



U.S. Navy Human Health Risk Assessment Guidance

Chapter 8 – Tier II Baseline Risk Assessment

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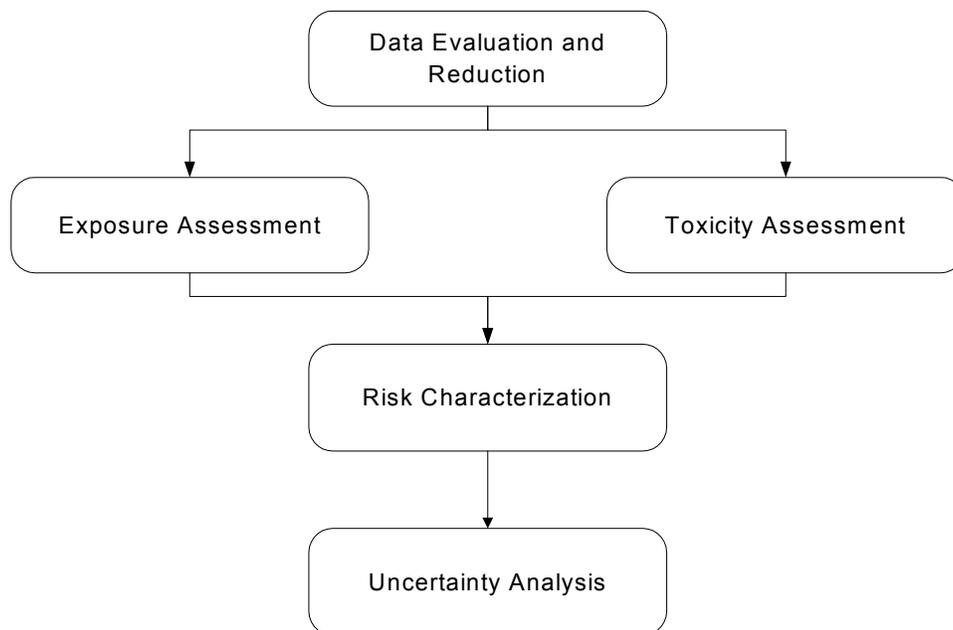
8.0 Introduction

This chapter presents the steps that comprise a Baseline Human Health Risk Assessment (BHHRA). The BHHRA is the second tier of the risk assessment evaluation process. BHHRAs are appropriate for sites that are too complex to be evaluated or eliminated from further consideration based on Tier I approaches. A Tier II BHHRA is performed when:

- 1.) site chemical concentrations are greater than Tier IA risk-based concentrations (RBCs); and/or
- 2.) site chemical concentrations are greater than Tier IB RBCs (optional step).

BHHRAs are also appropriate for sites where the conceptual site model (CSM) is different from the CSM that serves as the basis for the standard risk-based concentrations (RBCs). [Figure 8.1](#) presents an overview of the BHHRA process. The following sections discuss the components of the BHHRA.

Figure 8.1 – Overview of the Baseline Human Health Risk Assessment Process



8.1 Purpose and Objectives

The purpose of a BHHRA is to determine if a site poses acceptable risk levels based on current or future land use and current (i.e., baseline) site conditions if no remediation or institutional controls are applied at the site (USEPA, 1989). BHHRAs also provide a basis for determining levels of chemicals that can remain on site and still be adequately protective of public health.

BHHRAs are site-specific and therefore, may vary both in detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site (USEPA, 1989). The risk assessment report can range from a small chapter in the site characterization report, to a large, complex, independent document with many appendices (USEPA, 1989). The BHHRA is a vital component of risk management as it can identify what sites or constituents pose the greatest risk and therefore indicate where resources can be most effectively applied.



Note: As with all risk assessment activities, it is important that the BHHRA process is transparent and that the assumptions incorporated into the evaluation are appropriate to the site. Transparency results when all of the data and assumptions used in the evaluation are well documented so that others can easily understand and review the process.

8.2 Tier II Exit Criteria

8.2.1 EXIT CRITERIA

Exit criteria are quantitative expressions of acceptable risks that may be used in conjunction with institutional controls and land use to determine if a site can exit the HHRA process or warrants further evaluation. In general, if a BHHRA is performed it means that there are chemical concentrations present at a site that are greater than background concentrations and also greater than RBCs. The BHHRA provides risk estimates for different exposure scenarios and land uses. This information is used by Remedial Project Managers (RPMs) to make one of the following risk management decisions.

- 1.) **Exit the Human Health Risk Assessment Process** if:
 - a. **Incomplete Exposure Pathways** – The chemicals present on site are not currently accessible to humans or will not be accessible based on future land use (e.g., non-volatile chemicals under a building foundation, no human populations present, etc.) then there is no possibility for human exposure and, therefore, no risk.
 - b. **Background** – There are no chemical concentrations present on the site that are greater than background concentrations. *Note: This applies to all chemicals that are present in background samples. If a chemical was not detected in background samples, then it should not be screened out and should be evaluated further using risk-based approaches.*
 - c. **Risk-Based Screening** – There are no chemicals present at the site that are greater than RBCs. *Note: This comparison should also include chemicals detected at concentrations that are not representative of background concentrations. Essential nutrients (i.e., calcium, magnesium, potassium, iron and sodium) should be eliminated from consideration in the risk assessment because they are not associated with toxicity in humans under normal circumstances. Also, chemicals that are detected infrequently and at low concentrations (e.g., less than 5% frequency of detection and at concentrations slightly above the detection limit) should be eliminated from further consideration in the risk assessment process (USEPA, 1989).*
- 2.) **Determine that the Risks are Acceptable** (i.e., a hazard index less than 1 or a cancer risk less than 1E-04). Risk managers may determine that risks are acceptable based on the BHHRA and decide that no further action is necessary. The site would then exit the risk assessment process, although Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs), which are used to evaluate drinking water, and ecological risks should still be evaluated.
- 3.) **Determine that the Risks are Unacceptable** (i.e., a hazard index greater than 1 or a cancer risk greater than 1E-04). Risk managers may determine that risks are unacceptable based on the BHHRA and decide that further action is necessary. The options available at that point include:
 - a. **Modify Future Land Use Assumptions** - Modify the BHHRA based on institutional controls that will result in a different land use (only with stakeholder input).
 - b. **Gather Additional Site-specific Information** - The results of the BHHRA may, for example, suggest that a certain pathway of exposure is determining the overall outcome



of the risk assessment. An RPM could address the issue by collecting more site-specific exposure information, to reduce the uncertainty associated with evaluating this pathway in the BHHRA.

- c. **Feasibility Study** - Evaluate different remedial alternatives to determine if there are feasible ways for minimizing the risk.

- 4.) **Perform an Interim Removal Action** - Remove some or all of the contamination and then re-evaluate the site using the exit criteria presented above.

Note: If a site exits the human health risk assessment process, MCLs or non-zero MCLGs and ecological risks should still be considered. In addition, the exit criteria and risks presented in this section should not be viewed as discrete values. RPMs should evaluate each site on a case-by-case basis to determine if the risks are considered acceptable or unacceptable (USEPA, 1991c). In some situations, risks that are acceptable at one site may not be considered acceptable at another site. This may be due to a variety of site-specific factors, such as the uncertainty associated with characterizing exposure or the uncertainties associated with the toxicity values of chemicals responsible for the majority of the risk.

After completing Tier II, a site will either go to Tier III or exit the HHRA process. [Figure 8.2](#) presents exit criteria for the BHHRA in the context of the overall site remediation process. Regardless of the initial exit criteria that are pursued, it is important for RPMs to continually re-evaluate their sites with regard to the exit criteria, to determine if they may exit the HHRA process. In addition, sites that exit the HHRA portion of the process are not necessarily no further action sites. For example, an industrial site that meets the exit criteria through the implementation of institutional controls would require a proposed plan, action Record of Decision, and 5-year review.

8.2.2 BACKGROUND INFORMATION ON EXIT CRITERIA

Exit criteria are developed based on regulatory benchmarks and health risks (both cancer and noncancer). They may also take into account land use and/or institutional controls. The regulatory benchmarks and land use are discussed below. For more information on cancer and noncancer risks see sections 8.6 Toxicity Assessment and 8.7 Risk Characterization in this chapter.

Regulatory Benchmarks

The United States Environmental Protection Agency (USEPA) has typically used a hazard index (i.e., the cumulative noncancer risks for all chemicals) of 1 or greater or a hazard index for a target organ/critical effect of 1 or greater as a benchmark for evaluating noncarcinogenic hazard indices. For carcinogenic risk, the USEPA's approach "emphasizes the use of 1 chance in one million [i.e., 1E-06] as the point of departure while allowing site or remedy-specific factors, including potential future uses, to enter into the evaluation of what is appropriate at a given site." As risks increase above 1 chance in 1,000,000, they become less desirable, and the risk to individuals generally should not exceed 1 in 10,000 (i.e., 1E-04) (USEPA, 1991c). The USEPA recommends, "where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 1E-04 and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs [Maximum Contaminant Levels] or non-zero MCLGs [Maximum Contaminant Level Goals, which are used to evaluate drinking water] are exceeded, action generally is warranted (USEPA, 1991c)."

Impact of Land Use and Institutional Controls on Exit Criteria

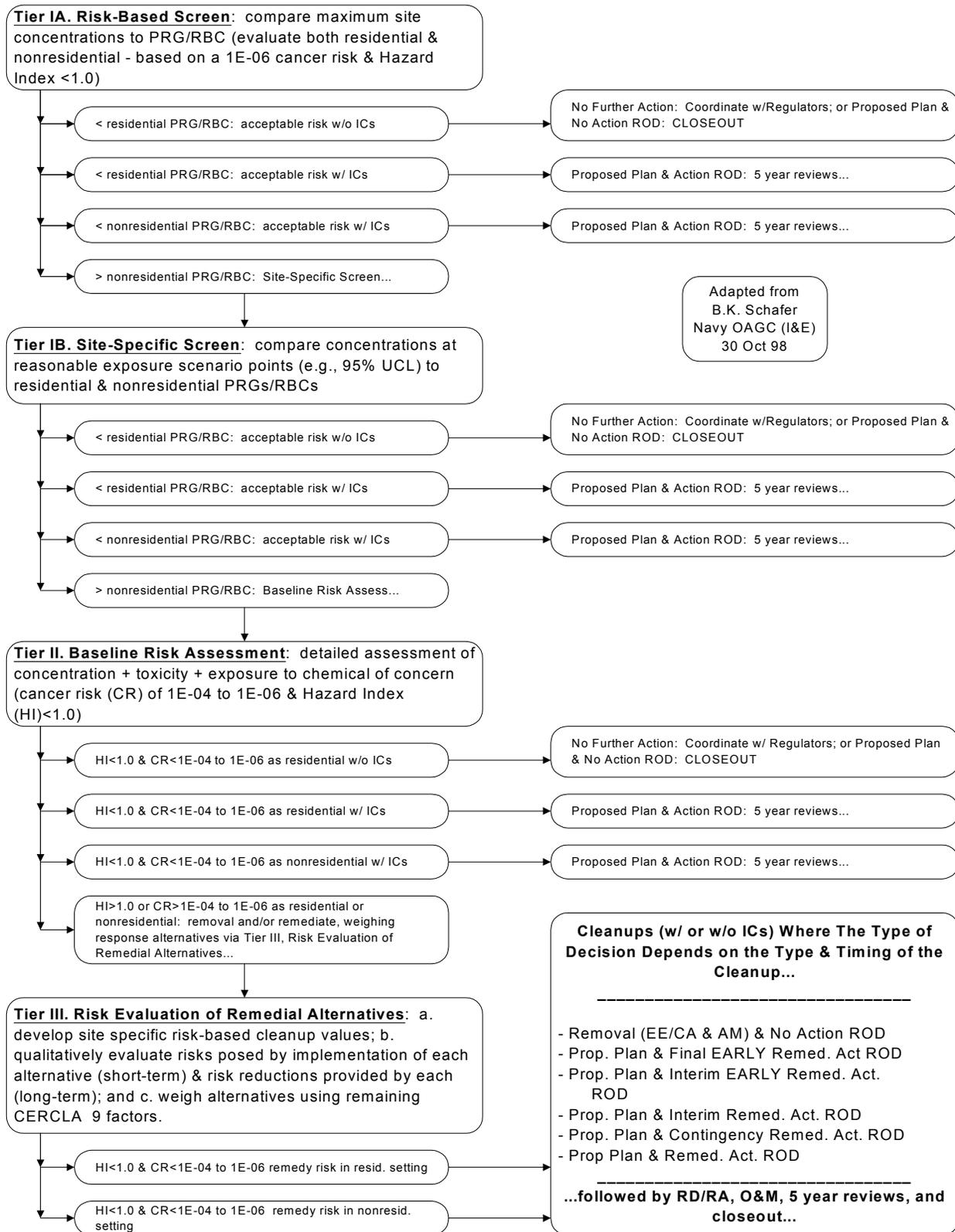
In some cases the Tier II BHHRA results depend on land use controls (LUCs), such as institutional controls or future land use decisions. It is important to understand the benefits of land use controls (LUCs), as well as the restrictions that accompany them. Implementing LUCs for a site can be beneficial because it allows the risk assessment to reflect actual future land use, which can lower the cost of the remediation if a land use other than residential is specified. This is due to the fact that exit criteria for land uses other than residential (e.g., industrial) are typically less stringent. Although LUCs may present a



viable option as part of a remedy, it is important to consider the long-term, life-cycle, costs of LUCs (e.g., long-term monitoring). The implementation of LUCs is a risk management decision and the long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use.



Figure 8.2 – Navy Tiered CERCLA Process





8.3 Elements of Tier II

The BHHRA process is iterative because many of the steps depend on other steps which, in turn, depend on information that is generated as part of the site evaluation process. For example, when additional site sampling data are gathered, new chemicals are often added to the risk assessment, which will result in changes to the toxicity assessment. In other cases, site characterization activities may indicate that an additional media is contaminated, which will result in modifications to both the CSM and the exposure assessment.

The BHHRA can be divided into five different steps that are organized as follows.

1.) Data Evaluation and Reduction

- ◆ Collate the data.
- ◆ Assess the quality of the data based on the site-specific Data Quality Objectives (DQOs).
- ◆ Evaluate the data to identify chemicals of potential concern (COPCs).
 - Compare site concentrations to background concentrations.
 - Compare site concentrations to RBCs.
 - Eliminate essential nutrients and chemicals detected infrequently from further consideration in the BHHRA.
- ◆ Calculate exposure point concentrations (EPCs).

2.) Exposure Assessment

- ◆ Develop or update the CSM. This includes identifying exposure scenarios and complete exposure pathways (for an example CSM see Figure 8-6).
- ◆ Identify exposure factors for receptors of concern.
- ◆ Calculate exposures for each COPC/medium/pathway combination.

3.) Toxicity Assessment

- ◆ Identify toxicity values for the COPCs.

4.) Risk Characterization

- ◆ Calculate the cancer risks and noncancer hazard indices.
- ◆ Summarize the site risks by chemical and medium for the receptors, exposure scenarios, and exposure pathways identified in the CSM.

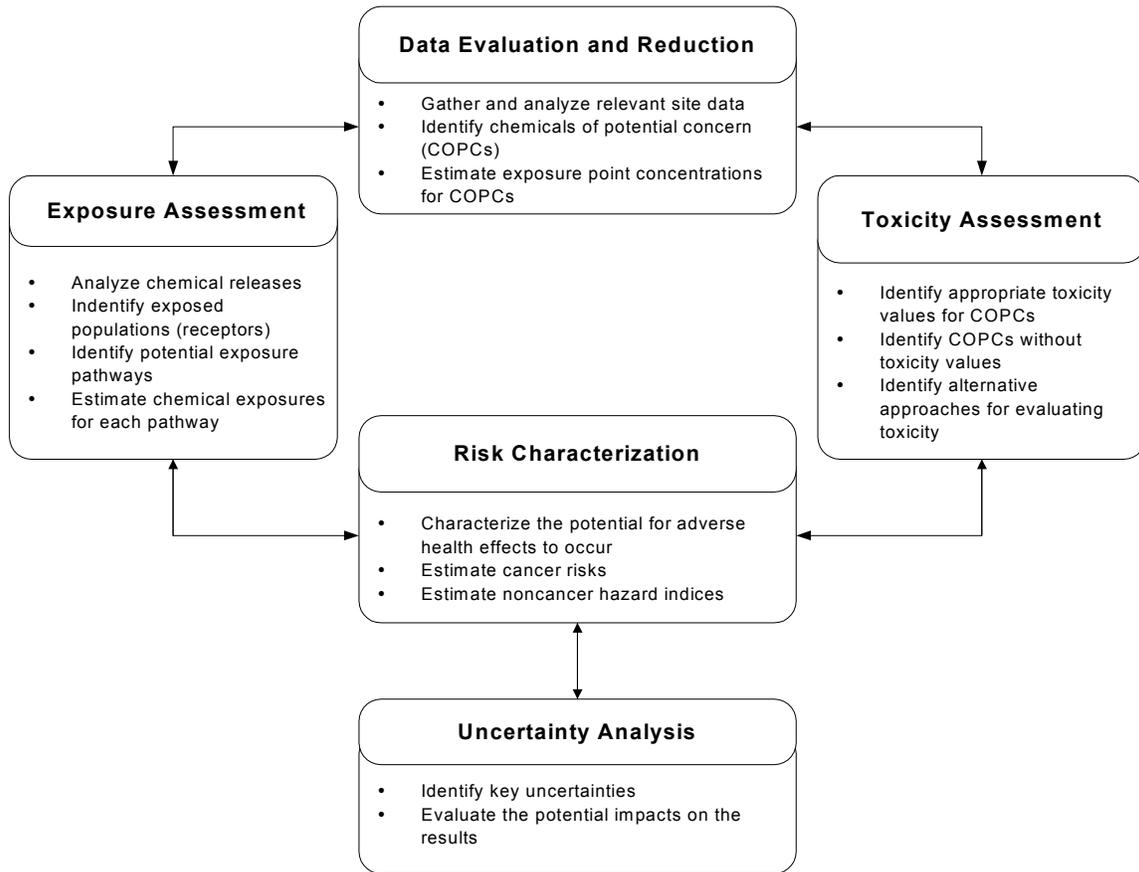
5.) Uncertainty Analysis

- ◆ Identify key uncertainties and evaluate their potential impacts on the results.

The BHHRA process is presented in [Figure 8.3](#).



Figure 8.3 – Baseline Risk Assessment Process



Data Evaluation and Reduction is the process of identifying COPCs for evaluation in the BHHRA. The Exposure Assessment begins with the refinement of the CSM and is completed when all of the plausible exposure pathways have been identified and exposures to the COPCs have been calculated. The Toxicity Assessment identifies toxicity values in order to evaluate cancer risks and noncancer hazards. Risk Characterization integrates the information from previous steps to produce numerical estimates of cancer risks and noncancer hazards. The Uncertainty Analysis identifies key uncertainties and evaluates their potential impacts on the risks. Each of these steps in the BHHRA process is discussed in detail in the following sections.

8.4 Data Evaluation and Reduction

8.4.1 INTRODUCTION

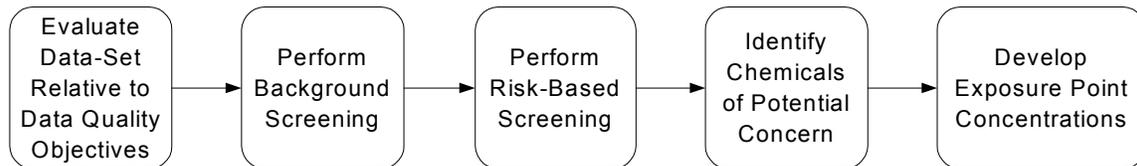
The purpose of the data evaluation and reduction process is to:

- 1.) identify COPCs; and
- 2.) calculate representative exposure point concentrations (EPCs) for the COPCs.



This process entails a variety of different analytical steps that result in a useable data set for evaluating exposures at a site. The level of effort and need for each step depends on the quantity of the data, the complexity of the site, and analytical results. Figure 8.4 identifies the steps in the process, which are discussed below.

Figure 8.4 – Data Evaluation and Reduction Process



8.4.2 EVALUATE DATA QUALITY OBJECTIVES

Analytical data are the foundation of a BHHRA and should be evaluated to ensure that the site-specific DQOs have been achieved. DQOs ensure that the information needed to perform a credible BHHRA is collected. The key data quality objectives for a BHHRA include the following.

- ◆ **Data Quality** – The analytical data should be of suitable quality for HHHRA purposes. That is, data should be collected in a manner that provides a basis for making remedial decisions at a site.

Note: Some of the data collected for the site investigation (e.g., Hnu organic vapor detector measurements) may not be suitable for the purposes of the BHHRA, because they do not meet the DQOs.

- ◆ **Site Characterization** – Enough samples should be collected to adequately characterize the site. In addition to sampling density and coverage considerations, it is important that all media of concern are sampled at likely exposure points.

Note: In many cases a BHHRA is performed after several different rounds or phases of data collection. It is important to incorporate all of the available data into the data evaluation and reduction process. If data are excluded from consideration in the risk assessment, then the rationale should be clearly documented.

- ◆ **Analytical Detection Limits** – The analytical methods used at a site are critical to the BHHRA because they can significantly influence the EPCs and, ultimately, the results of the evaluation. Therefore, it is important that the analytical methods selected for a site are sensitive enough to support the needs of the risk assessment (i.e., the detection limits for COPCs should be less than the applicable exit criteria).

8.4.3 BACKGROUND SCREENING

Purpose of Background Screening

On 18 September 2000 the Office of the Chief of Naval Operations (CNO) issued the Interim Final Navy Policy on the Use of Background Chemical Levels in Risk Assessment (USNAVY, 2000). The purpose of this policy is to provide clarification of the Navy's policy on the consideration of background chemical levels in the list of COPCs in the Environmental Restoration Program. The Policy describes how to consider background chemicals levels in the program by:

- 1.) identifying those chemicals that are in the environment due to releases from the site;
- 2.) eliminating from consideration in the risk assessment process both naturally occurring and anthropogenic chemicals that are present at levels below background;



- 3.) ensuring documentation and discussion of potential risk from chemicals that have been eliminated during the background evaluation process; and
- 4.) developing remediation action levels that are not below background.

Screening out chemicals based on site-specific background or reference-area concentrations is an important step in the identification of COPCs. The purpose of background screening is to focus the risk assessment on COPCs that are related to site activities and to eliminate chemicals that are present at background concentrations. Background is defined in the Interim Final Navy Policy on Background Chemical Levels as either naturally occurring (non-anthropogenic) or anthropogenic (non-naturally occurring), which are unrelated to Navy activities or operations (USNAVY, 2000). The purpose of a site risk assessment is to estimate the incremental risks associated with contamination present at the site due to Navy activities, not background contamination.

Determining Background Concentrations

Background concentrations of chemicals can be determined from existing site or base-wide information, published regional or national background concentrations, or by developing a sampling program to establish background concentrations. The following Navy Guidance documents present approaches for identifying background concentrations of chemicals and determining if site concentrations are significantly different.

- ◆ Naval Facilities Engineering Command. September 1998. Procedural Guidance for Statistically Analyzing Environmental Background Data. SWDIV and EFA WEST.
- ◆ Naval Facilities Engineering Command. July 1999. Handbook For Statistical Analysis of Environmental Background Data. SWDIV and EFA West.

8.4.4 RISK-BASED SCREENING

Tier IA or Tier IB risk-based screening should be performed on the data set to help focus the BHHRA on COPCs that will contribute significantly to the risk. Chemicals that are present at concentrations lower than their RBC should be excluded from the BHHRA. Chemicals that are present at concentrations higher than their RBC should be retained for further evaluation in the BHHRA. See Chapter 7 – Tier IA and Tier IB Risk-Based Screening for more information. Sites should be evaluated on a case-by-case basis because there are exceptions to these general rules. For example, if there are a number of chemicals present at concentrations just below their respective RBCs, they may be retained for further evaluation in the BHHRA because, collectively, they may impact the total risk.

Note: Some USEPA Regions use different target risk goals to develop RBCs depending on the type of evaluation being performed. For example, USEPA Region III recommends that a target risk goal of 1/10th the RBC be used when screening chemical concentration versus noncancer RBCs. Therefore, it is important to check USEPA Regional Guidance, if available, to determine the target risk goals that should be used in risk-based screening.

8.4.5 DEVELOP A LIST OF CHEMICALS OF POTENTIAL CONCERN

The purpose of this step is to identify a list of chemicals at a site that are present due to Navy activities. A list of COPCs is determined once analytical methods, quantification limits, qualifiers, and blanks have been evaluated and background screening and risk-based screening have been completed. These COPCs will then be the focus of the BHHRA. Eliminating chemicals from further consideration reduces the level of effort and focuses the BHHRA on chemicals that pose the majority of the risks. Criteria for identifying COPCs for a site are as follows.

- 1.) Chemicals that were not detected in any samples for a particular medium should be eliminated from further consideration in the BHHRA (USEPA, 1989).



- 2.) Essential nutrients (i.e., calcium, magnesium, potassium, iron and sodium) should be eliminated from consideration in the BHHRA because they are not associated with toxicity in humans under normal circumstances (USEPA, 1991a).
- 3.) Chemicals that are detected infrequently and at low concentrations (e.g., less than 5% frequency of detection and at concentrations slightly above the detection limit) should be eliminated from further consideration in the BHHRA (USEPA, 1989).
- 4.) Chemicals detected at concentrations that are not representative of background concentrations should be retained for further evaluation in the BHHRA.
- 5.) Chemicals detected at concentrations that exceed RBCs should be retained for further evaluation in the BHHRA.

The use of these criteria is contingent on the availability of sufficient data to characterize the site. It is also important to work with regulators and stakeholders to ensure that they agree with the decision rules that are employed to eliminate chemicals from further consideration in the BHHRA.

8.4.6 DEVELOP EXPOSURE POINT CONCENTRATIONS FOR CHEMICALS OF POTENTIAL CONCERN

The next step in the process, after COPCs have been identified for each medium, is to determine representative concentrations of each chemical to which populations will be exposed. The issues associated with developing representative exposure point concentrations are discussed in the following sections.

Field Duplicate Samples

Field duplicates are often collected, as part of the quality assurance process, to evaluate a laboratory's ability to provide reproducible results. Field duplicate results can either be combined into one sample or they can be included in the risk assessment as discrete results. In some cases, including both field results as independent samples may bias the overall exposure point concentrations by over representing a sample location. If this is a concern, then the field duplicate data can be grouped together using decision rules, such as:

- ◆ if a chemical is detected in both of the field duplicate samples, then use either the maximum of the two values or the average of the two values;
- ◆ if a chemical is detected in only one of the field duplicate samples, then use the detected value; or
- ◆ if a chemical is not detected in either of the field duplicate samples, then use the higher of the two sample-specific detection limits.

These decision rules should be modified in order to incorporate site-specific considerations.

Approaches for Incorporating Non-Detected Data into the Calculation of Exposure Point Concentrations

Most chemicals at a site are not detected in every sample, and therefore, the sample quantitation limit (SQL) is usually reported. SQLs are the sample-specific detection limits and take into account sample characteristics, sample preparation, and analytical adjustments. They are the most relevant quantitation limits for evaluating non-detected chemicals. From a risk assessment perspective, these results provide valuable information that should be incorporated into the evaluation. A chemical that was not detected in a sample above the SQL could actually be present in the sample at a concentration that is less than the SQL.

Incorporating non-detected results into the BHHRA requires professional judgment and site-specific information. The guiding principle when evaluating non-detected data is that the exposure point concentrations should be representative of site conditions. The USEPA recommends that if there is



reason to believe that the chemical is present in a sample at a concentration below the SQL, then ½ of the SQL should be used as a proxy concentration (USEPA, 1989).

RME and CTE Exposure Point Concentrations

The USEPA recommends that both a high-end descriptor of risk (i.e., Reasonable Maximum Exposure [RME]) and a central tendency exposure (CTE) (e.g., average or median estimate) descriptor of risk should be included in the BHHRA (USEPA, 1995a). Evaluating RME and CTE scenarios provides risk managers with a range of risks, which is useful in the decision-making process. In general, CTE estimates are created by replacing the exposure factors and, in some cases, the exposure point concentrations, used in the RME scenario, with average or median values. The USEPA recommends that the RME be based on a plausible upper-bound estimate of exposure rather than the worst-case exposure scenario. The CTE exposure estimate should be either the arithmetic mean exposure (average estimate) or the median exposure (median estimate) (USEPA, 1995a).

For the RME scenario, the EPC should be based on the 95 percent upper confidence limit (95% UCL) or the logarithmic 95% UCL on the average concentration. For the CTE scenario, the EPC should be based on the average, logarithmic average, median concentration, or the 95% UCL on the average concentration. The underlying distribution of the analytical data should be evaluated to determine if the arithmetic or the logarithmic statistic should be selected as the EPC. See the USEPA's *Supplemental Guidance to RAGS: Calculating the Concentration Term* for more information on calculating EPCs (USEPA, 1992b).

Note: The RME and CTE EPCs should not exceed the maximum detected concentration which may occur due to elevated SQLs. In instances where this occurs, the maximum detected concentration should be used as the EPC.

Background on Developing Representative Exposure Point Concentrations

The key step in determining representative exposure point concentrations is understanding the nature and extent of contamination at the site. For example, data at a site with a hot spot (i.e., significantly elevated chemical concentrations in a discrete area) may be grouped together differently than at a site that doesn't have a hot spot. At other sites there may be distinctly different patterns of contamination between surface soil and subsurface soil. In every case, the foundation of a good risk assessment is a clear understanding of the chemical data.

There are a variety of different ways to evaluate sites in order to develop representative EPCs, such as:

- ◆ subdivide the site based on future land use if portions of the site are going to be used for different purposes;
- ◆ subdivide the site based on historical information (e.g., production or disposal areas). For example, it is a good idea to evaluate hot spots separately from the rest of the site. Identifying hot spots eliminates the possibility that a small area of contamination will bias the overall evaluation; and/or
- ◆ subdivide data based on temporal trends. If the concentrations are significantly different over time it may make sense to use only the most current data.

Data Presentation Strategies

An important part of a BHHRA is the presentation of the chemical data that are used to develop EPCs. In general, brief statistical summaries of the site's chemicals should be presented in the body of the BHHRA, and the underlying data and summary statistics should be presented in an appendix. The key to effectively presenting data in the BHHRA is to help focus the reader on the chemicals that are responsible for the majority of the risks. This requires coordination between the Risk Characterization and Data



Evaluation and Reduction steps. The following list presents recommendations for effectively presenting data:

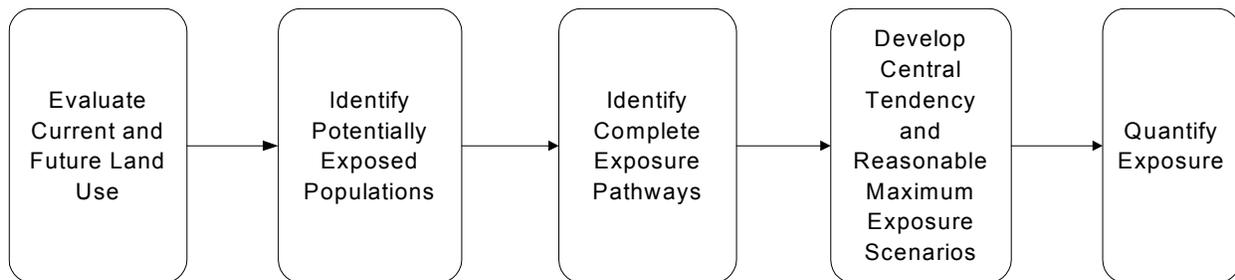
- ◆ present the steps that were used to identify COPCs for evaluation in the BHHRA;
- ◆ discuss significant site-specific considerations associated with the data (e.g., quality control issues);
- ◆ present the steps that were taken to identify natural and anthropogenic background concentrations, and which statistical tests were used to compare site concentrations to background;
- ◆ identify the source of the RBCs and the appropriateness of their use for screening out chemicals; and
- ◆ use maps, graphs, and other visual summaries to present chemical concentrations.

Some sites have a lot of data that, if presented in detail in the body of the BHHRA, might overwhelm the reader with unnecessary information. The data evaluation section should summarize the data in a manner that enables the reader to easily understand how the data were reduced to the final data-set that is evaluated in the BHHRA.

8.5 Exposure Assessment

The purpose of the exposure assessment is to quantify human exposure to COPCs for complete exposure pathways. The results of the exposure assessment are combined with toxicity information to characterize potential risks. [Figure 8.5](#) identifies the major steps in the exposure assessment and how these steps are related.

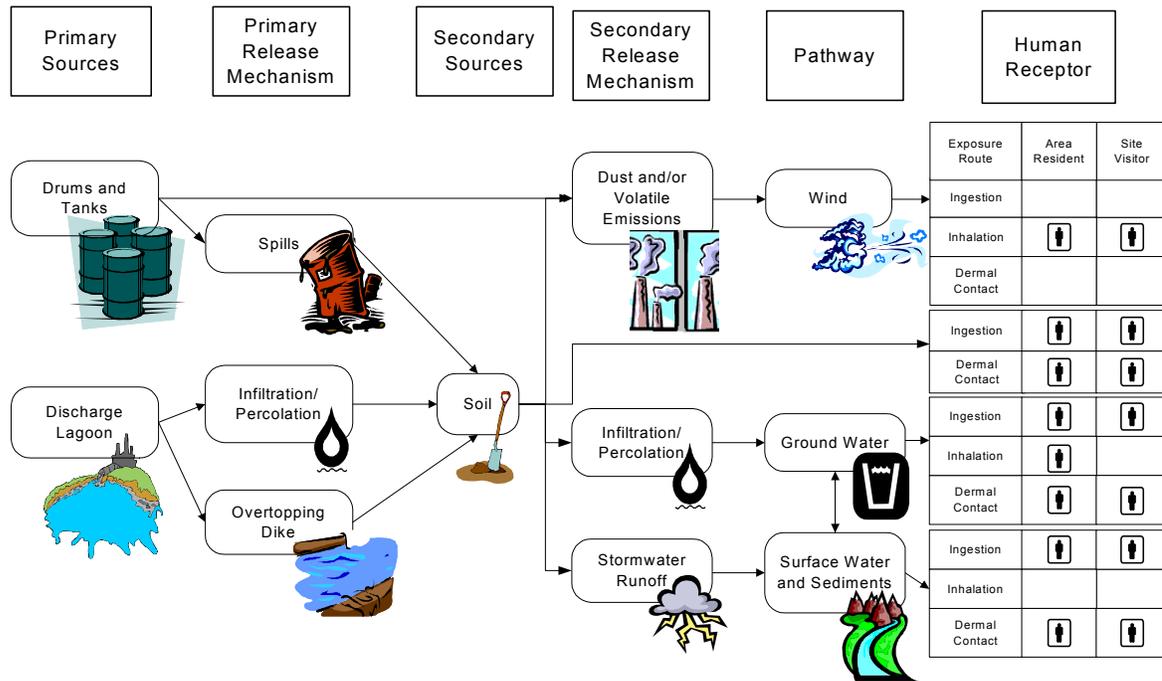
Figure 8.5 – Exposure Assessment Process



8.5.1 DEVELOP/RE-EVALUATE THE CONCEPTUAL SITE MODEL

The purpose of a CSM is to provide an understanding of the potential for exposure (under current and future land use) to chemicals at a site based on the source(s) of contamination, the release mechanism(s), the exposure pathway(s), and the receptor(s). One of the first steps in the exposure assessment is to review the CSM and to revise it, if appropriate – based on new site-specific information. This may result in changes in the exposure scenarios, receptors, and exposure pathways that are evaluated in the BHHRA. [Figure 8.6](#) presents an example of a CSM.

Figure 8.6 – Example of a Conceptual Site Model



8.5.2 CURRENT/FUTURE LAND USE CONSIDERATIONS

The Importance of Land Use Considerations

Land use is a critical component of the risk assessment process because it dictates which exposed populations (i.e., residential, industrial, or other) should be evaluated in the BHHRA. Land use concerns are addressed in both the risk assessment and the risk management efforts. Risk assessment addresses land use in terms of actual and assumed exposure scenarios, which determine exposed populations and affect exposure mechanisms, durations, and frequencies. The role of risk management in land use involves making decisions based on the use of the property, both current and plausible future use, and how any potential risk might be mitigated. Under these circumstances, land use information is shared between the risk assessment and risk management processes. In the event that a site is proposed for use or re-use with restrictions, the issue of LUCs must be addressed.

Land Use Controls

The Chief of Naval Operations issued interim final guidance on LUCs (USNAVY, 1999). LUCs are divided into two types: engineering controls (ECs) and institutional controls (ICs). ECs refer to engineered remedies that contain or reduce contamination and/or limit access to the contaminated property (including both land and water). ECs may include fences, signs, landfill caps, provision of potable water supplies, and guards (to prevent access). ICs are legal devices that ensure that ECs are properly managed and land use restrictions are enforced. ICs include easements, restrictive covenants, zoning, permits, and educational programs. Note that specific state and regional regulatory agencies may have established separate requirements for LUC implementation.

Background Information on Determining Future Land Use

Land use assumptions for conducting HHRA should be based on a factual understanding of site-specific conditions and reasonably-anticipated use. The land use evaluated in the risk assessment should not be based on a residential exposure scenario (i.e., the default worst-case), unless residential land use is plausible for the site. The USEPA has made the following recommendations in regard to land use considerations:



- ◆ future land use assumptions allow the baseline risk assessment and the feasibility study to focus on the development of practicable and cost-effective remedial alternatives, leading to site activities that are consistent with the reasonably-anticipated future land use;
- ◆ a range of land uses, and therefore exposure assumptions, may be considered dependent upon the amount and certainty of information supporting a land use evaluation;
- ◆ discussions with local land use planning authorities, appropriate officials, and the public, as appropriate, should be conducted as early as possible in the scoping phase of the project; and
- ◆ sites that are on federal facilities (e.g., military bases) may have different land use considerations than private property, because land use assumptions at sites that are undergoing base closure may be different than at sites where a federal agency will be maintaining control of the facility (USEPA, 1995b).

Various sources of information, including activity master plans and local zoning plans, can be utilized in making educated decisions about potential land use for a given site. Land use assumptions should take into consideration the interests of all affected stakeholders, including the local residents and municipal government. Land use issues should be carefully resolved, maintaining regular communication between the risk manager and the risk assessor.

8.5.3 DESCRIBE EXPOSURE SETTING

The exposure setting consists of a description of the physical environment as well as the potentially exposed populations. Basic characteristics such as climate, vegetation, groundwater hydrology, and the presence and location of surface water should be identified. In addition, population characteristics that influence exposure, such as location of people relative to the site, activity patterns, and presence of sensitive subpopulations, should be identified. A short summary of the site's history is often useful to readers because they may not be familiar with the site. An effective presentation of the exposure setting is important because it provides the reader with an understanding of key factors at a site that influence exposure to chemicals.

8.5.4 IDENTIFY COMPLETE EXPOSURE PATHWAYS.

Exposure pathways are identified based on consideration of the sources, releases, types, and locations of chemicals at the site. In order for a COPC to pose a risk to human health, a complete exposure pathway must be present. A complete exposure pathway consists of the following elements:

- 1.) a source and mechanism of chemical release to the environment (e.g., contaminated soil);
- 2.) an environmental transport medium for the released chemical (e.g., air);
- 3.) an exposure point (i.e., a point of potential human contact with the contaminated medium) that includes a location where humans are present and where there is activity that results in exposure, referred to as an "exposure scenario;" and
- 4.) an exposure route at the point of exposure (e.g., inhalation).

The identification of complete exposure pathways is a key step in the development of the CSM. If there are no complete exposure pathways under current and plausible future land use conditions, then there is no reason to perform a BHHRA because there is no risk to human health.

Exposure pathways should be plausible and consistent with site-specific information. For example, the incorporation of indirect exposure pathways, such as ingestion of homegrown beef/dairy/fruits/vegetables, in the BHHRA should be critically evaluated and should only be considered when warranted by site-specific information (e.g., a subsistence farmer living in the area). In addition, temporal trends should be considered when identifying complete exposure pathways. In some cases, receptors may not be currently



exposed to COPCs but may be in the future (e.g., COPCs in groundwater that migrate laterally and, in the future, impact a well used for drinking water). In this case exposures to contaminated groundwater should be evaluated based on exposures that are expected to occur in the future.

8.5.5 EXAMPLE EXPOSURE ALGORITHMS AND PARAMETERS TO CALCULATE EXPOSURE

The USEPA has identified standard default exposure parameters that are appropriate to use as a starting point when evaluating exposures at sites (USEPA, 1991b). Tables 8.1 through 8.4 present example algorithms and exposure parameters for incidental soil ingestion, dermal exposure to soil, inhalation of soil, and ingestion of groundwater for residential and industrial scenarios. However, each parameter in these equations has a range of possible values associated with it. The exposure parameters for a given pathway should be selected so that the combination of all exposure parameters results in a realistic estimate of the CTE and RME for that pathway. The source for each exposure parameter should be fully documented in the BHHRA so the goal of transparency can be met.

Note: There are a variety of issues that should be considered when evaluating dermal exposure to soil. See the Navy Dermal Contact With Soil Issue Paper for a complete discussion (PIONEER, 2001).

8.5.6 QUANTIFYING EXPOSURE

The last step in the exposure assessment is quantifying the daily intake of chemicals for the receptors identified in the CSM. The general equation used to calculate daily intake of a chemical is:

$$DI = C \times HIF \times MF$$

where,

Parameter	Definition
DI	Daily intake (mg of COPC per kg of body weight per day [mg/kg-day])
C	Concentration of the COPC (mg/kg, mg/m ³ , mg/L, etc.)
HIF	Human intake factor (day) ⁻¹ . Calculated by solving the exposure parameters portion of the intake equation.
MF	Exposure Pathway and Chemical-Specific Modifying Factors (e.g., percutaneous absorption rate) (variable units)

Quantitative characterization of carcinogenic and noncarcinogenic risks requires estimating the potential human intake levels for each COPC. Daily intakes for carcinogens are averaged over the lifetime of the exposed individual (i.e., 70 years) and are referred to as the Lifetime Average Daily Intake (LADI). Daily intakes for noncarcinogens are averaged over the duration of exposure and are referred to as the Average Daily Intake (ADI).



Table 8.1 – Example Exposure Parameters for Evaluating Incidental Soil Ingestion^(a,b)

Daily Intake ($\text{mg}/\text{kg}\text{-day}$) = $\frac{C_s \times FC \times IR \times ED \times EF \times CF}{BW \times AT}$								
Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_s	Chemical concentration in soil ^(c)	mg/kg	Central Tendency	RME	Central Tendency	RME	Central Tendency	RME
FC	Fraction from contaminated source	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
IR	Ingestion rate	mg/day	100 ^(d)	200	100	100	50	50
ED	Exposure duration	years	3 ^(e)	6	9 ^(f)	30	9 ^(g)	25
EF	Exposure frequency	days/year	275 ^(f)	350	275 ^(f)	350	250	250
CF	Conversion factor	kg/mg	1E-06	1E-06	1E-06	1E-06	1E-06	1E-06
BW	Body weight	kg	15	15	70	70	70	70
At_{nc}	Averaging time - noncarcinogenic (3, 6, 30-years)	days	1,095	2,190	3,285	10,950	3,285	9,125
At_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

^(a)RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991b). CTE exposure parameters were based on RME exposure parameters except where noted.

^(b)Some USEPA Regions require integrating the child and adult exposures into a single estimate of exposure and risk. Check the appropriate regional guidance to verify the approach for calculating intake.

^(c)The CTE and RME concentrations should be calculated as described in section 8.4.6 Develop Exposure Point Concentrations for Chemicals of Potential Concern.

^(d)Source is the USEPA Child-Specific Exposure Factors Handbook (USEPA, 2000a).

^(e)Assumes half the RME.

^(f)Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991a).

^(g)Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.



Table 8.2 – Example Exposure Parameters for Evaluating Dermal Contact With Soil^(a,b)

Daily Intake Absorbed $\left(\frac{\text{mg}}{\text{kg-day}}\right) = \frac{C_s \times FC \times AF \times AB \times SA \times ED \times EF \times CF}{BW \times AT}$								
Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_s	Chemical concentration in soil ^(c)	mg/kg	Central Tendency	RME	Central Tendency	RME	Central Tendency	RME
FC	Fraction from contaminated source	%	Site Specific					
AF	Soil to Skin Adherence Factor	mg/cm ²	0.6 ^(d)	1.0 ^(d)	0.6 ^(d)	1.0 ^(d)	0.6 ^(d)	1.0 ^(d)
AB	Absorbance factor	%	Chemical Specific					
SA	Skin surface area	cm ²	3,900 ^(e)	3,900 ^(e)	1,900 ^(d)	2,900 ^(e)	2,000 ^(f)	2,000 ^(f)
ED	Exposure duration	years	3 ^(g)	6	9 ^(d)	30	9 ^(h)	25
EF	Exposure frequency	days/year	275 ^(d)	350	275 ^(d)	350	250	250
CF	Conversion factor	kg/mg	1E-06	1E-06	1E-06	1E-06	1E-06	1E-06
BW	Body weight	kg	15	15	70	70	70	70
At_{nc}	Averaging time - noncarcinogenic	days	1095	2,190	3,285	10,950	3,285	9,125
At_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

^(a)RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991b). CTE exposure parameters were based on RME exposure parameters except where noted.

^(b)Some USEPA Regions require integrating the child and adult exposures into a single estimate of exposure and risk. Check the appropriate regional guidance to verify the approach for calculating intake.

^(c)The CTE and RME concentrations should be calculated as described in section 8.4.6 Develop Exposure Point Concentrations for Chemicals of Potential Concern.

^(d)Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991a).

^(e)The child exposure value is based on the assumption that the arms, legs, hands, and feet of a child are exposed. Adult surface area assumes 25% of the time at 5,000 cm² and 75% of the time at 1,900 cm² (USEPA, 1991a).

^(f)Skin Surface area available for exposure was determined based on the data presented in the Exposure Factors Handbook: Volume I - General Factors (USEPA, 1996). Value is based on the head and hands of an adult.

^(g)Assumes half the RME.

^(h)Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.



Table 8.3 – Example Exposure Parameters for Evaluating Inhalation of Particulates and Vapors^(a)

$\text{Daily Intake} \left(\frac{\text{mg}}{\text{kg} \cdot \text{day}} \right) = \frac{C_a \times FC \times IR \times ED \times EF}{BW \times AT}$								
Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_a	Chemical concentration in air ^(b)	mg/m ³	Central Tendency	RME	Central Tendency	RME	Central Tendency	RME
FC	Fraction from contaminated source ^(c)	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
IR	Inhalation rate	m ³ /day	7.5 ^(d)	7.5 ^(d)	20	20	20	20
ED	Exposure duration	years	3 ^(f)	6	9 ^(e)	30	9 ^(g)	25
EF	Exposure frequency	days/year	275 ^(e)	350	275 ^(e)	350	250	250
BW	Body weight	kg	15	15	70	70	70	70
At_{nc}	Averaging time – noncarcinogenic	days	1,095	2,190	3,285	10,950	3,285	9,125
At_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

^(a)RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991b). CTE exposure parameters were based on RME exposure parameters except where noted.

^(b)The CTE and RME concentrations should be calculated as described in section 8.4.6 Develop Exposure Point Concentrations for Chemicals of Potential Concern.

^(c)Outdoor and indoor inhalation exposures may be partitioned based on the amount of time an individual is outdoors. Adult and child residents are assumed to spend 30% of their time outdoors. This value is based on information presented in the Standard Default Exposure Factors which indicates that residents spend 5 out of 16 waking hours outdoors (USEPA, 1991b).

^(d)Source is the USEPA Child-Specific Exposure Factors Handbook (USEPA, 2000a).

^(e)Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991a).

^(f)Assumes half the RME.

^(g)Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.



Table 8.4 – Example Exposure Parameters for Evaluating Ingestion of Water^(a)

$Daily\ Intake\ (mg/kg-day) = \frac{C_w \times FC \times IR \times ED \times EF}{BW \times AT}$								
Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_g	Chemical concentration in water ^(b)	mg/l	Central Tendency	RME	Central Tendency	RME	Central Tendency	RME
FC	Fraction from contaminated source	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
IR	Ingestion rate	l/day	1 ^(c)	1 ^(c)	1.4 ^(d)	2	1	1
ED	Exposure duration	years	3 ^(e)	6	9 ^(d)	30	9 ^(f)	25
EF	Exposure frequency	days/year	275 ^(d)	350	275 ^(d)	350	250	250
BW	Body weight	kg	15	15	70	70	70	70
At_{nc}	Averaging time - noncarcinogenic (3, 6, 30-years)	days	1,095	2,190	3,285	10,950	3,285	9,125
At_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

^(a)RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991b). CTE exposure parameters were based on RME exposure parameters except where noted.

^(b)The CTE and RME concentrations should be calculated as described in section 8.4.6 Develop Exposure Point Concentrations for Chemicals of Potential Concern.

^(c)Source is the USEPA Child-Specific Exposure Factors Handbook (USEPA, 2000a).

^(d)Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991a).

^(e)Assumes half the RME.

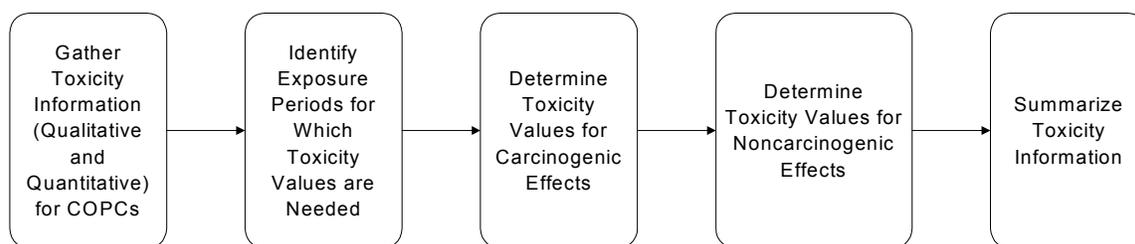
^(f)Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.

8.6 Toxicity Assessment

8.6.1 INTRODUCTION

The USEPA states that the purpose of the toxicity assessment is to “weigh available evidence regarding the potential for particular contaminants to cause adverse effects in exposed individuals and to provide, where possible, an estimate of the relationship between the extent of exposure to a contaminant and the increased likelihood and/or severity of adverse effects (USEPA, 1989).” The USEPA has completed the toxicity assessment for most chemicals found at sites and the resulting toxicity values have been peer reviewed. At some sites though, there will be issues that require toxicological evaluations. In general, the toxicity assessment step of the BHHRA consists of locating and collating toxicity information that can be combined with the Exposure Assessment information to calculate risks. The steps in the Toxicity Assessment are presented in [Figure 8.7](#). Each of these steps is discussed below.

Figure 8.7 – Toxicity Assessment Process



8.6.2 CARCINOGENIC TOXICITY VALUES

The mechanism for carcinogenesis is referred to as a “non-threshold” process, meaning any level of exposure to such a chemical poses a probability of generating cancer. Since risk at low exposure levels cannot be measured directly either by animal experiments or by epidemiological studies, a number of mathematical models and procedures have been developed for use in extrapolating risks from high to low doses. Different extrapolation models or procedures, while they may reasonably fit the observed data, may lead to large differences in the projected risk at low doses. It is assumed by the USEPA in developing carcinogenic slope factors (CSFs) that the risk of cancer is linearly related to dose. This means that relatively high doses, which are often used in animal studies, can be extrapolated downward to extremely small doses, with some incremental risk of cancer always possible. This assumes that even a small number of molecules (possibly a single molecule) of a carcinogen may cause changes in a single cell that could result in the cell dividing in an uncontrolled manner, eventually leading to cancer.

Note: There is some dispute as to whether extrapolation from high to low doses is a realistic approach. It has been argued that at low doses, cells may have the ability to detoxify carcinogens or repair cellular damage. Therefore, it is important to recognize the possibility that some carcinogens may have a threshold for toxicity.

A CSF is a numerical estimate of the potency of a chemical, which, when multiplied by the LADI, gives the probability of an individual developing cancer over a lifetime. CSFs are usually derived by USEPA by means of a linearized, multistage model and reflect the upper-bound limit of cancer potency of any chemical. As a result, the calculated carcinogenic risk is likely to represent a plausible upper limit to the risk. The actual risk is unknown but is likely lower than the predicted risk, and may be as low as zero (USEPA, 1989).

The USEPA uses a weight-of-evidence approach to classify the likelihood that a chemical is a carcinogen. Each chemical is assigned a weight-of-evidence for carcinogenicity. These groups are presented in [Table 8.5](#).



Table 8.5 – USEPA Weight-of-Evidence Categories for Carcinogenicity

USEPA Group	Description of Group	Description of Evidence
Group A	Human carcinogen.	Sufficient evidence from epidemiological studies to support a causal association between exposure and cancer.
Group B	Probable human carcinogen.	B1: Limited evidence of carcinogenicity in humans from epidemiological studies; sufficient evidence in animals. B2: Sufficient evidence of carcinogenicity in animals and no or inadequate evidence in humans.
Group C	Possible human carcinogen.	Limited evidence of carcinogenicity in animals.
Group D	Not classified.	Inadequate evidence of carcinogenicity in animals.
Group E	No evidence of carcinogenicity in humans.	No evidence of carcinogenicity in at least two adequate animal tests or in both epidemiological and animal studies.

8.6.3 NONCARCINOGENIC TOXICITY VALUES

A reference dose (RfD) is defined as “An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subgroups, that is likely to be without an appreciable risk of deleterious [e.g., organ damage, biochemical alterations, birth defects] effects during a portion of the lifetime (USEPA, 1989).” RfDs have been developed by the USEPA for subchronic- (short-term exposures), chronic- (long-term exposures), and developmental exposures (e.g., birth defects).

Noncarcinogenic chemicals are thought to exhibit threshold characteristics. That is, exposures less than a specific threshold dose will not result in adverse health effects, whereas exposures exceeding the threshold dose may produce adverse health effects. The assumption of a threshold for toxicity is based on the concept that the body has certain protective mechanisms that must be overcome before adverse effects are manifest. For example, there could be a large number of cells performing the same or similar function whose population must be significantly depleted before a toxic effect is observed.

The threshold concept is important in the regulatory context. The threshold hypothesis holds that a range of exposures from zero to some finite value can be tolerated by an individual with essentially no chance of expression of the toxic effect. Further, it is often prudent to focus on the most sensitive members of the population; therefore, regulatory efforts are generally made to keep intakes below the population threshold, which is defined as the lowest of the thresholds of the individuals within a population (USEPA, 2000b).

In general, an RfD is derived from a no-observed-adverse-effects-level (NOAEL) or a lowest-observed-adverse-effects-level (LOAEL) obtained from animal studies, or, occasionally, from human studies, by the application of standard order-of-magnitude uncertainty factors. In certain cases, an additional modifying factor is employed to account for professional assessment of scientific uncertainties in the available data (USEPA, 1989).

A NOAEL is an experimentally determined dose at which there was no statistically or biologically significant indication of the toxic effect of concern. The study chosen to establish the NOAEL is based on the criterion that the measured endpoint represents the most sensitive target organ or tissue (i.e., critical organ) for that chemical. In an experiment with several NOAELs, generally the lowest one is chosen as the critical NOAEL. Since many chemicals can produce toxic effects on several organ systems, with each toxic effect possibly having a separate threshold dose, the distinction of the critical toxic effect provides added confidence that the NOAEL is protective of human health.



Once the critical NOAEL is identified, the next step is to derive the RfD by dividing the NOAEL by safety factors as follows:

$$RfD \text{ (average daily human dose)} = \frac{NOAEL_{\text{Experimental Dose}}}{\text{Safety Factors} + \text{Modifying Factor}}$$

Generally, each safety factor represents a specific area of uncertainty inherent in the available data and accounts for uncertainties, such as:

- ◆ differences in responsiveness between humans and animals in prolonged exposure studies (factor of 10);
- ◆ variation in susceptibility among individuals in the human population (factor of 10); and
- ◆ incomplete databases (e.g., those for which only the results of subchronic studies are available) (factor of 10) (USEPA, 2000b).

In addition to the safety factors, a modifying factor is applied in some instances. Modifying factors range from 0 to 10 and are included to reflect a qualitative professional assessment of additional uncertainties in the critical study and in the entire database for the chemical not explicitly addressed by the uncertainty factors. The default value for the modifying factor is 1 (USEPA, 1997).

8.6.4 IDENTIFY THE SOURCES OF TOXICITY VALUES

The USEPA has evaluated numerous chemicals and has published the corresponding toxicity values, which have undergone peer review. The following sources, presented in order of priority, should be consulted to obtain toxicity values for use in a BHRA:

- 1.) the Integrated Risk Information System (IRIS) (USEPA, 2000b) ;
- 2.) the Health Effects Assessment Summary Tables–Annual Update (HEAST) (USEPA, 1997) ; and
- 3.) provisional toxicity values available from the National Center for Environmental Assessment (NCEA) Superfund Health Risk Technical Support Center (NCEA-CIN).

Many of the toxicological summaries on IRIS were developed prior to 1996 and the information and values presented were verified by either the USEPA Reference Dose/Reference Concentration (RfD/RfC) Work Group or the USEPA Carcinogen Risk Assessment Verification Endeavor (CRAVE). IRIS entries from 1997 to the present represent USEPA consensus information. All of the toxicity values presented in the HEAST document are considered “provisional” by USEPA because they have not been verified by an agency work group (USEPA, 1997). Provisional values are not listed in IRIS. Additional provisional and internal USEPA toxicity values can be obtained from USEPA. The values provided by NCEA-CIN include chronic and subchronic toxicity values, unit risks, and slope factors. The values that have been peer reviewed are considered provisional, while the values that have not been peer reviewed are considered internal USEPA values. Other potential sources of toxicity values include the California Environmental Protection Agency (CALEPA) and the Agency for Toxic Substances and Disease Registry (ATSDR).

8.6.5 ROUTE-TO-ROUTE EXTRAPOLATION TO DETERMINE DERMAL TOXICITY VALUES

Toxicity values are used in conjunction with exposure information to evaluate the potential for noncarcinogenic health effects and cancer risks. For dermal exposure, however, the USEPA has not developed toxicity values specifically for evaluating potential human health concerns. Most of the available toxicological criteria have been derived for the oral route of exposure, while criteria for the inhalation route of exposure are available for a limited number of chemicals. Therefore, an interim decision was made by the Superfund program to estimate dermal toxicity criteria based on existing oral criteria (i.e., route-to-route extrapolation).



Most exposure pathways, such as incidental soil ingestion, quantify exposure based on the amount of a chemical that an individual comes in contact with on a daily basis (i.e., intake). The toxicity values used to evaluate the risks associated with these exposure pathways are typically consistent with this approach in that they are also developed based on intake (often referred to by toxicologists as administered dose). In contrast, dermal exposure is determined based on the amount of chemical that penetrates the skin and is absorbed into the blood stream. Consequently, toxicity values based on administered dose should technically be adjusted to reflect the absorbed dose when evaluating the risks associated with dermal exposure.

The approach developed by USEPA to derive dermal toxicity values from oral toxicity values adjusts the administered dose based on how much of the chemical was absorbed in the gastrointestinal (GI) tract. Ideally the amount of GI absorption would be measured in the original oral toxicity study. However, this is rarely done. In the absence of study-specific GI absorption factors, factors are obtained from the scientific literature. Unfortunately, conservative default values are usually selected because of the paucity of information about GI absorption in the scientific literature. In addition, the current approach for developing GI absorption values does not take into account the method of administration (e.g., gavage, drinking water, or diet) in the original study or the vehicle of administration (e.g., solvent, oil, or solution, etc.) which may significantly impact the GI absorption rate. It is unlikely that the GI absorption rate in these studies is representative of the rate that would be found for the same chemical in soil. The current method recommended by the USEPA for converting toxicity values from administered to absorbed dose relies on the following assumptions:

- ◆ that the health effects following exposure are not route-specific; and
- ◆ that portal-of-entry effects (e.g., dermatitis associated with dermal exposure and respiratory effects associated with inhalation exposure) are not the principal effects of concern. For example, the USEPA recommends that the current default for evaluating dermal exposure is inappropriate for carcinogenic polycyclic aromatic hydrocarbons (PAHs), because this group of compounds cause skin cancer through direct action at the point of application (e.g., portal-of-entry effects) (USEPA, 1989). The USEPA further recommends that risks from dermal exposure to these compounds be qualitatively evaluated.

Oral toxicity values should only be adjusted when there is convincing empirical data that suggests that GI absorption is less than 100%. While this is less conservative than assuming some default value, it does avoid the problem of incorporating overly-conservative values in the absence of good data. This approach is consistent with USEPA guidance. USEPA recommends that the Environmental Criteria and Assessment Office (ECAO) be contacted for guidance on adjusting oral toxicity values to derive dermal toxicity values. In the absence of information from ECAO, USEPA recommends that "the assessor should describe the effects of the chemical qualitatively and discuss the implications of the absence of the chemical from the risk estimated in the uncertainty section of the risk assessment (USEPA, 1989)." Furthermore, USEPA's *Dermal Exposure Assessment: Principles and Applications* states that, "...if estimates of the gastrointestinal absorption fraction are available for the compound of interest in the appropriate vehicle, then the oral dose-response factor, unadjusted for absorption, can be converted to an absorbed dose basis..." and "Lacking this information, the oral factor should be used as is accompanied by a strong statement emphasizing the uncertainty involved (USEPA, 1992a)."



8.7 Risk Characterization

8.7.1 INTRODUCTION

Risk characterization integrates the results of the data evaluation, reduction, exposure assessment, and toxicity assessment into quantitative expressions of risk. The key components of the risk characterization process include the following:

- ◆ quantify risks from individual chemicals;
- ◆ quantify risks from multiple chemicals;
- ◆ combine risks across exposure pathways; and
- ◆ consider site-specific human studies (USEPA, 1989).

Risk characterization is the starting point for risk management considerations and the foundation for regulatory decision-making, but it is only one of the important components in such decisions.

8.7.2 REGULATORY RISK BENCHMARKS AND CANCER AND NONCANCER RISKS

The USEPA has typically used a hazard index (i.e., the cumulative noncancer risks for all chemicals) of 1 or greater, or a hazard index for a target organ/critical effect of 1 or greater as a benchmark for evaluating noncarcinogenic hazard indices. For carcinogenic risk, the USEPA's approach "emphasizes the use of 1 chance in one million [i.e., 1E-06] as the point of departure while allowing site or remedy-specific factors, including potential future uses, to enter into the evaluation of what is appropriate at a given site." As risks increase above 1 chance in 1,000,000, they become less desirable, and the risk to individuals generally should not exceed 1 in 10,000 (i.e., 1E-04) (USEPA, 1991c). The USEPA recommends that "where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 1E-04 and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs [Maximum Contaminant Levels] or non-zero MCLGs [Maximum Contaminant Level Goals, which are used to evaluate drinking water] are exceeded, action generally is warranted (USEPA, 1991c)."

Quantifying Cancer Risks

The risk of cancer from chemical exposure is described in terms of the probability that an exposed individual will develop cancer during his/her lifetime from that exposure. The risk estimate is calculated by multiplying the daily intake of a particular chemical over a lifetime by the carcinogenic slope factor.

$$RISK = LADI \times SF$$

where,

Parameter	Definition
RISK	Lifetime probability of developing cancer due to exposure to a chemical in the environment.
LADI	Lifetime average daily intake of chemical (mg/kg-day).
SF	Carcinogenic slope factor for chemical (mg/kg-day) ⁻¹ .

All carcinogenic risks for chemicals for each scenario and receptor are then summed to yield the total carcinogenic risk. A 1 in 1,000,000 cancer risk (i.e., 1E-06) means that, in a population of 1,000,000 people exposed under an identical exposure scenario (i.e., had exactly the same daily intake of a carcinogen over the same time period), there could be one additional case of cancer in the population.



Evaluating Noncancer Health Effects

Adverse noncarcinogenic health effects from exposure to a COPC are quantitatively expressed as a hazard quotient. The hazard quotient is the ratio of a human's estimated intake of a particular chemical to the RfD.

$$HQ = \frac{ADI}{RfD}$$

where,

Parameter	Definition
HQ	Hazard Quotient. The ratio of the estimated dose of a chemical to the RfD.
ADI	Average daily intake of chemical (mg/kg-day).
RfD	Reference dose for chemical (mg/kg-day).

The RfD is the threshold intake level for a particular chemical below which it is unlikely that even sensitive subpopulations would experience adverse health effects. Usually, only chronic hazard quotients are evaluated, as the subchronic effects within a given exposure scenario are typically less than or equal to the chronic effects for the same scenario.

For noncancer health effects, hazard quotients are added across chemicals when they target the same organ, or produce the same critical effect, to calculate a segregated hazard index. Segregation of hazard indices requires the identification of the major effects of each chemical, including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at a dose of 5 mg/kg-day and neurotoxicity at a dose of 25 mg/kg-day). Major effect categories include:

- ◆ neurotoxicity;
- ◆ developmental toxicity;
- ◆ reproductive toxicity;
- ◆ immunotoxicity; and
- ◆ adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects).

Although higher exposure levels may be required to produce adverse health effects other than the critical effect, the RfD can be used as the toxicity value for each effect category as a conservative and simplifying step (USEPA, 1989).

If the total segregated hazard index is less than one, it indicates that adverse noncarcinogenic health effects are unlikely. If the total segregated hazard index is greater than one, it indicates that adverse health effects are possible. Often times all hazard quotients are added together to determine the total hazard index. If the total hazard index is greater than one, then the hazard quotients should be segregated by target organ or critical effect and then compared to the target risk goal.



8.7.3 EVALUATING THE HEALTH EFFECTS ASSOCIATED WITH LEAD EXPOSURES

The traditional risk assessment approach for evaluating noncancer effects from exposure to chemicals involves comparison of chemical intakes to a reference dose (RfD). This approach is inappropriate for lead because a no-observed-adverse-effects-level (NOAEL) for lead has not been identified (i.e., there is no RfD for lead) by the USEPA. Blood lead concentrations are accepted as the preferred measure of cumulative lead exposures. Blood lead concentrations provide an index for evaluating the likelihood of adverse effects from lead exposure. A blood lead level of 10 µg/dL has been identified by the Centers for Disease Control as a benchmark for evaluating exposure to lead, and the USEPA defines a greater-than-5-percent probability of exceeding the 10 µg/dL criterion value as posing an unacceptable threat to human health (USEPA, 1994).

The risks associated with lead exposures should be evaluated based on the latest information available from the USEPA's Technical Review Workgroup (TRW) for lead. The TRW has developed approaches, such as the Integrated Exposure Uptake Biokinetic (IEUBK) Model and the Adult Pb Model, for evaluating exposures to lead that are protective of human health. See <http://www.epa.gov/oerrpage/superfund/programs/lead/trw.htm> for more information on evaluating lead exposures.

8.7.4 TOTAL RISK AND INCREMENTAL RISK

The goal of the BHHRA is to provide regulators, stakeholders, and risk managers with an understanding of the potential incremental risks to human health posed by a specific site and to document the uncertainties that are necessary to put the risks into proper context (USEPA, 1991c). This goal is consistent with the NCP, which states that the BHHRA should "characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to groundwater or surface water, releasing to air, leaching through soil, remaining in soil, and bioaccumulating in the food chain (Federal Register, 1990)." Incremental risks are the risks associated with exposure to chemicals related to a specific site and do not include other chemical exposures such as exposure to automobile exhaust. Total risks include the risks associated with exposures in the environment regardless of whether or not they are associated with the site under evaluation. The key point is that incremental risks differ from total risks and that only incremental risks should be evaluated at sites.

8.7.5 SUMMARIZING THE RISKS

The Risk Characterization section of the BHHRA report is the most important section of the document because it summarizes the results of the assessment. The risk characterization discussion should include the following components, as appropriate.

◆ Risk Information

- Present the magnitude of the cancer risks and noncancer hazard indices relative to the regulatory benchmarks (e.g., the cancer risk range of 1E-04 to 1E-06 and a noncancer hazard index of 1.0) for each location and receptor.
- Identify COCs, exposure pathways, and media responsible for the majority of the risks.
- Segregate noncarcinogenic hazard indices by endpoint or critical effect if the total hazard index is greater than one.

◆ Exposure and Toxicity Information

- Identify unique characteristics of the exposed populations that may be useful to decision makers (e.g., sensitive subpopulations in the area).



- Summarize the results of site-specific health studies, when available.
- Present the number of chemicals for which toxicity information was not available (USEPA, 1989).

In many cases, some of the information identified above may not be included in the BHHRA because it is not pertinent to the site being evaluated. The principle that should be adhered to is that the risk characterization section of the report should effectively identify and highlight noteworthy risk conclusions (USEPA, 1995a).

8.8 Uncertainty Analysis

8.8.1 PURPOSE OF THE UNCERTAINTY ANALYSIS

The purpose of the uncertainty analysis is to present an evaluation of the uncertainties that enter the risk assessment at each step of the process in order for regulators, stakeholders, and risk managers to put the risks in proper context. The risks presented in BHHRA are conditional estimates, based on a number of assumptions about exposure and toxicity given a particular land use scenario. Uncertainties are introduced to a risk assessment because a range of values could be used for each assumption, but only a few actually are. Consistent with USEPA policy, more conservative (i.e., upper bound) values are generally chosen for each parameter, while other values (i.e., values closer to the central tendency) may be more representative of site-specific conditions (USEPA, 1989). Choosing upper bound values for each parameter typically results in overly conservative risks that do not reflect site-specific conditions. Uncertainties are used to “bracket” the range of risks that could result from choosing alternate values for the parameters used in calculating risks. USEPA guidance for Risk Characterization states that, “Particularly critical to full characterization of risk is a frank and open discussion of the uncertainty in the overall assessment and in each of its components (USEPA, 1995a).” There are several key reasons why uncertainty should be discussed in the BHHRA:

- ◆ risk characterization involves the integration of a variety of different types of information. It is important to communicate the uncertainties associated with the different types of information in order to provide a context for evaluating the overall results;
- ◆ in order for a risk manager or stakeholder to evaluate a BHHRA, the magnitude of the uncertainties in the evaluation must be understood; and
- ◆ discussions of the uncertainties in a BHHRA will help risk managers to evaluate the need for collecting additional information (USEPA, 1995a).

8.8.2 GENERAL APPROACHES FOR PERFORMING AN UNCERTAINTY ANALYSIS

An uncertainty analysis for a BHHRA can take on many forms depending on the complexities of the site. The types of uncertainty analyses that are typically performed as part of a BHHRA are as follows.

- ◆ **Qualitative** – A qualitative uncertainty analysis for a BHHRA is the most common type of uncertainty analysis. The relative direction and magnitude of the uncertainty associated with the key assumptions/parameters used to calculate the risks are identified, usually in table form, based on the professional judgment of the risk assessor. This approach highlights the key uncertainties and attempts to provide some measure of the potential uncertainty and related impact on the site risk estimates.
- ◆ **Semi-Quantitative** – A semi-quantitative uncertainty analysis for a BHHRA is less common. This approach is used to evaluate the sensitivity of the risks to key model parameters (e.g., exposure factors) by recalculating the model with alternative assumptions. This provides information on the plausible upper and lower bounds of the risk estimates.



- ◆ **Quantitative** – A quantitative uncertainty analysis for a BHHRA is relatively uncommon. This approach is similar to the Semi-Quantitative approach, however more sophisticated statistical techniques (e.g., Monte Carlo Simulation) are used to evaluate/quantify uncertainty. The advantage of this approach is that a continuous distribution of risk, rather than an upper and lower bound, is developed. In addition, key issues, such as correlations between model parameters, can be accounted for in the statistical evaluation. See Chapter 9 – Other Tools: Using Probabilistic Risk Assessment to Further Characterize Risks for more detailed information.

Each approach for evaluating uncertainty should include a discussion of site-specific uncertainties and uncertainties inherent to the risk assessment process. Examples of each are presented below. [Table 8.6](#) presents a sample format for presenting uncertainties.

- ◆ **Examples of Site-Specific Uncertainties:**

- sampling methods;
- analytical methods;
- representativeness of the exposure point concentrations;
- representativeness of the exposure scenarios, pathways, and parameters;
- land use assumptions;
- fate and transport models; and
- the coverage of toxicity values by route of exposure (i.e., how many COPCs had toxicity values).

- ◆ **Examples of Uncertainties Inherent to the Risk Assessment Process:**

- extrapolating from animal studies to human toxicity;
- using dose response information from homogeneous animal populations or healthy human populations to predict effects that may occur in the general population, including sensitive subpopulations;
- high-to-low-dose extrapolation methods used to develop toxicity values;
- lack of chemical-specific dermal toxicity values; and
- synergistic or antagonistic effects associated with multiple chemical exposure.



Table 8.6 – Example of a Summary of Uncertainties in the Human Health Evaluation

Source of Uncertainty	Direction ^(a)	Magnitude ^(b)	Action or Result
Data Evaluation			
Identification of COPCs present in soil	+/-	0	Used site-specific information to develop sampling work plan and to focus sampling efforts.
Quality of analytical data	+/-	0	Used quality-assured data in evaluation.
Exposure Assessment			
Attenuation or enrichment of chemical concentrations in soil	+/-	2	Assumed that no attenuation or enrichment of soil concentrations occurs over time. This may result in an underestimation or overestimation of the risks.
Exposure assumptions	+/-	2	Used site-specific and USEPA Standard Default Exposure Factors in the evaluation.
Experimental dermal absorption rates	+/-	2	Used experimentally-derived dermal absorption rates to evaluate dermal contact with soil.
Toxicity Assessment			
Failure to include all chemicals because of lack of USEPA approved toxicity values	-	3	Results in an underestimation of the risks. Oral RfDs were available for 10 of the 25 COPCs, and Inhalation RfDs were available for 7 of the 25 COPCs. Oral slope factors were available for 8 of the 25 COPCs and inhalation slope factors were available for 7 of the 25 COPCs.
Extrapolation from animal studies to human toxicity	+	3	Used the USEPA's conservative approach of incorporating safety factors and upper-bound estimates.
Lack of chemical-specific dermal toxicity values	-	1	Used oral toxicity values as surrogates for dermal toxicity values, in order to evaluate risks associated with dermal exposure. This may result in an underestimation of the risks.
Using dose-response information from homogeneous animal populations or healthy human populations, to predict effects that may occur in the general population, including sensitive subpopulations.	-	1	This may underestimate the risks.
Risk Characterization			
Assumed that health effects of chemicals are additive	+/-	3	Assumed that health effects of chemicals are additive in risk calculations. Antagonistic and synergistic effects of chemical mixtures were not evaluated.

^(a)Direction of Effect
 + = May result risks that are overly conservative
 - = May result in risks that are not conservative

^(b)Magnitude of Effect
 0 = Negligible impact on risk calculations
 1 = Small effect on risks calculations
 2 = Medium effect on risk calculations
 3 = Large effect on risk calculations



8.9 References

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