, at least half of the samples should fall below the 60th percentile on Table G-2 or site-specific background, and no sample should exceed the 95th percentile listed on Table G-2 or site-specific background. The cabinet may approve other statistical methods proposed by the VERP applicant or party.

6. Produce a summary table that lists each hazardous substance or petroleum, site mean, Exposure Concentration, 1/10th of the screening value, frequency of detection (as a fraction), and, for inorganics, 95% UCL of the arithmetic mean of background. Include MCLs, Surface Water Standards, and NAAQS, if applicable. Identify those compounds as Contaminants of Concern (COCs) that exceeds the values in all applicable screens (i.e., is not eliminated by any screen). Highlight or denote with bold text the screen that eliminates the COPC from further evaluation, if applicable. Table 1 is an example of the summary table for soil.

Table 1. Summary of Results of Tier I Screening

Hazardous Substance	Mean	Exposure Concentration	1/10th Screening Value	Frequency of Detection	95% UCL of Background	COC?
Benzene	--	0.8 mg/kg	0.03 mg/kg	(8/30)	---	Yes
Arsenic	7.9 mg/kg	9.3 mg/kg	0.019 mg/kg	(24/30)	**9.4**	No

7. Segregate the COCs into carcinogens and noncarcinogens as described in the Preliminary Remediation Goals table in Appendix C. Radionuclides should be evaluated in the Tier I Screen using the screening values in Appendix E, if applicable. Calculate a Screening Index for all COCs by dividing the Exposure Concentration by the chemical-specific Preliminary Remediation Goal from Appendix C and summing the carcinogens and noncarcinogens:

$$\text{Screening Index (SI)} = \sum \frac{\text{Exposure Concentration x}}{\text{Screening Value x}} + \frac{\text{Exposure Concentration y}}{\text{Screening Value y}} + \frac{\text{Exposure Concentration z}}{\text{Screening Value z}} + \textit{etc.}$$

For noncarcinogens, a Screening Index of less than 1.0 indicates that exposure to all noncarcinogenic contaminants, when summed, do not exceed a HQ of 1.0. Likewise the carcinogenic constituents should also use the SI approach and multiply the result by 10^{-6} to determine the additive risk in the media. This approach should be used for all applicable media at a site and then summing the indices of the individual media. The VERP applicant or party may calculate a site-specific PRG for a Tier I risk assessment screen.

8. Present the results of the Screening Index in the risk assessment report (Section 2.6).
9. If the cumulative Screening Index (SI) exceeds 1.0 for noncarcinogens or 1 x 10^{-6} for carcinogens, a VERP Applicant or party should select the next course of action. They may select to complete a risk management plan (Section 2.4), initiate remedial action(s) (Section 2.5), or evaluate the risks further through a baseline risk assessment (Section 2.2).

Section 2.2. Tier II. Baseline Human Health Risk Assessment.

1. Based on the COCs that were identified in Tier I (Risk-Based Screening), conduct a baseline risk assessment.
2. Risk assessment guidance documents from the United States Environmental Protection Agency should be used in preparing the risk assessment. Primary guidance is the "Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual. (Part A)" (RAGS Part A) and RAGS Part B (U.S. EPA, 1989; 1991), the "Soil Screening Guidance: Technical Background Document" (U.S. EPA, 1996a), the "Soil Screening Guidance: Users Guide" (U.S. EPA, 1996b), the "Soil Screening Guidance for Radionuclides: Users Guide" (U.S. EPA, 2000), and the Supplemental Guidance to RAGS: Region 4 Bulletins (U.S. EPA, 2001c). Other supporting guidance documents should be used as needed.
3. Describe the collection of sampling data and the procedures used to evaluate the data that are included in the risk assessment. Evaluation is completed as described in RAGS Part A (U.S. EPA, 1989) and involves evaluating analytical methods, quality of data, quantitation limits, data qualifiers, and blanks.
4. Identify and calculate exposure to current and future receptors. Potential land uses should be identified including, but not limited to: residential, industrial, recreational, commercial, or

agricultural. The baseline risk assessment should address all current and potential future receptors including trespassers and residents. Exposure factors for common receptors are listed in Appendix A. Site-specific factors may be used, subject to cabinet approval. The factors and the rationale for their use should be documented in the risk assessment report.

5. Describe the toxicity of the COCs that were identified in Section 2.1. List the toxicity values that are associated with the COCs. The hierarchy for sources of toxicity values is: (1) U.S. EPA's Integrated Risk Information System (IRIS), (2) U.S. EPA's Health Effects Assessment Summary Tables (HEAST), (3) provisional values from U.S. EPA's National Center for Environmental Assessment (NCEA), and (4) Other sources. Other sources may include Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles, World Health Organization (WHO) documents, publications in the primary toxicological literature, or values withdrawn from IRIS or HEAST, with cabinet approval.
6. Calculate the risks associated with the receptors that were identified in Step 4.
7. Identify and describe the uncertainties associated with the risk assessment. Potential sources of uncertainty include COC selection, range of values for exposure parameters, characterization of the site, and interaction between chemicals (additivity, synergism). Uncertainty analysis is further discussed in RAGS Part A (U.S. EPA, 1989).

Section 2.3. Groundwater Evaluation.

Groundwater data from monitoring wells are evaluated in Tier I and II risk evaluations. Recoverable water from soil borings can also be evaluated with groundwater numbers (Preliminary Remediation Goals, MCLs) as described in Section 2.1 and 2.2. If no groundwater monitoring data are available, or data are not adequate, then compare Exposure Concentration(s) for soil to the Soil Screening Level(s) from the Preliminary Remediation Goals table in Appendix C as described in 401 KAR 100:100 Section 5 (5). Radionuclides should be evaluated using the Soil Screening Levels in Appendix E, if applicable.

If the bottom two sampling intervals in the soil boring do not exceed the SSL, modified SSL, site-specific SSL, or subsurface background, then further groundwater evaluation of soil as a potential source for groundwater contamination is not necessary. If soil concentrations in the bottom two sampling intervals of the soil boring do exceed the Soil Screening Level, Modified SSLs, or site-specific SSLs for protection of groundwater resources, and subsurface background, then this indicates a need to manage for migration of contaminants to groundwater or for a

groundwater investigation. Submit a plan to assess and protect groundwater or provide site-specific information that contamination doesn't pose a threat to groundwater.

Identify if the site is in an area where contamination of a karst aquifer is possible, or the contaminant(s) could result in a dense non-aqueous phase liquid (DNAPL) layer, or any other circumstances exist that would indicate a higher potential for contamination of groundwater. If such conditions exist, submit a plan for groundwater assessment and protection.

Section 2.4. Management of Risks.

1. Property Use. Management of risks can be accomplished by ensuring that a property is only used by a certain receptor. For example, a property that meets criteria for commercial or industrial use, but not residential, must remain commercial or industrial. Alternate land uses can be evaluated by using commercial/industrial screening values in place of the residential screening values that were used in Section 2.1, or in a baseline risk assessment.
2. Physical and Institutional Controls. Management of risks can be accomplished if exposure to contaminated media is controlled using a combination of soil cover, restrictive covenants, dig restrictions, fencing, or other approved methods.
3. Submit Corrective Action Plan for approval as described in 401 KAR 100:100 Section 8.

Section 2.5. Selection of Remedial Goals.

1. The primary goals of remediation is protection of human health at the hazard index of 1.0 and the carcinogenic risk of 1×10^{-6} at the point of exposure, and protection of ecological health. Ecological risks are addressed in Section 3.0.
2. The primary goals of remediation do not excuse compliance with other applicable standards, such as the National Ambient Air Quality Standards and the surface water standards.
3. The intended use must be ensured through physical and institutional controls and described in the Corrective Action Plan. The risk-based Preliminary Remediation Goals are found in the Appendix C table or derived based on approved receptor-specific values. Remedial goals

for radionuclides will be developed on a site-specific basis in consultation with the Kentucky Cabinet for Health Services. Generic inorganic background values are listed in Appendix G or may be derived using the guidance in 401 KAR 100:100 Section 7 (6).

4. The applicable risk-based remedial goals for surface soils are the residential and commercial/industrial soil numbers in the Appendix C Preliminary Remediation Goals table or those calculated based on approved receptor-specific values. Appendix E contains the risk-based concentrations for radionuclides, if applicable. The remedial goal for certain organic chemicals may be based on site-specific concentrations if it can be demonstrated to the cabinet that concentrations are the result of natural sources or are a by-product of combustion of fuels and not the result of activities on the property or site. For subsurface soils, a VERP applicant or party may select ten times the surface soil risk-based concentrations as an initial remedial goal with implementation of the institutional and physical controls and should not be a source of groundwater contamination. If contaminants are in the surface soil horizon, this can be attained through the use of cover (6 inches of pavement (e.g., asphalt or concrete), 12 inches of soil, or other approved method). For example, if the commercial/industrial soil number is 1.3 mg/kg on the risk-based PRGs table in Appendix C, and the contamination is more than a foot below the surface or is covered with a foot of clean soil, then the concentration that is left in place can be 13 mg/kg and the use of the site would need to be restricted to commercial or industrial use with the soil cover maintained in place.

Section 2.6. Human Health Risk Assessment Report Format.

The risk assessment results should be presented as part of the environmental remediation process wherever risk assessment is used for environmental decision-making. This may be included as part of the site characterization report, corrective action completion report, in an appendix to those reports, or as a separate document.

1. Screening. The screening report should consist of a brief description of the property, site characterization activities, a summary of the analytical data along with the statistical calculations of the 95% UCL, the summary table as described in Section 2.1 6., and results of the Screening Index.

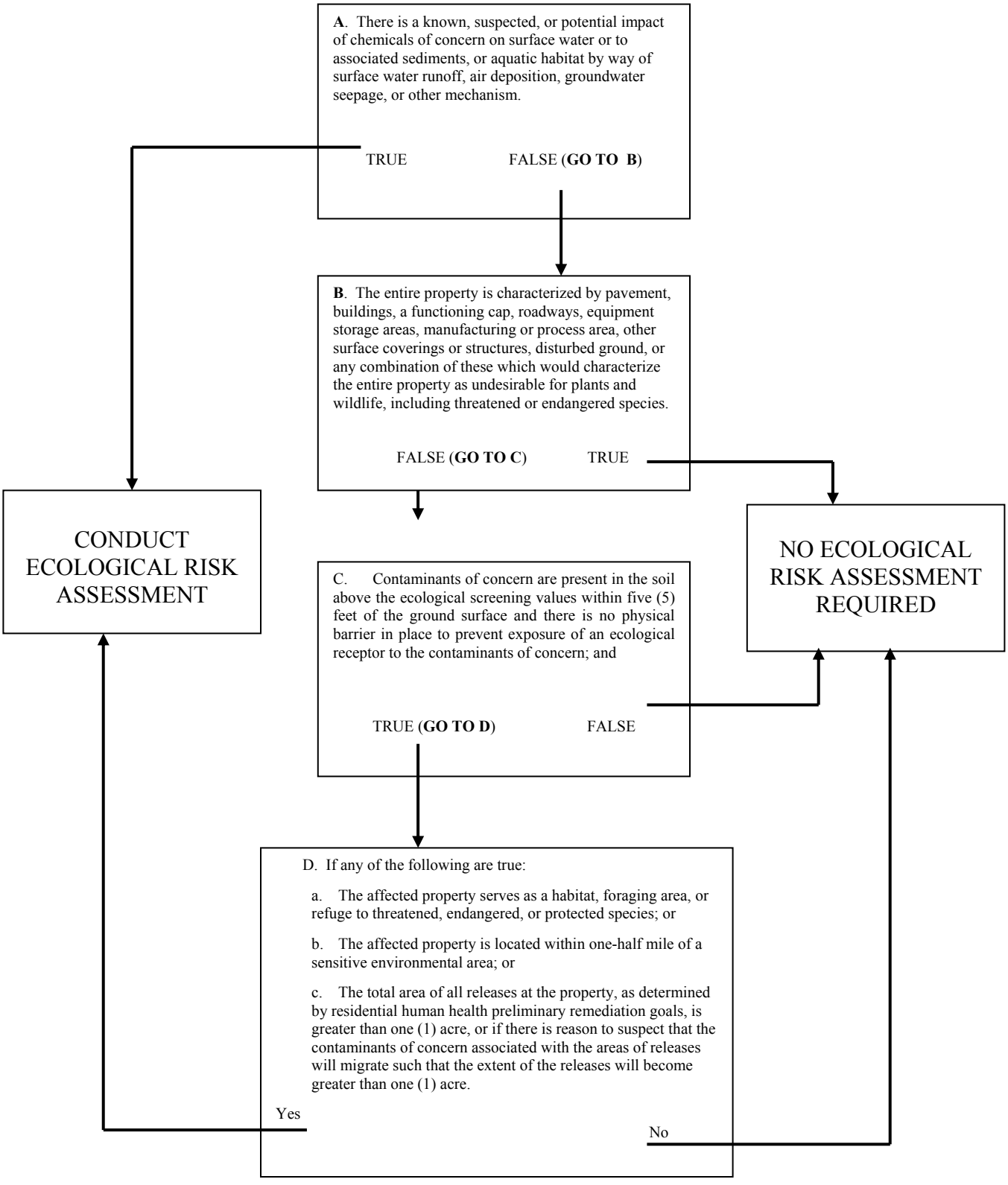
2. Baseline Risk Assessment. The baseline risk assessment report should follow the general outline shown in Appendix B. A copy of the screening risk assessment may be included with the baseline risk assessment to provide information that was used in the baseline risk assessment (selection of COCs, calculation of 95% UCL).

Section 3.0 Ecological Risk Assessment

If it has been determined that an Ecological Risk Assessment (ERA) needs to be conducted (401 KAR 100:100 Section 5 (8)), this document provides the outline for that process. The flowchart in Figure 3 is the process for determining if an ERA needs to be conducted. The checklist in Appendix F can be used to identify features of the environmental setting that are related to ecological receptors.

The phrase "ecological risk assessment" refers to a qualitative and/or quantitative appraisal of the actual or potential impacts from a hazardous compound or physical stressor on plants and animals. Documents from various federal programs (Simini et. al., 2000; USEPA 1993; USEPA 1997a; USEPA 1998) were consulted in the process of developing this document and the procedures used in calculating risk-based concentrations. Figure 4 outlines the process of the ERA.

Figure 3. Flowchart For Determining An Ecological Risk Assessment



The ERA process is based on two major elements: characterization of effects and characterization of exposure. These provide the focus for conducting the phases of risk assessment: planning, problem formulation, analysis, risk characterization, and risk management.

a) Planning – The Planning phase involves the determination of level-of-effort necessary for the ERA. ERA management goals and objectives are determined (i.e., what plant, animal, or ecosystem is at risk and might need protection), the focus of the ERA is laid out, and the time frame for the assessment is set.

b) Problem Formulation – The overall strategy for estimating risk at a site is developed in Problem Formulation. During this phase, the Conceptual Site Model (CSM) is created, the receptors potentially at risk are defined, and a plan is written that describes the data to be analyzed and the process to be used to calculate risk.

c) Analysis – This component of the ERA consists of data collection, the technical evaluation of the data, the calculation of the existing and potential exposures, and corresponding ecological effects.

d) Risk Characterization – The likelihood and severity of the risk is evaluated for the assessment endpoints, and the ERA's uncertainty is described in the Risk Characterization. A good description of the risk, including the level of adverse effects, is important for interpreting the risk results.

e) Risk Management – In this component, the results of the ERA are integrated with other considerations to make and justify remedial decisions. In a screening level ERA, the risk management decision is whether a baseline ERA is needed.

Section 3.1. Tier 1. Screening-Level Ecological Risk Assessment.

The purpose of the screening-level risk assessment is to evaluate whether existing data justify a decision that site contaminants do not pose a risk to ecological receptors or whether additional evaluation is necessary. If no potential for risk is identified in a screening-level risk assessment, then risk managers can confidently conclude that no further action is required at the site. Tier 1 of ERA consists of two steps:

Step 1. Screening-Level Problem Formulation and Ecological Effects Evaluation.

Step 2. Screening-Level Preliminary Exposure Estimate and Risk Calculation.

Steps 1 and 2 of the ERA process contain the following elements:

- Site visit
- Screening-level problem formulation (preliminary Conceptual Site Model)
- Exposure pathways and endpoints
- Screening-level effects evaluation (toxicity threshold benchmarks)
- Screening-level exposure estimate (site concentration data)
- Screening-level risk calculation (site concentration data screens)
- Documentation

a) Preliminary Conceptual Site Model (CSM). As part of Tier 1, Step 1 of the ERA, use available information to develop a preliminary CSM. Available information may include observations made during site visits, historical documents, existing data, and professional judgement of technical experts who are familiar with the site. The preliminary CSM should describe the environmental setting of the individual site, the site's immediate surroundings, and the contaminants known to exist at the site. The preliminary CSM should identify fate and transport mechanisms of contaminants potentially moving off-site, and briefly discuss the ways that site contaminants act on likely receptors.

b) Exposure Pathways and Endpoints. Based on the preliminary CSM, the ecological risk assessor should identify the potentially complete exposure pathways and endpoints for the screening assessment. The exposure pathways and endpoints for the site specify which ecological effects data are required. The screening-level effects data are screening-level benchmarks and concentrations of substances in the abiotic media (e.g., soil, air or water). If groundwater potentially discharges to surface water, groundwater concentrations are compared to surface water screening benchmarks.

c) Identify Chemicals of Potential Concern. As part of Tier 1, Step 2, determine (COPCs) by eliminating COPCs from further evaluation:

- Background Comparisons**.** Compare the mean concentration for inorganic constituents on-site against the 95% UCL of the mean concentrations of background for inorganic

constituents. At least ½ of the data points should be less than the 60th percentile, and no data point above the 95th percentile. Generic inorganic background values are listed in Appendix G or may be derived in accordance with 401 KAR 100:100 Section 7 (6).

- Screening Table Comparison. Compare the lesser of the maximum concentration or 95% UCL on site for substances in a given exposure medium to the screening-level benchmarks (Appendix D) for those substances. Compare site concentrations to screening-level benchmarks for surface soil, sediment, surface water, and groundwater (if site conditions will potentially result in exposure to ecological receptors).

d) Retaining Chemicals of Concern. If any constituent in an abiotic medium to which organisms are potentially exposed is present at a concentration exceeding screening-level benchmark and ambient background or if there is not a screening-level benchmark, then further evaluation of the potential risk will be required. Chemicals with known synergistic effects or that bioaccumulate will be retained as COPCs. If existing data does not have adequate detection limits (i.e., detection limits above screening benchmarks) new data must be collected to replace it.

e) Documentation. The documentation of Steps 1 and 2 should include the following:
   - Brief habitat description, and map;
   - Preliminary CSM;
   - Tables of screening results;
   - List of wildlife species actually or potentially occurring at the site, including threatened and endangered plant and animal species;
   - Discussion of uncertainties. The discussion of the uncertainties should identify constituents for which there are no screening-level benchmarks or analytical chemistry data.

At the end of Tier 1, the decision whether to collect additional data for screening, to proceed with the ERA, or to take no further action can be documented in the report.

Section 3.2. Tier 2 Baseline Ecological Risk Assessment

The baseline ecological risk assessment is a continuation of the screening ERA. It consists of 6 steps:

Step 3. Baseline Risk Assessment Problem Formulation

Step 4. Study Design and Data Quality Objectives

Step 5. Field Verification of Sampling Design

Step 6. Site Investigation and Analysis of Exposure and Effects

Step 7. Risk Characterization

Step 8. Risk Management

a) Step 3. Baseline Risk Assessment Problem Formulation. The Baseline Risk Assessment Problem Formulation should provide sufficient information to support a risk management decision concerning the need for additional evaluation of ecological risk. Further evaluation may mean site-specific ecological investigation at the site. This will require a work plan, documenting Step 4 of the process, and describing how the data will be used in Step 7 to make a remedial decision for the site. Important inputs to this decision are:

- Site concentration data;
- Conceptual Site Model;
- Habitat Description;
- Preliminary Hazard Quotients. The Hazard Quotient should be calculated for COPCs using toxicity values from current literature and intake factors from the Wildlife Exposure Factors Handbook (USEPA 1993) for the species listed below. A Hazard Quotient is calculated by dividing the site concentration (the lessor of the 95% UCL of the mean or maximum) by the No-Observed Adverse Effect Level (NOAEL). If the Hazard Quotient is above 1.0, that compound continues through the baseline ERA.

  For terrestrial habitats, receptors must include (1) earthworm (Lumbricus terrestris), (2) short-tailed shrew (Blarina brevicauda), (3) long-tailed weasel (Mustela frenata), (4) meadow vole (Microtus pennsylvanicus) or prairie vole (Microtus ochrogaster), and (5) American woodcock (Scolopax minor). For aquatic habitats, receptors must include; mink (Mustela vison) little brown bat (Myotis lucifugus), and belted kingfisher (Cerlye alcyon). The above list of species should not be considered exclusive. If there are other species on site that exposure factors, intake rates, and

toxicity values are known, those species should be included in the ERA. Species that are on the Federal and/or State Threatened or Endangered Species List and either known to have been on or in the vicinity of the site or if the site contains habitat known to support those species, then they should also be included in the ERA.

- The identification of COPCs that warrant further evaluation.
- An understanding of the effects of COPCs on ecological receptors (including toxicity reference values).
- The identification of complete exposure pathways by which COPCs are brought into contact with ecological receptors (include bioaccumulation factors and ingestion rates for wildlife receptors).
- The identification of assessment endpoints (e.g., protection of fish eating birds from eggshell thinning due to DDT exposure) and measurement endpoints (e.g., natural population structure, feeding, resting, and reproductive cycles).
- Discussion of uncertainties should include the lack of site concentration or toxicity data for COPCs.

b) In Step 4, the process identifies the study design and data quality objectives (DQOs) for the site investigation. The work plan (WP) and the sampling and analysis plan (SAP) are the primary products of Step 4. The WP and SAP must specify the study design in sufficient detail to evaluate its adequacy for collecting the data necessary to answer the risk questions.

The WP or SAP should include the following:

- The number and location of samples of each medium for each purpose
- The comparison of analytical detection limits and threshold concentrations
- The full description of toxicity tests and population/community study designs
- A description of how the results of site investigations will be used in the risk characterization (Step 7) to answer risk questions.

c) In Step 5, the Verification of Field Sampling Design process evaluates the probability of successfully completing the study as designed. The WP or SAP should describe the methods for verifying the study design. The verification process and any remaining uncertainties

about the study design should be discussed when the results of the site investigation are reported.

d) Step 6, the Site Investigation and Data Analysis, is the implementation of the site investigation designed in Step 4 and verified in Step 5. Approved alterations in the work plan should be documented in the report containing the risk characterization (i.e., the baseline risk report).

e) Risk Characterization (Step 7) is conducted after data collected during the site investigation have been analyzed. The risk characterization evaluates the exposure and effects data to assess the risk to the assessment endpoints (risk estimation). The risk characterization also presents information necessary to interpret the risk assessment and to decide upon adverse effect thresholds for the assessment endpoints (risk description). This presentation should include a qualitative and quantitative summary of risk results and uncertainties.

   In risk estimation, the lines of evidence, for which data were collected in the site investigation, are integrated in the risk characterization to support a conclusion about the significance of ecological risk. The different possible lines of evidence could be tissue concentration data, toxicity test results, and/or population/community data.

   If site-specific tissue concentration data are available from the site investigation, HQs for wildlife receptors preying on those tissues are calculated. These HQs are calculated using appropriate exposure estimates and toxicity reference values.

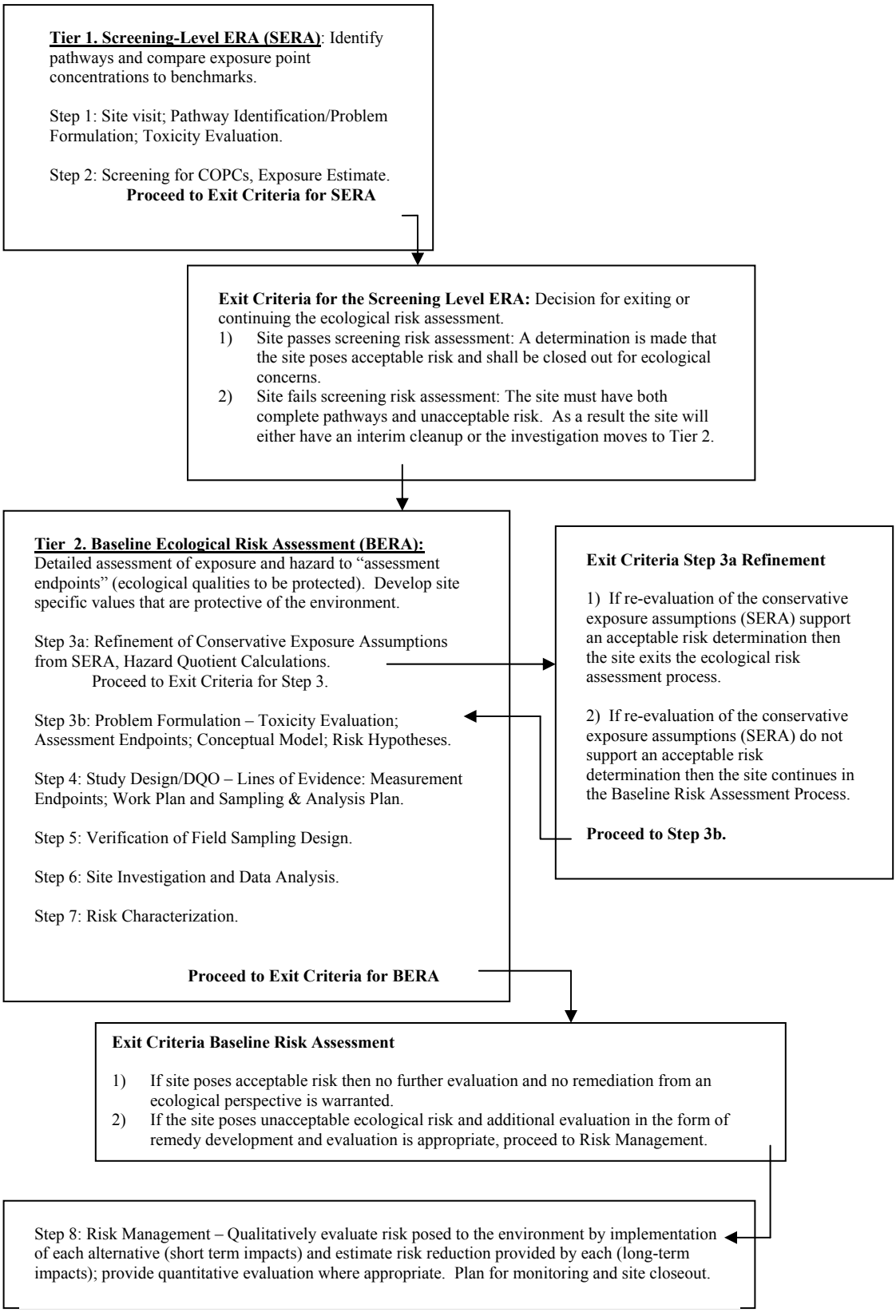
   In the ERA, the risk characterization should put the level of risk at the site in context. The risk description should identify threshold concentrations in source or exposure media for effects on the assessment endpoint. All site-specific parameter values used to calculate HQs must be described and the source of the values identified.

   At Step 7, the uncertainty about the risk posed by a substance should have been reduced to a level that allows risk managers to make a technically defensible remedial decision. The risk characterization provides information to judge the ecological significance of the estimated risk to assessment endpoints in the absence of any remedial action.

f) Step 8 of the ERA is Risk Management. The role of ecological risk assessors is to advise the risk managers during the final actions. If the risk characterization concludes there is a risk to

ecological receptors, the risk management decision is whether to remediate the site or to leave the constituents of concern in place with controls on exposure and monitoring.

Figure 4. Ecological Risk Assessment Flow Chart



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Appendix A
Exposure Factors

Table 1 Incidental Soil Ingestion Pathway.

Parameter	Value
Chemical Concentration in Soil	95 % UCL of the mean or maximum
Ingestion Rate: Child less that 7 years Child 7 through 18 years, and Adult Adult Worker (8 hour work day) Outdoor Adult (landscaping, construction, Rural outdoor activities, tilling and gardening)	 200 mg/day 100 mg/day 50 mg/day 480 mg/day
Exposure Frequency: Resident General Workers Adult Outdoors (urban) Adult Outdoors (rural) Outdoor Worker Child Outdoors (recreational or trespasser)	 350 days/year 250 days/year 52 days/year 104 days/year 185 days/year 140 days/year
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult Adult Worker	 6 years 12 years 12 years 22 years 25 years
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adult	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 2 Dermal Contact with Stressors in Soil Pathway.	
Parameter	Value
Chemical Concentration in Soil	95 % UCL of the mean or maximum
Skin Surface Area: Child less than 7 years Child 7 through 18 years Residential Adult Adult (Industrial) Outdoor Worker	 2800 cm^2/day (face, forearms, hands, lower legs, and feet) 7500 cm^2/day (arms, hands, legs, and feet) 5700 cm^2 (face, hands, forearms, and lower legs) 3300 cm^2/day (face, forearms, and hands) 4700 cm^2/day (arms, hands, and head)
Exposure Frequency: Resident General Workers Adult Outdoors (urban) Adult Outdoors (rural) Outdoor Worker Child Outdoors (recreational or trespasser)	 350 days/year 250 days/year 52 days/year 104 days/year 185 days/year 140 days/year
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult Adult Worker	 6 years 12 years 12 years 22 years 25 years
Dermal Absorption Factor	0.25 Volatile Organics (unitless) 0.1 Semivolatiles (unitless) 0.05 Inorganics (unitless)
Skin Contact Time (fraction of day soil remains on skin): Residential Worker Recreational or Trespasser	 12 hours/24 hours (0.5 unitless) 8 hours/24 hours (0.33 unitless) 12 hours/24 hours (0.5 unitless)
Soil to Skin Adherence Factor	1.0 mg/cm^2
Body Weight: Child less than 7 years Child 7 through 18 years Adult	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 3 Inhalation of Particulate-phase Stressors from Soil Pathway.	
Parameter	Value
Chemical Concentration in Soil	95 % UCL of the mean or maximum
Inhalation Rate: Resident (Children and Adults) Trespasser Worker (Indoor and Outdoor)	 20 m^3/day (0.833m^3/hour, 24 hr/day) 20 m^3/day (2.5 m^3/hour, 8 hr/day) 12.5 m^3/day (2.5 m^3/hour, 5 hr/day)
Exposure Frequency: Resident General Worker Adult Outdoors (urban) Adult Outdoors (rural) Outdoor Worker Child Outdoors (recreational or trespasser)	 350 days/year 250 days/year 52 days/year 104 days/year 185 days/year 140 days/year
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adults Residential Rural Adults Adult Worker	 6 years 12 years 12 years 22 years 25 years
Inhalation Absorption Factor	1.0 (unitless) or chemical-specific
Particulate Emission Factor: Residential Commercial/Industrial	 9.3 x 10^8 m^3/kg or site-specific 6.2 x 10^8 m^3/kg or site-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adults	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 4 Inhalation of Airborne (Vapor Phase) Stressors from Soil Pathway.	
Parameter	Value
Chemical Concentration in Soil	95 % UCL of the mean or maximum
Inhalation Rate: Resident (Children and Adults) Trespasser Worker (Indoor and Outdoor)	 20 m^3/day (0.833 m^3/hour, 24 hr/day) 20 m^3/day (2.5 m^3/hour, 8 hr/day) 12.5 m^3/day (2.5 m^3/hour, 5 hr/day)
Exposure Frequency: Resident General Worker Adult Outdoors (urban) Adult Outdoors (rural) Outdoor Worker Child Outdoors (recreational or trespasser)	 350 days/year 250 days/year 52 days/year 104 days/year 185 days/year 140 days/year
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult Adult Worker	 6 years 12 years 12 years 22 years 25 years
Inhalation Absorption Factor	1.0 (unitless) or chemical-specific
Volatilization Factor	Derived using Equation 8 of the Soil Screening Level Guidance User's Guide (U.S. EPA 1996b)
Body Weight: Child less than 7 years Child 7 through 18 years Adult	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 5 Ingestion of Stressors from Water Pathway.	
Parameter	Value
Chemical Concentration in Water	95 % UCL of the mean or maximum
Ingestion Rate: Child less than 3 years old Child 3 through 18 years and Adult Adult Worker (up to an 8 hour work day)	 1.0 liter/day 2.0 liters/day 1.0 liter/day
Exposure Frequency: Resident General Worker	 350 days/year 250 days/year
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult Adult Worker	 6 years 12 years 12 years 22 years 25 years
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adult	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 6 Ingestion of Stressors in Surface Water While Swimming Pathway.	
Parameter	Value
Chemical Concentration in Water	95 % UCL of the mean or maximum
Ingestion Rate:	50 milliliters/hour
Exposure Time:	2.6 hours/day
Exposure Frequency:	45 days/year
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult	 6 years 12 years 12 years 22 years
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adults	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 7 Dermal Contact with Stressors in Water while Swimming or Wading Pathway.	
Parameter	Value
Chemical Concentration in Water	95 % UCL of the mean or maximum
Skin Surface Area: Child swimmer 3 through 6 years Child swimmer 7 through 18 years Adult swimmer Child wader 1 through 6 years Child wader 7 through 18 years Adult wader	 0.6500 m^2/day 1.3100 m^2/day 1.8150 m^2/day 0.3300 m^2/day (arms, hands. legs and feet) 0.7500 m^2/day (arms, hands. legs and feet) 1.0600 m^2/day (arms, hands. legs and feet)
Exposure Time	2.6 hours/day
Dermal Permeability factor (Kp)	Use RAGS Part E (U.S. EPA 2001b) Appendix B. If measured K_ps are available, then those should be used instead of the modeled values for those chemicals.
Exposure Frequency: Swimming Child and Adolescent Wading Adult Wading	 45 days/year 140 days/year 52 days/year
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult	 6 years 12 years 12 years 22 years
Dermal Absorbed Dose per Event (DA_{event})	Calculated using RAGS Part E (U.S. EPA, 2001b)
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adult	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 8 Dermal Contact with Stressors in Water during Showering or Bathing Pathway.	
Parameter	Value
Chemical Concentration in Water	95 % UCL of the mean or maximum
Skin Surface Area: Child 3 through 6 years Child 7 through 18 years Adult	 0.6500 m^2/day 1.3100 m^2/day 1.8150 m^2/day
Exposure Time	0.2 hours/day
Dermal Permeability factor (Kp)	Use RAGS Part E (U.S. EPA 2001b) Appendix B. If measured K_ps are available, then those should be used instead of the modeled values for those chemicals.
Exposure Frequency: Residents Workers in the work place	 350 days/year 250 days/year
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult Adult Worker	 6 years 12 years 12 years 22 years 25 years
Dermal Absorbed Dose per Event (DA_{event})	Calculated using RAGS Part E (U.S. EPA, 2001b)
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adult	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 9 Inhalation of Airborne (Vapor Phase) Stressors in Water during Showering Pathway	
Parameter	Value
Chemical Concentration in Water	95 % UCL of the mean or maximum
Concentration of Stressor in Air	Use Schaum, et al., 1994, Showering Exposure
Inhalation Rate	0.833 m^3/day
Exposure Time	0.2 hours/day (12 minutes/day)
Exposure Frequency: Residents Workers in the work place	 350 days/year 250 days/year
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adults Residential Rural Adults Adult Worker	 6 years 12 years 12 years 22 years 25 years
Inhalation Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adults	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Table 10 Inhalation of Airborne (Vapor Phase) Stressors in Water during General Home Use Pathway.

Parameter	Value
Chemical Concentration in Water	95 % UCL of the mean or maximum
Concentration of Stressor in Air	Use Schaum et al., 1994, Whole House Model
Inhalation Rate	20 m^3/day
Water Flow Rate	890 L/day
House Volume	450 m^3
Air Exchange Rate	10 changes/day
Fraction Volatilized	0.5 (unitless)
Mixing Coefficient (how well mixed in the home)	0.5 (unitless)
Exposure Frequency: Resident	 350 days/year
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 7 years Child 7 through 18 years Residential Urban Adult Residential Rural Adult	 6 years 12 years 12 years 22 years
Inhalation Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 7 years Child 7 through 18 years Adults	 15 kg 43 kg 70 kg
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for noncarcinogens

Other Pathways. Other pathways may be used at sites that have current or potential future pathways that are not listed in this Appendix. Examples include: consumption of contaminated fish, produce, and livestock. Exposure factors should be based on site-specific conditions and may be obtained from U.S. EPA documents including Exposure Factors Handbook, Risk Assessment Guidance for Superfund (Part A), and Risk Assessment Guidance for Superfund (Part B).

Appendix B
General Outline for Baseline Risk Assessment

Outline of Components of a Human Health Baseline Risk Assessment

This is a general outline and not all components of the outline are applicable to all sites.

1.0 INTRODUCTION

- 1.1 Overview
  - 1.1.a General Problem at site
  - 1.1.b Site-specific objectives of risk assessment
- 1.2 Scope of Risk Assessment
  - 1.2.a Complexity of risk assessment and rationale
  - 1.2.b Overview of study design

2.0 IDENTIFICATION OF STRESSORS OF POTENTIAL CONCERN

- 2.1 General Site-Specific Data Collection Considerations
  - 2.1.a Preliminary identification of potential human exposure
  - 2.1.b Modeling parameter needs
- 2.2 General Site-Specific Data Evaluation Considerations
  - 2.2.a Steps used (including statistical methods used for evaluation and data selection)
  - 2.2.b Criteria employed in evaluating data
  - 2.2.c Discussion of data uncertainty
- 2.3 Stressor Analytical Data (Complete for All Media)
  - 2.3.a Listing of analytical methods used
  - 2.3.b Evaluation of chemical limits
  - 2.3.c Evaluation of qualified and coded data
  - 2.3.d Contaminants in field and laboratory blanks
  - 2.3.e Tentatively identified compounds
  - 2.3.f Further limitation of number of stressors
  - 2.3.g Uncertainties, limitations, gaps in quality of collection or analysis
- 2.4 Summary of Stressors of Potential Concern

3.0 EXPOSURE ASSESSMENT

- 3.1 Characterization of Exposure Setting
  - 3.1.a Summary of Physical Setting
  - 3.1.b Potentially Exposed Individuals, Populations, and Communities (Human)
    - 3.1.b.1 Relative locations of individuals, populations, and communities with respect to site
    - 3.1.b.2 Current land use

3.1.b.3 Potential alternate future land uses

3.1.b.4 Subpopulations of potential concern

3.2 Identification of Exposure Pathways

3.2.a Sources of the release and receiving media

3.2.b Fate and transport in release media

3.2.c Exposure points and exposure routes

3.2.d Integration of sources, releases, fate and transport mechanisms, exposure points, and exposure routes into complete exposure pathways

3.2.e Summary of exposure pathways to be quantified in this assessment

3.3 Quantification of Exposure

3.3.a Exposure concentrations

3.3.b Estimation of chemical intakes for individual pathways

3.4 Identification of Uncertainties

3.4.a Current and future land-use

3.4.b Environmental sampling and analysis

3.4.c Exposure pathways evaluated

3.4.d Fate and transport modeling

3.4.e Parameter values

3.5 Summary of Exposure Assessment

4.0 TOXICITY ASSESSMENT

4.1 Toxicity Information for Noncarcinogenic Effects (Human Health)

4.1.a Appropriate exposure periods for toxicity values

4.1.b Up-to-date reference doses (RfDs) for all stressors

4.1.c One-and ten-day health advisories for shorter-term oral exposures

4.1.d Overall data base and the critical study on which the toxicity value is based (including the critical effect and the uncertainty and modifying factors used in the calculation)

4.1.e Effects that may appear at doses higher than those required to elicit the critical effect

4.1.f Absorption efficiency considered

4.2 Toxicity Information for Carcinogenic Effects

4.2.a Exposure averaged over a lifetime

4.2.b Up-to-date slope factors for all carcinogens

4.2.c Weight-of-evidence classification for all carcinogens (Groups A, B, and C)

4.2.d Type of cancer for Group A, B, and C carcinogens

4.2.e Concentration above which the dose-response curve is no longer linear, if applicable

4.3 Stressors for Which No EPA Toxicity Values are Available

4.3.a Sources of values

4.3.b Qualitative evaluation

4.3.c Documentation or justification of any new toxicity values developed

4.4 Uncertainties Related to Toxicity Information

4.4.a Quality of the individual studies

4.4.b Completeness of the overall data base

4.5 Summary of Toxicity Information

5.0 RISK CHARACTERIZATION

5.1 Current Land-use Conditions (Human Health)

5.1.a Carcinogenic risk of individual stressors in individual pathways

5.1.b Chronic hazard quotient calculation (individual stressors, individual pathways)

5.1.c Subchronic hazard quotient calculation (individual stressors, individual pathways)

5.1.d Shorter-term hazard quotient calculation (individual stressors, individual pathways)

5.1.e Noncarcinogenic hazard index (individual stressors, all pathways)

5.1.f Carcinogenic risk (individual stressors, all pathways)

5.2 Future Land-Use Conditions (Human Health)

5.2.a Carcinogenic risk of individual stressors in individual pathways

5.2.b Chronic hazard quotient calculation (individual stressors, individual pathways)

5.2.c Subchronic hazard quotient calculation (individual stressors, individual pathways)

5.2.d Noncarcinogenic hazard index (individual stressors, all pathways)

5.2.e Carcinogenic risk (individual stressors, all pathways)

5.3 Uncertainties

5.3.a Site-specific uncertainty factors

5.3.a.1 Definition of physical setting

5.3.a.2 Model applicability and assumptions

5.3.a.3 Parameter values for fate or transport and exposure calculations

5.3.b Summary of toxicity assessment uncertainty

5.3.b.1 Uncertainty and identification of potential human health effects

5.3.b.2 Derivation of toxicity value including completeness of overall database

5.3.b.3 Potential for synergistic or antagonistic interactions

5.3.b.4 Uncertainty in evaluating less-than-lifetime exposures

5.4 Comparison of Risk Characterization Results to Human Studies (if available)

5.4.a Health assessment from the Agency for Toxic Substances and Disease Registry (ATSDR)

5.4.b Site-specific health studies (pilot studies or epidemiological studies)

5.4.c Incorporation of studies into the overall risk characterization

5.5 Summary Discussion and Tabulation of the Risk Characterization

5.5.a Key site-related stressors and key exposure pathways identified

5.5.b Types of health risk of concern

5.5.c Level of confidence in the quantitative information used to estimate risk

5.5.d Presentation of qualitative information on toxicity

5.5.e Confidence in the key exposure estimates for the key exposure pathways

5.5.f Magnitude of the carcinogenic and noncarcinogenic risk estimates

5.5.g Magnitude of chronic and subchronic risk estimates

5.5.h Major factors contributing to risk

5.5.i Major factors (COCs and Pathways) contributing to uncertainty

5.5.j Exposed population and community characteristics

5.5.k Comparison with site-specific health studies

5.5.l Comparison of chemical concentrations with natural background

6.0 SUMMARY AND CONCLUSIONS

6.1 Stressors of Potential Concern

6.2 Exposure Assessment

6.3 Toxicity Assessment

6.4 Risk Characterization

6.5 Uncertainties

Outline of Components of an Ecological Baseline Risk Assessment

This is a general outline and not all components of the outline are applicable to all sites.

STEP 1: SCREENING-LEVEL PROBLEM FORMULATION AND ECOLOGICAL EFFECTS EVALUATION

1.1 INTRODUCTION

1.2 SCREENING-LEVEL PROBLEM FORMULATION

- 1.2.1 Environmental Setting and Contaminants at the Site
- 1.2.2 Contaminant Fate and Transport
- 1.2.3 Ecotoxicity and Potential Receptors
- 1.2.4 Complete Exposure Pathways
- 1.2.5 Assessment and Measurement Endpoints

1.3 SCREENING-LEVEL ECOLOGICAL EFFECTS EVALUATION

- 1.3.1 Preferred Toxicity Data
- 1.3.2 Dose Conversions
- 1.3.3 Uncertainty Assessment

1.4 SUMMARY

STEP 2: SCREENING-LEVEL EXPOSURE ESTIMATE AND RISK CALCULATION

2.1 INTRODUCTION

2.2 SCREENING-LEVEL EXPOSURE ESTIMATES

- 2.2.1 Exposure Parameters
- 2.2.2 Uncertainty Assessment

2.3 SCREENING-LEVEL RISK CALCULATION

2.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

2.5 SUMMARY

STEP 3: BASELINE RISK ASSESSMENT PROBLEM FORMULATION

3.1 THE PROBLEM-FORMULATION PROCESS

3.2 REFINEMENT OF PRELIMINARY CONTAMINANTS OF CONCERN

3.3 LITERATURE SEARCH ON KNOWN ECOLOGICAL EFFECTS

3.4 CONTAMINANT FATE AND TRANSPORT, ECOSYSTEMS POTENTIALLY AT RISK, AND COMPLETE EXPOSURE PATHWAYS
3.4.1 Contaminant Fate and Transport
3.4.2 Ecosystems Potentially at Risk
3.4.3 Complete Exposure Pathways
3.5 SELECTION OF ASSESSMENT ENDPOINTS
3.6 THE CONCEPTUAL MODEL AND RISK QUESTIONS
3.6.1 Conceptual Model
3.6.2 Risk Questions
3.7 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)
3.8 SUMMARY

STEP 4: STUDY DESIGN AND DATA QUALITY OBJECTIVE PROCESS
4.1 ESTABLISHING MEASUREMENT ENDPOINTS
4.1.1 Species/Community/Habitat Considerations
4.1.2 Relationship of the Measurement Endpoints to the Contaminant of Concern
4.1.3 Mechanisms of Ecotoxicity
4.2 STUDY DESIGN
4.2.1 Bioaccumulation and Field Tissue Residue Studies
4.2.2 Population/Community Evaluations
4.2.3 Toxicity Testing
4.3 DATA QUALITY OBJECTIVES AND STATISTICAL CONSIDERATIONS
4.3.1 Data Quality Objectives
4.3.2 Statistical Considerations
4.4 CONTENTS OF WORK PLAN AND SAMPLING AND ANALYSIS PLAN
4.4.1 Work Plan
4.4.2 Sampling and Analysis Plan
4.4.3 Field Verification of Sampling Plan and Contingency Plans
4.5 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)
4.6 SUMMARY

STEP 5: FIELD VERIFICATION OF SAMPLING DESIGN
5.1 PURPOSE

5.2 DETERMINING SAMPLING FEASIBILITY
5.3 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)
5.4 SUMMARY

STEP 6: SITE INVESTIGATION AND ANALYSIS PHASE
6.1 INTRODUCTION
6.2 SITE INVESTIGATION
    6.2.1 Changing Field Conditions
    6.2.2 Unexpected Nature or Extent of Contamination
6.3 ANALYSIS OF ECOLOGICAL EXPOSURES AND EFFECTS
    6.3.1 Characterizing Exposures
    6.3.2 Characterizing Ecological Effects
6.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)
6.5 SUMMARY

STEP 7: RISK CHARACTERIZATION
7.1 INTRODUCTION
7.2 RISK ESTIMATION
7.3 RISK DESCRIPTION
    7.3.1 Threshold for Effects on Assessment Endpoints
    7.3.2 Likelihood of Risk
    7.3.3 Additional Risk Information
7.4 UNCERTAINTY ANALYSIS
    7.4.1 Categories of Uncertainty
    7.4.2 Tracking Uncertainties
7.5 SUMMARY

STEP 8: RISK MANAGEMENT
8.1 INTRODUCTION
8.2 ECOLOGICAL RISK MANAGEMENT
    8.2.1 Other Risk Management Considerations
    8.2.2 Ecological Impacts of Remedial Options
    8.2.3 Monitoring

8.3 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

8.4 SUMMARY

Appendix C
Human Health Screening Values

Development of Risk Based Concentrations for Environmental Remediation in Kentucky

Introduction

This appendix details the procedures used to develop risk-based concentrations that will be used for the Voluntary Environmental Remediation Program, KRS 224.01-400 and KRS 224.01-405 cleanups, and other programs where risk-based concentrations are needed. Documents from the United States Environmental Protection Agency were consulted in the process of developing this document and the procedures used in calculating risk-based concentrations.

Application

It is intended for this table to have several applications to sites undergoing environmental remediation. Applications include: preliminary screening of site contaminants, closure of small spills, determination of potential toxic conditions, and reduction and refinement of the number of Chemicals of Concern (COCs) at a site during a baseline risk assessment. The values are also one of the factors that should be considered when selecting remedial goals. The values consider the more common exposure routes but if an individual site has other exposure routes that play a major role in the site-related exposures, these values may underestimate the risk.

Calculation of Risk-Based Values

The formulae for calculating the risk-based concentrations are primarily from U.S. EPA guidance including Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A), commonly referred to as RAGS Part A (U.S. EPA, 1989), RAGS part B (U.S. EPA, 1991), Soil Screening Guidance: Users Guide (U.S. EPA, 1996c), and Soil Screening Guidance: Technical Background Document (U.S. EPA, 1996b). "Estimating Dermal and Inhalation Exposure to Volatile Chemicals in Domestic Water" (Schaum *et al*., 1994) was used to represent the inhalation exposure to water based on the Whole House Dispersion Model. The assumptions that are used in estimating the risk-based concentrations are selected to be protective of sensitive subpopulations.

KYDEP incorporated applicable exposure routes into each medium of exposure. For residential and occupational exposure to soil; ingestion, dermal and inhalation exposure was considered. Dermal exposure to soil used default absorption values of 0.25 for volatiles, 0.1 for semivolatiles, and 0.05 for metals. Default dermal absorption factors were derived from literature reviews of dermal absorption. The Agency for Toxic Substances and Disease Registry

(ATSDR) Toxicological Profiles were a valuable source of absorption and chemical specific data. Ten compounds had chemical-specific dermal absorption rates as listed in RAGS Part E (U.S, EPA, 2000a). Inhalation of contaminants found in soil used two factors: a Volatilization Factor (VF), and a Particulate Emission Factor (PEF). Potential volatilization from soil to air was represented for volatiles by the volatilization factor that was calculated using the formula in the Soil Screening Guidance: User's Guide (U.S. EPA, 1996c). A compound was assumed to be volatile when the molecular weight was less than 200 mg/mol and the Henry's Law Constant (H) was greater than 10^{-5} atm-m^3/mol. The respective default dispersion factor for residential and commercial/industrial exposures were derived for Kentucky sites using exhibit 11 in U.S. EPA, 1996c. Climatic zone VII was used to calculate the dispersion factor term since that is the logical zone for Kentucky sites. For a residential dispersion factor, the 90% lower confidence limit was calculated for a 0.5-acre site size. A commercial/industrial value for dispersion factor was calculated based the 90% lower confidence limit of the values listed under a site size of 5 acres.

Inhalation was the route that was used for air exposures. Tap water exposure used ingestion and inhalation, the latter using the Schaum (1994) Whole House Exposure Model. The model describes the average indoor air concentration as a result of water use throughout the house. This model considers water use such as washing dishes, bathing, washing clothes, and cooking. The formula is:

$$C_a = \frac{WHF \times C_w \times f}{HV \times ER \times MC}$$

where:

Ca = concentration in air, mg/m^3

Cw = concentration in water, mg/L

WHF = water flow rate in whole house, 890 L/day

HV = house volume, 450 m^3

ER = exchange rate, 10 air changes/day

MC = mixing coefficient, 0.5 (unitless)

f = fraction of contaminant that volatilizes, 0.5 (unitless)

The default values for these parameters were selected from the text of the Schaum (1994) chapter and are listed following the description.

Formulae

The formulae for calculation of the risk-based values are the result of taking the standard exposure equations used in risk assessments and solving for the concentration term. Toxicity values were used to represent the potential toxicity of each compound. These values are obtained from several sources. The source is listed next to each toxicity value. The abbreviations in order of preference are: "i" U.S. EPA's Integrated Risk Information System (IRIS), "h" U.S. EPA's Health Effects Assessment Summary Tables (HEAST), "n" U.S. EPA's National Center for Environmental Assessment (NCEA), "w" withdrawn from IRIS or HEAST, "o" other EPA documents, "r" route extrapolation, and "s" when the toxicity value of a surrogate compound was used based on physicochemical characteristics. The Risk-Based Screening Values are based on a target risk of 1 x 10^{-6} for carcinogens and a Hazard Index of 1.0 for noncarcinogens in each media. The carcinogenic risk of 1 x 10^{-6}, or one excess cancer in one million is standard practice in risk assessment for *de minimis* risk. The target Hazard Index of 1.0 indicates that the noncarcinogenic risk is below a toxicity threshold represented by the reference dose. The basis for each screening value in the table is denoted by "ca" for a carcinogenic endpoint, and "nc" for a noncarcinogenic endpoint. A soil saturation limit was derived using the formula in U.S. EPA, 1996c. A ceiling limit was set at 10^{+5} as a maximum soil concentration. If the risk-based screening value exceeded the saturation limit or the maximum, then the soil screening value was set at the saturation limit (denoted as "sat") or the maximum ceiling limit (denoted as "max") The following formulae were used to calculate the risk-based screening values for each media.

Noncarcinogenic Effects

Residential Soil

$$\frac{(ED_c \times BW_c \times 365 \times THQ)}{(IRA_c \times (1/VF + 1/PEF_r) \times EF_r \times ED_c \times 1/RfDi) + (SA_c \times AF \times ABS \times EF_r \times ED_c \times 0.000001 \times 1/RfDo) + (IRS_c \times EF_r \times ED_c \times 0.000001 \times 1/RfDo)}$$

Commercial/Industrial Soil

$$\frac{(ED_a \times BW_a \times 365 \times THQ)}{(IRA_a \times (1/VF + 1/PEF_o) \times EF_o \times ED_o \times 1/RfDi) + (SA_i \times AF \times ABS \times EF_o \times ED_o \times 0.000001 \times 1/RfDo) + (IRS_o \times EF_o \times ED_o \times 0.000001 \times 1/RfDo)}$$

Ambient Air

$$\frac{(ED_c \times BW_c \times 365 \times THQ \times RfDi \times 1000)}{(IRA_c \times EF_r \times ED_c)}$$

Tap Water

$$\frac{(BW_c \times ED_c \times 365 \times THQ \times 1000)}{\left(\frac{(IRW_c < 3 \times 3) + (IRW_c > 3 \times 3)}{ED_c} \times EF_r \times ED_c \times 1/RfDo\right) + \left(\frac{(890 \times 0.5)}{(450 \times 10 \times 0.5)} \times IRA_c \times EF_r \times ED_c \times 1/RfDi\right)}$$

Carcinogenic Effects

Residential Soil

$$\frac{(AT \times 365 \times TR)}{(InF_adj \times (1/VF + 1/PEF_r) \times EF_r \times SFi) + (SFS_adj \times AF \times ABS \times EF_r \times 0.000001 \times SFo) + (IFS_adj \times EF_r \times 0.000001 \times SFo)}$$

Commercial/Industrial Soil

$$\frac{(AT \times BW_a \times 365 \times TR)}{(IRA_a \times (1/VF + 1/PEF_o) \times EF_o \times ED_o \times SFi) + (SA_i \times AF \times ABS \times EF_o \times ED_o \times 0.000001 \times SFo) + (IRS_o \times EF_o \times ED_o \times 0.000001 \times SFo)}$$

Ambient Air

$$\frac{(AT \times 365 \times TR \times 1000)}{(InhF_adj \times EF_r \times SFi)}$$

Tap Water

$$\frac{(AT \times 365 \times TR \times 1000)}{(IFW_adj \times EF_r \times SFo) + \left(\frac{(890 \times 0.5)}{(450 \times 10 \times 0.5)} \times InhF_adj \times EF_r \times SFi\right)}$$

Four age adjusted factors were calculated for carcinogenic exposure calculations. The formula for each factor is shown below.

Ingestion Factor for Soil

$$\left(\frac{IRS_c \times ED_c}{BW_c}\right) + \left(\frac{IRS_a \times ED_adol}{BW_adol}\right) + \left(\frac{IRS_a \times ED_a}{BW_a}\right)$$

Skin Contact Factor for Soil

$$\left(\frac{SA_c \times ED_c}{BW_c}\right) + \left(\frac{SA_adol \times ED_adol}{BW_adol}\right) + \left(\frac{SA_a \times ED_a}{BW_a}\right)$$

Inhalation Factor

$$\left(\frac{IRA_c \times ED_c}{BW_c}\right)+\left(\frac{IRA_a \times ED_adol}{BW_adol}\right)+\left(\frac{IRA_a \times ED_a}{BW_a}\right)$$

Ingestion Factor for Water

$$\left(\frac{IRW_c < 3 \times 3}{BW_c}\right)+\left(\frac{IRW_a, c > 3 \times 3}{BW_c}\right)+\left(\frac{IRW_a, c > 3 \times ED_adol}{BW_adol}\right)+\left(\frac{IRW_a, c > 3 \times ED_a}{BW_a}\right)$$

Table 1 summarizes the exposure factors that were used to calculate the risk-based screening values.

Table 1. Exposure Factors

Parameter (units)	Value	Abbreviation
Target Cancer Risk	1×10^{-6}	TR
Target Hazard Quotient	1	THQ
Body weight, age 1-6 (kg)	15	BW_c
Body weight adolescent (kg)	43	BW_adol
Body weight, adult (kg)	70	BW_a
Surface area , child (cm^2/day)	2800	SA_c
Surface area , adolescent (cm^2/day)	7500	SA_adol
Surface area , adult resident (cm^2/day)	5700	SA_a
Surface area , adult industrial (cm^2/day)	3300	SA_i
Adherence factor (mg/cm^2)	1	AF
Dermal absorption in soil (volatiles)	0.25	ABS_vol
Dermal absorption in soil (semivolatiles)	0.1	ABS_semi
Dermal absorption in soil (metals)	0.05	ABS_met
Averaging time (years)	70	AT
Inhalation rate (m^3/d)	20	IRA_a
	20	IRA_c
Drinking water ingestion (L/d)	2	IRW_a, c>3
	1	IRW_c<3
	1	IRW_o
Volatilization factor - soil (m^3/kg)	Chemical specific	VF_S
Particulate emission factor (m^3/kg)	9.3E+08	PEF_r
	6.2E+08	PEF_o
Soil ingestion - adolescent & adult resident (mg/d)	100	IRS_a
Soil ingestion - age 1-6 (mg/d)	200	IRS_c
Soil ingestion – commercial/industrial (mg/d)	50	IRS_o
Exposure frequency (d/yr)	350	EF_r
Commercial/Industrial Exposure Frequency (d/yr)	250	EF_o
Exposure duration, age 1-6 (yr)	6	ED_c
Exposure duration, age 7-18 (yr)	12	ED_adol
Exposure duration, adult (yr)	12	ED_a
Commercial/Industrial Exposure Duration (yr)	25	ED_o
Total residential duration (yr)	30	ED_total
Age-adjusted factors (for carcinogens only)		
Ingestion factor for soils ([mg*yr]/[kg*d])	125.050	IFS_adj
Skin contact factor for soils ([cm^2*yr]/[kg*d])	4190.166	SFS_adj
Inhalation factor ([m^3*yr]/[kg-d])	17.010	InhF_adj
Ingestion factor for water ([L*yr]/[kg-d])	1.501	IFW_adj

The formulae for calculating the volatilization factor (VF), particulate emission factor (PEF), and soil screening levels (SSL) are contained in the Soil Screening Guidance: Users Guide (U.S. EPA, 1996c) and are listed below. The assumptions for those calculations are listed in the Soil Screening Guidance: Users Guide. The only factors in this document that were different were the dispersion factor (Q/C) values for residential (64.177) and commercial/industrial (43.07). The Kentucky-specific values for Q/C were estimated based on the 90% Lower Confidence Level of the mean dispersion factor of Climatic Zone VII of Table 3 of the SSL Technical Background Document (U.S. EPA, 1996b). Volatilization Factors are used in the soil exposure scenario to estimate partitioning between soil and vapor in the exposure zone, and the particulate emission factor represents the concentration of respirable particulates in air. The chemical specific values of D_i in the VF calculation were obtained from the U.S. EPA Region 9 Preliminary Remediation Goals Table dated November 1, 2000. Region 9 used several sources: Superfund Exposure Assessment Manual (U.S. EPA, 1988), Subsurface Contamination Reference Guide (U.S. EPA, 1990c), Fate and Exposure Data (Howard, 1991), and the Superfund Chemical Data Matrix (U.S. EPA 1994). Some chemicals required the use of a surrogate for physicochemical data based on chemical structure and characteristics.

The Soil Screening Level uses modeling to estimate soil concentrations that are protective of human health exposure to groundwater with a Dilution and Attenuation Factor of 1. The endpoint that was chosen for the SSL was the MCL from U.S. EPA (2001b) or the risk-based tap water concentration as calculated in the table if an MCL was not available.

Volatilization Factor

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

where

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

and:

Q/C	=	*64.177 (residential)*
		43.07 (commercial/industrial)
T	=	*9.5E+8 seconds*
ρ_b	=	*1.5 g/cm3*
θ_a	=	*0.28 L_{air}/L_{soil}*
D_i	=	*chemical-specific*
H'	=	*H x 41*
H	=	*Henry's Law Constant (chemical-specific)*
θ_w	=	*0.15 L_{water}/L_{soil}*
D_w	=	*chemical-specific*
n	=	*0.43 L_{pore}/L_{soil}*
K_d	=	*chemical-specific*

Particulate Emission Factor

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

where:

Q/C	=	*64.177 (residential)*
		43.07 (commercial/industrial)
V	=	*0.5 (unitless)*
U_m	=	*4.69 m/s*
U_t	=	*11.32 m/s*
F(x)	=	*0.194 (unitless)*

Soil Screening Level

$$SSL(mg/kg) = C_w \left[K_d + \frac{\theta_w + \theta_a \times H'}{\rho_b} \right]$$

where the C_w is the MCL or risk-based tap water value in mg/L from the table.

and:

K_d	=	*chemical-specific*
θ_w	=	*0.3 L_{water}/L_{soil}*
θ_a	=	*0.13 L_{air}/L_{soil}*
H'	=	*H x 41*
H	=	*Henry's Law Constant (chemical-specific)*
ρb	=	*1.5 g/cm3*

Exceptions

There are a few exceptions to the standard procedures described in this document where modifications in the exposure assumptions or toxicity value were necessary to meet a certain class of chemicals.

Metals. Many of the metals only have oral toxicity values listed in IRIS or HEAST. In order to have complete information, it was necessary to extrapolate the oral toxicity values to inhalation exposures as well. The exposure routes were also modified based on the characteristics of metals. Soil exposure included ingestion, dermal exposure, and particulate inhalation. Exposure to tap water considered only ingestion. Elemental mercury, even though it is a metal, was assumed to be a volatile for exposure to soil and water. These conditions fit typical exposure conditions for tap water. If a site has potential exposure to mists containing metals in water, then exposure via inhalation should be considered in a site-specific tap water screening value calculated for the site using the formulae contained in this document.

Gases. Some of the constituents on the table are considered to be gases or vapors at standard temperature. In consideration of their physical state, both soil and water exposure consider only inhalation since their residence time in soil would not be expected to be long for ingestion or dermal exposure.

Extrapolation. Some chemicals had only oral or inhalation toxicity values listed on the Region IX PRGs Table. In those cases, extrapolation was necessary. Literature reviews were done to verify the potential for effects in other media of exposure.

Lead. U.S. EPA has implemented use of the IEUBK Model to estimate environmental levels that will result in a target blood lead level. KYDEP performed a review of lead issues (KYDEP, 1996) and determined that the most appropriate metric for lead risk assessment was the RfD_o and RfD_i derived based on the LOAEL in laboratory rats. For further discussion of lead see the Lead Issues document (KYDEP, 1996). KYDEP also has an action level of 50 ppm in residential or unrestricted use in soil, 400 ppm in commercial or industrial soils, and a tap water action level of 0.015 mg/L that are listed on the table. The soil value of 50 mg/kg was originally developed in the UST program.

MTBE. Methyl t-Butyl Ether had an oral RfD issued by NCEA, which was withdrawn. The RfD was retained and listed as withdrawn on the table. U.S. EPA has a Drinking Water Advisory: Consumer Acceptability Advisory level in water of 20 µg/L to 40 µg/L based on odor and taste, respectively. This is below the carcinogenic and noncarcinogenic risk-based numbers.

PCBs. PCBs also received special consideration. KYDEP has used the high risk value of 2.0 $(mg/kg\text{-}day)^{-1}$ based on the observation that as a mixture of PCBs weathers, the lower chlorinated biphenyls are more likely to degrade, leaving the higher chlorinated biphenyls in a higher proportion. Since the higher chlorinated biphenyl mixture (Arochlor 1260) exhibit more toxicity, the high-risk value was used for the screening values. For noncarcinogenic effects, the table has two mixtures listed. Arochlor 1254 is applied by KYDEP for the higher chlorinated mixtures (Arochlor 1260, 1254, and 1248) and the Arochlor 1016 value is applied to mixtures that are less chlorinated (1242, 1016).

How To Use the Table

When evaluating an area using the screening values, it is useful to develop a Conceptual Site Model to verify that it fits into the assumptions that were used to derive the screening values. The first step is to identify the areas of potential contamination and analyze grab samples for a broad range of potential contaminants (typically the HSL, TAL/TCL, etc.) in several

samples to refine analytical parameters. The contaminants of potential concern are then identified. The potential ecological and human health receptors should be determined and also the potential pathways of exposure.

The screening values table is organized with the toxicity values in the left-hand columns, each one followed by the source of the RfD or Slope Factor. The VOC Column identifies (with "1" being volatile) which compounds use a volatilization factor in the soil exposure. The soil dermal absorption value is shown for each compound, and the Chemical Abstract Service (CAS) registry number and contaminant name are shown. The next four columns represent the risk-based concentration associated with each of the contaminants for soil, air, and water.

The Soil Screening Levels are determined for most volatiles and the compounds listed in the Soil Screening Guidance (U.S. EPA, 1996c). The Dilution and Attenuation Factor (DAF) of 1 is applicable for a screening value where there is the potential for shallow aquifers, karst terranes (a major factor in Kentucky), and areas of significant permeability. It is possible to develop Soil Screening Values for a higher DAF if site-specific information indicates that the depth to groundwater, soil type, and geological formations support that there is significant dilution between the contaminated zone and the groundwater. 401 KAR 100:100 Section 5(5) establishes procedures to modify the SSL based on site-specific conditions.

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Appendix D
Ecological Screening Values

Appendix E
Radionuclide Screening Values

Appendix F
Checklist for Ecological Assessment/Sampling

Checklist for Ecological Assessment/Sampling

I. SITE DESCRIPTION

1. Site Name: _____

   Location: _____

   _____

   County: _____ City: _____ State: _____

2. Latitude: _____ Longitude: _____

3. What is the approximate area of the site? _____

4. Please attach to the checklist USGS topographic map(s) of the site, if available.

5. Are aerial or other site photographs available? ☐ yes ☐ no If yes, please attach any available photo(s).

6. What type of facility is located at the site?

   ☐ Chemical ☐ Manufacturing ☐ Mixing ☐ Waste disposal

   ☐ Other (specify) _____

7. What are the suspected contaminants of concern at the site? If known, what are the maximum concentration levels?

8. Do any potentially sensitive environmental areas exist adjacent to or in proximity to the site, e.g., Federal and State parks, National and State monuments, wetlands, lakes, streams? *Remember, flood plains and wetlands are not always obvious; do not answer "no" without confirming information.*

9. Please provide the source(s) of information used to identify these sensitive areas, and indicate their general location on the site map.

10. The land use on the site is:

_____% Urban
_____% Rural
_____% Residential
_____% Industrial (☐ light ☐ heavy)
_____% Agricultural
(*Crops*:_____)
_____% Recreational
(Describe; note if it is a park, etc.)
_____
_____
_____% Undisturbed
_____% Other

The area surrounding the site is:

_____ mile radius
_____% Urban
_____% Rural
_____% Residential
_____% Industrial (☐ light ☐ heavy)
_____% Agricultural
(*Crops*:_____)
_____% Recreational
(Describe; note if it is a park, etc.)
_____
_____
_____% Undisturbed
_____% Other

11. If known, what is the approximate depth to the water table? _____

12. Is the direction of surface runoff apparent from site observations? ☐ yes ☐ no If yes, to which of the following does the surface runoff discharge? Indicate all that apply.

☐ Surface water ☐ Groundwater ☐ Sewer ☐ Collection impoundment

13. Is there a navigable waterbody or tributary to a navigable waterbody? ☐ yes ☐ no

14. Is there a waterbody anywhere on or in the vicinity of the site?

☐ yes (approx. distance_____) ☐ no

15. Is there evidence of flooding? ☐ yes ☐ no *Wetlands and flood plains are not always obvious; do not answer "no" without confirming information.*

16. Are any threatened and/or endangered species (plant or animal) known to inhabit the area of the site?

☐ yes ☐ no

17. Are there any wooded areas at the site? ☐ yes ☐ no.

18. What percentage or area of the site is wooded? (_____% _____ acres). Indicate the wooded area on the site map which is attached to a copy of this checklist.

19. Is shrub/scrub vegetation present at the site? ☐ yes ☐ no.

20. What percentage of the site is covered by scrub/shrub vegetation? (_____% _____ acres). Indicate the areas of shrub/scrub on the site map.

21. Are there open (bare, barren) field areas present at the site? ☐ yes ☐ no

22. What percentage of the site is open field? (_____% _____ acres). Indicate the open fields on the site map.

23. Based on observations and/or available information, are designated or known wetlands definitely present at the site? ☐ yes ☐ no

24. Please note the sources of observations and information used (e.g., USGS Topographic Maps, National Wetland Inventory, Federal or State Agency, etc.) to make this determination.

25. CONTINUE WITH ECOLOGICAL RISK ASSESSMENT. **YES**_____ **NO**_____

Record weather conditions at the time this checklist was prepared:

DATE: _____

_____Temperature (EC/EF) _____Normal daily high temperature

_____Wind (direction/speed) _____Precipitation (rain, snow)

_____Cloud cover

Completed by _____ Affiliation _____

Additional Preparers _____

Site Manager_____

Date ___

Appendix G
Development of Generic Background Concentrations for Kentucky Soils

Development of Generic Background Concentrations for Kentucky Soils

Background, as defined in 401 KAR 42:005 (definitions codified to support the Underground Storage Tank regulations), means the concentration of substances consistently present in the environment at, or regionally proximate to, a release but outside the influence of the release. There are two types of background:

a) Natural background is the amount of naturally occurring substances in the environment, exclusive of that from anthropogenic sources.

b) Ambient background means the concentrations of naturally-occurring inorganic substances and ubiquitous anthropogenic inorganic substances in the environment that are representative of the region surrounding the site and not attributable to activities on the property.

Since sites undergoing environmental assessment are often found in industrialized and potentially contaminated areas, the determination of site-specific background concentrations is difficult. Generic ambient background values applicable to all sites in Kentucky would be useful for comparison to site data for the purpose of identifying those constituents requiring remedial action (i.e., removal or exposure control). These generic ambient background values would provide a party or VERP applicant an alternative to attempting to identify site-specific background soils in areas that are likely contaminated.

To address this issue, the NREPC used background sample values provided by regulated facilities, as well as background sample values collected by cabinet employees. These samples were collected from areas generally considered to be outside of the influence of site activities, but were potentially impacted by regional or citywide activity. Therefore, these samples represent "ambient," as opposed to "natural," background. From 400 to over 800 samples for each constituent were used in the analysis. For each constituent, a 95% Upper Confidence Limit (UCL) of the arithmetic mean, 60^{th} Percentile, and 95^{th} percentile were calculated. The 95% UCL is the value that represents that the mean of the data set falls below that value with 95% confidence. The 60^{th} and 95^{th} percentiles indicate that 60 percent and 95 percent of the data falls below those values.

The following methodology was employed to calculate ambient background:

1. Values reported as "non-detected" were retained in the database at ½ the reporting limit (USEPA, 1998).

2. As the data sets came from areas having varied uses (e.g., industrial, commercial, residential, agricultural, woodlands, etc.), the probability that some of the samples were taken in contaminated areas is significant. Data sets were tested for outliers by the Grubb's test, and individual samples that had a calculated Z-score above 3.8 were generally removed from the background data set. The Grubb's test formula is as follows:

$$Z = \frac{\left| population\ mean - value\ of\ individual\ sample \right|}{standard\ deviation}$$

3. The descriptive statistics of mean and standard deviation were calculated by standard parametric methods assuming normality and are listed in Table G-1. Parametric methods were used to allow for comparisons between NREPC background values and other published values.

   a. Standard deviation was calculated by the "nonbiased" method employing the formula:

$$S.D. = \sqrt{\frac{\sum \left(X_i - \overline{X} \right)^2}{n-1}}$$

   b. Mean was calculated as the sum of all individual scores divided by the total number of observations.

4. The data sets were analyzed with Lillefor's test for normality. Since the data sets are not normally or log normally distributed, the parameters that are to be used in determining if site samples are consistent with background (i.e. 95% UCL of mean, 60th percentile and 95th percentile) were calculated by nonparametric methods and are listed in Table G-2.

5. The 95% upper confidence limit of the arithmetic mean for each constituent was calculated on the trimmed data set using ProUCL. ProUCL is a statistical package developed by Lockheed Martin under contract with the U.S. EPA.

6. The 60th percentile value is used as the midpoint for each constituent. It was calculated as follows:
   a. The constituent values were ranked in increasing order of magnitude.
   b. The quantity 60(n)/100 was used to identify the measurement with the resulting rank.

7. The 95th percentile value is used as the upper bound value for each constituent and was calculated as follows:
   a. The constituent values were ranked in increasing order of magnitude.
   b. The quantity 95(n)/100 was used to identify the measurement with the resulting rank.

The thallium data were characterized by a large number of non-detects (633 non-detects verses 54 detects). Due to the large number of non-detects, non-detects were <u>not</u> entered as ½ the non-detect concentration. Each non-detect sample was assumed to have a concentration equal to the recorded non-detect concentration. Considering the number of non-detects and the likelihood that the recorded values skew thallium concentrations upward, only the 95th percentile of the total data is cited in table G-2.

Comparison to Background

- The mean site concentration for inorganic constituents must be below the 95% UCL of the mean concentrations of background for inorganic constituents. At least ½ of the data points should be less than the midpoint (60th percentile), and no data point above the upper bound value (95th percentile). The site data should be segregated by surface and subsurface data. The surface and subsurface site data may be compared to the statewide numbers in Table G-2, or to site-specific background samples.

Horizontal and Vertical Extent

401 KAR 100:100 Section 5(4) states that during site characterization, a minimum of two additional sampling locations is required for each sampling point at the edge of an area of concern that exceeds the method detection limit or ambient background and shall be located at a

minimum distance of ten (10) feet from the previous sampling point that had a confirmed exceedance of method detection limits, or ambient background. The following criteria may be used to determine if the sampling point exceeds generic or site-specific ambient background.

- If the value for the individual sample is less than the 95% UCL of the arithmetic mean of background, then no additional samples are required.
- If the sampling point is greater than the 95th percentile of background, then a minimum of two additional sampling points are required.
- If the sampling point is between the 95$^{\%}$ UCL of background and the 95th percentile of background, then the complete dataset needs to be evaluated to determine if two additional sampling locations are required. If at least half of all data points at the edge of the AOC are at or below the 95% UCL of background and the remaining data points are between the 95% UCL of background and the 95th percentile of background, then no additional samples are required. If this criteria is not met, then two additional sampling points are required.

The cabinet may require additional sample locations if the data indicate that the extent of contamination has not been determined.

Literature Cited

United States Environmental Protection Agency (USEPA), 1995. Determination of Background Concentrations of Inorganics in Soils and Sediments at Hazardous Waste Sites. Office of Research and Development. Office of Solid Waste and Emergency Response. EPA/540/S-96/500. December, 1995.

United States Environmental Protection Agency (USEPA), 1998. Statistical Tests for Background Comparison at Hazardous Waste Sites. Supplemental Guidance to RAGS: Region 4 Bulletins – Addition #1. Interim Draft. USEPA Region 4, Waste Management Division. Atlanta, Georgia. November, 1998.

Table G-1. Summary Statistics for Ambient Inorganic Chemicals

Element	Number of Samples	Range (mg/kg)	Mean (mg/kg)	Standard Deviation (mg/kg)
Aluminum	679	1290 - 38,100	10969	5462.9
Arsenic	539	0.059 - 55.5	8.9	7
Barium	756	6.14 – 1160	111.3	92.4
Beryllium	696	0.061 - 3.57	0.8	0.5
Cadmium	701	0.004 - 9.46	0.68	1.4
Chromium	771	2.83 - 168	20.5	13.9
Cobalt	649	0.29 - 67.6	11.9	8.1
Copper	729	0.49 - 636	18.9	39.7
Iron	697	222 - 86,900	22456	13269.7
Lead	808	0.03 - 284	30	31.3
Manganese	685	8.43 - 5100	1017	854.9
Mercury	459	0.007 - 0.721	0.06	0.1
Nickel	716	0.39 - 83.7	20.9	13.1
Selenium	714	0.001 - 3.93	0.94	0.7
Silver	697	0.006 - 5.2	0.42	0.6
Thallium	633	0.13 - 28		
Vanadium	679	4.82 - 92.1	26.9	11.8
Zinc	721	6 - 470	55	46.3

Table G-2. Generic Statewide Ambient Background for Kentucky

Element	**Mean (mg/kg)**	**95% UCL of Mean (mg/kg)**	**60th Percentile (mg/kg)**	**95th Percentile (mg/kg)**
Aluminum	10969	11314	10800	21000
Arsenic	8.9	9.4	8.3	21.2
Barium	111.3	116.9	100	241
Beryllium	0.8	0.83	0.75	1.8
Cadmium	0.68	0.78	0.27	3.9
Chromium	20.5	21.3	19.3	40
Cobalt	11.9	12.4	13.1	25.1
Copper	18.9	21.3	13.8	41.7
Iron	22456	23284	22000	47600
Lead	30	33	20.9	84.6
Manganese	1017	1071	948	2620
Mercury	0.06	0.07	0.059	0.14
Nickel	20.9	21.7	20.2	46.8
Selenium	0.94	0.99	1.38	2.1
Silver	0.42	0.45	0.257	1.2
Thallium				7.95
Vanadium	26.9	27.7	27.3	48.6
Zinc	55	57	48.6	115