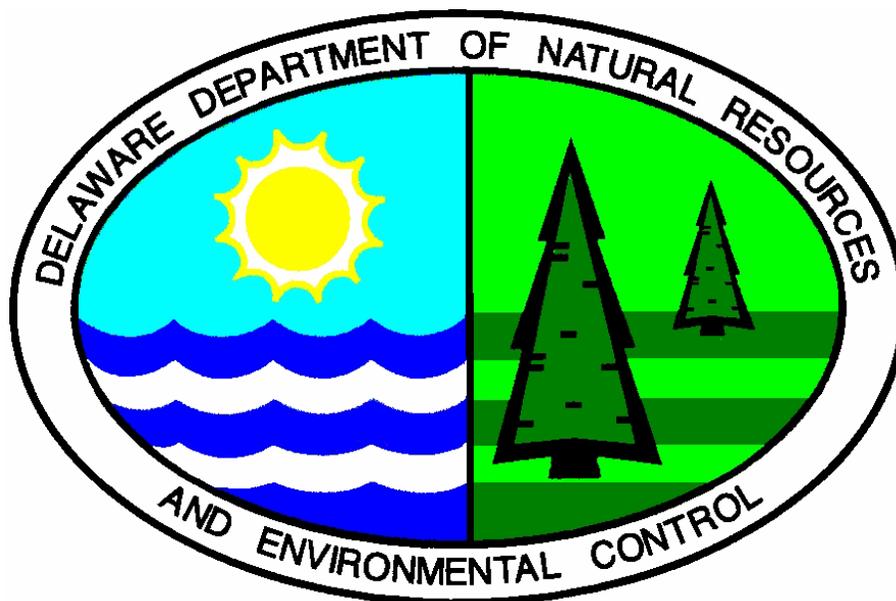


STATE OF DELAWARE

Guidance for Human Health Risk Assessments (HHRA) under the Hazardous Substance Cleanup Act (HSCA)



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Revised October 2017
Revised July 2020

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Listing of Acronyms

BFI	Brownfield Investigation
CMMP	Contaminated Materials Management Plan
COCR	Certificate of Completion of Remedy
COCs	Contaminants of Concern
COPC	Contaminants of Potential Concern
CSF	Cancer Slope Factor
CSM	Conceptual Site Model
DNREC-RS	Delaware Department of Natural Resources and Environmental Control, Remediation Section
EPA	United States Environmental Protection Agency
EPC	Exposure Point Concentration
ESA	Environmental Site Assessment
FE	Facility Evaluation
HHRA	Human Health Risk Assessments
HI	Hazard Index
HSCA	Hazardous Substance Cleanup Act
IEUBK	Integrated Exposure Uptake Biokinetic Model
ITRC	Interstate Technical and Regulatory Council
J&E	Johnson & Ettinger Model
MDL	Method Detection Limit
MOC	Maximum Observed Concentration
NTU	Nephelometric Turbidity Units
PCB	Polychlorinated Biphenyls
RAGS	Risk Assessment Guidance for Superfund
RAIS	Risk Assessment Information System
RfDs	Reference Doses

RI	Remedial Investigation
SAP	Sampling Analysis Plan
SOPCAP	Standard Operating Procedures for Chemical Analytical Programs under HSCA
SVOC	Semi Volatile Organic Compound
TAL/TCL	Total Analyte List/Total Compound List
TIC	Tentatively Identified Compound
UCL	Upper Confidence Limit
VI	Vapor Intrusion
VISL	Vapor Intrusion Screening Level
VOC	Volatile Organic Compound

1.0 Introduction

This Guidance describes the steps that should be followed to perform Human Health Risk Assessments (HHRA) under the Hazardous Substance Cleanup Act (HSCA). Any variations from this Guidance should be approved in writing by DNREC-RS prior to inclusion of submittals. This Guidance is based primarily on the US EPA Risk Assessment Guidance for Superfund (RAGS) and incorporates the use of the Risk Assessment Information System (RAIS), a web-based risk assessment tool. DNREC-RS 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 should be pre-approved by DNREC-RS prior to their use on a site by site basis. Please note that output from any other calculators should equal the RAIS output unless a justified explanation for the difference is provided and approved by DNREC-RS. This Guidance overlaps with several other sections of the HSCA guidance and references are provided to the applicable sections as needed.

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-RS. Details regarding the initial screening and subsequent conditional No Further Action are provided in the HSCA Conditional No Further Action (CNFA) Guidance. A detailed HHRA is performed based on Remedial Investigation (RI)/Brownfield Investigation (BFI) findings and the steps in the HHRA are provided in this Guidance.

Please note that several of the guidance documents referenced within this text have not been completed. As a result, please contact DNREC-RS for guidance on these areas until the documents have been completed. In addition, please contact DNREC-RS for any other questions or clarifications.

1.2 Glossary

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

Background Level: A background level is the concentration of substances widely present in the soil, sediment, air, surface water, and/or groundwater in the vicinity of a facility or Certified Brownfield, 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.

Baseline Risk Assessment: A 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. The composite worker could also potentially be exposed to combined shallow and deep soil if deep soil is brought to the surface from construction or excavation activities. Examples of general office activities include any activity that is conducted inside of a building.

Construction Worker: The construction worker exposure scenario refers to adults who could potentially be exposed to shallow and combined shallow and deep soil during activities on the site. This exposure scenario is site specific and can be estimated for both air and soil. The potential soil exposure can be further modified for either unpaved road traffic or other construction activities. The unpaved road traffic scenario also requires site specific input including: number of cars and trucks, tons per car and truck, and days per year with limited precipitation. Please note that for a construction worker scenario to be used, it should be pre-approved within the CSM-SAP.

Contaminant of Concern (COC): A hazardous substance identified during a remedy, which exceeds the HSCA screening level and contributes to the unacceptable site specific risk.

Contaminant of Potential Concern (COPC): A hazardous substance that may or may not be contributing to the unacceptable risk of the site. Generally, COPCs exceeds the HSCA Screening Level whether from a calculated 95% UCL or a MOC and will need to be further evaluated. The use and grouping of exposure units should also be discussed and agreed upon.

Deep Soil: The deep soil refers to soil encountered at a depth greater than two (2) feet below ground surface.

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 Pathway: The route a chemical or a physical agent takes from a source area to an exposed organism or receptor.

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.

Exposure Unit: Areas of a site that may be grouped together because of current and reasonably predicted future use and potential for exposure, or for a particular environmental media that a receptor may come in contact through current or future site use.

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 and combined shallow and deep soil if deep soil is brought to the surface from construction or excavation activities. 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.

Mixed Use: A mixed use end use of a property assumes that the property will be a combination of commercial and residential use. Exposure scenarios that could have repeated contact with the contaminated media include residents and workers.

Outdoor Worker: The outdoor worker exposure scenario refers to adults who could potentially be exposed to the shallow soil during site activities and combined shallow and deep soil if deep soil is brought to the surface from construction or excavation activities.

Recreator: The recreator exposure scenario refers to adults and children 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 can be developed on a site specific basis with pre approval from DNREC-RS as needed.

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. This contact is expected to be with the shallow soil, groundwater, and potentially combined shallow and deep soil if deep soil is brought to the surface from construction or excavation activities. The assumptions in this case account for daily exposure over the long term and generally result in the highest potential exposures and risk.

Surface Soil: The surface soil refers to the top six (6) inches below the ground surface of soil/grass.

Shallow Soil: The shallow soil refers to the top two (2) feet below ground surface of soil.

Sensitive Receptors: Include, but not limited to, playgrounds/areas of open soil, hospitals, daycare facilities, elderly housing and convalescent facilities. These are areas where the occupants are more susceptible to the potential adverse effects of exposure to toxic chemicals, pesticides, and other potential contaminants. Extra care and consideration must be taken when assessing sites with contaminants in close proximity to areas with recognized sensitive receptors.

Site Specific Risk Assessment: A site specific risk assessment accounts for individual site characteristics to be included within the risk assessment calculations. These changes can include different exposure duration, frequency, and time of each event.

Trespasser: The trespasser exposure scenario and assumptions should be used whenever there is a risk of an unauthorized person accessing the site for a limited period of time. Trespassers could be exposed to any surface water bodies, sediment, the top two feet of soil, and potentially combined shallow and deep soil if deep soil is brought to the surface from construction or excavation activities. Other routes of exposure would be on a site specific basis and pre-approved by DNREC-RS.

2.0 Baseline Human Health Risk Assessment

This section of the guidance describes 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 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 additional bioavailability factors, sub-chronic risk factors other than the default within RAIS, and acute risk are subject to written pre-approval by DNREC-RS 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-RS review. Once the risk assessment report is approved by DNREC-RS, the input factors used in the risk assessment calculations will be considered final for the purposes of issuing a Certificate of Completion of Remedy (COCR). Thus, future changes in default exposure factors, toxicity data or other values set adopted by the EPA and/or DNREC will not in general require a recalculation of risk. However, if there are compelling reasons, DNREC-RS, at its discretion, may require re-evaluation of risk.

DNREC-RS will not require the evaluation of additional exposure scenarios for a particular media if the risk is acceptable under a residential scenario. However, a statement should be included in the risk assessment indicating that the risk under the other exposure scenarios (e.g. indoor worker, trespasser) is acceptable because the risk under the more conservative residential scenario is acceptable.

2.1 Planning and Scope of the Risk Assessment

The planning stage of a risk assessment should begin early in the investigation process and include a discussion of goals and expectations between the risk assessor and DNREC-RS. 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 vapor intrusion (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-RS. 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

2.1.1 Exposure Units

Exposure units 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. An example of an exposure unit is the lot size (i.e. 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 (OU) proposed for a site, then they should be evaluated as separate exposure units. The exposure units proposed in the CSM are subject to DNREC-RS approval.

2.1.2 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.

2.1.2.1 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, 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. As a result, DNREC-RS recommends modifying the existing recreator exposure scenario to reflect the trespasser risk scenario. Please refer to Section 2.1.2.2 for the specifics on what modifications are pre-approved. Please note that when modeling potential future exposures in the baseline risk assessment, existing fences should not be considered a deterrent to future site access.

2.1.2.2 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 should be approved by DNREC-RS prior to use. Any modification to the default assumptions should be preapproved by DNREC-RS 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.

Table 1: Exposure Scenarios

	Resident	Indoor Worker	Outdoor Worker	Composite Worker	Excavation Worker	Recreator	Trespasser ¹
Exposure Frequency (days per year)	350	250	225	250	20	75 (soil or sediment) 45 (surface water)	58
Exposure Time (hours per day)	24	8	8	8	8	1	3.9
Exposure Duration (years)	Total: 26 Child: 6 Adult: 20	25	25	25	1	Child: 6 Adult: 20	Adult (6-16): 10

¹ Trespasser values are not default RAIS values but are from Table 16-1: Recommended Values for Activity Patterns, Time Outdoors (total), EPA Exposure Factors Handbook (2011 Edition). For more information on the trespasser exposure scenario, please refer to the text below.

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. Please include each potential pathway within the site's CSM if these are potential exposure pathways for the site. For specific information, please refer to RAIS.

Table 2: Exposure Pathways

Receptor	Exposure Pathway								
	Surface Soil	Shallow Soil	Combined Shallow and Deep Soil	Sediment ⁵	Groundwater	Air ³	Tap ⁴ Water	Surface Water	Fish
Resident	X	X	X ⁶		X	X	X		X
Indoor Worker	X	X	X ⁶		X	X	X ¹		
Outdoor Worker	X	X	X ⁶			X			
Composite Worker	X	X	X ⁶			X			
Construction Worker	X	X	X ⁶			X			
Excavation Worker	X	X	X ⁶			X			
Recreator	X	X ²	X ⁶	X				X	
Trespasser	X	X ²	X	X				X	

¹ Indoor Worker water exposure is assumed to be industrial water

² Recreator and trespasser soil exposures are assumed to be surface or shallow soil/sediment

³ The air pathway calculated with RAIS is not part of a potential vapor intrusion analysis. Vapor intrusion must be evaluated per Section 3.1.5. For Resident and Indoor Worker indoor air is the media of concern. For Outdoor Worker ambient air is the media of concern while for Composite, Construction, and Excavation Worker trench air is the media of concern. Trench air risk is not addressed in risk assessment but is managed using a CMMP. Risk associated with soil gas and sub-slab should be evaluated with Vapor Intrusion Screening Levels (VISL) or the Johnson & Ettinger (J&E) Model with updated toxicity values (pre-approved for use by DNREC-RS).

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-RS is not requesting an evaluation of public water.

⁵ Sediment exposure pathway should only be used for the applicable site specific conditions.

⁶ If the deeper soil is more contaminated than the shallow soil, then a risk calculation for the combined shallow and deep soil should be completed. DNREC-RS will consider intermediate depth samples on a site specific basis when the deep sample ending depth is considerably below any potential human exposure.

The trespasser exposure scenario can be utilized by modifying the RAIS recreator risk scenario to evaluate the adolescent age group of 6 to 16 years old. Since this is a more sensitive receptor than an adult and their exposure would be equal to or greater than adults, only the risk to the adolescent trespasser should be evaluated. It is assumed, and previously noted in the table above, that the trespasser would be exposed to the shallow soil (or sediment) for 58 days per year (exposure frequency) and 3.9 hours per day (exposure time). The default RAIS recreator risk scenario should be modified to reflect this. These assumptions were derived from Table 16-1, Recommended Values for Activity Patterns – Time Outdoors (total), in EPA’s Exposure Factors Handbook: 2011 Edition. The average time spent outdoors for the 6 to 11 year old age group is

132 minutes per day, which is equivalent to 2.2 hours per day or approximately 33 days per year. The average time spent outdoors for the 11 to 16 year old age group is 100 minutes per day, which is equivalent to 1.7 hours per day or approximately 25 days per year. The average time spent outdoors for both age groups is 1.95 hours per day and 29 days per year. Since 1.95 hours per day and 29 days per year are central tendency values, they were doubled to derive a reasonable maximum exposure value of 3.9 hours per day (exposure time) and 58 days per year (exposure frequency) spent outdoors. DNREC-RS determined that this is a conservative estimate and more representative than the default recreator assumptions for the trespasser risk scenario.

The Mixed Use exposure scenario is a combination of a commercial and residential land use exposure scenario. As a result, how each media is evaluated varies and application of the mixed use scenario is only for specific circumstances. For a mixed use exposure scenario to be considered a detailed development plan must be submitted with the CSM/SAP in order to define specific areas and layout of the site. If a firm and detailed development plan is not included, then a standard residential exposure scenario will be applied and reflected within the environmental covenant. The investigation and remediation will be based on the development plan provided with the CSM/SAP and will remain in effect throughout the progress of the site. For the mixed use exposure scenario, the soil, groundwater and vapor intrusion exposure route should be evaluated for residential use to be as conservative as possible. If the development plan changes at a later date, additional sampling and/or a revised cumulative risk assessment may be performed for DNREC-RS's approval. DNREC-RS may consider utilizing OUs based on portions of the Site that will be residential or commercial. This will require a firm and detailed development plan noting the divisions of the OUs. In addition, a metes and bounds survey would have to be performed and recorded with the Environmental Covenant.

The Farmer exposure scenario can be used for community garden sites on a site specific basis and with pre-approval by DNREC for soil only.

DNREC-RS is aware of the effects that contamination can have on sensitive receptors and a potential commercial use scenario for both soil and vapor intrusion. As previously stated, while the calculated cancer risk is a lifetime exposure, the calculated hazard index is an age specific exposure scenario. To address the potential commercial exposure to sensitive receptors, soil (i.e. playgrounds or potential exposed soil) and vapor intrusion must be evaluated under a child residential risk. If the property owner or developer does not want to evaluate the potential vapor intrusion risk to child, a restriction must be placed on the Environmental Covenant stating that the property can not be occupied by sensitive receptors.

Modifications to any other exposure scenarios can be done on a site specific basis and should be pre-approved by DNREC with documented viable sources for the modified assumptions.

DNREC-RS will allow for the use of surface soil samples in the risk assessment on a site specific basis and with pre-approval by DNREC. The surface samples must not be in the same location as the shallow soil samples. Collection of surface soil samples does not preclude collection of shallow soil samples. For more information on collection of surface and shallow soil samples, please refer to the HSCA Investigation Guidance and DNREC SOPs.

2.1.2.3 Site Specific Risk Assessment

While DNREC-RS strongly suggests using the default assumptions within RAIS, DNREC-RS is aware that occasionally the default assumptions do not provide an accurate estimation of risk for the end use of the site. As such, DNREC-RS allows a site specific risk assessment to be performed where several of the default assumptions can be changed to accurately reflect the potential exposure scenarios. The exposure assessment details that can be modified include the exposure time, exposure duration, time of event and years. Please note that in an effort to be protective, DNREC-RS assumes that all school end use assumptions are for elementary schools. As a result, the most conservative age group will be evaluated to determine if a remedial action is needed.

Any changes should be pre-approved by the DNREC-RS and identified within the CSM-SAP and should be appropriately documented with either published data or a previously approved site specific study. Please note that for the excavation worker scenario, the default exposure time and duration can be increased based on site specific conditions but can not be decreased from the RAIS default values. DNREC-RS can not enforce or manage the length of time the construction staff are on site. As previously stated, any changes to the default assumptions of the exposure scenarios must be pre-approved by DNREC-RS and be discussed within the text of the report.

2.1.2.4 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 and analysis requirements will be provided in the HSCA Investigation Guidance. However, it is recommended that a minimum of 10 samples from each soil exposure unit (i.e., shallow soil and deep soil) be collected. DNREC believes that 10 samples will provide a valid data set. However, DNREC is aware that ProUCL is able to calculate valid statistics on data sets of less than 10. DNREC will accept, at its discretion, valid ProUCL statistics on data sets less than 10. As a default, soil samples should be screened for full Target Compound List (TCL)/organics, Total Analyte List (TAL) inorganics, and any site specific contaminants of concern (COCs). The screening is typically performed by the DNREC-RS Screening Laboratory. However, a HSCA Certified Laboratory may also perform the screening. Other methods or laboratories should be approved by DNREC-RS 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 specific analysis with DNREC-RS approval. However, a select number of samples should be analyzed for full TAL/TCL at a HSCA Certified Laboratory to confirm the screening analysis. For example, if arsenic is the COPC in shallow soil as indicated by screening, then it is recommended that a minimum of 10 samples should be analyzed for arsenic. DNREC-RS may, at its discretion, allow a lower number of samples, however, appropriate statistical methods as recommended by ProUCL including non-parametric analysis (i.e. average for lead) is required to determine Exposure Point Concentrations. It should be noted that data from temporary wells is considered to be equivalent to screening level data and as such can not be used within the risk assessment.

Per the DNREC-RS Policy for Polychlorinated Biphenyl (PCB) Analysis Method (issued November 24, 2014), samples should by default be analyzed utilizing Method 680. However, results from Method 680 may illustrate that a congener analysis per Method 1668 maybe needed. For more specific information on when it is needed and how to incorporate the data into the risk assessment, please refer to Section 3.1.8 Considerations of PCBs and Analysis for all Media for more information.

3.0 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 exceed the corresponding HSCA Screening Level. This is done through the determination of COPCs. 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 should be explained and documented in the text of the report. 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. All COPCs should be summarized in Table B: *Selection of Chemicals of Potential Concern*. All analytes with positive detections in confirmatory laboratory results should be included in Table B along with the selected COPC. Please refer to Appendix 1 for a copy of the Table B template.

3.1 Determination of Contaminants of Potential Concern (COPCs)

The first step in the hazard assessment is to determine the COPCs for the exposure unit. It is assumed that the data used in the risk assessment was previously evaluated and meets the QA/QC requirements. Please refer to the DNREC-RS HSCA Standard Operating Procedures for Chemical Analytical Programs under HSCA (SOPCAP) and further guidance for more information on data usability and QA/QC requirements. DNREC-RS uses the HSCA Screening Level Table, a single table for contaminant screening that combines background, risk-based values and applicable, relevant and appropriate values in soil, ground water, surface water and soil gas for COPC determination. The HSCA Screening Level Table is updated on a semi-annual basis, generally in January and July.

Some HSCA Screening Levels are below the routine laboratory method detection limit (MDL). If the MDL exceeds the screening level, then the routine MDL shall become the screening level and analytes will be considered COPCs if they exceed the MDL (i.e. if detected, the analyte is a COPC). Analytes with J qualifiers, indicating an estimated concentration, should also be considered detections. Removal of any data, and the rationale, from the hazard assessment process should be documented in the risk assessment report. The COPCs discussion in reports should be divided by exposure unit (as necessary) and by sample media type.

3.1.1 Determination of COPCs for Soil (Shallow and Deep)

COPCs for both shallow and deep soil are determined by comparing the maximum observed concentration (MOC) or calculated 95% UCL to the appropriate HSCA Screening Level for human health. If the contaminant MOC or calculated 95% UCL is above the appropriate HSCA

Screening Level, it is retained as a COPC. If the MOC or calculated 95% UCL for the contaminant is at or below the HSCA Screening Level, it is not retained for further evaluation.

3.1.2 Determination of COPCs for Groundwater

Prior to sampling a well, attempts should be made to develop and purge each monitoring well sufficiently so that a sample representative of the aquifer can be collected. The representativeness of the sample is determined by collecting groundwater quality parameters such as conductivity, pH, and turbidity measurement in Nephelometric Turbidity Units (NTUs) and noting when the parameters stabilize. Please review the DNREC-RS SOP for Groundwater Sampling for additional details. However, in some cases a less turbid sample cannot be achieved even after these attempts are made. In these cases, if the turbidity of the sample is less than 10 NTUs and the other groundwater quality parameters have stabilized, use the unfiltered (total) groundwater sample results to determine the COPC. If the turbidity is greater than 10 NTUs and the other groundwater quality parameters have stabilized, use the filtered (dissolved) groundwater sample results to determine the COPC. Please note that there are site specific situations that may preclude the use of the above procedure in determining COPCs such as the aquifer quality and its use. These cases could be evaluated on a site specific basis and should be pre-approved by the DNREC-RS.

Once the listing of groundwater contaminants is provided, whether or not the contaminant is a COPC would be determined by comparing the MOC to the appropriate HSCA Screening Level. If the contaminant is above the appropriate HSCA Screening Level, the contaminant should be retained as a COPC. If the contaminant is at or below the HSCA Screening Level, the contaminant does not need to be further evaluated.

3.1.3 Determination of COPCs for Sediment

COPCs for sediment are determined by comparing the MOC or calculated 95% UCL to the appropriate soil HSCA Screening Level for human health. If the contaminant MOC or calculated 95% UCL is above the HSCA Screening Level, it is retained as a COPC. If the MOC or calculated 95% UCL for the contaminant is at or below the HSCA Screening Level, it is not retained for further evaluation.

3.1.4 Determination of COPCs for Surface Water

COPCs for surface water are determined by comparing the MOC or calculated 95% UCL to the appropriate groundwater HSCA Screening Level for human health. If the contaminant is above the HSCA Screening Level, it is retained as a COPC. If the MOC or calculated 95% UCL for the contaminant is at or below the HSCA Screening Level, it is not retained for further evaluation. Please note that for inorganic results, the total metals concentrations should be used to determine whether or not the contaminant is a COPC. For specifics on ecological risk assessment, please refer to the Ecological Risk Guidance.

3.1.5 Determination of COPCs for Air and Vapor Intrusion

The vapor forming chemicals, which may include VOCs, some SVOCs, some PCBs and some metals, have been identified in the HSCA Screening Level Table so that users can compare the sample values with the correct screening value. If soil gas/sub-slab data is not available for the particular contaminant, then groundwater data can be used to determine the potential for a Vapor Intrusion (VI) risk. This screening process should take place for soil gas or groundwater samples when the sample is located within 100 feet of an existing or proposed building or in a preferential pathway. Please review the HSCA Screening Level Table for more details. If the MOC exceeds the groundwater screening level, then groundwater results should be evaluated using the Vapor Intrusion Screening Level (VISL) calculator with commercial or residential settings. VISL is available through the US EPA website. The Johnson & Ettinger (J&E) Model may be used to evaluate groundwater and soil gas results with updated toxicity values as long as it has been pre-approved for use by DNREC-RS for the specific Site. When the MOC exceeds the HSCA Screening Level, then the analyte becomes a COPC for the risk assessment. If the MOC does not exceed its respective HSCA Screening Level, it will not be considered for further risk evaluation.

The VI 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 but not limited to groundwater, 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 to the receptor, the weight of evidence may indicate that the pathway is incomplete. If the preponderance of evidence indicates that VI is occurring, then the COPCs are retained for further evaluation within the risk assessment. 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 VI is not occurring. For a detailed discussion, please refer to the Interstate Technical and Regulatory Council (ITRC) Vapor Intrusion document (ITRC, 2007. Vapor Intrusion Pathway: A Practical Guideline. VI-1. Washington, D.C.: Interstate Technology & Regulatory Council, Vapor Intrusion Team) and 2015 USEPA OSWER Vapor Intrusion Guidance (USEPA, 2015. Final OSWER Technical Guide for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air).

3.1.6 Consideration of Duplicate Samples for all Media

Occasionally, contaminants can either be present or present at higher concentrations in the duplicate sample of a parent sample. The calculated average of the parent and duplicate samples should be used to determine whether or not that contaminant is a COPC. The method detection limit should be used in place of the non-detect value for averaging. Also, if the duplicate sample has a higher concentration of the detected contaminant than the original sample, the calculated average concentration should be used to determine whether the contaminant is a COPC. In addition, the calculated average of the parent and duplicate sample should be used for any 95% UCL calculations within ProUCL. Any variation will be on a site specific basis and pre-

approved by DNREC-RS. Please note that this applies to all media (soil, groundwater, and sediment).

3.1.7 Evaluation of Tentatively Identified Compounds (TICs)

The routine HSCA analysis includes 8260 VOA and 8270 SVOC analysis by GC/MS. Each analysis will have a list of reportable targeted compounds. Each of these targeted compounds will be included in a calibration solution that is used to confirm the identification of the compound and help with the calculation of the compound's concentration. TICs on the other hand, are compounds that are not included in the calibration solution. They are identified by comparing the ion spectra for that compound against a library of thousands of compounds and making a determination whether or not there is a compound match. This determination can be performed by the instrument with pre-established acceptance criteria or the result of a manual search by a qualified analyst. The end result will be a series of TICs with full compound identification, some with partial identification such as an unknown aromatic or an unknown chlorinated hydrocarbon, or possibly just unknown. There will also be an estimated concentration applied to the TIC.

TIC evaluation presents challenges because there are no defined rules that can be applied to all sites. An example would be analysis results from one site indicates significant TIC activity but the site risk is already driven by the presence of targeted compounds while another site may have the same level of TIC activity but no targeted compounds. The overriding rule is that professional judgement should be applied to properly evaluate TICs and their effect on the site's overall risk. The person evaluating the TICs and their potential effect on risk should have the necessary training and experience to provide a professional evaluation. DNREC-RS should be contacted if there are any questions regarding the type of training or experience required.

Step 1- Determine if any of the TICs have a compound specific identification, including a CAS number. If so, that compound should be evaluated for its contribution to the overall site risk. If that TIC (along with all other TICs) has no effect or no additional effect on the overall site risk, then the report should describe in detail how that determination was made.

Step 2- An initial risk determination for TICs that are to be included in a risk calculation should be performed. The "J" flagged result should be used initially. If there is any uncertainty following that initial risk calculation, the laboratory may need to be instructed to perform a TIC study to obtain a calibration standard in order to acquire a defensible result. Site specific conditions, along with coordination with DNREC-RS, will dictate if re-sampling is required. The targeted compound value should also be used within the risk assessment, even if the TIC concentration is higher.

Step 3- The effect that non-compound specific TICs may play in site characterization should be determined. Compounds that do not have specific identification but a generic "family" identification, such as unknown aromatic or unknown chlorinated hydrocarbon, should also be evaluated but concentration will play a greater role in the determination of effect. An example would be the presence of large concentrations of unknown petroleum hydrocarbons with or without targeted petroleum hydrocarbons. It may be necessary to obtain EPH/VPH results by the Massachusetts Method to properly assess the TIC effect. If it is the judgement of the evaluating professional that there is too much uncertainty within the TIC population to make a reasonable

decision on the effect, that decision should be detailed in the Data Quality Assessment section of the report.

Step 4- TICs listed as unknowns, with no additional identification, should be acknowledged in the text of the report with a determination that their effect cannot be evaluated.

In all cases, the presence of TICs will be acknowledged in the text of the report with a determination that risk can or cannot be evaluated. Any questions about how to evaluate TICs should be brought to the attention of the DNREC-RS Project Officer and Chemist.

3.1.8 Consideration of PCBs and Analysis for all Media

As previously discussed in Section 2.1.2.4 Sampling and Analysis Considerations and the DNREC- RS Policy for Polychlorinated Biphenyl (PCB) Analysis Method (issued November 24, 2014), a site may have data from both Method 680 and Method 1668. This section provides guidance on how to properly assess the detected PCBs under HSCA. As noted within the Policy for Polychlorinated Biphenyl (PCB) Analysis Method EPA Method 680 (Homolog Method) is the current standard at RS, due to its cost-effective ability to detect the presence of total PCBs within the environment. Method 1668 (Congener Method) may be required in accordance with the Policy for PCB Analysis and applicable other RS guidance. In addition, Method 1668a analysis will be required if PCBs are the only contaminant of concern that exceeds the Screening Level of its most toxic congener or locations where site-specific conditions indicate the need for fingerprint analysis of PCBs. These conditions are outlined within the Policy for Polychlorinated Biphenyl (PCB) Analysis and other RS Guidance and will not be discussed here. Please refer to the additional RS guidance for further information.

Analytical data received from a HSCA certified lab will be compared to the appropriate section of the current HSCA Screening Level Table to determine if those compounds should be included within the risk assessment. If the measured levels are higher than the screening criteria, then they should be included within the risk assessment.

RAIS has three options under Chemicals of Interest for PCBs. These include Polychlorinated Biphenyls (high risk), Polychlorinated Biphenyls (low risk), and Polychlorinated Biphenyls (lowest risk). The option that should be chosen within in RAIS is based on Table 4-1 from the Environmental Protection Agency's (EPA) report entitled "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures" (EPA/600/P-96/001F, September 1996) and is presented for each analytical method below.

EPA Method 680: Data should be summed across all homologs to produce a total PCB value. This total PCB value should be compared to the Total PCBs High Risk or Total PCBs Low Risk HSCA Screening Level as indicated below. If the total is above the Screening Level, the value will be retained for the risk assessment and included within the RAIS inputs. For soil and sediment data, the Polychlorinated Biphenyls (high risk) scenario should be selected, and risk should be calculated for direct ingestion/inhalation scenarios. For groundwater and surface water data, the Polychlorinated Biphenyl (low risk) scenario should be selected, and risk should be calculated for direct ingestion, inhalation, and dermal exposure scenarios. A lowest risk scenario should not be used unless it is pre-approved by DNREC on a site specific basis. Please

note that it must be shown that the Criteria for Use listed for the Lowest Risk and Persistence according to Table 4-1 is the most appropriate.

EPA Method 1668: From the 1668 data, coeluters should be removed to eliminate any double counting. A Toxicity Equivalence Factor (TEF) approach should then be utilized to calculate the risk from the dioxin-like PCBs. The risk associated with dioxin-like PCBs will be added to the risk from the non-dioxin-like PCBs, and from the other contaminants of concern, in order to obtain a cumulative risk. The toxic equivalence (TEQ) for a sample is the sum of TEQs calculated for each of the twelve dioxin-like PCB congeners. TEQ is the concentration of the individual congener multiplied by the congener's associated Toxicity Equivalence Factor (TEF), where TEF is unitless and the concentration is in ug/L.

$$\text{TEQ} = ((\text{Concentration of Congener in sample}) \times (\text{TEF}))$$

TEF Values are provided in the Screening Level Table. Please refer to the most current Screening Level Table for the most recent values.

The TEQs for the 12 dioxin-like PCB congeners should then be summed. Using RAIS, risk should then be calculated for this total TEQ value, utilizing "TCDD, 2,3,7,8" as the selected Chemical of Interest. The remaining 197 PCB Congeners (209 minus the twelve with TEF values) should then be summed. Risk should then be calculated from this calculated total PCB value using the Polychlorinated Biphenyl (high risk) for soil and Polychlorinated Biphenyl (low risk) for groundwater. The summation of the PCB risk value and the TCDD, 2,3,7,8 risk value will then determine the total risk of PCBs. Please note that if data from Method 1668 is available, data from Method 680 should not be used within the risk assessment. Any variation from this method must be pre-approved by the DNREC-RS.

3.2 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 text of the report shall present pertinent information needed to verify the model and to recreate the output. Required information includes, but not limited to, input parameters and assumptions. The model should be submitted as well.

Risk assessments performed under HSCA shall retain the default RAIS exposure assumptions. However, DNREC-RS will review requests to substitute site-specific assumptions. Variations to the default assumptions should be submitted for approval within the CSM-SAP. Also, any changes to previously approved risk calculators should be reviewed and approved by DNREC-RS prior to its use and on a site by site basis.

3.2.1 Exposure Point Concentrations

The Exposure Point Concentrations (EPCs) are the concentrations of the COPCs in the environmental media at the point of human exposure. DNREC-RS recommends the use of EPA's most current version of the ProUCL software to calculate the EPC of COPCs due to its

wide availability, ease of use, and the regular updates provided by US EPA. Statistical software other than ProUCL should be preapproved by DNREC-RS prior to their use and on a site by site basis. ProUCL is available as a free download from the US EPA. The ProUCL output pages shall be included in the appendices of the report. The ProUCL input files shall be submitted in electronic format with descriptive file names. Selection of the EPCs should 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-RS does not require separate tables for this purpose as does RAGS. However, the RAIS output file is not labeled. Therefore, the RAIS output file should 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.

3.2.2 Exposure Point Concentrations for Soil

The EPCs to be used in risk calculations for soil should be the 95% UCL of the mean of the COPC analytical data set. The ProUCL software takes into account non-detects and calculates the 95% UCL using various methods and recommends the most appropriate UCL to use based on the data. DNREC-RS requires the number of soil samples collected and analyzed to be based on the Data Quality Objectives (DQOs). A minimum of 10 soil samples is recommended to calculate a more reliable UCL but the minimum number of samples may vary depending on site conditions and as determined by DNREC-RS. Using certain statistical methods, ProUCL calculates a UCL for data sets with non-detects (NDs). The ProUCL guidance recommends the use of the detection limit (DL) for non-detects and use of an indicator column with a value of 0 for all non-detects and 1 for all detects. The term DL is used interchangeably for the method detection limit (MDL). DNREC-RS requires the use of the MDL for ND values when calculating a 95% UCLs in ProUCL. If ProUCL recommends an EPC that is above the MOC, then the MOC should be used or other alternatives such as resampling or hot spot elimination can be used with DNREC-RS pre-approval.

Confirmatory results from a fixed laboratory should be used in estimating EPCs. However, on a case by case basis, and in consultation with DNREC-RS prior to use, analytical screening results from the DNREC-RS Screening Laboratory may be incorporated in the calculation of the EPCs. Please note that if the calculated 95% UCL is greater than the MOC, then the MOC should be used as the EPC. However, DNREC-RS may allow other statistical results to be used as EPCs on a site specific basis and with pre-approval.

Lead shall be evaluated separately from other analytes and does not affect the cumulative cancer risk or the Hazard Index. Therefore, lead should not be evaluated in RAIS. Lead should be retained as a COPC if the average is greater than 400 mg/kg. The screening level for restricted use sites (i.e. end uses that are not residential) shall be 800 mg/kg. For the evaluation of lead in the base line risk assessment, the EPC for lead shall be determined by calculating an average or other approved methods. Remediation for lead will normally be required if the EPC is greater than 400 mg/kg (or 800 mg/kg for restricted use sites). DNREC-RS does not anticipate that the child or adult Integrated Exposure Uptake Biokinetic Model (IEUBK) models will be routinely used to evaluate risks due to lead. The models are most useful when the input parameters (in addition to lead in soil concentration) can be established for the exposed population. However, DNREC-RS may allow the use of the IEUBK model on a site specific basis with pre-approval

from DNREC-RS. Additionally, at its discretion, DNREC-RS may require modeling lead exposures if conditions, such as knowledge of elevated lead in drinking water, warrant it.

A special procedure can apply to aluminum, arsenic, chromium, cobalt, iron, manganese and vanadium in soil. Please refer to Appendix 1.3 “Two Sample Hypothesis Testing” for more specific information.

In June 2016, RAIS modified the assumptions for chromium. As a result, the assessment of chromium within the soil risk assessment has changed as well. Unless a site has a history of chromium use, total chromium results in soil should be evaluated as Chrome III, insoluble salts in the risk assessment. If a site has a history of chromium use and the concentration to be used in the human health risk evaluation is above the DNREC-RS developed background screening value, valent-specific data should be collected and used for risk assessment.

3.2.3 Alternative Methods for Calculating Exposure Point Concentrations-Soil

DNREC-RS will accept alternative methods of calculating EPCs for soil provided that DNREC-RS determines that the approach is relevant and appropriate for the Site conditions and is pre-approved by the DNREC-RS.

3.2.4 Exposure Point Concentrations for Sediment

The EPCs for sediment are based on the MOC observed in the samples representing loading from the site and not from an upstream location. The MOC is then inputted into the risk calculator to determine if the contaminant poses a risk to human health. However, if adequate sample results are available to calculate 95% UCL then it can be used for EPC. For both the recreator and trespasser exposure scenario, the sediment and soil sample results can be combined to determine the EPCs for risk evaluation except for site specific concerns. Impact of the sediment from the site soil and groundwater is discussed in the HSCA Mass Loading Guidance. Ecological risk posed by the contaminated sediments will be addressed under the HSCA Ecological Risk Assessment Guidance.

3.2.5 Exposure Point Concentrations for Groundwater

EPC for groundwater should represent a potential future receptor. Therefore, wells should be located 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 restricting groundwater use. Whether an active groundwater remedy is needed should be evaluated under certain criteria and will be discussed within the HSCA guidance for Feasibility Studies and Remedial Actions. EPC for groundwater discharging at a surface water body near the site should be determined using the HSCA Mass Loading Guidance.

The EPC for groundwater should generally be the MOC however, modeling can be used for predicting an EPC if it is pre-approved by DNREC-RS within the CSM-SAP. A 95% UCL can only be calculated and used for determining an EPC for groundwater when certain requirements are met and pre-approved by DNREC-RS. Please refer to the “Determining Groundwater

Exposure Point Concentrations, Supplemental Guidance” (March 2014) document from the Assessment and Remediation Division of the Office of Superfund Remediation and Technology Innovation from the US EPA for more specific information.

Lead shall be evaluated separately from other analytes and does not affect the cumulative cancer risk or the Hazard Index. Therefore, lead should not be evaluated in RAIS. Lead should be retained as a COPC if the MOC is greater than 15 ug/l. Remediation for lead may be required if the EPC is greater than 15 ug/l.

As previously stated, how chromium is assessed within the risk assessment has changed. If the site does not have a history of chromium use and the concentration is above the HSCA Screening Level for total chromium, then the dissolved total chromium results in groundwater should be evaluated as Chrome III, insoluble salts. If the site has a history of chromium use,, then valent-specific data should be collected during the investigation and used within the risk assessment. In any case, one does not need to collect valent-specific data if the site passes residential standards when assuming all detected chromium is chromium VI in the HHRA.

3.2.6 Exposure Point Concentrations for Surface Water

The EPCs for surface water are based on the MOC observed in the samples representing loading from the site and not from an upstream location. The MOC is then inputted into the risk calculator to determine if the contaminant poses a risk. However, if adequate sample results are available to calculate 95% UCL, then that value can be used for the EPC. Impact of the surface water from the site soil and groundwater are discussed in the HSCA Mass Loading Guidance. Ecological risk posed by the contaminated surface water will be addressed under the HSCA Ecological Risk Assessment Guidance.

3.2.7 Exposure Point Concentrations for Vapor Intrusion

It is preferred that EPCs for VI be based upon indoor air samples. However, EPCs for VI can be based on the maximum soil gas or sub-slab results if there are background issues related to indoor air samples. In these cases, the use of indoor air data is problematic due to the high likelihood of indoor sources or outdoor ambient sources of VOCs. Note, 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. Due to the high variability of the sample data on a monthly, daily, or hourly basis, the maximum concentration in soil gas, sub-slab or indoor air should be used as the exposure point concentration. However, if adequate data is available for each sample type, such as soil- gas or sub-slab, to calculate a 95% UCL then that value can be used for the EPC.

3.3 Toxicity Assessment

The risk assessment shall be performed using the default chronic toxicity values used in RAIS, except for VI which was described in the sections 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. RAIS or VISL can be used to calculate risk from inhalation to indoor air but is not to eliminate a potential vapor intrusion evaluation. Since RAIS updates toxicity values without notice, the data 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 protective. That is, “new information” shall not be taken to include a change in the slope factor or reference dose. However, if there are compelling reasons, DNREC-RS at its discretion, may require re-evaluation of risk. DNREC-RS does not require that the risk assessment report include discussion of the health effects of individual chemicals. Human health risk assessment performed for DNREC-RS under HSCA programs shall address a combination of sub-chronic and chronic risks for the appropriate exposure scenarios. Any deviation from the default RAIS sub-chronic values are subject to pre-approval by DNREC-RS. In an effort to be consistent with EPA Region 3, all child exposure scenarios will be based upon chronic values.

3.3.1 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. 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.

The relative bioavailability of one chemical, arsenic, is currently addressed in RAIS. RAIS has assigned a conversion factor of 0.6 and it is automatically accounted for in the risk calculations. The 0.6 factor infers that approximately 60% of the inputted arsenic concentration is bioavailable. All other chemicals are assigned a relative bioavailability factor of 1.0. Inclusion of any other relative bioavailability factors in the risk calculations are subject to approval by DNREC-RS. DNREC-RS 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-RS's satisfaction. If a consultant would like to consider bioavailability on a site specific basis, all information on how it will be assessed should be presented for approval prior to including within reports. This is performed on a site by site basis.

4.0 Risk Calculators

DNREC-RS 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-RS 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 should be pre-approved by DNREC-RS. 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 highlights instances when DNREC-RS has a preference between the practices in RAGS and RAIS. Risk assessors are strongly encouraged to use the RAIS resources and calculators for DNREC-RS submittals. RAGS provides pre-formatted spreadsheet files for the presentation of data and calculations in “Standard Tables” (RAGS Part D). To streamline the risk assessment, DNREC-RS 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 and examples of these tables are provided in Appendix 1.0.

Risk from the VI pathway should be calculated using the most recent version of the Vapor Intrusion Screening Level calculator (VISL) or the Johnson & Ettinger (J&E) model with updated toxicity values. The VISL is the preferred method for determining VI, followed by the J&E model with updated toxicity values. The risk for all parts of the air pathway (groundwater, soil gas, sub-slab and indoor air) should be calculated and evaluated as part of a multiple lines of evidence approach (see Section 3.1.5). 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. When evaluating vapors in groundwater using the VISL or the J&E model, use either the default temperature value of 25 degrees centigrade (77 degrees Fahrenheit) or the maximum groundwater temperature as observed during groundwater sampling and documented in the groundwater sampling forms. The other default input values should be used in both models, except where Site specific information is present (J&E-soil types, building size, etc.) which can and should be documented. For the J&E model, the calculated indoor air concentrations are shown on the Intercalcs tab under “Infinite Source Building Concentration”.

Excavation 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.

If a specific region is selected for the particulate wind emissions factor within the air evaluation (i.e. Philadelphia), instead of the default, please specify within the text of the Risk Assessment report. All variations on default parameters must be thoroughly discussed within the appropriate sections of the Risk Assessment report.

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.

5.0 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. While the cancer risks to a site can be summed over the adult and child risk to determine whether or not a remedial action is needed, the non-cancer risk is determined by the child HI. If the child HI for a decision unit is greater than one (>1), then the Hazard Quotients for the COCs should be grouped according to target organ for all routes of exposure and recalculated. In accordance with EPA Region 3, the chronic reference dose and concentration target organs should be selected for the grouping instead of the unit risk target organ. This is because the unit risk target organ assumes that the risk is linear. The HI per target organ shall be presented on Table D. If the child HI value exceeds 1, with rounding, then a remedial action should be proposed. DNREC-RS determined that this is a conservative estimation of risk because a child is generally a more sensitive receptor than an adult. The calculated residential adult risk can only be used to determine whether or not a remedy is needed if the end use is adult only specific. In this case, restriction on site use by a child must be reflected within the Environmental Covenant.

In keeping with EPA Guidance (RAGS Part A Chapter 8 p. 12ff and Exhibits 8-2 & 8-3), individual and cumulative cancer risks, hazard indexes and hazard quotients should be reported using one (1) significant digit. Note that RAIS output typically reports risk with unwarranted precision. Do not change RAIS output, but the risk assessment narrative should use only one significant digit (example: cancer risk due to arsenic = $5E-6$). Initial rounding should be to three significant figures. The final rounding should be to one significant figure. For example, $1.4325684E-5$ is rounded to $1.433E-5$ and then rounded to $1E-5$.

6.0 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 the 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 1.2. Risk assessments submitted to DNREC-RS should include all parameters used in calculation of risk values so as to facilitate verification of the results. Departures from RAIS should be pre-approved by DNREC-RS 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 as a separate electronic file with an electronic copy of the report.

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References and Helpful Links

Delaware Regulations Governing Hazardous Substance Cleanup. March, 2019. The Delaware Department of Natural Resources and Environmental Control, Division of Waste and Hazardous Substances, Site Investigation and Restoration Section.
<https://regulations.delaware.gov/AdminCode/title7/1000/1300/1375.pdf>

Determining Groundwater Exposure Point Concentrations, Supplemental Guidance. March, 2014. United States Environmental Protection Agency, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation.
<https://nepis.epa.gov/Exe/ZyNET.exe/P100NXHC.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2011+Thru+2015&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C11thru15%5CTxt%5C00000018%5CP100NXHC.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL>

Exposure Factors Handbook. 2011 Edition. United States Environmental Protection Agency.
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APPENDIX 1.0 - Risk Assessment Tables

Table A: Selection of Exposure Pathways (Example)

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	Shallow Soil	Shallow Soil (0-2' 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	Shallow Soil	Shallow Soil (0-2' bgs)	Outdoor Worker	Adult	Ingestion, Dermal, Inhalation	
Current/Future	Soil	Shallow Soil	Shallow Soil (0-2' bgs)	Resident	Child/Adult	Ingestion, Dermal, Inhalation	Resident gardener may be exposed to soil to a depth of 2' bgs.
Current/Future	Soil	Combined Soil	Soil (0-10' bgs)	Resident	Child/Adult	Ingestion, Dermal, Inhalation	Resident may be exposed to deep soil excavated during construction activities and combined with shallow soil at site surface.
Current/Future	Soil	Shallow Soil	Shallow Soil (0-2' bgs)	Outdoor Worker	Adult	Ingestion, Dermal, Inhalation	
Current/Future	Soil	Shallow Soil	Shallow Soil (0-2' bgs)	Indoor Worker	Adult	Ingestion, Inhalation	
Current/Future	Soil	Shallow Soil	Shallow Soil (0-2' bgs)	Composite Worker	Adult	Ingestion, Dermal, Inhalation	
Current/Future	Soil	Shallow Soil	Shallow Soil (0-2' bgs)	Construction Worker	Adult	Ingestion, Dermal, Inhalation	

Current/Future	Soil	Combined Soil	Soil (0-10' bgs)	Construction Worker	Adult	Ingestion, Dermal, Inhalation	
Current/Future	Soil	Combined Soil	Soil (0-10' bgs)	Excavation Worker	Adult	Ingestion, Dermal, Inhalation	Excavation 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 B: Selection of Contaminants of Potential Concern- Soil (Example)

Site Name
DE# XXXX

Medium	Exposure Medium	Chemical	Maximum Concentration	Lab Qualifier	Units	DNREC Screening Value	COPC Flag (Y/N)	Comment
Soil	Shallow Soil (0-2' bgs)	Arsenic	9		mg/kg	11	N	
Soil	Shallow Soil (0-2' 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		mg/kg	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) (Example)

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	Shallow Soil	Benzo(a)pyrene	10/20	3	3.8	4.2	mg/kg	UCL	Nonparametric 95% Chebyshev
Soil	Shallow Soil	Lead	5/20	750	--	990	mg/kg	Mean	
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	Exposure Route	EPC	Units	Carcinogenic Risk	Hazard Index	Target Organ	Comment

Table D: Risk Summary for Receptors (Example)

Site Name

DE# XXXX

Timeframe: Future

Receptor: Excavation Worker

Exposure Media	Exposure Route	COPC	EPC	Units	Carcinogenic Risk	Hazard Index	Target Organ	Comment	
Shallow 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 1.1 - Determining Contaminants of Concern Using the Background Threshold Values and Hypothesis Testing

Background Threshold Values (BTV) 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 95th 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 the 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 its presence is consistent with naturally occurring conditions), DNREC-RS recommends a two sample hypothesis test using data from the subject site and DNREC-RS' 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

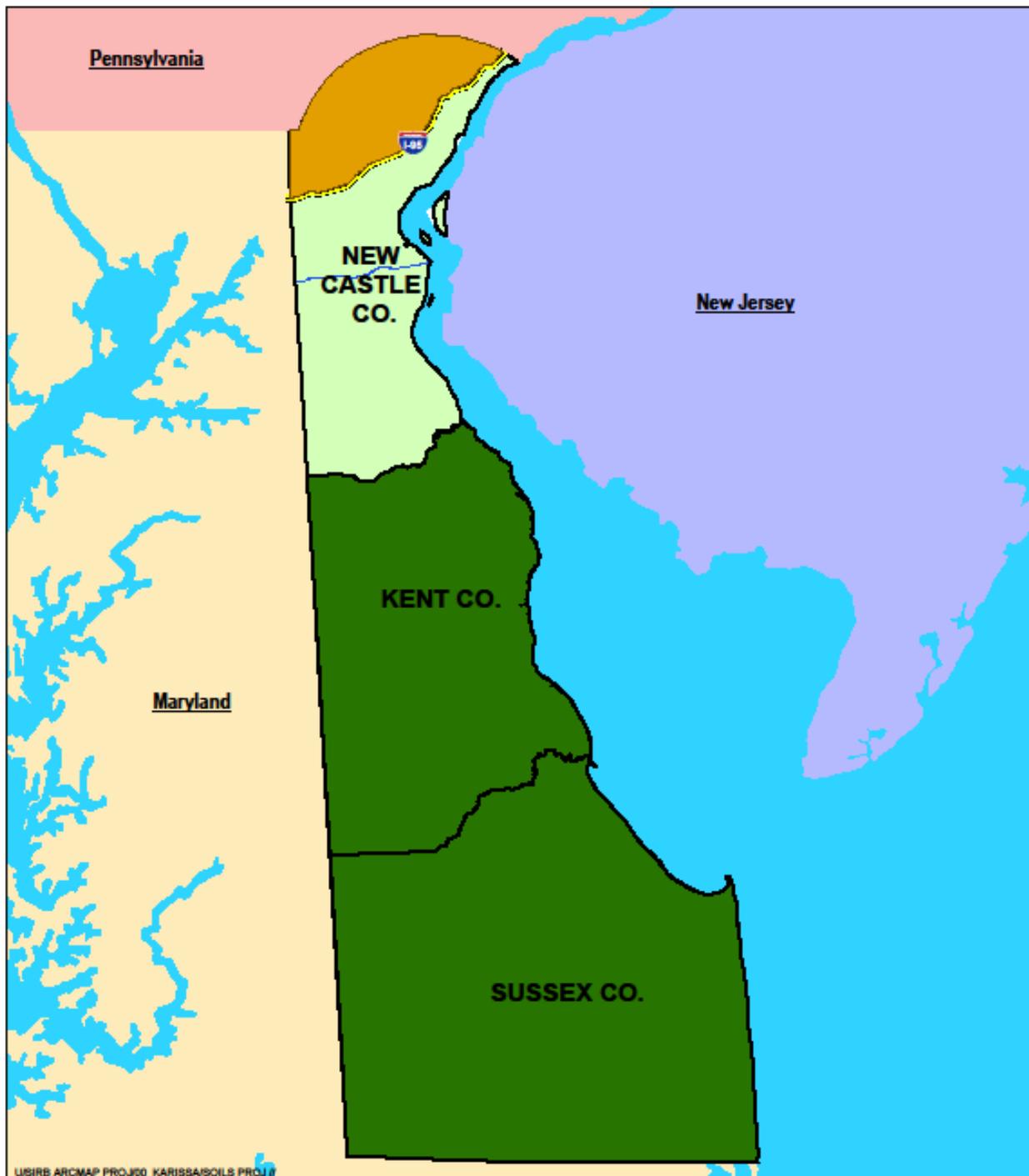
t-test, Wilcoxon-Mann-Whitney (WMW) test or Gehans test. DNREC-RS has provided ProUCL-ready input files for the three reference data sets.

The hypothesis testing procedure is outlined below. NOTE: *only follow these steps if the maximum observed concentration of an analyte at the 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 for non-detections or 1 for detects.
- 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.¹ For all tests, retain the ProUCL default option for the form of the null hypothesis¹. 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-RS on request.



Legend

- Piedmont
- Northern Coastal Plain
- Coastal Plain



**FIGURE 1
BACKGROUND
PROVINCE BOUNDARIES**

0 10 20 Miles 1:700,000

KDH00_2013GIS2013KDHGIS2013_0004

APPENDIX 1.2: 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 should be approved by DNREC-RS 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 Contaminants of Potential Concern

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

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 receptors, 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.

APPENDIX 2: Summary of 2020 Revisions to Human Health Risk Assessment Guidance under HSCA

1. Revised DNREC-SIRS to DNREC-RS to reflect the new section name.
2. Revised the Default Assumptions for Each Receptor table within Section 2.1.2.2 for recreator to reflect the updated RAIS assumptions. Exposure frequency for surface water was updated to 45 days from 75 days.
3. Added clarification on any changes to the exposure duration and frequency for the excavation worker risk scenario.
4. Added clarification on the evaluation of air media within RAIS.
5. Added clarification on mixed use scenario.
6. Added text stating that commercial use must evaluate the child HI vapor intrusion pathway or restrict the property that it can not be occupied by sensitive receptors on the Environmental Covenant. Added clarification that playgrounds will be evaluated under the residential use risk scenario.
7. Added a definition of “sensitive receptors”.
8. References to “sensitive populations” were changed to “sensitive receptors”.
9. Added clarification that COPC can be eliminated from further consideration if the calculated 95% UCL is below the appropriate HSCA Screening Level.
10. Added clarification on the evaluation of TIC and targeted compounds within the risk assessment
11. Added definitions of COPC and COC
12. Added text stating that risk to residential should be determined on the calculated child HI and not the calculated adult HI. Using the calculated adult HI is only appropriate for adult specific end uses and must be reflected in an Environmental Covenant.
13. References and Helpful Links sections were combined into the References.
14. Clarified that the “restricted use” term for lead exposure is referring to any end use other than residential.
15. Adding clarification to rounding calculated risk values.
16. Clarification on the use of surface and shallow soil samples in risk assessment.
17. Added text stating that DNREC-RS would consider the use of intermediate samples for risk determination when the ending depth on the deep sample is considerably lower than any potential human interaction and risk on a site specific basis.
18. Clarified the text on the use of valid ProUCL calculated statistics of data sets less than confirmatory 10 samples.

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