Kentucky Risk Assessment Guidance

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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 in Appendix B, is a four-part process. The first step, Data Collection and Evaluation, assesses the available data and, using a screening process, 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 non-carcinogenic 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. It's during this step that Contaminants of Concern (COCs) are identified for each receptor. For a given receptor (e.g., a teen recreational user), a COPC evaluated over all pathways must contribute at least 1 x 10^{-6} risk to total excess lifetime cancer risk to be considered a COC. For a given receptor, when the total non-carcinogenic hazard index evaluated over all COPCs and pathways exceeds HI=1, a COPC is generally considered a COC if its total HQ evaluated over all pathways contributes at least 0.1 to the total HI. If different target organs are affected, it is typical to further refine COC selection on a target organ basis. When a target organ HI exceeds 1, any COPC contributing an HQ of at least 0.1 across all pathways to that target organ HI would be considered a COC for the given receptor. COCs are identified during a Baseline Human Health Risk Assessment (Section 2.2).

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. It 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 initial screening

against default risk-based screening values and incorporating more site-related data as the assessment progresses. 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, enough samples should be collected to meet the needs of those statistical tests. Human health risk assessment is described in Section 2. The subsections within Section 2 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 details the ecological risk assessment procedures.

SECTION 2. HUMAN HEALTH RISK ASSESSMENT

This section provides methods for screening environmental data to identify COPCs, 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 224.1-400 (18)-(21).

Figure 1. Flowchart for Residential Cleanup Options

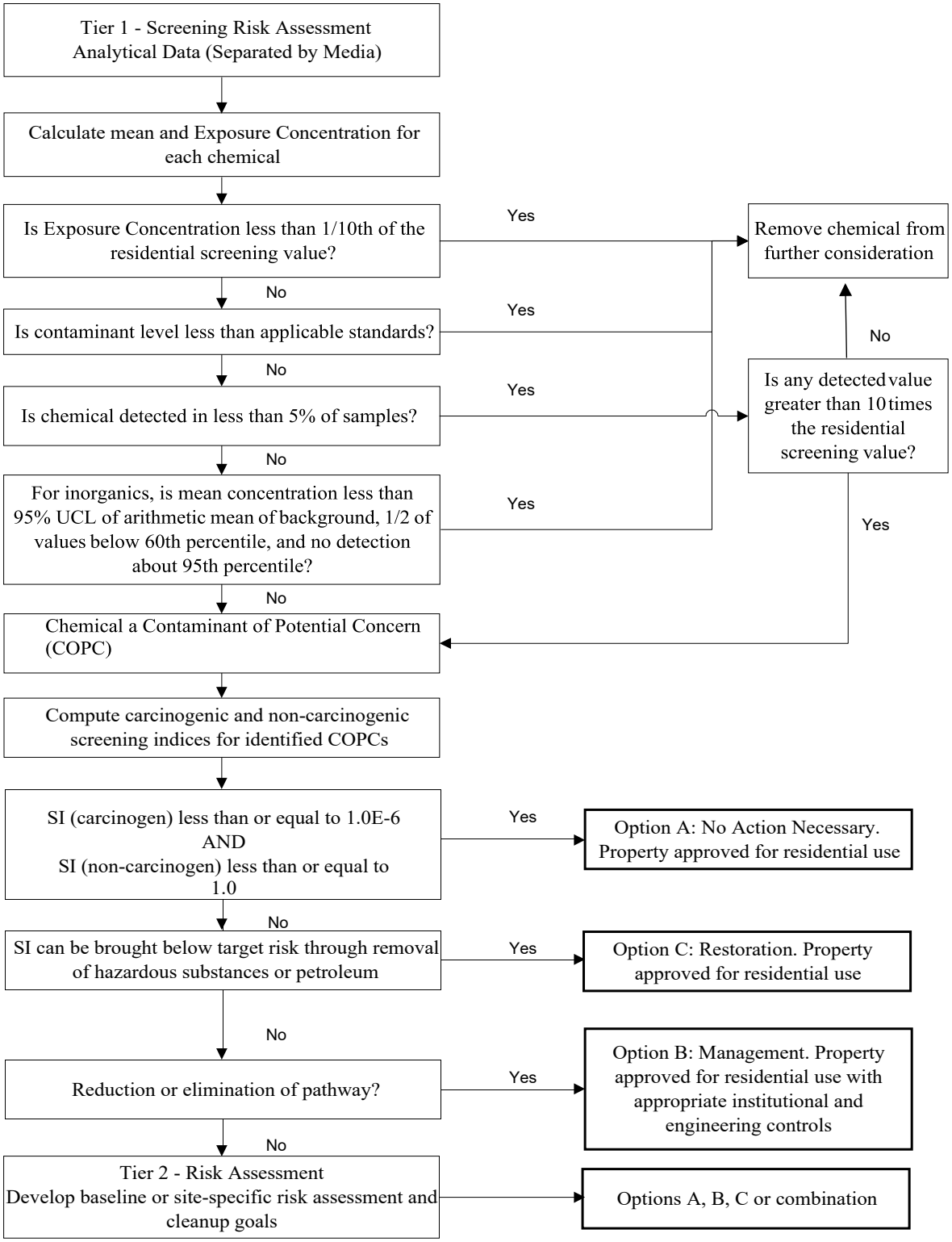
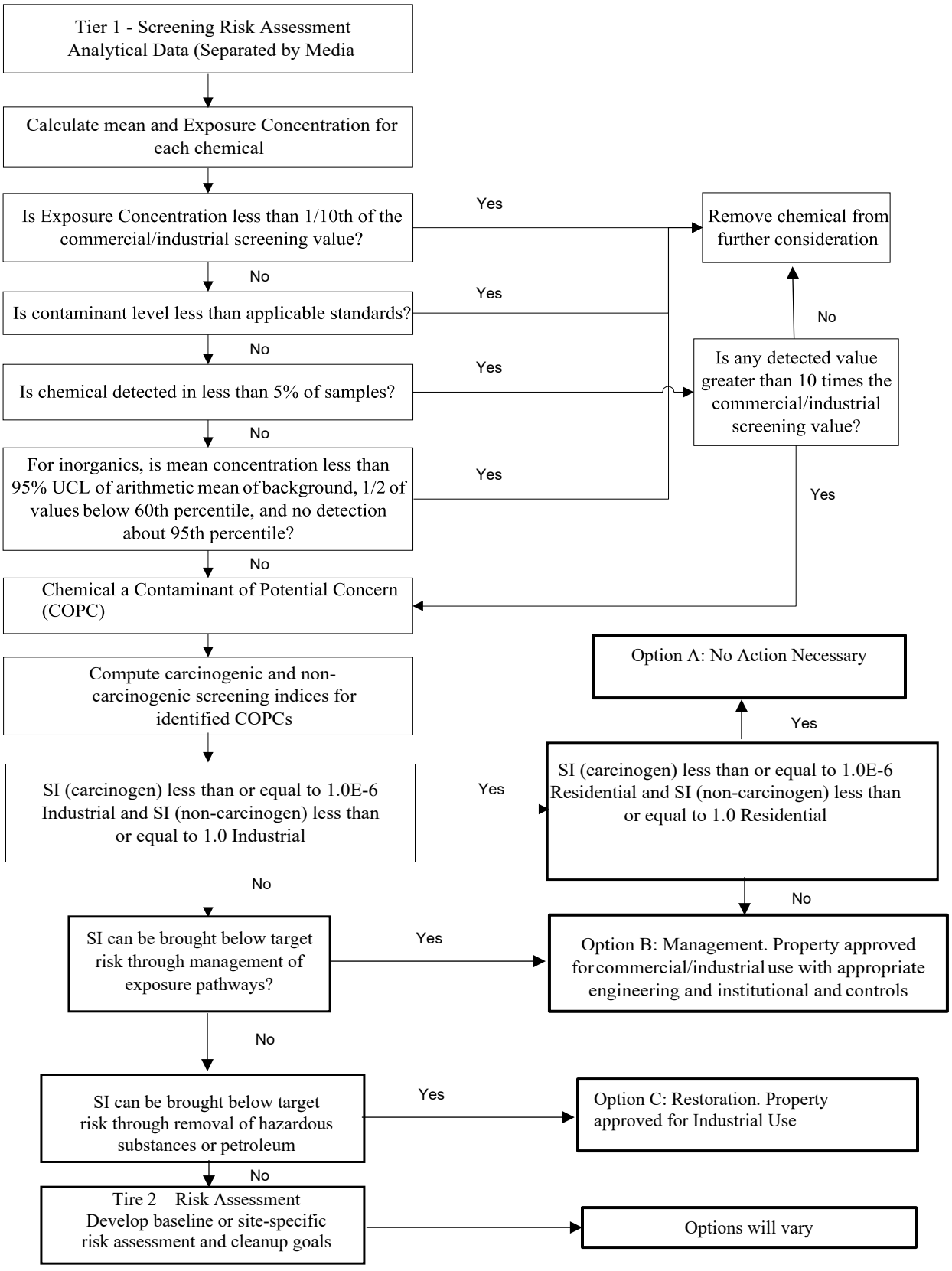


Figure 2. Flowchart for Commercial/Industrial Cleanup Options



Section 2.1. Tier 1. 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 COPCs. For this guidance, hazardous substance or petroleum shall have the meaning as defined in KRS 224.1-512. 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 *Supplemental Guidance to RAGS: Calculating the Concentration Term* (U.S. EPA, 1992). Use all samples from the property and site(s). It is recommended that the latest version of ProUCL be used to calculate the 95% UCL (do not use ½ detection limit). 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).

3. Compare the Exposure Concentration to $1/10^{th}$ of the residential or commercial/industrial U.S. EPA Regional Screening Level (RSL), as appropriate. Use the version of the RSL tables corresponding to TR=1E-06 and THQ=1. Assuming an environmental covenant is not already in place that prohibits future residential use, all surface soil exposure concentrations should be compared to residential screening values. When screening, use carcinogenic effects for arsenic and use Toxicity Equivalency Factors (TEFs) to calculate a Toxicity Equivalency Quotient (TEQ) for dioxins. Instead of 1/10th of the screening value for lead, use 200 mg/kg for residential soils, and 800 mg/kg for commercial/industrial soils. Compare the Exposure Concentration to the following standards when applicable: Maximum Contaminant Levels (MCLs) for tap water and groundwater (401 KAR 8:250, 401 KAR 8:300), National Ambient Air Quality Standards (NAAQS) for air, and Surface Water Standards (401 KAR 10:031) 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 5 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 COPC 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 2 in Appendix D. In addition to the site mean being less than the 95% UCL of background, at

least half of the samples should fall below the 60th percentile listed on Table 2 and no sample should exceed the 95th percentile listed on Table 2. Site-specific background may be determined using Appendix D guidance in accordance with 401 KAR 100:030 Section 7 (2)(a). The cabinet may approve other statistical methods proposed by the Voluntary Environmental Remediation Program (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 COPCs that exceed the values in all applicable screens (i.e., is not eliminated by any screen). Highlight or denote with bold text the screen that eliminates a compound from further evaluation, if applicable. Table 1 is an example of the summary table for soil.

Table 1. Summary of Results of Tier 1 Screening

Hazardous Substance	Mean	Exposure Concentration	1/10th Screening Value	Frequency of Detection	95% UCL of Background	COPC?
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 COPCs into carcinogens and non-carcinogens. Radionuclides should be evaluated in the Tier 1 Screen using the U.S. EPA screening values found at https://epa-prgs.ornl.gov/radionuclides/, if applicable. Calculate a Screening Index for all COPCs by dividing the Exposure Concentration by the chemical and scenario-specific U.S. EPA Regional Screening Level (RSL) located at https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide and then by summing the carcinogens and non-carcinogens:

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

For non-carcinogens, a Screening Index of less than 1.0 indicates that exposure to all non-carcinogenic 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. The sum of the indices for the individual media should then be computed. The VERP applicant or party may calculate a site-specific screening level for a Tier 1 risk assessment screen, subject to cabinet approval.

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 non-carcinogens 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 2. Baseline Human Health Risk Assessment

The following steps should be followed when completing a baseline human health assessment:

1. Based on the COPCs that were identified in Tier 1 (Risk-Based Screening), conduct a baseline risk assessment.

2. Risk assessment guidance documents from the U.S. EPA should be used in preparing the risk assessment. Primary guidance includes the following documents:

    - *Risk Assessment Guidance for Superfund* (RAGS). *Volume I. Human Health Evaluation Manual (Part A)* (U.S. EPA, 1989)

    - *Risk Assessment Guidance for Superfund: Volume I – Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals)* (U.S. EPA, 1991)

    - *Soil Screening Guidance: Technical Background Document* (U.S. EPA, 1996a)

    - *Soil Screening Guidance: Users Guide* (U.S. EPA, 1996b)

    - *Soil Screening Guidance for Radionuclides: Users Guide* (U.S. EPA, 2000)

    - *Supplemental Guidance to RAGS: Region 4 Bulletins* (U.S. EPA, 2001c)

    - *Region 4 Human Health Risk Assessment Supplemental Guidance* (U.S. EPA, 2018a)

    - Other supporting guidance documents 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 COPCs that were identified in Section 2.1. List the toxicity values that are associated with the COPCs. The hierarchy for sources of toxicity values is:

    - U.S. EPA's Integrated Risk Information System (IRIS)
    - Provisional Peer Reviewed Toxicity Values (PPRTVs) derived by EPA's Superfund Health Risk Technical Support Center (STSC)
    - EPA's Office of Pesticide Programs (OPP) Human Health Benchmarks for Pesticides (HHBPs)
    - Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels (MRLs)
    - California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA)
    - Screening toxicity values in an appendix to certain PPRTV assessments
    - U.S. EPA's Health Effects Assessment Summary Tables (HEAST)
    - Other sources may include World Health Organization (WHO) documents, publications in the primary toxicological literature, or values withdrawn from IRIS or HEAST, with cabinet approval.

6. Calculate the risk and hazard associated with the receptors that were identified in Step 4 and determine COCs for that receptor (these COCs are ultimately the focus of any required remedial action).

7. Identify and describe the uncertainties associated with the risk assessment. Potential sources of uncertainty include COPC 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 1 and 2 risk evaluations. Recoverable water from soil borings can also be evaluated with groundwater numbers (RSLs, 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 Soil Screening Level(s) in accordance with Kentucky Guidance for Groundwater Assessment Screening as referenced in 401 KAR 100:030 Section 7(2)(b). Radionuclides should be evaluated using the Soil Screening Levels found at https://epa-prgs.ornl.gov/radionuclides/, 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 does not pose a threat to groundwater.

Identify if the site is in an area where contamination of a karst aquifer is possible, if the contaminant(s) could result in a dense non-aqueous phase liquid (DNAPL) layer, or if 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

- 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.

- 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.

- Submit Corrective Action Plan for approval as described in 401 KAR 100:030 Section 8.

Section 2.5. Selection of Remedial Goals

- The primary goals of remediation are protection of human health at the hazard index of 1.0 and the carcinogenic risk of 1 x 10^{-6} at the point of exposure, and protection of ecological health. Ecological risks are addressed in Section 3.

- 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.

- The intended use must be ensured through physical and institutional controls and described in the Corrective Action Plan. U.S. EPA RSLs can be used as remedial goals or remedial goals can be derived based on Cabinet 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 D or may be derived using the Appendix D guidance in accordance with 401 KAR 100:030 Section 7 (2)(a).

- The applicable risk-based remedial goals for surface soils are the residential and commercial/industrial U.S. EPA RSLs or those calculated based on cabinet approved receptor-specific values. Risk-based concentrations for radionuclides can be found at https://epa-prgs.ornl.gov/radionuclides/. 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 institutional and physical controls if the contaminant is not a source of groundwater contamination. If contaminants are in the surface soil horizon, this can be attained through the use of cover (e.g., 6 inches of pavement such as asphalt or concrete, 12 inches of soil, or other approved method). For example, if the commercial/industrial soil number is 1.3 mg/kg 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.

- 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, and results of the Screening Index.

- 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 COPCs, calculation of 95% UCL).

SECTION 3. ECOLOGICAL RISK ASSESSMENT

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; U.S. EPA, 2018b) were consulted in the process of developing this guidance. If it has been determined that an Ecological Risk Assessment (ERA) is necessary (401 KAR 100:030 Section 7 (2)(c)), this section along with Figure 4 provide the outline for that process.

The flowchart in Figure 3 is the process for determining if an ERA needs to be completed. This process would be completed prior to conducting a screening level ecological risk assessment (SLERA). It is possible that an ecologist or wildlife specialist may need to be consulted at certain stages of this process (e.g., to identify federal/state threatened or endangered species, to determine suitability of site to serve as habitat for plants and wildlife). In Figure 3, "disturbed ground" refers to highly urbanized or commercial-industrial sites where potentially once valuable habitat has been modified in such a way as to make it unattractive and potentially unusable by ecological receptors (TCEQ, 2018). If receptors exist in these areas, it may be difficult to determine whether any observed negative effects are the result of exposure to site-related contaminants, non-site-related contaminants or other environmental stressors. The term "sensitive environmental area" refers to areas that may require special protection due to the presence of critical habitat for threatened or endangered species or other valued resource (e.g., wetlands) or because it has special protected status under the law (U.S. EPA,1997a). The checklist in Appendix C should be used at the beginning of this process to identify features of the environmental setting that are related to ecological receptors.

Figure 3. Flowchart for Determining an Ecological Risk Assessment

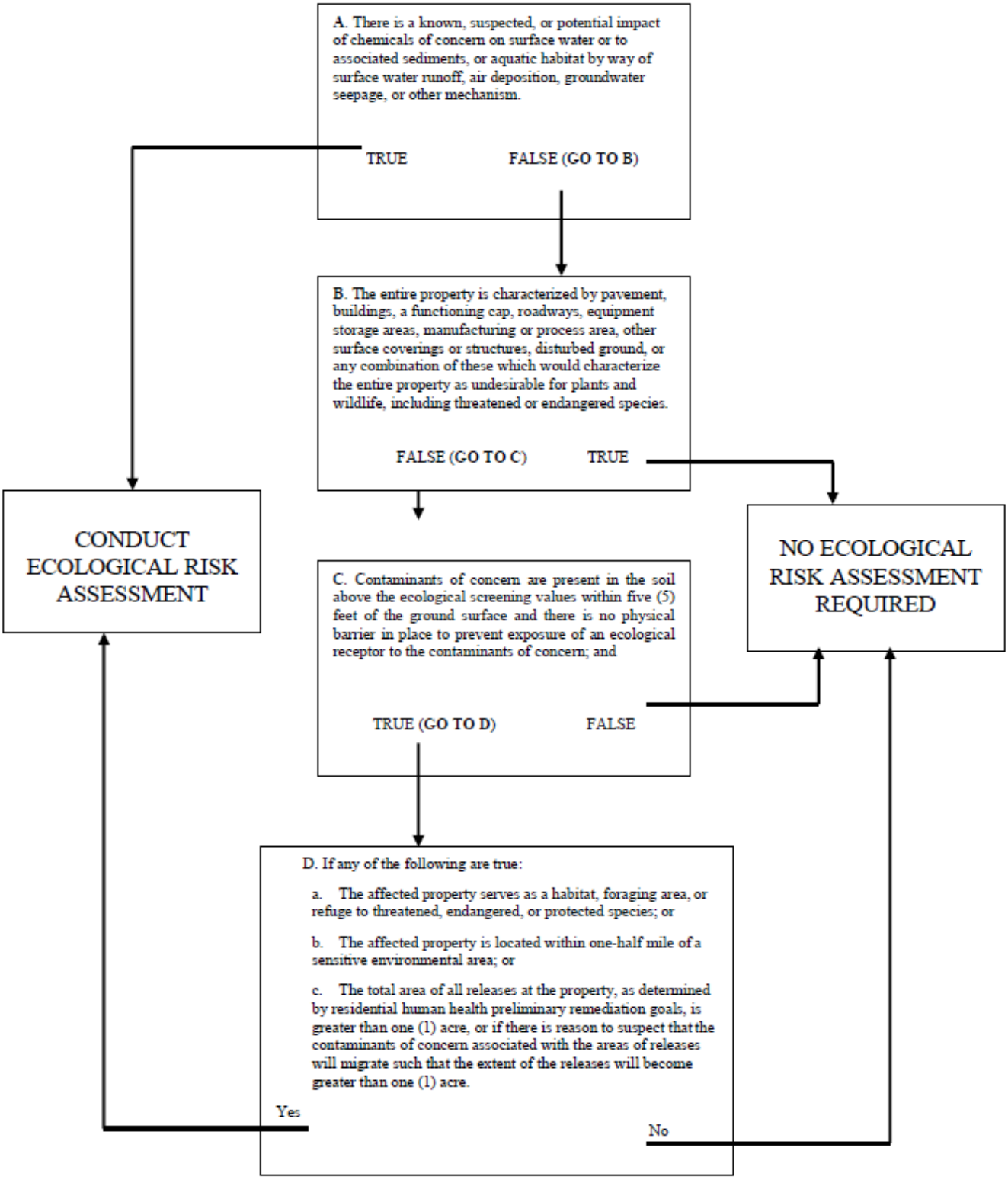
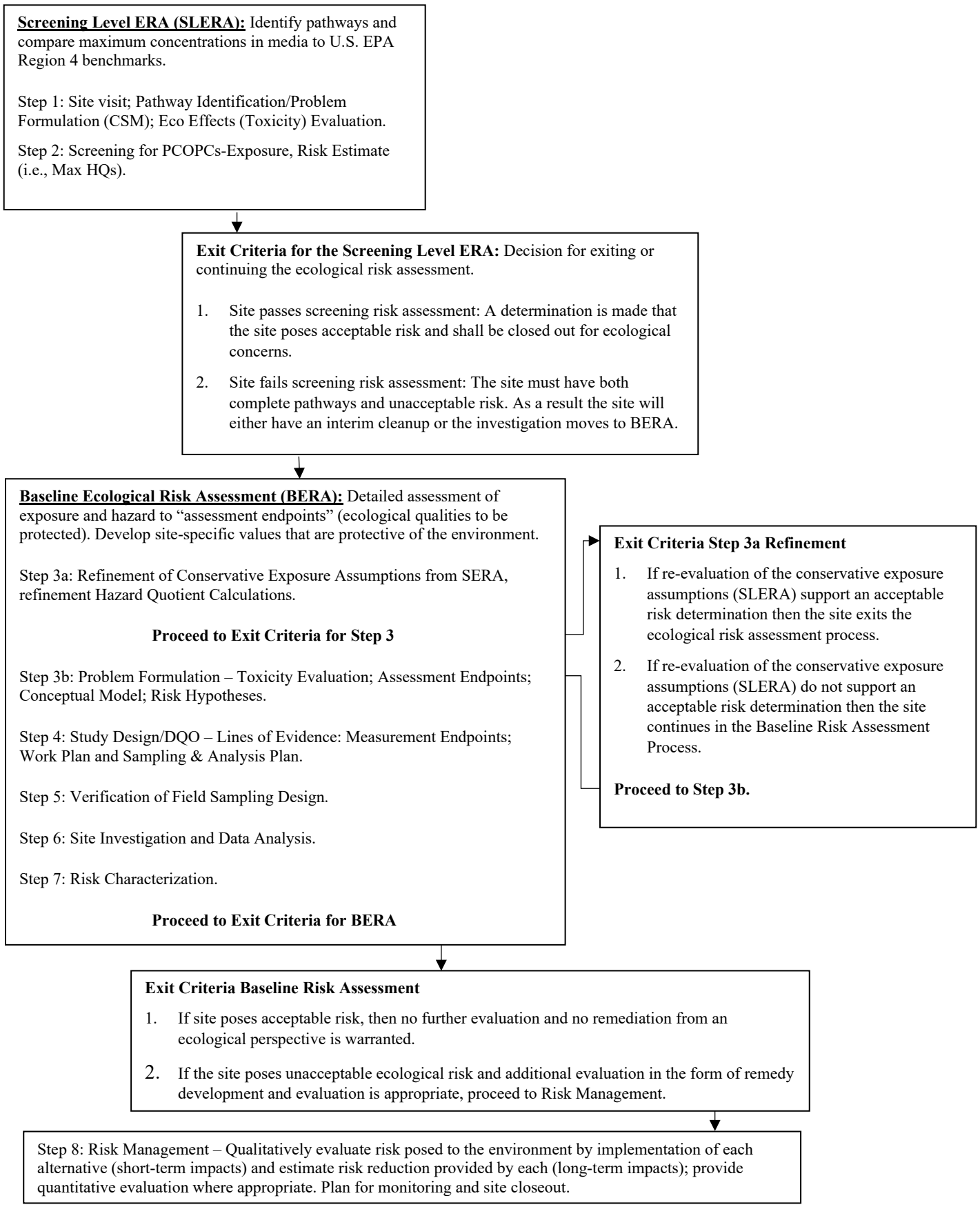


Figure 4. Ecological Risk Assessment Flow Chart



The ERA process (includes both screening and baseline ecological risk evaluations) is based on two major elements: characterization of exposure and characterization of effects. These provide the focus for conducting the five general phases of ecological risk assessment: planning, problem formulation, analysis, risk characterization, and risk management.

1. 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 timeframe for the assessment is set.

2. 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.

3. 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.

4. 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.

5. 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.

ERAGS (U.S. EPA, 1997a) further identifies eight specific steps to be followed when conducting an ecological risk assessment. These steps are as follows:

1. Screening-level Problem Formulation and Ecological Effects Evaluation

2. Screening-level Exposure Estimate and Risk Calculation

3. Baseline Problem Formulation

4. Study Design and Data Quality Objectives (DQO) Process

5. Field Verification of Sample Design

6. Site Investigation and Analysis of Exposure and Effects

7. Risk Characterization

8. Risk Management

Section 3.1. Screening-Level Ecological Risk Assessment

The purpose of the screening-level ecological risk assessment (SLERA) 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. The SLERA consists of two steps:

1. Screening-Level Problem Formulation and Ecological Effects Evaluation

2. Screening-Level Preliminary Exposure Estimate and Risk Calculation

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

A. Preliminary Conceptual Site Model (CSM). As part of 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 Assessment Endpoints. Based on preliminary CSM, the ecological risk assessor should identify the potentially complete exposure pathways. During the screening level ecological risk assessment, site-specific assessment endpoints (ecological qualities to be protected such as reproduction, survival, etc.) have not yet been developed. Consequently, as specified in ERAGs (U.S. EPA, 1997a), screening-level benchmark values have been developed which "are based on generic assessment endpoints (e.g., protection of aquatic communities from changes in structure or function) and are assumed to be widely applicable to sites around the United States". 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. In most cases, the most recent version of the U.S. EPA Region 4 screening-level benchmarks should be used.

C. Identify Preliminary Chemicals of Potential Concern (PCOPCs). As part of Step 2, determine (PCOPCs) by eliminating chemicals that don't exceed relevant Region 4 benchmark values from further evaluation:

- Background Comparisons. Compare the mean concentration for inorganic constituents in on-site soils 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 60^{th} percentile, and no data point should be above the 95^{th} percentile. Generic

inorganic background values are listed in Appendix E. Site-specific values may be derived using Appendix E in accordance with 401 KAR 100:030 Section 7 (2)(a).

- Screening Table Comparison. Compare the maximum concentration on site for substances in a given exposure medium to the Region 4 screening-level benchmarks 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). This comparison entails dividing the maximum concentration of a contaminant by its media-specific benchmark value to generate a Max Hazard Quotient (U.S. EPA, 2018b). The Max HQ values should be listed in a media-specific table along with the contaminant's frequency of detection in that medium (e.g., soil), background value (soil only), inorganic mean concentration, range of detected values, location of maximum detected value, screening value used, the frequency at which the screening value was exceeded and whether the contaminant is retained as a PCOPC as well as the justification for retaining or not retaining it.

D. Retaining PCOPCs. 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 (inorganics only), then retain the constituent as a PCOPC. If there is not a screening-level benchmark, then further evaluation of the potential risk will be required and the contaminant moves to Step 3A below. Several Region 4 screening values are available that are protective of bioaccumulative effects (wildlife-based values). When available, contaminants should be screened against both the direct contact and wildlife-based screening values. Detected chemicals that have known synergistic effects or that are known to bioaccumulate but don't have a wildlife-based screening value must be retained as PCOPCs. 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 the SLERA, 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. Baseline Ecological Risk Assessment

The baseline ecological risk assessment is a continuation of the screening ERA. It consists of Steps 3-8:

3. A. **Refinement of PCOPCs**. At this stage of the process, multiple lines of evidence are used to help identify those chemicals most likely to be of ecological concern. PCOPCs identified during Steps 1 and 2 should be screened against the most current version of the Region 4 Refinement Screening Values (RSVs), when available (U.S. EPA, 2018b). RSVs are slightly less conservative screening levels that are more likely to reflect more realistic conditions. If Region 4 RSVs are unavailable for a particular contaminant/media combination, then it will be necessary to develop an RSV. Region 4 guidance documents are available to assist with this process. If available, Region 4 wildlife-based screening levels may be used as RSVs for bioaccumulative PCOPCs; however, in some instances, food chain modeling may be required to develop these values. In all cases, the 95 % UCL should be calculated for all PCOPCs identified during Steps 1 and 2. The 95% UCL exposure point concentration is then divided by the RSV to generate a refinement Hazard Quotient. More than one exposure point concentration may need to be calculated if more than one habitat is present. A COPC refinement screening table is then generated for each remaining affected media. The table should contain the following information: frequency of detection, maximum detected concentration, refinement screening value (RSV), source of RSV, frequency exceeding RSV, refinement HQ value, 95% UCL concentration and COPC status (yes or no). The frequency of detection screen can be used to eliminate a contaminant if it is detected in less than 5% of samples and only in one to two media; however, contaminants detected at concentrations significantly above RSVs should not be eliminated since they may be indicative of a hot spot or source zone. The spatial relationship of detections exceeding an RSV should also be evaluated relative to the home range of potential receptors. COPCs identified during Step 3A are carried forward to Step 3B. Chemicals that exceed state ARARs (e.g., state ambient water quality criteria) cannot be screened out during this process and must be carried forward to Step 3B.

   In addition to the RSV screen, if sensitive or protected species, including but not limited to those that are on the Federal and/or State Threatened and Endangered Species List, are known or likely to be present at the site, or if habitat supporting those species exists at the site, then more conservative screening should be conducted for those specific species. PCOPCs in each affected media that may represent a potentially complete exposure

pathway for a particular sensitive or protected species should be screened against NOAEL-based values using the 95% UCL. If a contaminant exceeds the NOAEL-based value for a given medium, then the average of a NOAEL-based and LOAEL-based value for that contaminant should be calculated. The 95% UCL should then be compared to this average value. If the 95% UCL does not exceed the average value and also passes the RSV screen, it can be removed from the COPC list (TCEQ, 2018). If the 95% UCL exceeds the average value, then that contaminant must be retained as a COPC to be carried forward to Step 3b, and the sensitive or protected species must be evaluated further in the baseline risk assessment.

B. **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
- 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)
- Discussion of uncertainties should include the lack of site concentration or toxicity data for COPCs

4. **Study Design and Data Quality Objectives**. 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:

- Identification of measurement endpoints (e.g., natural population structure, feeding, resting, and reproductive cycles).
- 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.

5. **Field Verification of Sampling Design**. 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.

6. **Site Investigation and Analysis of Exposure and Effects**. Step 6 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).

7. **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.

8. **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.

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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 than 6 years Child 6 to 16 years Adult Indoor Adult Worker (8 hour workday) OutdoorWorker Construction Worker	 200 mg/day* 100 mg/day* 100 mg/day* 50 mg/day* 100 mg/day* 330 mg/day*
Exposure Frequency: Resident General Workers (industrial) Construction Worker Outdoor Worker Child Recreational	 350 days/year* 250 days/year* 250 days/ year* 225 days/year* 140 days/year (or site-specific*)
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult Adult Worker	 6 years* 10 years* 10 years* 25 years*
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific*
Body Weight: Child less than 6 years Child 6 to 16 years Adult	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022
†U.S. EPA Exposure Factors Handbook, September 2011

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 6 years Child 6 to 16 years Adult Worker (general, outdoor, construction)	 2373 cm^2/day* (weighted average mean values for head, forearms, hands, lower legs, and feet) 6032 cm^2/day* (weighted average mean values for head, forearms, hands, lower legs, and feet) 6032 cm^2/day* (weighted average mean values for head, forearms, hands, lower legs, and feet) 3527 cm^2/day* (weighted average of mean values for head, forearms, and hands)
Exposure Frequency: Resident General Workers (industrial) Construction Worker Outdoor Worker Adult Recreational Child Recreational	 350 days/year* 250 days/year* 250 days/ year* 225 days/year* 104 days/year (or site-specific*) 140 days/year (or site-specific*)
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult Adult Worker	 6 years* 10 years* 10 years* 25 years*
Dermal Absorption Factor	0.1 Semivolatiles (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 Resident/Recreator Child Resident/Recreator Adult Outdoor Worker Composite Worker Construction Worker	 0.2 mg/cm^2 ‡ 0.07 mg/cm^2 ‡ 0.12 mg/cm^2 † 0.12 mg/cm^2 † 0.3 mg/cm^2 ‡

Body Weight: Child less than 6 years Child 6 to 16 years Adult	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022
†U.S. EPA Exposure Factors Handbook, September 2011
‡U.S. EPA 2002, OSWER 9355.4-24

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 (Child) Resident (Adult) Trespasser Worker (Indoor and Outdoor)	 10 m^3/day‡ 20 m^3/day‡ 20 m^3/day 60 m^3/day (2.5 m^3/hr, 8 hour day)‡
Exposure Frequency: Resident General Workers (industrial) Construction Worker Outdoor Worker Adult Recreational Child Recreational	 350 days/year* 250 days/year* 250 days/ year* 225 days/year* 104 days/year (or site-specific*) 140 days/year (or site-specific*)
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult Adult Worker	 6 years* 10 years* 10 years* 25 years*
Particulate Emission Factor: Residential Commercial/Industrial	 9.3 x 10^8 m^3/kg 6.2 x 10^8 m^3/kg
Body Weight: Child less than 6 years Child 6 to 16 years Adults	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022

†U.S. EPA Exposure Factors Handbook, September 2011

‡U.S. EPA PRG for Radionuclides at Superfund Sites User's Guide, July 2020

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 (Child) Resident (Adult) Trespasser Worker (Indoor and Outdoor)	 10 m^3/day‡ 20 m^3/day‡ 20 m^3/day 60 m^3/day (2.5 m^3/hr, 8 hour day)‡
Exposure Frequency: Resident General Workers (industrial) Construction Worker Outdoor Worker Adult Recreational Child Recreational	 350 days/year* 250 days/year* 250 days/ year* 225 days/year* 104 days/year (or site-specific*) 140 days/year (or site-specific*)
Fraction of Soil from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult Adult Worker	 6 years* 10 years* 10 years* 25 years*
Volatilization Factor	Derived using Equation 8 of the *Soil Screening Level Guidance User's Guide* (U.S. EPA 1996)
Body Weight: Child less than 6 years Child 6 to 16 years Adult	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022
†U.S. EPA Exposure Factors Handbook, September 2011
‡U.S. EPA PRG for Radionuclides at Superfund Sites User's Guide, July 2020

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 6 years old Adult Adult Worker (up to an 8-hour workday)	 0.78 liter/day* 2.5 liters/day* 1.25 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 6 years Child 6 to 16 years Adult Adult Worker	 6 years* 10 years* 10 years* 25 years*
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 6 years Child 6 to 16 years Adult	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022
†U.S. EPA Exposure Factors Handbook, September 2011
‡ U.S. EPA 1991, OSWER Dir 9285.6-03

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: Child less than 6 years Child 6 to 16 years Adult	 120 ml/hour* 124 ml/hour* 98 ml/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 6 years Child 6 to 16 years Adult	 6 years* 10 years* 10 years*
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 6 years Child 6 through 16 years Adults	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022
†U.S. EPA Exposure Factors Handbook, September 2011
‡U.S. DOI, 1973.
§U.S. EPA, 2018.

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 less than 6 years Child swimmer 6 through 16 years Adult swimmer Child wader 1 through 6 years Child wader 6 through 16 years Adult wader	 0.6365 m^2/day* 1.3350 m^2/day* 1.9652 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 2004) Appendix B. For organics in water, modeled Kd values should be used in place of experimentally measured values.
Exposure Frequency: Swimming Child and Adolescent Wading Adult Wading	 45 days/year‡ 140 days/year (or site-specific§) 52 days/year (or site-specific§)
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult	 6 years§ 10 years§ 10 years§
Dermal Absorbed Dose per Event (DA_{event})	Calculated using *RAGS Part E* (U.S. EPA, 2004)
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 6 years Child 6 through 16 years Adult	 15 kg§ 44 kg* 80 kg§
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens§

*U.S. EPA Exposures Factor Handbook, 2011(weighted mean)

†U.S. DOI, 1973.
‡U.S. EPA, 2018.
§U.S. EPA RSL User's Guide, May 2022

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 less than 6 years Child 6 through 16 years Adult	 0.6365 m^2/day* 1.3350 m^2/day* 1.9652 m^2/day*
Exposure Time Child less than 6 years Adult	 0.54 hours/event† 0.71 hours/event†
Dermal Permeability factor (Kp)	Use *RAGS Part E* (U.S. EPA 2004) Appendix B. For organics in water, modeled Kd values should be used in place of experimentally measured values.
Exposure Frequency: Residents Workers in the workplace	 350 days/year† 250 days/year†
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult Adult Worker	 6 years† 10 years† 10 years† 25†
Dermal Absorbed Dose per Event (DA_{event})	Calculated using *RAGS Part E* (U.S. EPA, 2004)
Ingestion Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 6 years Child 6 through 16 years Adult	 15 kg† 44 kg* 80 kg†
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens†

*U.S. EPA Exposures Factor Handbook, 2011(weighted mean)
†U.S. EPA RSL User's Guide, May 2022

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/hour
Exposure Time Child less than 6 years Adult	 0.54 hours/event* 0.71 hours/event*
Exposure Frequency: Residents Workers in the workplace	 350 days/year* 250 days/year*
Fraction of Water from a Source Impacted by a Release	1.0 (unitless)
Exposure Duration: Child less than 6 years Child 6 to 16 years Adult Adult Worker	 6 years* 10 years* 10 years* 25*
Inhalation Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 6 years Child 6 through 16 years Adult	 15 kg* 44 kg† 80 kg*
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens*

*U.S. EPA RSL User's Guide, May 2022

†U.S. EPA Exposures Factor Handbook, 2011(weighted mean)

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 6 years Child 6 to 16 years Adult	6 years† 10 years† 10 years†
Inhalation Absorption Factor	1.0 (unitless) or chemical-specific
Body Weight: Child less than 6 years Child 6 through 16 years Adult	15 kg† 44 kg‡ 80 kg†
Exposure Averaging Time	25,550 days for carcinogens Exposure Duration (years) x 365 days/year for non-carcinogens†

*Schaum, et al., 1994.

†U.S. EPA RSL User's Guide, May 2022

‡U.S. EPA Exposures Factor Handbook, 2011(weighted mean)

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).

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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. INTRODUCTION

1.0 Overview

1.0.a General Problem at site

1.0.b Site-specific objectives of risk assessment

1.1 Scope of Risk Assessment

1.1.a Complexity of risk assessment and rationale

1.1.b Overview of study design

2. IDENTIFICATION OF STRESSORS OF POTENTIAL CONCERN

2.0 General Site-Specific Data Collection Considerations

2.0.a Preliminary identification of potential human exposure

2.0.b Modeling parameter needs

2.1 General Site-Specific Data Evaluation Considerations

2.1.a Steps used (including statistical methods used for evaluation and data selection)

2.1.b Criteria employed in evaluating data

2.1.c Discussion of data uncertainty

2.2 Stressor Analytical Data (Complete for All Media)

2.2.a Listing of analytical methods used

2.2.b Evaluation of chemical limits

2.2.c Evaluation of qualified and coded data

2.2.d Contaminants in field and laboratory blanks

2.2.e Tentatively identified compounds

2.2.f Further limitation of number of stressors

2.2.g Uncertainties, limitations, gaps in quality of collection or analysis

2.3 Summary of Stressors of Potential Concern

3. EXPOSURE ASSESSMENT

3.0 Characterization of Exposure Setting

3.0.a Summary of Physical Setting

3.0.b Potentially Exposed Individuals, Populations, and Communities (Human)

3.0.b.1 Relative locations of individuals, populations, and communities with respect to site

3.0.b.2 Current land use

3.0.b.3 Potential alternate future land uses

3.0.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. TOXICITY ASSESSMENT

4.0 Toxicity Information for Non-carcinogenic Effects (Human Health)

4.0.a Appropriate exposure periods for toxicity values

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

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

4.0.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)

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

4.0.f Absorption efficiency considered

4.1 Toxicity Information for Carcinogenic Effects

4.1.a Exposure averaged over a lifetime

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

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

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

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

4.2 Stressors for Which No EPA Toxicity Values are Available

4.2.a Sources of values

4.2.b Qualitative evaluation

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

4.3 Uncertainties Related to Toxicity Information

4.3.a Quality of the individual studies

4.3.b Completeness of the overall data base

4.4 Summary of Toxicity Information

5. RISK CHARACTERIZATION

5.0 Current Land-use Conditions (Human Health)

5.0.a Carcinogenic risk of individual stressors in individual pathways

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

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

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

5.0.e Non-carcinogenic hazard index (individual stressors, all pathways)

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

5.1 Future 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 Non-carcinogenic hazard index (individual stressors, all pathways)

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

5.2 Uncertainties

5.2.a Site-specific uncertainty factors

5.2.a.1 Definition of physical setting

5.2.a.2 Model applicability and assumptions

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

5.2.b Summary of toxicity assessment uncertainty

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

5.2.b.2 Derivation of toxicity value including completeness of

overall database

5.2.b.3 Potential for synergistic or antagonistic interactions

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

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

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

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

5.3.c Incorporation of studies into the overall risk characterization

5.4 Summary Discussion and Tabulation of the Risk Characterization

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

5.4.b Types of health risk of concern

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

5.4.d Presentation of qualitative information on toxicity

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

5.4.f Magnitude of the carcinogenic and non-carcinogenic risk estimates

5.4.g Magnitude of chronic and subchronic risk estimates

5.4.h Major factors contributing to risk

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

5.4.j Exposed population and community characteristics

5.4.k Comparison with site-specific health studies

5.4.l Comparison of chemical concentrations with natural background

6. SUMMARY AND CONCLUSIONS

6.0 Stressors of Potential Concern

6.1 Exposure Assessment

6.2 Toxicity Assessment

6.3 Risk Characterization

6.4 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

Checklist for Ecological Assessment/Sampling

Checklist for Ecological Assessment/Sampling

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 D

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 (US EPA, 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:

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

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:

$$S.D. = \sqrt{\frac{\sum(x_i - \overline{x})^2}{n-1}}$$

    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 not 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 E-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 E-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