MINNESOTA POLLUTION CONTROL AGENCY
SITE REMEDIATION SECTION

DRAFT GUIDELINES
RISK-BASED GUIDANCE FOR THE SOIL-HUMAN HEALTH PATHWAY
USER'S GUIDE

WORKING DRAFT, September 1998

Comment Period Ends December 31, 1998

Send Written Comments to:
Guidance Coordination Team
Minnesota Pollution Control Agency
Site Remediation Section
520 Lafayette Road
St. Paul, Minnesota 55155-4194
Fax (651) 296-9707

NOTICE

THIS DOCUMENT IS A WORKING DRAFT. The Site Remediation Section of MPCA is developing guidelines for evaluating risks to human health and the environment at sites that may require investigation or response actions pursuant to the Minnesota Environmental Response and Liability Act, Minn. Stat. § 115B.01 to 115B.24 (MERLA).

DEVELOPMENT OF A SITE REMEDIATION SECTION SITE EVALUATION MANUAL. The attached document and other documents will be incorporated into a Site Remediation Risk-Based Site Evaluation Manual which will contain guidelines for conducting MERLA-related evaluations, including risk evaluations under the State Superfund program and the MPCA Voluntary Investigation and Cleanup (VIC) Program.

MPCA staff intend to use the policies and procedures in the manual as guidelines to evaluate the need for investigation or remedial actions to address releases and threatened releases of hazardous substances or pollutants or contaminants under MERLA, and the scope and nature of such actions. These policies and procedures are not exclusive and do not have the force and effect of law. MPCA staff may use other policies or procedures to evaluate the need for or adequacy of response actions under MERLA, including procedures set forth in outstanding MPCA Requests for Response Action and Consent Orders. The final standard for all such evaluations is the MERLA statutory requirement that such actions must be reasonable and necessary to protect the public health and welfare and the environment.

The Minnesota state Superfund program, governed by the Minnesota Environmental Response and Liability Act (MERLA) and the supplementary rules, and the federal Superfund program, governed by the Comprenhesive Environmental Response, Compensation and Liability Act (CERCLA) and the federal regulations in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), work together to clean up various types of sites.

~ Continued ~

~ Continuation ~

Under CERCLA, failure to act consistently with the NCP can result in a party not recovering its response costs from a RP. There is no NCP consistency requirement in MERLA, although under MERLA the costs must be reasonable and necessary. The guidance documents are intended to function in a similar manner to the NCP. However, because the guidance documents do not require every procedural specification of the NCP, parties are advised to consult an attorney early in the cleanup process if they intend cost recovery under CERCLA, which specifically states that the party seeking reimbursement must show that its costs are "consistent" with the NCP.

For removals, investigations and National Priority List sites, the federal and state governments must act consistently with the NCP. Note that CERCLA requires "consistency," or "accordance," as distinguished from "compliance," with the NCP. This infers some flexibility in selecting the appropriate remedy while following the basic requirements of the NCP. The extent of flexibility is still debated in courts. The NCP provides that a party does not have to comply with every single requirement of the NCP verbatim, but that the response action, when evaluated as a whole, be in "substantial compliance" with the NCP and result in a CERCLA-quality cleanup. The courts have emphasized that the community relations aspects are a part of the NCP response action, including the right of the public to participate in the remedial action selection process.

The preamble to the NCP recognizes government programs, like the Minnesota program under MERLA which has similarities to the NCP, that achieve the same objectives, but are not congruent with the NCP in every respect. EPA believes that these governmental bodies, consistent with CERCLA intent, should have flexibility to implement response actions and bring cost recovery actions for those response actions as long as the response actions are not inconsistent with the NCP, even if achieved by different methods. EPA believes that it is not necessary to define what actions are "not inconsistent with the NCP," and will make determinations on a case-by-case basis.

EXPLANATION:

[NOTE TO WORK GROUP: Include qualifying remarks specific to your document in this "explanation" box.]

.

Users of this document are responsible for confirming with the MPCA Site staff the version of the working draft to be used.

Distribution List:

(NOTE TO WORK GROUPS: Copies distributed to non-MPCA staff must be accompanied by instructions to the recipient and where to focus their review. A specific list of questions may be appropriate.)

(NOTE TO PERSONS OTHER THAN THE SITE REMEDIATION SECTION (SRS) STAFF: As necessary, please distribute this draft document to selected members of your staff for review and comment. Based on past interactions with SRS, suggested staff are indicated in parenthesis)

@SRS

Jim Warner (MD)
Gary Pulford (CO)
Cathy Moeger (GWPD)
Duane Anderson (MD/OP) (Dann White, Dave Maschwitz)
Bruce Brott (MD/SR) (Beth Gawrys, Bryon Adams)
Mike Kanner (MD/SR) (Chris Zadak, Mike Bares)
Dave Thornton (PP/MF) (Cynthia Hollerbach)
Alan Williams (AG)
Rita Messing (MDH)
Larry Gust (MDH)
Dan Stoddard (Dept. Ag) (Cathy Villas-Horn, John Moeger)

DRAFT GUIDELINES
RISK-BASED GUIDANCE FOR THE SOIL-HUMAN HEALTH PATHWAY USER'S GUIDE

MINNESOTA POLLUTION CONTROL AGENCY
SITE REMEDIATION SECTION

TABLE OF CONTENTS

LIST OF TABLES

Note: For definitions of terms and concepts, please refer to the RBSE Glossary document.

EXECUTIVE SUMMARY

This document is designed to assist users in properly applying risk based guidance for evaluating the human health risk caused by exposure to contaminated soil at sites administered by the Superfund and Voluntary Investigation and Cleanup Programs (SF/VIC) of the Minnesota Pollution Control Agency (MPCA). The human exposure evaluation considers the risk posed by human contact with contaminated soil. Procedures are presented to estimate soil contaminant concentrations that must be addressed because they pose an unacceptable risk to human health. Soil contaminant-specific concentrations above which an unacceptable risk to human health is predicted to exist are referred to as Soil Reference Values (SRVs). The SRVs are derived by MPCA staff using risk assessment methodology, modeling, and risk management policy. It is imperative that users of this guidance understand the exposure scenarios and other assumptions that are incorporated into calculation of the SRVs, and have sufficient knowledge of the site to which they are being applied to evaluate the validity of the resulting soil-human health risk characterization. A risk characterization will be meaningful only when the SRVs are properly applied and any uncertainties are clearly identified. Additional technical support for the SRVs and more detailed guidance for conducting risk characterizations of the soil-human health exposure pathway can be found in the "Working Draft - Risk-Based Site Evaluation Guidance for Soil - Human Health-Based Exposure Pathways (Technical Support Document, September ??, 1998).

The tier-based approach to risk evaluation is based on the concept of incorporating progressively more site-specific information as the evaluation proceeds upward through the tiers. A Tier 1 evaluation is a screening level characterization of the soil-human health exposure pathway. It is assumed at Tier 1 that limited site-specific information is available; consequently, conservative assumptions are applied to assess whether an unacceptable risk may be present at a site that warrants additional investigation and/or evaluation. A Tier 1 risk characterization is generally accomplished by comparing maximum site soil contaminant concentrations directly to the Tier 1 SRVs. The Tier 1 SRVs are based on the assumption that human exposure to the contaminants is long term (chronic) and occurs in a residential site setting through a defined set of common exposure pathways. A residential exposure scenario is generally the most conservative human exposure scenario because people typically spend a greater portion of their lives living and sleeping in their homes than at their places of work or recreation, and therefore human exposure to any contaminants that may be present in a residential setting is proportionately greater. Contaminant concentrations that exceed acceptable risk limits should be further evaluated through additional site characterization and/or a Tier 2 risk characterization.

In a Tier 2 risk characterization, it is assumed that the areas of contamination are better characterized than at Tier 1 and that representative soil contaminant concentration(s) can be determined for the area(s) of concern with reasonable confidence. For Tier 2, SRVs were developed for human exposure scenarios based on industrial and recreational property use categories to enable the risk assessor to select the human exposure scenario that best fits the actual site use. When the representative site soil contaminant concentrations exceed the SRVs for the appropriate site use category, an unacceptable risk to human health is concluded to exist. In most cases, a remedy will be needed to reduce site risk to an acceptable level.

Sites that have potentially important exposure pathways or other conditions that are not incorporated into a Tier 1 or 2 risk characterization must be evaluated in Tier 3. A Tier 3 risk characterization is a fully site-specific risk assessment for which site-specific SRVs are calculated that account for all potentially significant exposure pathways and characteristics of the site. MPCA staff expect that only a trained risk assessor or other qualified professional will perform Tier 3 risk characterizations. Refer to the Technical Support Document for additional information about Tier 3 risk characterizations.

RISK-BASED GUIDANCE FOR THE SOIL-HUMAN HEALTH PATHWAY USER'S GUIDE

1.0 INTRODUCTION

This document is designed to assist users in properly applying risk based guidance for evaluating the human health risk caused by exposure to contaminated soil at sites administered by the Superfund and Voluntary Investigation and Cleanup Programs (SF/VIC) of the Minnesota Pollution Control Agency (MPCA). The human exposure evaluation considers the risk posed by human contact with contaminated soil. Procedures are presented to estimate soil contaminant concentrations that must be addressed because they pose an unacceptable risk to human health. Soil contaminant-specific concentrations above which an unacceptable risk to human health is predicted to exist are referred to as Soil Reference Values (SRVs). The SRVs are derived by MPCA staff using risk assessment methodology, modeling, and risk management policy. It is imperative that users of this guidance understand the exposure scenarios and other assumptions that are incorporated into calculation of the SRVs, and have sufficient knowledge of the site to which they are being applied to evaluate the validity of the resulting soil-human health risk characterization. A risk characterization will be meaningful only when the SRVs are properly applied and any uncertainties are clearly identified. Additional technical support for the SRVs and more detailed guidance for conducting risk characterizations of the soil-human health exposure pathway can be found in the "Working Draft - Risk-Based Site Evaluation Guidance for Soil - Human Health-Based Exposure Pathways (Technical Support Document, September ??, 1998).

2.0 THE TIERED FRAMEWORK

The tier-based approach to risk evaluation is based on the concept of incorporating progressively more site-specific information as the evaluation proceeds upward through the tiers. A Tier 1 evaluation is a screening level characterization of the soil-human health exposure pathway. It is assumed at Tier 1 that limited site-specific information is available; consequently, conservative assumptions are applied to assess whether an unacceptable risk may be present at a site that warrants additional investigation and/or evaluation. A Tier 1 risk characterization is generally accomplished by comparing maximum site soil contaminant concentrations directly to the Tier 1 SRVs. The Tier 1 SRVs are based on the assumption that human exposure to the contaminants is long term (chronic) and occurs in a residential site setting through a defined set of common exposure pathways. A residential exposure scenario is generally the most conservative human exposure scenario because people typically spend a greater portion of their lives living and sleeping in their homes than at their places of work or recreation, and therefore human exposure to any contaminants that may be present in a residential setting is proportionately greater. Contaminant concentrations that exceed acceptable risk limits should be further evaluated through additional site characterization and/or a Tier 2 risk characterization.

In a Tier 2 risk characterization, it is assumed that the areas of contamination are better characterized than at Tier 1 and that representative soil contaminant concentration(s) can be determined for the area(s) of concern with reasonable confidence. For Tier 2, SRVs were developed for human exposure scenarios based on industrial and recreational property use categories to enable the risk assessor to select the human exposure scenario that best fits the actual site use. When the representative site soil contaminant concentrations exceed the SRVs for the appropriate site use category, an unacceptable risk to human health is concluded to exist. In most cases, a remedy will be needed to reduce site risk to an acceptable level.

Minnesota Pollution Control Agency
Site Remediation Section
520 Lafayette Road
St. Paul, Minnesota 55155-4194

Sites that have potentially important exposure pathways or other conditions that are not incorporated into a Tier 1 or 2 risk characterization must be evaluated in Tier 3. A Tier 3 risk characterization is a fully site-specific risk assessment for which site-specific SRVs are calculated that account for all potentially significant exposure pathways and characteristics of the site. MPCA staff expect that only a trained risk assessor or other qualified professional will perform Tier 3 risk characterizations. Refer to the Technical Support Document for additional information about Tier 3 risk characterizations.

3.0 BACKGROUND AND CONSIDERATIONS FOR TIER-BASED RISK CHARACTERIZATION

General background information and considerations for conducting a tier-based soil-human health risk characterization is presented in this section. Note that additional, more detailed discussion of the assumptions inherent in the Tier 1 and 2 SRVs is provided in Sections 5.2 and 6.3 of this document.

3.1 Exposure assumptions and target risk levels incorporated into the SRVs

Human contact with soil can occur during a diverse range of activities. These include work, play and gardening on residential properties; recreation on public and private land; and construction, utility and landscaping on industrial properties. The most common exposure pathways for soil are incidental ingestion of contaminated soil, dermal absorption of contaminants from contaminated soil, and inhalation of dust or vapors from contaminated soil. Table 3.1 presents several potential human-soil exposure pathways that can occur during common site activities and use.

Table 3.1. Soil-related Exposure Pathways.**

EXPOSURE ROUTE		
Ingestion	**Dermal**	**Inhalation**
*** Incidental ingestion of contaminated particulate.** * Ingestion of produce contaminated via contaminants transferred from soil. * Ingestion of livestock products contaminated via contaminants transferred from soil or produce. * Mother's milk contaminated by maternal ingestion of contaminated soil or food contaminated via transfer from soil.	*** Contact with contaminated soil**	*** Inhalation of soil vapors in outdoor air.** *** Inhalation of resuspended soil particulate in outdoor air.** * Inhalation of soil vapors in indoor air. * Inhalation of resuspended soil particulate in indoor air

**Bolded pathways are incorporated into the Tier 1 and Tier 2 SRVs.

The Tier 1 and 2 SRVs incorporate the most common human exposure pathways (incidental ingestion, dermal contact and inhalation of contaminants volatilized from soil in outdoor air) using a set of generic exposure assumptions. When exposure pathways not accounted for in the Tier 1 and 2 SRVs are likely to be important at a site, a Tier 1 or 2 risk characterization will not adequately evaluate risk and it will be necessary to perform a Tier 3 risk characterization.

The SRVs are calculated such that risk to human health will be at or below acceptable risk levels established by the MPCA. Risk is evaluated separately for carcinogenic (cancer-causing) and non-carcinogenic effects. It assumed that the risk posed by individual contaminants with similar target endpoints (i.e., that affect the same parts of the body, such as the liver or kidney) is additive. Therefore, when multiple contaminants having carcinogenic and/or non-carcinogenic effects are present at a site, the combined risk posed by the contaminants must be evaluated. Evaluation of the combined risk is facilitated by a set of spreadsheets available in Appendix 3 of the Technical Support Document that were developed by SF/VIC staff for this purpose.

The acceptable risk levels targeted by the risk -based site evaluation process are as follows:

- **Carcinogenic effects** - a total or cumulative excess lifetime cancer risk (ELCR) not to exceed 1 in 100,000 (i.e., 1E-5) for chronic exposure. In other words, the acceptable risk level is a maximum of one additional case of cancer per 100,000 chronically exposed individuals *above* background cancer rates in the general population. For subchronic exposure (1 year or less) the acceptable total ELCR is limited to 10 percent of the chronic total ELCR (i.e., 1 E-6); and
- **Non-carcinogenic effects** - a non-cancer risk not to exceed a hazard quotient (HQ) of 0.2 per contaminant for chronic exposure or 1 for subchronic and acute exposure and a total hazard index (HI) of 1 for contaminants with similar target endpoints. The HQ is determined by dividing the site contaminant exposure concentration by the contaminant reference dose, which is an estimate of the daily exposure concentration that is not likely to result in an appreciable risk of deleterious effects during a lifetime. The HI is determined by adding the HQs for each contaminant of potential concern (COPC) with similar endpoints.

Note that the acceptable risk levels remain the same regardless of the tier under which a site is being evaluated.

The Tier 1 and 2 SRVs are generally developed assuming chronic or long-term exposure to the contaminants. However, some contaminants present a risk to human health from one-time (acute) or short-term (subchronic) exposure. Where toxicity information indicates that one-time or short-term exposure to a contaminant poses a higher risk to human health than low level chronic exposure, the Tier 1 and 2 SRVs are derived based upon an acute or subchronic exposure scenario. Appendices 3 and 4 of the Technical Support Document note which contaminants are considered acutely toxic or toxic on the basis of a short-term exposure. Additional guidance pertaining to acutely toxic contaminants is available in the Technical Support Document. The Technical Support Document also details the exposure equations, default values, and chemical specific information used to calculate the Tier 1 and 2 SRVs.

3.2 Safety Risk and Short-Term Hazard Evaluation

All risks to human health posed by contaminated soil at a Site are not accounted for using the SRVs. Examples include physical hazards such as the presence of rusted and/or leaking drums or the threat of fire or explosion, and short-term hazards related to the presence of acutely toxic chemicals that may not be recognized early in the risk characterization process unless a preliminary short-term hazard evaluation is performed. To address these risks, SF/VIC staff require that risk to safety and the need for a short-term hazard evaluation be considered at every site as part of the tier-based risk characterization process.

Evaluation of the risk to safety and potential short-term hazards requires the use of professional judgment and, in most cases, assessment of qualitative criteria. The scope of the evaluation is expected to vary from site to site in accordance with the likelihood of potential risks. In many cases, evaluation of the risk to safety is addressed sufficiently through preparation of a site health and safety plan, which accounts for potential hazards based on known information. Some common examples of conditions that constitute a risk of harm to safety are as follows: rusted or corroded drums or containers; weakened berms; the threat of fire or explosion, including the presence of explosive vapors resulting from the release of contaminants; reactive chemical(s) stored or disposed of in a way that does not reasonably preclude uncontrolled reactions; unsecured pits, ponds, lagoons, or other dangerous structures; any uncontained materials that exhibit the characteristics of corrosivity, reactivity, flammability, or are considered infectious materials; and the presence of ionizing or nonionizing radiation.

A short-term hazard evaluation should be performed whenever it is believed that human exposure is occurring or is likely to occur. An example would be a site where surficial soil contamination exists at a location where children commonly play. In evaluating a potential short-term hazard, the types of contaminants that people are being exposed to is important, since contaminants that are capable of causing severe effects after a one-time or short-term exposure present more serious risks. At the onset of a site investigation, short-term hazard evaluations are necessarily qualitative in nature. After site data is available, it is possible to conduct a quantitative short-term hazard evaluation. Quantitative short-term hazard evaluations are typically conducted when the short-term risk posed by contaminants at the site is not clearly determinable without going through the risk characterization procedure. Quantitative short-term hazard evaluations are usually conducted following the Tier 3 risk assessment procedures, however the scope of the evaluations are considerably more limited than for full risk characterizations, as they focus only on current exposures, contaminants that are likely to be of concern over the short term, and current site uses.

As discussed further in Section 8.0, the SF/VIC requires that documentation of Tier 1, 2, and 3 risk characterizations include evaluation of the risk to safety and short-term hazards at the site. Additional guidance for conducting risk to safety and short-term hazard evaluations is provided in the Technical Support Document.

3.3 DATA COLLECTION AND EVALUATION

Site investigations are generally performed to answer a number of questions about contamination at a site, including the types and identity of the contaminants, and the location and extent of contaminated areas. Data collected during a site investigation, however, may not be sufficient to conduct a risk assessment. Typically, this is because data collected to characterize soil contamination (identity and concentration) is not collected at locations where human exposure is likely to occur (the exposure points), or is otherwise not representative of human exposure at the site, currently or in the future. Another common problem is that the data collected to characterize the magnitude of contamination is not suitable for evaluating the risk to human health.

Examples of

Minnesota Pollution Control Agency
Site Remediation Section
520 Lafayette Road
St. Paul, Minnesota 55155-4194

such data include the following: data from field screening tests for indicator parameters, such as jar headspace tests; quantitative analytical data that is not compound-specific, such as the analysis for total petroleum hydrocarbons, for which toxicological profiles are not available; quantitative analytical data obtained with insufficient quality assurance/quality control (QA/QC) measures; quantitative analytical data where the sample detection limit is above or very close to the SRV; and composited sample data.

The three key data needs for conducting an exposure assessment are as follows:

1. Information about the contamination:

   Contaminant identity and magnitude of concentration, and the physical occurrence of the contamination, including its horizontal and vertical extent.

2. Information about Human Receptors:

   Potential human receptors and their use of the site and surrounding area must be identified so that activities that occur or could potentially occur can be assessed. The risk characterization must include all activities that are consistent with the current site use, even if some of the activities are not occurring at the time of evaluation. Tier 1 is conducted exclusively on the assumption of residential property use, but in Tier 2 and 3 current property use as well as future planned use (known or foreseeable) must be evaluated as part of the risk evaluation.

3. Information about Exposure Areas and Pathways:

   The identity and location of the contamination relative to the activities that occur on the site and surrounding area is used to identify the relevant exposure areas (i.e., areas where contaminated soil is present and exposure can occur) and exposure pathways (i.e., ways in which exposure occurs).

The site investigation work plan should be prepared with the needs of the soil-human health risk characterization in mind. A comprehensive discussion of data quality issues and criteria is presented in EPA's Guidance for Data Useability in Risk Assessment (EPA 540G-90/008, October 1990). Additional discussion of considerations for conducting site investigations that will yield data valid for conducting human exposure evaluations is contained in the Technical Support Document.

3.4 Exposure Areas and Exposure Concentrations

The concentration of a contaminant in soil at a site that is used to evaluate risk to human health is referred to as the *exposure concentration*. The area of soil containing the contaminant is termed the *exposure area*. At any given site there may be several exposure areas, and the chemicals of potential concern in each exposure area may be different from one another.

Though the Tier 1 and 2 risk characterization process in some respects appears simplistic, the validity of the risk characterization is directly related to the assessor's recognition of the quality of the information available for a site. A number of issues must be evaluated when determining exposure areas and exposure concentrations. For example, if too few samples are collected for analysis, or the samples are collected from dubious locations, or if the samples are analyzed using analytical methods unable to detect the presence of likely contaminants, the conclusions drawn from the risk characterization will have little meaning. Thorough consideration of the available site-specific information is a critical aspect of the tiered risk characterization process.

The first step in determining an exposure concentration is defining the exposure area. Again, the exposure area is defined as an area of *contaminated* soil; thus, analytical results from non-contaminated soil samples collected on the boundary of the exposure area should not be combined with results for contaminated samples to derive the exposure concentration. Some exposure areas may contain discrete zones where the concentrations of contaminants are substantially higher than in other portions of the exposure area; in cases like this, the "hot spots" should be evaluated individually to assure that risk is adequately addressed. Even when areas of contamination are not located where human exposure is likely to occur, such as when soil contamination exists several feet below the ground surface, the areas of contamination can not be dropped out of the risk characterization process. This is due to the possibility that these areas could be exposed in the future due to excavation, construction, or other activities. Additional guidance on defining exposure areas and estimating exposure concentrations is provide in Sections 4.0 and 7.4 of the Technical Support Document.

For a Tier 1 risk characterization, it is recommended that the maximum detected contaminant concentration be used as the exposure concentration. This is recommended to add to the protectiveness of the risk characterization, since for Tier 1 it is assumed that only limited characterization of the contamination at the site has been conducted. When adequate contaminant characterization has occurred the exposure concentration should represent the average concentration within the potential exposure area, since this concentration is most like the time-weighted average exposure concentration used to derive the SRV. Note that the use of rigorous statistics to derive an average contaminant concentration for a given exposure area is not recommended, since few site investigations result in the collection of a large enough number of randomly-collected samples to make this approach valid. Instead, the SF/VIC recommends the use of simple summary statistics (e.g. range, mean, median, and standard deviation) and professional judgment to derive exposure concentrations. SF/VIC staff believe that consideration of all relevant site information (including historical uses of the site, etc.) is less likely to lead to erroneous conclusions than the use of a formal inferential statistical test with inadequate data sets.

In the case of acutely toxic contaminants, the risk estimate for a "one time" exposure may exceed the risks from the long-term exposure on which the SRVs are generally based. Therefore, the Tier 1 and 2 SRVs for acutely toxic contaminants are based on the concentration above which a "one-time" dose could pose a significant risk. *To be protective, the exposure concentration for acutely toxic compounds should, without exception, be the maximum concentration detected at the Site.* The acutely toxic compounds for which SRVs have been developed are highlighted in the SRV Tables in Appendix 3 of the Technical Support Document

3.5 Contaminants of Potential Concern

All contaminants detected at a site are considered chemicals of potential concern (COPCs) at the onset of a site investigation. In fact, when limited information is available about a site, the list of COPC should include contaminants that have been detected as well as those that are suspected to be present or are considered potentially present at the site. It is not possible to identify a complete list of COPCs until analytical data for soil have been collected, evaluated, and found to be of acceptable quality.

Once this is done, all detected contaminants should be considered COPCs and carried through the risk characterization process unless there is a specific, justifiable rationale for eliminating a contaminant from the list of COPCs. The risk characterization will be used to determine which contaminants likely pose an unacceptable risk and will be the focus of further investigation and/or remediation.

Contaminants can generally be eliminated from further consideration if one of the following conditions is met:

- the contaminant is present at a low frequency of detection and at concentrations below the acceptable risk limit;
- the contaminant is present at concentrations that are consistent with background concentrations and there is no evidence that its presence is related to site activities; or
- the contaminant is a field or laboratory contaminant.

4.0 COMPARISON OF THE SOIL-HUMAN HEALTH RISK CHARACTERIZATION TIERS

Under the risk-based site evaluation process, limited site-specific information is used to identify problem areas and guide further site investigation and the determination of whether remedial action is needed. Table 4.1 presents a summary of the distinctions between the risk characterizations for the soil-human-health pathway at each tier level.

Table 4.1. Tier-Based Risk Characterization for the Soil-Human Health Pathway

Tier 1 Screening/Generic	Tier 2 Site-Specific	Tier 3 Unique/Detailed Site-Specific
Exposure pathways: Incidental ingestion, dermal contact and inhalation of outdoor vapors or particulate. *Exposure Scenario:* -Residential property use -Default exposure factors -Typically use maximum contaminant concentration as surrogate for exposure concentration. *Environmental Fate and Transport:* -Default source area and soil characteristics (e.g., soil properties, source area size). -Default chemical properties.	*Exposure pathways*: Incidental ingestion, dermal contact and inhalation of outdoor vapors or particulate. *Exposure Scenario:* -Site-specific property use designation. Institutional controls. -Default exposure factors -Average concentration within contaminated zone. Consideration of background concentrations. *Environmental Fate and Transport:* -Site-specific source area and soil characteristics (e.g., soil properties, source area size). -Default chemical properties.	*Exposure pathways*: Include common pathways addressed in Tier 1 and 2, plus potentially important site-specific pathways not included in Tier 1 and 2 (e.g., uptake into food chain). *Exposure Scenario:* -Site-specific property use designation. Institutional controls. - Site-specific exposure factors (including probabilistic evaluation) with Agency approval. -Average concentration within contaminated zone. With SRS approval, site-specific exposure area. Consideration of background concentrations. *Environmental Fate and Transport:* -Site-specific source area and soil characteristics (e.g., soil properties, source area size). -Site-specific chemical properties (e.g., bioavailability, degradation rates, Kd)

Note that at sites with more than one exposure area, it is possible to evaluate the risk posed by each exposure area separately. This may be advantageous if several of the exposure areas can be eliminated from further consideration at Tier 1 or 2, leaving only a portion of the site that requires additional evaluation and/or remediation. However, it is important in this situation to assure that risk is evaluated as cumulative risk. As long as the Tier 1 or Tier 2 risk assessments are site-appropriate and the potential cumulative risks from multiple contaminants are taken into account, the cumulative impact of contamination at the site is adequately addressed. But if one or more of the exposure areas requires a Tier 3 risk characterization, it is necessary to pay particular attention to the way the characterization is performed and how the results are interpreted to insure that the cumulative risk limit is met for the entire site. The Technical Support Document contains additional guidance on this topic.

5.0 TIER 1 (SCREENING LEVEL) RISK CHARACTERIZATION

The Tier 1 (Screening Level) risk characterization provides a straightforward method of evaluating the potential risk to human health from contaminated soil by evaluating site contaminant concentrations relative to the Tier 1 SRVs. When site soil contaminant concentrations exceed the Tier 1 SRVs, the risk to human health posed by the contaminated soil may exceed acceptable target risk levels.

5.1 General Approach

The primary condition that must be satisfied in order to proceed with a Tier 1 risk characterization is that the exposure pathways of concern and the site conditions match the assumptions used in calculating the SRVs. *It is important to bear in mind that the SRVs are generic in nature and may not be applicable to all sites.*

The assessor must identify likely source areas, exposure pathways, and potential receptors at the site prior to proceeding with the risk characterization. In addition, the assessor must know the identity of the contaminants and the concentrations of the contaminants in the most highly impacted areas of the Site. Overall confidence in the risk characterization process is directly related to the quality of the site characterization data.

A Tier 1 SRV risk characterization always includes the following steps, although the scope and level of effort of the risk characterization depends upon the complexity of the site:

- Information gathered as part of the site investigation is used to determine the nature and magnitude of contamination.
- The risk to safety is characterized and evaluation of short-term hazards is performed.
- The applicability of Tier I criteria is affirmed through review of assumptions and site conditions.
- The exposure concentrations are compared to the applicable Tier 1 SRVs to assess exceedence of target risk and cumulative risk levels.
- A conclusion is drawn as to whether site conditions pose a potential unacceptable risk of harm to human health and safety.

5.2 Affirmation of Tier 1 SRV Applicability

As stated previously in this document, the key requirement for use of the Tier 1 SRVs is that the site conditions are compatible with the assumptions incorporated into the SRVs. **Before proceeding with a Tier 1 risk characterization,** the assessor must evaluate the compatibility of the site with the generic conditions contained in the SRV calculations. Many of the basic assumptions inherent in the SRVs are discussed in Section 3.1 of this document. This section provides more in depth discussion of the default assumptions and models that are used to calculate the Tier 1 SRVs.

The SRVs account for the human exposure pathway of direct soil contact via the inhalation of resuspended soil particulate using a numerical model that estimates the concentration of particulate in air. The model used by SF/VIC staff relates the concentration of particulate that is released from the soil surface to the site conditions. The default site conditions are partially vegetated soil with particulate generation occurring due

to wind erosion. This default assumption does not account for conditions that may result in higher levels of dust generation, such as vehicle traffic, tilled agricultural soils, or construction activities. Consequently, if the exposure pathway of inhalation of resuspended soil particulate is potentially significant at a site, and conditions such as these are present, evaluating risk using the Tier 1 SRVs may not be valid.

The human exposure pathway of indirect soil contact via the inhalation of volatilized contaminants is also incorporated into the Tier 1 SRVs using a model. The model defines the relationship between the concentration of the contaminant in soil and the flux of the volatilized contaminant to air. The size of the source area and the soil characteristics are important input parameters into the model. Some of the default assumptions used to calculate the concentration of the contaminants in air are as follows:

- a source area of five acres
- soil moisture content of 10%
- soil organic carbon content of 0.5%.

If the site specific source area or soil characteristics are significantly different than the default values, the Tier 1 SRVs may be too high or too low. In this case the risk assessor may choose to proceed to a Tier 2 risk characterization, where site-specific modifications of some of the default soil parameters can be incorporated into the SRVs (see Section 6.3.2).

Other conditions that can affect the validity of the risk characterization include the presence of landfill gases, which increase the flux of volatile contaminants in/through the soil and result in a higher risk than would be calculated on the basis of soil contaminant concentrations alone. The presence of shallow ground water contaminated with volatile organic compounds would have a similar effect on the validity of the risk characterization. Another example would be if the concentrations of the contaminant in soil exceeded the saturation point for that compound. This condition would render Henry's Law, used in the model for calculating the SRVs, invalid.

When a simple Tier 1 risk characterization is not adequate to evaluate the potential risk to human health at a site, it is sometimes possible to supplement the Tier 1 risk evaluation using Tier 3 methodology to assess the pathway(s) or condition(s) that are not accounted for, rather than dispensing with the Tier 1 risk characterization completely.

The Technical Support Document provides a complete discussion of the models used and assumptions involved in derivation of the SRVs.

5.3 Conclusions of a Tier 1 SRV Risk Characterization

The purpose of the Tier 1 risk characterization is to determine whether further investigation and/or remediation is needed at a site, based on an estimate of the potential human health risk from soil contamination. There are four possible outcomes of the Tier 1 SRV risk characterization:

Outcome 1: the site clearly "passes" the screening comparison;

Outcome 2: the site barely passes the screening comparison;

Outcome 3: the site barely fails the screening comparison; or

Outcome 4: the site clearly "fails" the screening comparison.

Sites where all contaminant exposure concentrations fall below the acceptable target risk limits (Outcome 1) require no further site investigation regarding human health concerns resulting from direct contact with soil.

If a site marginally passes the screening criteria (Outcome 2), confirmation sampling may be requested. This is especially likely if SF/VIC staff have concerns regarding the quality of the existing site data. No further action would likely be required if the confirmation sampling supports the original conclusion that the contaminants in soil at the site do not pose an unacceptable risk to human health.

However, if one or more of the contaminant exposure concentrations exceed the acceptable target risk limits, including cumulative limits (Outcome 3 or 4), additional site evaluation is generally recommended. The collection of additional site data and performance of a more site-specific, Tier 2 risk characterization may demonstrate that the risk to human health estimated at Tier 1 does not exist. Of course it is equally possible the Tier 2 risk characterization will simply substantiate the conclusions of the Tier 1 risk characterization. Depending on the site conditions and the scale of contamination, the responsible or voluntary party may choose to accept the results of the Tier 1 risk characterization and implement a remedy directly, rather than spending additional resources on a Tier 2 risk characterization.

At sites with more than one area of contamination, the tiered risk characterization process can be used to prioritize the areas of contamination that pose the greatest potential risk to human health, and in this way assist the responsible party in making site decisions.

6.0 TIER 2 (SIMPLE SITE-SPECIFIC) RISK CHARACTERIZATION

A Tier 2 risk characterization is very similar to a Tier 1 risk characterization but provides choices for modifying the human exposure scenario by choosing SRVs developed for different land use categories. In addition, some of the default soil parameters used to calculate the SRVs can be modified to incorporate site-specific soil characteristics.

6.1 Features and Data Needs for the Tier 2 Risk Characterization

Under Tier 2, the following site-specific factors can be incorporated into the risk characterization:

- Current and planned property use (residential, industrial/commercial or recreational).
- Where volatile contaminants are a concern, site-specific soil characteristics can be used to derive SRVs that more closely reflect actual site conditions.
- Background concentrations can be taken into account in assessing whether a contaminant is an actual contaminant of concern at a site.

Because a site is expected to be more fully characterized for a Tier 2 risk characterization than for Tier 1, the exposure concentrations are generally average soil contaminant concentrations, as determined by an evaluation of the site data. If the exposure concentrations exceed the target risk levels (including an evaluation of cumulative risk) then the risk to human health from contaminated soil is considered unacceptable,

and SF/VIC staff will typically require a response action. Alternatively, there may be reason to suspect that a fully site-specific or Tier 3 risk characterization may demonstrate that the risk to human health is not above target levels; the responsible party may then choose to discuss performing a Tier 3 risk characterization with SF/VIC staff.

Data needed to support a Tier 2 evaluation include:

- Identity, concentration, and extent of contaminants
- Representative contaminant exposure concentration
- Planned property use on the site and on surrounding properties (current and future)
- Background contaminant concentration (if applicable to the site conditions) (optional)
- Soil Properties (bulk density, soil porosity, etc.) (optional)

6.2 General Approach

A Tier 2 risk characterization includes the all the steps outlined in Section 5.0 for a Tier 1 risk characterization with some additional steps. The additional steps are identified below in italicized printing:

- Information gathered as part of the site investigation is used to determine the nature, magnitude, and *extent* of contamination.
- The safety risk is characterized and evaluation of short-term hazards is performed
- The applicability of Tier 2 criteria is affirmed through a review of assumptions and site conditions
- *Property use on the site and the surrounding area is identified and the appropriate category or categories of Tier 2 SRVs is identified*.
- *If the list of COPC includes volatile contaminants, site specific soil characteristics affecting environmental fate and transport of volatile contaminants are identified and used to modify the Tier 2 SRVs (optional)*
- *If the list of COPC includes contaminants that may be present at background concentrations in the surrounding area, the concentrations of these contaminants are determined in background samples for comparison purposes (optional)*
- The contaminant exposure concentrations are compared to the applicable Tier 2 SRVs to assess the exceedence of target risk and cumulative risk levels.
- A conclusion is drawn as to whether site conditions pose a potential unacceptable risk of harm to health and safety.

6.3 Affirmation of Tier 2 SRV Applicability

As for a Tier 1 risk characterization, the assessor must evaluate whether the exposure pathways are fully accounted for and the site conditions are compatible with the generic conditions on which the SRVs are based. Since the Tier 2 SRVs are derived using same models and default conditions as the Tier 1 SRVs, the conditions discussed for affirmation of the Tier 1 SRVs in Section 5.2 of this document apply fully to Tier 2 risk characterizations. If potentially important exposure pathways or other site conditions are not accounted for and/or invalidate the assumptions on which the SRVs are based, a Tier 2 risk characterization will not be valid

and it will be necessary to perform a Tier 3 risk characterization to ensure that the risk posed by the site is adequately evaluated. The following sections discuss additional considerations for application of the Tier 2 SRVs.

6.3.1 Property Use Considerations

Property use is characterized by the activities that occur on the property and the receptors (child or adult) that take part in those activities. The property use categories for which SRVs have been developed include the following: residential or unrestricted commercial property use; restricted commercial or industrial property use; and recreational property use. The distinction between restricted and unrestricted commercial property use is based upon the human exposure potential from the site activities. A complete description of the property use categories is contained in the Working Draft Guidelines for Incorporation of Planned Property Use into Site Decisions (August 25, 1997). **Note that though the SRVs are referred to as Tier 1 or Tier 2 SRVs, the only difference between them is the human exposure scenario for the respective land use category. The Tier 1 SRVs for residential land use may be applied to Tier 2 sites and modified as described for the Tier 2 SRVs, however the Tier 2 SRVs for industrial and recreational property use may <u>not</u> be applied totter 1 sites. This is because a Tier 1 risk characterization is a screening level risk characterization and as such is designed to employ more conservative assumptions.**

The Tier 2 SRVs, like the Tier 1 SRVs for the residential property use category, are derived using generic exposure scenarios developed for the industrial and recreational property use categories. The exposure scenarios are based on the occurrence of activities that are consistent with the property use and are intended to encompass the maximum exposure that is reasonably expected to occur at a site (otherwise known as reasonable maximum exposure). For example, the generic exposure scenario for industrial property use assumes the primary receptors are adults with the main exposure route being through indoor work activities, with limited outdoor work activity. For another example, the generic exposure scenario for recreational property use evaluates the most susceptible receptors, in this case children who may be exposed to contaminated soil in play areas. It is important to note that the risk characterization must include the entire range of activities that is consistent with the current or planned use of the property, even if these activities are not presently occurring at the site.

When evaluating the activities that occur or could potentially occur at a particular site, it is useful to evaluate activities that take place on the surrounding and/or adjacent properties, since they may give an indication of potential site activities that should be considered in the risk characterization. For example, a site that is located next to an elementary school should evaluate the exposures that could occur if the site is routinely visited by school-age children. Community input is often indispensable in identifying activities that occur at a site. (The Risk-Based Site Evaluation Manual includes a guidance document on Community Involvement that may be helpful in this regard.) All reasonable activities that could occur under present and planned property use must be evaluated as part of the risk characterization. If these activities are not incorporated into the generic exposure assessment for the property use category that best fits the site, a Tier 3 risk evaluation will be needed to assess the risk posed by site-specific activities.

The exposure equations and recommended default exposure parameters for the various property use exposure scenarios (i.e., residential/unrestricted commercial, industrial/restricted commercial, and recreational land use) are summarized in Appendix 1 of the Technical Support Document. The SRVs are presented in Appendix 3 of the Technical Support Document.

6.3.2 Modification of Tier 2 Volatilization Factor Model Defaults

In developing the Tier 1 and 2 SRVs for volatile contaminants, SF/VIC staff selected default soil characteristics to use in the model that calculates the concentration of the contaminant that will volatilize from contaminated soil into outdoor air, as discussed previously in Section 5.2 of this document. In a Tier 2 risk characterization there is the option of modifying the default soil characteristics to reflect actual site soil characteristics. Depending on the site, the modifications could result in higher or lower Tier 2 SRV concentrations for volatile contaminants. The modifications are accomplished by substituting site-specific soil parameters in the appropriate exposure equation(s) to derive modified site-specific SRVs, as detailed in Appendix 1 of the Technical Support Document.

As an alternative to the method described above, it is permissible to conduct direct environmental monitoring to determine a measured concentration of volatilized contaminants in outdoor air for calculating modified site-specific Tier 2 SRVs. This alternative is permissible ONLY IF the monitoring is conducted under conditions that would maximize volatilization. Risk assessors wishing to pursue this alternative should discuss their proposal with SF/VIC staff prior to implementation.

6.3.3 Comparing Site Contaminant Concentrations to Background Levels

Background concentration refers to the concentration of a chemical that is ubiquitous and consistently present in the environment, and would be present even if the site of concern did not exist. Most frequently, the issue of background concentrations becomes important when metals that occur naturally in the environment are chemicals of potential concern at a Site. Occasionally, however, other types of contaminants present at background concentrations in an area as a consequence of contamination from a non-site-related release. In this case the "background concentrations" are not truly representative of background conditions. *Note that it must be assumed that a detected contaminant is present above background concentrations unless it can be otherwise demonstrated.*

SF/VIC staff do not recommend using published background concentration data as a basis for determining whether site contaminants are above or below background concentrations unless the reference has been specifically recommended by SF/VIC staff. Generally, it is necessary to collect soil samples from off-site locations and apply statistical methods to determine whether site contaminant concentrations are consistent with or above background concentrations. Refer to the Technical Support Document for more detailed guidance on evaluating background concentrations.

6.4 Conclusions of a Tier 2 Risk Characterization

Once the exposure concentrations and appropriate land use category for the site have been determined, the applicability of the SRVs has been assessed and verified, and any site-specific modifications of the Tier 2 SRVs performed, the risk characterization involves a simple comparison of the exposure concentrations to the applicable Tier 2 SRVs to assess whether acceptable target risk levels have been exceeded. A condition of acceptable risk to human health from contaminated soil exists if none of the exposure concentrations exceed the applicable Tier 2 SRVs (including a cumulative risk evaluation). When this is the case no remedy may be needed. However, depending on the location and concentration of the contaminated soil and the planned property use, SF/VIC staff may require that institutional controls be implemented. For example, an industrial property that was found to be below acceptable target risk levels on the basis of the Tier 2 SRVs for industrial property use, but above acceptable target risk levels based on the SRVs for residential property use would generally not be

required

Minnesota Pollution Control Agency
Site Remediation Section
520 Lafayette Road
St. Paul, Minnesota 55155-4194

to implement a remedy. However, SF/VIC staff would likely require that institutional controls be implemented to notify potential future property owners of the presence of contaminants and the probable need for a remedy if the site land use or configuration is changed in the future. Refer to the Draft Guidance on Incorporation of Planned Property Use into Site Decisions (August 25, 1997) for further guidance on this issue.

If one or more exposure concentrations exceed acceptable target risk levels, then a condition of acceptable risk does not exist and a response action will likely be necessary. However, the risk assessor could choose to perform a more site-specific risk characterization (Tier 3) to further evaluate the site. For some sites where a Tier 2 risk characterization has indicated that a condition of acceptable risk has not been achieved, the Tier 3 evaluation may demonstrate that, in fact, a level of acceptable risk does exist. Of course, it is always possible that the more detailed risk characterization will yield the same conclusions as the Tier 2 risk characterization.

Alternatively, the responsible or voluntary party may choose to conduct a response action to reduce the concentrations of contaminants to levels below cleanup goals derived from the applicable SRVs. Remedial response actions can be combined with institutional controls (including engineering controls, monitoring, and maintenance) to achieve a condition of acceptable risk. Refer to the Draft Guidance for Incorporation of Planned Property Use into Site Decisions (August 25, 1997) and the Draft Guidance for Remedy Selection for additional guidance on institutional controls and remedy selection. If institutional controls are employed as part of a remedy to limit human exposure to contaminants in soil, an evaluation of the potential for the control to fail should be considered. The magnitude of the potential risk that could result from failure of the institutional control should be evaluated and considered in the remedial response action decision.

Remember that evaluation of the soil-human health pathway is only one element in determining whether the risk posed by contamination at a site is below acceptable target risk levels. The potential risks from contaminated ground water and surface water and the risk to ecological receptors must also be evaluated to determine whether a remedial action is necessary.

7.0 TIER 3 (DETAILED SITE-SPECIFIC) RISK CHARACTERIZATION

A Tier 3 risk characterization is a fully site-specific assessment of the risk posed to human health by contaminated soil. As such, a Tier 3 risk characterization must be performed by a qualified individual with adequate training and experience. For this reason, this user's guide provides only a brief summary of the Tier 3 risk characterization process. A detailed description of the elements and considerations that go into a Tier 3 risk characterization is provided in the Technical Support Document; however, the information provided in the Technical Support Document is intended only to provide guidance and is not a procedure manual.

The risk assessor must obtain approval from SF/VIC staff prior to conducting a Tier 3 risk characterization. The risk assessor must demonstrate to SF/VIC staff that the Tier 3 risk characterization has a strong potential for an improved characterization of the site conditions or exposure pathways relative to Tier 2, and is supported by sufficient site-specific data to ensure accurate and reliable results. It is the responsibility of the risk assessor to obtain approval from SF/VIC staff prior to conducting the risk characterization. A checklist for preparing a proposal and scope of work for a Tier 3 risk characterization for approval by the SF/VIC is contained at the end of Section 8.0 in the Technical Support Document.

A Tier 3 risk characterization for the soil-human health pathway approach involves five steps: hazard identification, toxicity (dose-response) assessment, exposure assessment, risk characterization, and uncertainty analysis. The Tier 3 risk characterization must meet the same target risk levels established by SF/VIC as the Tier 1 and 2 risk characterizations (see Section 2.1 of this document), and exposure must be evaluated using the same exposure equations. (The exposure equations are provided in Appendix 1 of the Technical Support Document.) The five steps of the risk characterization are described briefly below:

- Hazard Identification involves identification of contaminants of potential concern.
- The Toxicity (Dose-Response) Assessment describes the relationship between the level of exposure and the likelihood and/or severity of an adverse effect, or in other words describes the toxicity potential of the contaminant.
- The Exposure Assessment involves identifying potential routes of exposure; characterizing the populations exposed; and determining the frequency, duration and extent of exposure.
- The Risk Characterization combines information from the previous three steps to describe the type (e.g., carcinogenic or non-carcinogenic) and magnitude of the risks to exposed populations.
- The Uncertainty Analysis identifies the nature and, when possible, the magnitude of the uncertainty and variability inherent in the characterization of risks. The results of any risk assessment reflect scientific uncertainty resulting from limitations in available data and assumptions that are made in the absence of such data, and the variability in exposure and toxicological response expected given the diversity within the human population. The assumptions and limitations that are part of all risk characterizations should be explicitly discussed.

Having obtained the results of the Tier 3 risk characterization, remediation of the site is required if the estimated cancer or non-cancer risks associated with human exposure to contaminated soil exceed the acceptable target risk levels. Proposed remedial alternatives must be evaluated to determine if they will result in attainment of an acceptable risk condition at the site.

8.0 DOCUMENTATION OF TIER 1 AND 2 RISK CHARACTERIZATIONS

Documentation of Tier 1 and 2 risk characterizations need not follow a formal reporting format, however, a standard set of information is expected. Most of the information that forms the basis of the risk characterization (e.g., exposure areas, exposure concentrations) is commonly submitted to the MPCA in the site investigation report. Keep in mind that at any given site it may be necessary to evaluate several different exposure pathways to assess the risk posed to human health and the environment; the guidance contained in this document is applicable only to the evaluation of risk via the soil-human health pathway.

In general, the report documenting the results of the risk characterization should include a discussion for each step of the characterization, as outlined in the Sections 5.1 and 6.2. The discussions will vary in length and content according to whether the risk characterization was Tier 1 or 2 and according to the complexity of the site. In addition, for every site SF/VIC staff will require a discussion of cumulative risk and an uncertainty analysis. An uncertainty analysis is a critical component of a risk characterization, since all risk characterizations involve making many assumptions and scientific judgments. *The results of a risk characterization should never be interpreted as absolute estimates of the risk to human health!*

The uncertainty analysis should contain a brief discussion of the possible sources of uncertainty present in the site assessment and risk characterization process that could affect the conclusions of the assessment. To the extent that it is known, the uncertainty discussion should describe whether the uncertainty is due to an incomplete knowledge of the site (e.g., unidentified hot spot), incomplete data from the scientific literature or other information source (e.g., lack of toxicity information for some COPCs), or from the effects of natural, unquantified variability (e.g., natural fluctuation in moisture content of soil). The discussion should also indicate whether or not the uncertainty has a biased impact on the risk characterization results (e.g., leading to an over- or under-estimation of risk) and, if possible, the magnitude of the effect.

Finally, the report shall discuss the conclusions of the risk characterization, and provide recommendations for further site investigation, risk characterization, or an evaluation of potential remedial actions, including a through rationale for each.

Appendix 2 of the RBSE Manual contains a documentation checklist with summary tables, which may be helpful in documenting the risk characterization process.