9.0 RISK ASSESSMENT

This Section of the HSCA Guidance describes the methods and procedures for performing a Human Health Risk Assessment (Section 9.1) and Ecological Risk Assessment (Section 9.2).

9.1 Human Health Risk Assessment

This section describes the steps that should be followed to perform Human Health Risk Assessments (HHRA) under HSCA. Any variations from this Guidance must be approved in writing by DNREC-SIRS prior to inclusion in submittals. This guidance is based primarily on the US EPA Risk Assessment Guidance (RAGS) and incorporates the use of the Risk Assessment Information System (RAIS), a web-based risk assessment tool. DNREC-SIRS recommends the use of RAIS to perform risk calculations due to its wide availability, ease of use and the regular updates provided by the software developer. Other risk assessment software or variation from RAIS must be preapproved by DNREC-SIRS prior to their use on a site by site basis. Also, any changes to previously approved risk calculators must be reviewed and approved by DNREC-SIRS prior to use and on a site by site basis. This Guidance overlaps with several other sections of the HSCA guidance and references are provided to the applicable sections as needed.

9.1.1 Glossary

This section provides a listing of the technical terms and a brief description used in the text of the HHRA Section. Several of the definitions appear in the Delaware Regulations Governing Hazardous Substance Cleanup.

Background Level: the concentration of substances widely present in the soil, sediment, air, surface water or groundwater in the vicinity of a facility, or at a comparable reference area, due to natural causes or human activities other than releases from, or activities on, the facility, as determined by the Department. Please note that typically, site specific background values are not utilized within the HSCA program.

Baseline Risk Assessment: is an analysis of the nature and probability of adverse health effects in humans who may be exposed (currently or in the future) to hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action).

Commercial/ Industrial Land Use: Under this type of land use, workers are exposed to contaminants at a commercial area or industrial site. This scenario applies to those individuals who work on the site. Under this land use, workers are expected to routinely be exposed to contaminated media. Exposure duration may be lower than that under the residential scenarios, because it is generally assumed that exposure is limited to 8 hours a day for 250 days per year.

Composite Worker: The composite worker exposure scenario refers to adults who could potentially be exposed to shallow soil during activities at the site. These activities include a combination of general office activities and soil disturbing activities limited to the top 2 feet. Examples of general office activities include any activity that is conducted inside of a building.

Excavation Worker: The excavation worker exposure scenario refers to adults who could potentially be exposed to shallow and deep soil during infrequent excavation activities at the site. These activities could include placement or repair of utilities or other construction activities involving digging.

Exposure Scenario: Exposure scenarios are tools to help develop estimates of exposure dose and risk. Exposure scenarios typically include data, assumptions, inferences and professional judgment. Exposure scenarios can be determined for various exposure pathways and can show how data can be used to estimate risk. The Exposure Factors Handbook from US EPA is one of several tools used in drafting exposure scenarios.

Indoor Worker: The indoor worker exposure scenario refers to adults who could potentially be exposed to the shallow soil and tap water during activities at the site. These activities could include general office activities.

Maximum Observed Concentration (MOC): The highest concentration for a specific contaminant detected in an environmental medium. This value is determined through a review of the analytical sample results.

Outdoor Worker: The outdoor worker exposure scenario refers to adults who could potentially be exposed to the shallow soil during site activities. These activities could include soil disturbance of the top 2 feet.

Recreator: The recreator exposure scenario refers to people who spend a limited amount of time at the site while playing, fishing, hunting, hiking, or engaging in other outdoor activities for pleasure. This includes what is often described as the ‘trespasser” or “site visitor” scenario. Since all sites do not provide the same opportunities, recreational scenarios must be developed on a site-specific basis.

Resident: The resident or the residential exposure scenarios and assumptions should be used whenever there are or may be occupied residences on the site. Under this land use, residents are expected to be in frequent, repeated contact with the contaminated media. The assumptions in this case account for daily exposure over the long term and generally result in the highest potential exposures and risk.

9.1.2 Human Health Risk Assessment Overview

Human Health Risk Assessments can be performed on HSCA sites at several stages. An Initial Screening can be performed based on the results of the Facility Evaluation (FE) or a Phase II Environmental Site Assessment (ESA), if the Phase II is determined to be equivalent to FE by DNREC-SIRS. A detailed HHRA is performed based on Remedial Investigation (RI) findings. The detailed steps for these two assessments are provided in their respective sections.

9.1.3 Initial Screening

Initial Screening can be considered a preliminary risk assessment based on the limited data obtained through a FE or an equivalent Phase II ESA. The purpose of the Initial Screening is to determine whether a Site poses a potential threat to human health, welfare and the environment under current and potential future conditions, based on the limited data collected under a FE. The Initial Screening can be performed by a HSCA Certified consultant and submitted to DNREC-SIRS for review or can be performed by DNREC-SIRS. The three potential outcomes of the Initial Screening process are: (a) determination that the Site does not pose an unacceptable risk under its current use and warrants the issuance of a Conditional No Further Action (CNFA) letter, (b) determination that there has been a release on the Site and a requirement for further evaluation of the Site under HSCA, or (c) determination that the Site does not pose an unacceptable risk under current and potential future use and no action under HSCA is necessary. The following are the steps involved in the Initial Screening Process and a flow diagram showing the steps are presented in Appendix 9.1.

Step 1: Submit a Phase II Investigation, Facility Evaluation, Site Inspection or equivalent investigation for the property performed by a HSCA certified consultant or an environmental professional as defined in EPA 560-F-14-005. The final rule defines an environmental professional as someone who possesses sufficient specific education, training, and experience necessary to exercise professional judgment to develop opinions and conclusions regarding conditions indicative of releases or threatened releases of hazardous substances on, at, in, or to a property, sufficient to meet the objectives and performance factors of the rule. Submit a Phase I, if available, along with all pertinent data.

Step 2: DNREC-SIRS reviews the report and determines if it is equivalent to an FE investigation.

Step 3: If it is determined that the report is not equivalent to a FE, DNREC-SIRS may request additional samples to be collected to make the investigation equivalent.

Step 4: If it is determined that the report is equivalent to an FE, the MOC for each detected contaminant in their respective environmental media, is compared to the current HSCA Screening Level. The HSCA Screening Levels can be found at the DNREC-SIRS's website.

Step 5: If the MOC for each individual contaminant does not exceed the respective HSCA Screening Level, then SIRS will conclude that the property does not pose a risk above the acceptable standard or above the threshold background standard, and the property will not be required to enter the HSCA program and become a site at this time. A letter summarizing the decision will be sent to the property owner. This letter does not preclude any future actions to be taken on the property should DNREC-SIRS receive new evidence of a release on the property. If the property is already a site under HSCA it will be administratively closed.

Step 6: If the MOC for any contaminant is above the HSCA Screening Level, DNREC-SIRS will evaluate the potential risk pathways and exposure scenarios based on the current condition of the property. Groundwater MOCs may also present a risk for the groundwater to indoor air pathway. If the groundwater MOC for any volatile constituent as defined in Section X exceeds the Groundwater Screening Level, the COPC should be carried to the next step in the vapor intrusion assessment process. This is to account for the possibility that the MOC in groundwater may eventually flow under an existing building or a building may be constructed over the location in the future.

For more information on evaluating risk pathways and exposure scenarios, please refer to Section 9.1.4.1 Planning and Scope of the Risk Assessment. The current condition refers to the property "as-is" with no remedial action being conducted and/or no change in property use. At this time DNREC-SIRS will assign a "DE number" and the property will be considered a Site.

Step 7: If there is a plan to change the use of the property, the Site must be further evaluated by DNREC-SIRS through the HSCA process. The type of site the property will become under the SIRS program (i.e., Brownfields, VCP or HSCA) will be dependent on the property ownership and property details.

Step 8: If the current "as-is" condition of the property is going to be maintained, a risk determination should be performed by DNREC-SIRS or a HSCA certified consultant using RAIS. The risk determination should be performed using the current exposure scenarios and the MOC for each contaminant. For the vapor intrusion evaluation for sub-slab gas, please use the most recent version of the Johnson and Ettinger Model. For more specific information on how to use RAIS, please refer to the RAIS website tutorial.

Step 9: If the cumulative risk calculated in Step 8 exceeds the DNREC-SIRS acceptable risk values of 1×10^{-5} or a Hazard Index of 1, the Site must be further evaluated through the DNREC-SIRS HSCA process.

Step 10: If the risk calculated in Step 8 does not exceed the DNREC-SIRS acceptable risk values under the current exposure scenario, the Site may be eligible for a Conditional No Further Action (CNFA). This determination is based on the maintenance of the current property use and "as-is" condition. Should the use change or DNREC-SIRS receives additional information regarding a release of hazardous substance on the Site, further evaluation through the DNREC-SIRS HSCA process will be required.

9.1.4 Baseline Human Health Risk Assessment

This section of the guidance will describe the process for completing a comprehensive baseline HHRA as a part of the Brownfield Investigation (BFI), as part of the Remedial Investigation (RI), or as a stand-alone document under certain situations. The baseline risk assessment is an analysis of the potential adverse health effects (current and future) caused by a hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action). Any deviation from this standard procedure including bioavailability, sub-chronic risk factors, and acute risk are subject to written pre-approval by DNREC-SIRS and before inclusion within submittals.

An important goal of this guidance is to promote consistency, accuracy, and completeness in the risk assessment reports and to facilitate the DNREC-SIRS review. Once the report is approved by DNREC-SIRS, the input factors used in the risk assessment calculations will be considered final for the purposes of issuing a Certificate of Completion of Remedy. Thus, future changes in default exposure factors, toxicity data or other values set and adopted by the EPA will not in general require a recalculation of risk. However, if there are compelling reasons, DNREC-SIRS, at its discretion, may require re-evaluation of risk.

9.1.4.1 Planning and Scope of the Risk Assessment

The planning stage of a risk assessment should begin early in the Remedial Investigation and include a discussion of goals and expectations between the risk assessor and DNREC-SIRS. Persons performing the risk assessment should be involved with the preparation of the Conceptual Site Model (CSM) as it relates to risk assessment. The CSM should include VI considerations. The CSM shall be used to depict all potential releases (i.e., suspected sources of contamination), all potentially contaminated environmental media, exposure routes, and actual and potential receptors that may be exposed to the contaminants released at the site. The use and grouping of exposure units should also be discussed and agreed upon at this stage. The data necessary for the risk assessment shall be considered when drafting the Sampling and Analysis Plan (SAP) for the number, location and analytical requirements for environmental samples in each identified exposure unit. The HSCA Investigation Guidance will provide more specifics on the SAP and CSM.

The risk assessment shall have a written scope which will reflect the complexity of the site and should be included in the CSM, which is subject to approval by DNREC-SIRS. The scope of the risk assessment should address the following items initially in the CSM and as more data becomes available these items should be updated:

- Exposure Units
- Exposure Pathways
- Receptors
- Exposure Factors
- Sampling and Analysis, Data Needs
- Software to be used for statistics, risk calculation and fate and transport models

9.1.4.1.1 Exposure Units

Exposure units at the site reflect areas of the site that may be grouped together based on current and reasonably predicted future use and potential for exposure, or for a particular environmental media (i.e., soil, groundwater etc.) that a receptor may come in contact through current or future site use. The CSM shall describe potential exposure units with dimensions and locations. Data for each exposure unit should be grouped separately from other exposure units. For example, a shallow soil exposure point concentration for residential exposure scenario should be separate from a deep soil exposure point concentration, which may be used for construction and/or utility worker exposure scenario. Another example of an exposure unit is the lot size (i.e. default ¼ of an acre or other proposed lot size) for a proposed residential development, for which exposure point concentration should be calculated separately. If there are separate operable units proposed for a site, then they should be evaluated as separate exposure units. The exposure units proposed in the CSM are subject to DNREC-SIRS approval.

9.1.4.1.2 Exposure Pathways

The exposure pathways should be identified in the CSM for all probable current and future site use scenarios using Table A: Selection of Exposure Pathway. Any contaminated media including soil, soil-gas, groundwater, sediment, and surface water where the contaminants are detected above HSCA Screening Levels, should be included in risk assessment. For example, for groundwater there may not be a current complete exposure pathway because there is not a potable well at or near the site, but there is a potential future pathway if a well is installed. Therefore, the groundwater pathway should be considered as a future complete pathway. For vapor, if an elevated soil gas sample is closer than 100 feet to the proposed building or if a preferential pathway is discovered, then the vapor intrusion pathway should be considered for VI applicable chemicals.

9.1.4.1.2.1 Receptors

Receptors under both the current and future site use scenarios should be evaluated. The potential receptors include the following: resident, indoor worker, outdoor worker, composite worker, excavation worker, recreator, farmer, trespasser and any other potential site specific receptors. The RAIS calculator does not have a default trespasser risk calculation because it is highly dependent upon the individual site characteristics, the surrounding area demographics, and the level of security. Current exposures are likely to be higher at inactive sites than at active sites because there is generally little supervision of abandoned facilities. At most active sites, security patrols and normal maintenance of barriers, such as fences, tend to limit (if not entirely prevent) trespassing. When modeling potential future exposures in the baseline risk assessment, however, existing fences should not be considered a deterrent to future site access. DNREC-SIRS should be consulted for site specific input parameters for the trespasser scenario prior to use.

9.1.4.1.2.2 Default Assumptions for Each Receptor

For each of the receptors, the RAIS calculator uses specific assumptions of exposure frequency, exposure time and exposure duration that are built into the calculation to achieve the best estimate of risk that is reflective of the exposure of each receptor. Additionally, only specific exposure pathways are evaluated based on the receptor. In order to effectively evaluate the potential receptors, an understanding of those assumptions is needed. Provided below is a table illustrating the default exposure assumptions for each receptor in RAIS. Please note that this table is not all inclusive. For specific information on each receptor, please refer to RAIS. Additional exposure scenarios other than those presented within the table will be considered on a site specific basis and must be approved by DNREC-SIRS prior to use. Any modification to the default assumptions must be preapproved by DNREC-SIRS prior to use on a site specific basis. Because RAIS is frequently updated, please confirm that the assumptions provided below are the most current prior to use.

	Resident	Indoor Worker	Outdoor Worker	Composite Worker	Excavation Worker	Recreator
Exposure Frequency (days per year)	350	250	225	250	20	75
Exposure Time (hours per day)	24	8	8	8	8	1
Exposure Duration (years)	Total: 26 Child: 6 Adult: 20	25	25	25	1	Child: 6 Adult: 20
Weight (kg)	Child: 15 Adult: 80	80	80	80	80	Child: 15 Adult: 80

Provided below is a table illustrating the exposure pathways that RAIS evaluates for each receptor. The evaluation of the fish consumption pathway is performed on a site specific basis and is not typically evaluated for DNREC-SIRS sites. Please include each potential pathway within the site's Conceptual Site Model if these are potential exposure pathways for the site. For specific information, please refer to RAIS.

Receptor	**Exposure Pathway**				
	Soil	**Air**[3]	**Tap**[4] **Water**	**Surface Water**	**Fish**
Resident	X	X	X		X
Indoor Worker	X	X	X[1]		
Outdoor Worker	X	X			
Composite Worker	X	X			
Excavation Worker	X	X			
Recreator	X[2]			X	

[1] Indoor Worker water exposure is assumed to be industrial water
[2] Recreator soil exposures are assumed to be soil/sediment
[3] Air is for indoor concentration. Risk associated with soil gas and sub-slab must be evaluated with the Johnson & Ettinger Model.
[4] The provided tap water category is for the evaluation of groundwater. The term" tap water" was used to be consistent with the RAIS terms. Evaluation of groundwater consumption is needed to determine if a groundwater restriction is needed or not. DNREC-SIRS is not requesting an evaluation of public water.

Use of any other receptors and the associated parameters should be pre-approved by DNREC-SIRS.

9.1.4.1.3 Sampling and Analysis Considerations

The number of samples analyzed at a HSCA certified laboratory should be representative of the site based on the exposure scenario and size of the site. Specific information on the sampling requirements and analysis will be provided in the HSCA Investigation guidance. However, every effort should be made to collect and analyze a minimum of 10 samples from each soil exposure unit (i.e., shallow soil and deep soil). First, samples should be screened for full TCL/organics and any site specific COCs. This is typically performed by the DNREC-SIRS

Screening Laboratory however; a HSCA Certified Laboratory can also perform the screening. Other methods or laboratories must be approved by DNREC-SIRS prior to use. Based on the results of the screening, contaminants of potential concern (COPC) at the site for each of the exposure units should be selected for analyte specific analysis with DNREC-SIRS approval. However, a select number of samples should be analyzed for full TAL/TCL at a fixed lab to confirm the screening analysis. For example, if arsenic is the COPC in shallow soil as indicated by screening, then a minimum of 10 samples should be analyzed for arsenic. DNREC-SIRS may at its discretion allow a lower number of samples, however, use of maximum detected concentrations or non-parametric analysis is required to determine Exposure Point Concentrations.

9.1.4.1.4 Hazard Assessment

The hazard assessment phase of the risk assessment will screen out substances that may be present in the specific media, but do not meet the regulatory definition of "release". This is done through the determination of contaminants of potential concern. In the hazard assessment phase, data is collected and evaluated to identify the chemical hazards. The origin of any data to be used in the risk assessment must be explained and documented in the text. While sampling results from multiple phases of the investigation may be combined for the risk assessment, mixing of different data types (screening and laboratory) in tables, graphs and maps should be avoided.

Determination of Contaminants of Potential Concern (COPCs):

The first step in the hazard assessment is to determine the contaminants of potential concern (COPCs) for the exposure area. It is assumed that the data used in the risk assessment was previously evaluated and meets the QA/QC requirements set forth in the DNREC QAPP. Compare the maximum observed concentration (MOC) for each exposure unit to the appropriate value in the HSCA Screening Level Table. DNREC-SIRS uses a single table for contaminant screening that combines background, risk-based values and applicable, relevant and appropriate values in soil, ground water, and soil gas. If soil gas/sub-slab data is not available, then groundwater data can be used to determine the potential for a vapor intrusion risk. Please review the HSCA Screening Level Table for more details. If the MOC exceeds for groundwater screening level, then groundwater results should be evaluated with the J&E Model for vapor intrusion. The HSCA Screening Level Table is updated on a semi-annual basis, generally in January and July. When the MOC exceeds the HSCA Screening Value, then the analyte becomes a COPC for the risk assessment. If not, it will not be considered in the risk characterization. Removal of any data, and the rationale, from the hazard assessment process must be documented in the risk assessment report.

The vapor intrusion pathway assessment requires an additional step in hazard assessment. This additional step is called the multiple lines of evidence approach. All of the data sources including soil gas, sub-slab soil gas, indoor air and ambient (outdoor) air, and other factors should be weighed against each other to determine if a complete pathway from the source to indoor air exists. Although individual results may indicate a risk even to the receptor, the weight of evidence may indicate that the pathway is incomplete. If the preponderance of evidence indicates that vapor intrusion is occurring, then the COPC are retained in the risk assessment process. However, if the evidence does not indicate that VI is occurring then these chemicals are screened out of the risk assessment process. For example, if ambient air and indoor air are elevated but there are no exceedances of the sub-slab or soil gas values, then there is a preponderance of evidence that vapor intrusion is not occurring. For a more detailed discussion, please see Interstate Technical and Regulatory Council (ITRC) Vapor Intrusion document.

Occasionally, contaminants can either be present or present at higher concentrations in the duplicate sample of a corresponding sample. If a duplicate sample of one sample has a detect but the corresponding sample is non-detect for that contaminant, the calculated average of the two samples should be used to determine whether or not that contaminant is a COPC. Also, if the duplicate sample has a higher concentration of the detected contaminant, the calculated average concentration should be used to determine whether the contaminant is a COPC.
At sites in New Castle County, a special procedure will apply to aluminum, arsenic, chromium, cobalt, iron, manganese and vanadium in soil. See Appendix 9.3 “Two Sample Hypothesis Testing”.

All COPCs should be summarized in Table B: *Selection of Chemicals of Potential Concern.* All analytes with positive detections in laboratory results should be included in Table B along with the selected COPC. Please refer to Appendix 9.2 for a copy of the Table B template.

9.1.4.1.5 Exposure Assessment

The purpose of the exposure assessment is to estimate the magnitude of actual and/or potential human exposures, the frequency and duration of these exposures, and the pathways by which humans are potentially exposed. This is specific to the environmental medium and receptor for each exposure unit. When fate and transport models are used to estimate exposure, the report shall present pertinent information needed to verify the model and to recreate the output. Required information includes input parameters and assumptions. The model must be submitted as well.

Risk assessments performed under HSCA shall retain the default RAIS exposure assumptions. However, DNREC-SIRS will review proposals to substitute site-specific assumptions, especially in the case of infrequent used exposure scenarios, such as construction worker, trespasser or recreator. Submission for review must be done prior to submission of the draft risk assessment. Also, any changes to previously approved risk calculators must be reviewed and approved by DNREC-SIRS prior to use and on a site by site basis.

9.1.4.1.5.1 Exposure Point Concentrations

The Exposure Point Concentrations (EPCs) are the concentrations of the COPCs in the environmental media at the point of human exposure. For soil, in most instances, the EPCs to be used in risk calculations will be the 95% UCL of the mean of the COPC analytical data set. The maximum concentration should be used when there is an insufficient number of samples to calculate a 95% UCL or at DNREC-SIRS’s discretion. However, on a case by case basis, and in consultation with DNREC-SIRS prior to use, analytical screening results from the DNREC-SIRS laboratory maybe incorporated in the calculation of the EPCs. DNREC-SIRS recommends the use of ProUCL to calculate the 95% UCL due to its wide availability, ease of use and the regular updates provided by US EPA. Other statistical software must be preapproved by DNREC-SIRS prior to their use on a site by site basis. Please use the most current version of ProUCL. ProUCL is available as a free download from the US EPA. The ProUCL output pages shall be included in the appendices of the Risk Assessment report. The ProUCL input files shall be submitted in digital format with descriptive file names. Selection of the EPCs will be summarized in Table C: Exposure Point Concentration (EPC). The RAIS output file includes all of the factors included in the risk calculation. Therefore, DNREC-SIRS does not require separate tables for this purpose as does RAGS. However, the RAIS output file is not labeled. Therefore, the RAIS output file must be manually labeled with the site name, exposure unit, exposure scenario and risk scenario. The labeled output shall be included in an appendix to the risk assessment report.

9.1.4.1.6 Exposure Point Concentrations for Groundwater

EPC for groundwater should be at a potential future receptor such as a drinking water well near the most contaminated part of the plume at the site or portion of the site. This is a conservative approach but generally the remedial action selected for sites where there is no current drinking water receptor is an institutional control, such as a covenant on the property deed restricting groundwater use. Whether an active groundwater remedy is needed should be evaluated under certain criteria and will be discussed under HSCA guidance for feasibility study. EPC for groundwater discharging at a surface water body near the site should be determined through modeling for groundwater to surface water loading calculations.

9.1.4.1.7 Exposure Point Concentrations for Vapor Intrusion

Many times EPCs for vapor intrusion (VI) are based on the maximum soil gas or sub-slab results because of the background issues related to indoor air samples. Use of indoor air data is problematic due to the high likelihood of indoor sources or outdoor ambient sources of VOCs. If indoor air concentrations are determined to be from a sub-surface source, indoor air data is the preferred source of data to calculate risk. Soil gas data is preferred when there is a suspected indoor air source.

9.1.4.1.8 Toxicity Assessment

The risk assessment shall be performed using the default toxicity values used in RAIS, except for VI which was described in the section above. The toxicity assessment component of the baseline risk assessment considers: the types of adverse health effects associated with chemical exposures; the relationship between magnitude of exposure and adverse effects; and related uncertainties such as the weight of evidence of a particular chemical's carcinogenicity in humans. Since RAIS updates toxicity values without notice, the date that the risk calculation is based on shall be included on the output file. Once the risk assessment is approved, the values in the risk calculation are “set” for as long as the risk assessment remains operable. That is, “new information” shall not be taken to include a change in the slope factor or reference dose. DNREC-SIRS does not require that the risk assessment report include discussion of the health effects of individual chemicals. Human health risk assessment performed for DNREC-SIRS under HSCA programs shall address chronic risks only unless otherwise directed by DNREC-SIRS.

9.1.4.1.8.1 Relative Bioavailability

In most cases, the toxicity of an ingested chemical depends, in part, on the degree to which it is absorbed from the gastrointestinal tract into the body. Because oral reference doses (RfDs) and cancer slope factors (CSFs) are generally expressed in terms of ingested dose (rather than absorbed dose), accounting for potential differences in absorption between different exposure media can be important to site risk assessments (U.S. EPA, 1989). This is true for all chemicals, but is of special importance for metals. This is because metals can exist in a variety of chemical and physical forms, and not all forms of a given metal are absorbed to the same extent. For example, a metal in contaminated soil may be absorbed to a greater or lesser extent than when ingested in drinking water or food. Thus, if the oral RfD or CSF for a metal is based on studies using the metal administered in water or food, risks from ingestion of the metal in soil might be underestimated or overestimated. Even a relatively small adjustment in oral bioavailability can have significant impacts on estimated risks and cleanup goals.

Inclusion of relative bioavailability factors in risk calculations are subject to approval by DNREC-SIRS. DNREC-SIRS on a site specific basis may consider the relative bioavailability in the toxicity assessment if relevant site specific data supporting the relative bioavailability can be provided to DNREC-SIRS's satisfaction. If a consultant would like to consider bioavailability on a site specific basis, all information on how it will be assessed must be presented for approval prior to including within reports. This is performed on a site by site basis.

9.1.4.2 Risk Calculators

DNREC-SIRS strongly recommends the use of the software Risk Assessment Information System (RAIS) to perform risk calculations due to its wide availability, ease of use and the regular updates provided by the software developer. The methods, procedures and tools for performing a human health risk assessment are found on the RAIS website under the heading "RAIS Main Tutorial". This guidance will not repeat all the information in the RAIS tutorial; however, key ideas and concepts relating to DNREC-SIRS will be highlighted. A chemical risk calculator is present under the heading "Risk Models/Chemical Calculator" in the RAIS webpage. If any other risk assessment tools/software are planned to be used, it must be pre-approved by DNREC-SIRS. The following text describes some additions or departures from the procedures described in RAIS.

In general, the tools and resources available in the RAIS conform to the EPA's Risk Assessment Guidance for Superfund (RAGS). However, there are a few differences between the RAIS and the RAGS. The text of this guidance will also highlight instances when DNREC-SIRS has a preference between the practices in RAGS and RAIS. Risk assessors are strongly encouraged to use the RAIS resources and calculators for DNREC-SIRS submittals. RAGS provides pre-formatted spreadsheet files for the presentation of data and calculations in "Standard Tables" (RAGS Part D). To streamline risk assessment, DNREC-SIRS has identified content of the Standard Tables that is duplicated in the output of the RAIS risk calculators. The result is a group of four simplified tables (Tables A through D) containing the minimum information required to reproduce the risk calculations and memorialize the factors used in the Risk Assessment report. Templates of these tables are provided in Appendix 9.2.

Risk from the vapor intrusion pathway should be calculated using indoor air data (where no indoor air source is present) in RAIS or the most recent version of the Johnson & Ettinger (J&E) model, or the most recent version of the Vapor Intrusion Screening Level (VISL). The J&E model is the preferred model since it allows for site specific values, such as building specifications and subsurface conditions. The J&E model is set to model for residential scenarios; however, modifications can be made to model for indoor worker commercial scenarios according to the parameters in Section 9.1.4.2.3.1. If the risk assessment includes exposure data resulting from fate and transport models, the input files shall be included in the submittal in digital format. For the J&E Model, the calculated indoor air concentrations are shown on the Intercalcs tab under "Infinite Source Building Concentration".

Construction workers may encounter contaminated soil or groundwater during utility work and as a result vapor inhalation risk may occur. This risk should be addressed through the Contaminated Material Management Plan (CMMP) and is not included within the risk assessment at this time.

The expected outcome of the risk assessment is a determination of whether the site presents an unacceptable risk and would therefore require remediation under HSCA. In the course of identifying hazards and pathways, the risk assessment provides a decision basis for the selection of remedial alternatives. However, the results of the risk assessment are only one component in risk management.

9.1.4.2.1 Risk Characterization

The risk characterization step synthesizes all the information gathered in the previous steps to estimate the likelihood that a potential exposure may adversely impact human health. Risk characterization should communicate key risk findings and conclusions and the confidence in these findings that is the degree of certainty.

Cumulative cancer and non-cancer risks shall be assembled from the RAIS output and totaled in Table D. Table D should utilize for each unique combination of exposure unit and exposure scenario. The total cancer risk and the Hazard Index (HI) for each decision unit shall be expressed to one significant digit. If the HI for a decision unit is greater than one (>1), then the Hazard Quotients for the COCs should be grouped according to target organ and recalculated. The HI per target organ shall be presented on Table D.

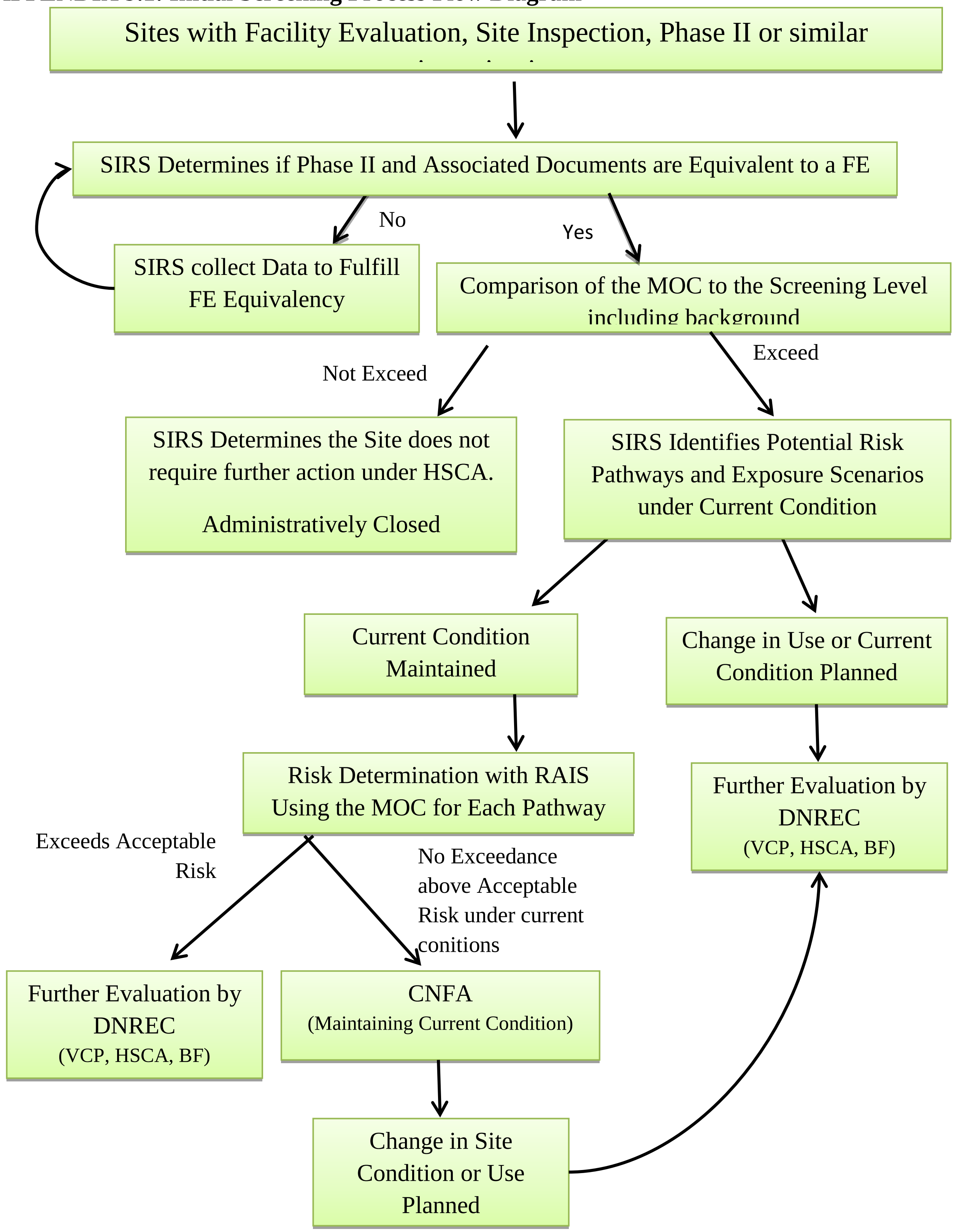
9.1.4.2.2 Risk Assessment Report

The risk assessment report is generally included as part of the Remedial Investigation report or a Brownfields Investigation report. Including risk assessment in RI or BFI reduces the repetition of background and other associated information that would be needed in a separate risk assessment report. The format of the risk assessment report as part of the RI or BFI has been standardized and is provided in Appendix 9.4. Risk assessments submitted to DNREC-SIRS should include all parameters used in calculation of risk values so as to facilitate verification of the results.

Departures from RAIS must be previously approved by DNREC-SIRS and explained in the text of the report. RAIS output files used in the risk assessment shall be labeled and logically organized in an appendix. The RAIS risk calculator should be run using the "show toxicological data" option so that the output includes slope factors and reference doses for the analytes.

The report of the baseline risk assessment should not be combined with consideration of remedial action alternatives. Additionally, please provide copies of the RAIS and ProUCL output, tables and files if possible on a disc with an electronic copy of the report.

APPENDIX 9.1: Initial Screening Process Flow Diagram



APPENDIX 9.2: Risk Assessment Tables

Table A: Selection of Exposure Pathways
Site Name
DE# XXXX

Scenario Timeframe	Medium	Exposure Medium	Exposure Point	Receptor Population	Receptor Age	Exposure Route	Rationale for Selection or Elimination of Exposure Pathway
Current/Future	Soil	Surface Soil	Surface Soil (0-1' bgs)	Resident	Child/Adult	Ingestion, Dermal, Inhalation	The site is mainly covered with asphalt, however there is a small area that is not.
Current/Future	Soil	Surface Soil	Surface Soil (0-1' bgs)	Outdoor Worker	Adult	Ingestion, Dermal, Inhalation	
Current/Future	Soil	Surface Soil	Surface Soil (0-2' bgs)	Resident	Child/Adult	Ingestion, Dermal, Inhalation	Resident gardner may be exposed to soil to a depth of 2' bgs.
Current/Future	Soil	Surface Soil	Surface Soil (0-2' bgs)	Outdoor Worker	Adult	Ingestion, Dermal, Inhalation	
Current/Future	Soil	Surface Soil	Surface Soil (0-2' bgs)	Indoor Worker	Adult	Ingestion, Inhalation	
Current/Future	Soil	Soil	Soil (0-10' bgs)	Excavation Worker	Adult	Ingestion, Dermal, Inhalation	Construction worker is assumed to excavate to a depth of 10' bgs. Future outdoor workers or resident may be exposed to excavated soil that has been redistributed on the site surface.
Current/Future	Groundwater	Groundwater	Shallow Upper Aquifer	Resident	Child/Adult	Ingestion, Inhalation, Dermal	Potential groundwater to be used in the future as primary drinking water source.
Current/Future	Groundwater	Groundwater	Shallow Upper Aquifer	Indoor Worker	Adult	Ingestion, Inhalation, Dermal	
Current/Future	Groundwater	Surface Water	Surface Water	Recreator	Child/Adult	Ingestion, Dermal	The creek bank of approximately 200 feet downgradient of the site.
Current/Future	Groundwater	Soil Gas	Indoor Air	Resident	Child/Adult	Inhalation	
Current/Future	Sediment	Sediment	Sediment	Recreator	Child/Adult	Ingestion, Inhalation, Dermal	Contact with exposed sediments by future and current recreators.

Table A: Selection of Exposure Pathways
Site Name
DE# XXXX

Scenario Timeframe	Medium	Exposure Medium	Exposur e Point	Receptor Population	Receptor Age	Exposure Route	Rationale for Selection or Elimination of Exposure Pathway

Table B: Selection of Contaminants of Potential Concern- Soil
Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentration	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment

Table B: Selection of Contaminants of Potential Concern- Groundwater
Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentration	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment

Table B: Selection of Contaminants of Potential Concern- Sediment
Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentratio n	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment

Table B: Selection of Contaminants of Potential Concern- Surface Water
Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentration	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment

Table B: Selection of Contaminants of Potential Concern- Soil Gas
Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentration	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment

Table B: Selection of Contaminants of Potential Concern- Soil
Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentration	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment
Soil	Surface Soil (0-1' bgs)	Arsenic	9		mg/kg	11	N	
Soil	Surface Soil (0-1' bgs)	Benzo(a)pyrene	1.4		mg/kg	0.09	Y	
Soil	Shallow Soil (0-2' bgs)	Benzo(a)pyrene	0.8		mg/kg	0.09	Y	
Soil	Shallow Soil (0-2' bgs)	PCE	15		ug/L	1	Y	
Soil	Subsurface Soil (2'-10' bgs)	Arsenic	12		mg/kg	11	Y	
Soil	Subsurface Soil (2'-10' bgs)	Lead	1200		mg/kg	400	Y	

Table C: Selection of Exposure Point Concentrations (EPC)
Site Name
DE# XXXX

Exposure Medium	Exposure Point	COPC	# of Detects/# of Samples	Arithmetic Mean	95% UCL	Maximum Concentration	Units	Selected EPC	Distribution /Comment

Table C: Selection of Exposure Point Concentrations (EPC)
Site Name
DE# XXXX

Exposure Medium	Exposure Point	COPC	# of Detects/# of Samples	Arithmetic Mean	95% UCL	Maximum Concentration	Units	Selected EPC	Distribution/Comment
Soil	Surface Soil	Benzo(a)pyrene	10/20	3	3.8	4.2	mg/kg	UCL	Nonparametric 95% Chebyshev
Soil	Surface Soil	Lead	5/20	750	--	990	mg/kg	Max	Too few detects, calculated UCL not reliable
Soil	Subsurface Soil	Benzo(a)pyrene	4/10	2	--	3	mg/kg	Max	Too few detects, calculated UCL not reliable
Groundwater	Groundwater	PCE	2/5	4.5	--	8	ug/L	Max	Too few detects, calculated UCL not reliable

Table D: Risk Summary for Receptors
Site Name
DE# XXXX
Timeframe
Receptor

Medium	COPC	EPC	Carcinogenic Risk	Hazard Index	Target Organ	Comment

Table D: Risk Summary for Receptors
Site Name
DE# XXXX
Timeframe: Future
Receptor: Excavation Worker

Exposure Media	Exposure Route	COPC	EPC	Units	Carcinogenic Risk	Hazard Index	Target Organ	Comment
Surface Soil	Ingestion	Benzo(a)pyrene	0.4	mg/kg	9.4E-09	--		
		Benzo(b)fluoranthene	1.1	mg/kg	2.6E-09	--		
		Manganese	450	mg/kg	--	--	--	
	Total for Exposure Route				1.2E-08	--		
	Inhalation	Benzo(a)pyrene	0.4	mg/kg	8.5E-14	--		
		Benzo(b)fluoranthene	1.1	mg/kg	2.3E-14	--		
		Manganese	450	mg/kg	--	--	--	
	Total for Exposure Route				1.1E-13	--		
	Dermal	Benzo(a)pyrene	0.4	mg/kg	3.9E-09	--		
		Benzo(b)fluoranthene	1.1	mg/kg	1.1E-09	--		
		Manganese	450	mg/kg	--	--	--	
	Total for Exposure Route				4.9E-09	--		
Total for Exposure Media					1.7E-08	--		
Subsurface Soil	Ingestion	Benzo(a)pyrene	2	mg/kg	4.7E-08	--	--	
	Total for Exposure Route				4.7E-08	--	--	
	Inhalation	Benzo(a)pyrene	2	mg/kg	4.2E-13	--	--	
	Total for Exposure Route				4.2E-13	--	--	
	Dermal	Benzo(a)pyrene	2	mg/kg	1.9E-08	--	--	
	Total for Exposure Route				1.9E-08	--	--	
Total for Exposure Media					6.7E-08	--	--	

APPENDIX 9.3: Determining Contaminants of Concern Using the Background Threshold Values and Hypothesis Testing

Background Threshold Values contained in the **DNREC-SIRS Screening Levels Table** were derived from data reported in the **Statewide Soil Background Study** (DNREC, 2012). Background Threshold Values were set at the 95 95 UTL (Upper Tolerance Limit) of 160 soil samples taken at 8 reference sites covering all three counties (US EPA1). The BTVs apply statewide. There are seven TAL inorganics for which the BTV is greater than the risk-based concentration. Consequently, the screening value is set at the BTV as shown in Table 1.

Analyte	Screening value (mg/kg)
Aluminum	51200
Arsenic, Inorganic	11
Chromium, Total	214
Cobalt	34
Iron	74767
Manganese	2100
Vanadium and Compounds	134

Table 1: Screening Values for 7 Metals

The background study showed significant differences in the concentrations of TAL inorganics in three geological provinces of Delaware: the Piedmont, the northern Coastal Plain and the Coastal Plain. Consequently, the statewide BTVs (and therefore screening levels) are slightly high for sites in the Coastal Plain and slightly low for sites in the northern Coastal Plain and Piedmont. To minimize the false positive error (that is, determining that an analyte is a COPC for risk assessment when it's presence is consistent with naturally occurring conditions), DNREC-SIRS recommends a two sample hypothesis test using data from the subject site and DNREC-SIRS' reference data from the relevant geological province (Coastal Plain, northern Coastal Plain, or Piedmont). Figure 1 shows the location of the province boundaries that will be used in this comparison.

The appropriate statistical test for the central tendency of the site data set depends on its distribution and the presence of non-detects. The test will be selected from among the Students t-test, Wilcoxan-Mann-Whitney (WMW) test or Gehans test). DNREC-SIRS has provided ProUCL-ready input files for the three reference data sets.

The hypothesis testing procedure is outlined below. NOTE: *only follow these steps if the maximum observed concentration of an analyte at the subject site exceeds the screening level.*

- Locate the subject site on Figure 1 and identify the reference data base to be used in the comparison.
- Construct a ProUCL input file in MS Excel by combining the subject site data and the appropriate reference site data following the conventions as shown in the file for the reference site.
- There are two columns in the input file for each analyte: one for the lab reported value and one for a detect flag, either 0 (not detected) or 1 (detected).
- Run G.O.F. statistics under the Goodness of Fit tab to determine normality.
- "It is recommended to supplement statistical results and test statistics with graphical displays, such as the multiple Q-Q plots and side-by-side box plots as graphical displays do not require any distributional assumptions and are not influenced by outlying observations and NDs." [US EPA2, 149]
- If there are no non-detections (NDs) in either data set, chose the t-test if both data sets are normally distributed. If either data set is not normal, choose the WMW test.[i] For all tests, retain the ProUCL default option for the form of the null hypothesis[ii]. Change the "confidence level" to 90%.
- If the test result in the t-test or WMW test is "Do not reject Ho," then the analyte is to be considered background and would therefore not be a contaminant of potential concern in further evaluation of site risks.
- If there are non-detects in either data set, run the Gehan test. WARNING: do not use the WMW test if there are non-detects in the results.

If the null hypothesis is not rejected, then the presence of analyte shall be considered a background condition. The analyte will not be a COPC for the risk assessment. The process is shown on the attached flow chart.

The ProUCL output file including the goodness-of-fit statistics and graphics shall be provided in the report of the risk assessment. The digital input file shall be provided to DNREC-SIRS on request.

References

DNREC—Statewide Soil Background Study: Report of Findings (2012)

Helsel, Dennis R.—Unofficial Guide to ProUCL (2013) (available on Amazon as e-book)

US EPA—User Guide for ProUCL 5.0
(http://www.epa.gov/osp/hstl/tsc/software.htm#References)

US EPA2—Technical Guide for ProUCL 5.0
(http://www.epa.gov/osp/hstl/tsc/software.htm#References)

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[i] When there are multiple DLs in the data set, the WMW test loses information compared to the Gehan test. (Helsel).
[ii] The default confidence level is 95% and the default form of the null hypothesis is “AOC <= Background (Form 1)”

FIGURE 1
BACKGROUND
PROVINCE BOUNDARIES

APPENDIX 9.4: Risk Assessment Report Format

Provided below is the format for the Risk Assessment portion of a report. Please adhere to this template. Variations to this template must be approved by DNREC-SIRS prior to use. Please modify the section numbering based on the report being submitted. Section 1.0 is provided for an example only.

Section 1.0 Baseline Risk Assessment

1.1 Risk Assessment Approach

Describe the risk assessment approach that was used for the site and explain why. For example, a default background standard was used for metals in soils, and a risk calculator (e.g., RAIS) was used for organic contaminations using 95% UCL of mean, etc. Please include input parameters in a table.

1.2 Identification of Potential Contaminants of Concern

Describe how the Potential Contaminants of Concern (PCOCs) were identified (for example, by using HSCA Screening Table for contaminants that exceed) for each media (soil, groundwater, etc.). Provide a table with PCOCs. Include a brief description of the toxicity of the PCOCs.

1.3 Exposure Pathway Assessment

1.3.1 Conceptual Site Exposure Model

Describe the sources and fate and transport of contamination in each medium and the exposure routes and the receptors (graphically and in tabular form) based on the investigation results and observations (updated from CSM_SAP document)

1.3.2 Exposure Assessment- Human Health

Describe how (through ingestion, inhalation, etc.) the contaminants in different media (soil, groundwater, etc.) will be exposed to the human population (residents, remediation workers, utility workers, sensitive populations, etc.) at and near the site, and what the exposure point concentrations are. Describe how the exposure point concentrations were determined (i.e. fate and transport modeling) (updated from CSM_SAP document)

1.4 Human Health Risk Characterization

1.4.1 Estimation of Non-Cancer Hazards

1.4.2 Estimation of Cancer Risk

1.4.3 Residential Exposure Scenario

1.4.4 Indoor Worker Exposure Scenario

1.4.5 Outdoor Worker Exposure Scenario

1.4.6 Composite Worker Exposure Scenario

1.4.7 Excavation Worker Exposure Scenario

1.4.8 Recreator Exposure Scenario

1.4.9 Farmer Exposure Scenario (if applicable)

1.4.10 Summary of Risk Calculations

1.4.10 Risk Management Evaluation

1.4.11 Human Health Uncertainty Analysis

Describe the uncertainty associated with the risk assessment for the site and how it may have affected the results.

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