A Tier 3 risk assessment is a detailed, site-specific evaluation that the remediating party may choose to conduct when Tier 2 risks exceed acceptable levels and it is not cost-effective or feasible to remediate the site to Tier 2 site-specific target levels.

As shown in Table 2-1, compared to a Tier 2 risk assessment, a Tier 3 risk assessment may use the most recent toxicity factors, physical and chemical properties, site-specific exposure factors, and alternative models. A Tier 3 risk assessment may include a Level 1, Level 2, or Level 3 ecological risk assessment as described in Section 6.11.

The Tier 3 risk assessment requires the following steps:
1. Develop a Tier 3 work plan approved by the department,
2. Collect additional data, if necessary,
3. Calculate Tier 3 risk,
4. Compare Tier 3 risk with acceptable risk levels and if necessary, develop clean-up levels,
5. Recommend the next course of action, and
6. Complete a Tier 3 Risk Assessment Report.

10.1 STEP 1: DEVELOP TIER 3 WORK PLAN

Tier 3 risk assessment provides considerable flexibility to the remediating party. Examples are:
- Evaluation of additional site-specific receptors (other than residential and non-residential considered in Tier 1 and Tier 2) such as recreational users or trespassers,
- Use of site-specific exposure factors,
- Use of toxicity values different than the values listed in Appendix E, Table E-1, and may include the use of subchronic toxicity values for non-carcinogenic effects when the exposure duration is less than seven years (Note that subchronic toxicity values are not as widely available as chronic values, and unlike chronic reference dose values (RfDs) and reference dose concentration values (RfCs), no EPA work group exists to review and verify subchronic RfDs or RfCs. Subchronic toxicity values for a limited number of compounds are available from EPA's Health Effects Assessment Summary Tables (HEAST). The Agency for Toxic Substances and Disease Registry (ATSDR) publishes Minimal Risk Levels (MRLs) that may be suitable for use as subchronic toxicity values),
- Use of alternative fate and transport models,
- Alternative definition of surface soils based on site-specific considerations, and
- As discussed in Appendix E, Appendix E.10, the IEUBK model may be used to develop site-specific target levels for lead.

In each case, the specific choice must be technically justified. Because of this flexibility and the very site-specific nature of the Tier 3 evaluations, the department must approve a Tier 3 work plan.

In Tier 3, the only receptors that need to be considered are those for which the risk in Tier 2 exceeds acceptable levels and any additional receptors that are identified in Tier 3. Receptors for whom the Tier 2 risk is not exceeded need not be evaluated. However, none of the chemicals of concern (COCs) considered in the Tier 2 risk assessment can be eliminated at Tier 3. Thus the COCs considered in Tier 2 and Tier 3 risk assessments would be identical, unless new data collected subsequent to the Tier 2 risk assessment indicates otherwise. Typically a Tier 3 risk assessment follows a Tier 2 risk assessment. However, in a few cases it may be appropriate to proceed directly to a Tier 3 risk assessment after a DTL or Tier 1 risk assessment or after a site characterization.

The technical portion of the work plan must, at a minimum, include the following:

- Identification of the receptors that will be evaluated in Tier 3.

- Identification of the COCs and the complete and potentially complete exposure pathways for which Tier 3 risk will be calculated. Typically, these would be the same as for a Tier 2 risk assessment.

- An explanation of the fate and transport models to be used for the calculation of risk for the complete and potentially complete exposure pathways. The remediating party may propose the use of a model(s) different than that used in Tier 1 or Tier 2 risk assessment. At a minimum, the proposed model must:
  (i) Be peer reviewed,
  (ii) Be publicly available or a copy provided to the department at no cost to the department,
  (iii) Have a history of use on similar projects, and
  (iv) Be technically defensible.

- A tabulation of the input parameters required to compute the Tier 3 risk. For each of these parameters, the remediating party must justify the use of the selected value. Examples of input parameters that may be specific to Tier 3 are:
  (i) Chemical-specific physical properties,
  (ii) Chemical-specific toxicological properties,
  (iii) Site-specific or other alternate exposure factors, and
  (iv) Media and site-specific parameters required by the selected fate and transport models.

  In (iii), if alternative exposure factors are used for the inhalation pathway, the remediating party must review and adjust, as appropriate, both the inhalation exposure time (hours/day) and inhalation rate (m^3/hour).

- A discussion of the data and the methodology that will be used to calculate the representative concentrations (see Appendix C for further information).

- An explanation of data gaps, if any, that require additional fieldwork. A scope of work for the collection of this data must be included in the Tier 3 risk assessment work plan.

- A discussion of the variability and uncertainty in the input parameters and the manner in which the impact of this variability on the final risk will be evaluated. Uncertainty analysis techniques range from sensitivity analysis to detailed Monte Carlo simulations.

- An evaluation of ecological risk. Ecological Risk Assessments previously completed at any tier are also acceptable in Tier 3 and do not need to be re-done.

After receiving approval of the Tier 3 work plan, the remediating party can perform a Tier 3 risk assessment. Any changes to the methodology or input parameters made subsequent to the department's approval must also be approved by the department and documented by the remediating party.

10.2 STEP 2: COLLECT ADDITIONAL DATA, IF NECESSARY

Upon approval of the Tier 3 work plan, the remediating party must perform the necessary fieldwork to collect the data. Any changes in the data collection due to field conditions or logistics of fieldwork must be discussed with the department prior to completion of the field effort. Depending on the nature and type of field work and data gaps, it may not be necessary to submit a separate report to the department describing the data collection activities. Documentation of the data collection efforts may be included as an appendix to the Tier 3 Risk Assessment Report.

10.3 STEP 3: CALCULATE TIER 3 RISK

Step 3 estimates the carcinogenic and non-carcinogenic risk for all COCs, receptors and exposure pathways, using the models and data in accordance with the approved work plan. At Tier 3, the risk values must be calculated for each COC and each exposure pathway. Then, the total risk for each COC (sum of risk for all the complete exposure pathways for a chemical) and the cumulative site-wide risk for each receptor (sum of risk for all COCs and all complete exposure pathways) must be calculated. If needed, ecological risk should also be considered as per the work plan.

10.4 STEP 4: COMPARE TIER 3 RISKS WITH ACCEPTABLE RISK LEVELS AND IF NECESSARY, DEVELOP CLEAN-UP LEVELS

In Step 4, total risks for each COC as well as cumulative site-wide risk for each receptor are compared with their respective acceptable risk levels. The total acceptable individual excess lifetime cancer risk (IECLR) for each COC is 1×10^{-5}. The acceptable risk level for the cumulative site-wide IECLR is 1×10^{-4}. The total acceptable hazard index for each COC and all exposure pathways as well as the cumulative site-wide hazard index is 1. The comparison will result in the following possibilities:

- The calculated total IECLR for each COC and the cumulative site-wide IECLR are below the acceptable risk levels. In this case, it will not be necessary to develop Tier 3 site-specific target levels for carcinogenic COCs.

- Either the individual chemical or the cumulative site-wide IECLR exceeds the acceptable risk level. In this case, Tier 3 site-specific target levels must be developed. As explained in Appendix I, considerable flexibility is allowed in the calculation of the site-specific target levels. Therefore, the remediating party must carefully explain the method and the assumptions used to calculate the target levels.

- The calculated cumulative site-wide hazard index (sum of the hazard quotients for all chemicals for all exposure pathways) is acceptable (less than 1.0). In this case, the non-carcinogenic risk is deemed acceptable and it will not be necessary to develop Tier 3 site-specific target levels for non-carcinogenic health effects.

  The hazard index for each COC is acceptable (less than unity), but the cumulative site-wide hazard index is unacceptable (greater than unity). In this case, it may be appropriate to segregate the COCs by target organ, system or mode of action and derive hazard indices for each. As an example, if there are 10 COCs at a site, four of which affect the kidney only, three affect the central nervous system only, and three affect the liver only. In this case, the COCs may be grouped into three categories, those that affect the (1) kidney, (2) central nervous system, and (3) liver. A cumulative hazard index for each of these organs must be developed. In this example, the remediating party would develop three cumulative hazard indices: one each for the kidney, central nervous system and the liver. If each of these cumulative hazard indices is acceptable (less than one), it will not be necessary to develop Tier 3 site-specific target levels for these COCs for non-carcinogenic health effects. If not acceptable, it will be necessary to develop the target levels for the COCs in the group that exceed the hazard index of unity.

  A professional must perform the organ-specific, health-effects analysis that is conceptually described above. Note that COCs may affect multiple organs and have multiple adverse health effects. In calculating the hazard index, COCs with multiple effects must be included in each category of organ that the COC affects. This professional should be knowledgeable about the adverse health effects of chemicals on human beings and application of quantitative toxicity factors in risk assessment. The knowledge may be a result of formal education, participation in continuing education courses or professional experience.

In addition to the human health risk assessment, ecological risks or levels protective of ecological receptors must be considered.

10.5 ANALYTICAL DETECTION LIMITS

During the course of demonstrating that target concentrations have been achieved, the analytical detection limit for certain COCs in environmental media may be higher

(sometimes by orders of magnitude) than the corresponding Tier 3 target cleanup level for that chemical. This happens because the concentrations of chemicals that can be positively detected are limited by the capabilities of the analytical method used.

Because Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW-846) are widely used, the following are identified in Appendix B:

- COCs with DTLs, WQC, or Tier 1 Risk-Based Target Levels lower than the detection limit or a Practical Quantitation Limit (PQL) (as judged by the department's Environmental Services Program) of methods contained in SW-846, and
- COCs that do not have a standard method listed in SW-846.

This discussion identifies the approaches that may be used in instances where the target cleanup level for a particular COC(s) cannot be achieved using standard analytical methods. In such circumstances, the following approaches may be useful:

1. Check the data to confirm that the standard detection limits are indeed higher than the Tier 3 target cleanup levels and that no errors were committed (for example, transposing numbers, misplacing a decimal point, or unit conversion).
2. With department approval, use alternative analytical methods that achieve detection limits lower than the Tier 3 target levels.
3. Perform a more focused risk assessment to determine if the levels that can be analytically quantified for the problem chemical are protective of human health and the environment given the complete and/or potentially complete exposure pathways. This approach could involve the use of a detection-based scenario (i.e., using the maximum detection limit of the problem COCs) in conjunction with alternate site-specific exposure factors to calculate if the risk is acceptable.
4. Develop areal contaminant trends that can then be used to extrapolate contaminant extent to the target level(s) followed by calculation of average concentrations based on those extrapolations. Fate and transport models used in conjunction with "above analytical detection limit results" for certain problematic chemicals could also be used to extrapolate contaminant extent, thereby facilitating calculation of average concentrations for comparison to target cleanup levels.

These approaches may be most useful where short-term decisions regarding the completion of cleanup are desired. Other approaches may be appropriate if a longer-term cleanup is anticipated. In longer-term situations where cleanup is required, it may not be productive to engage in protracted up-front discussion of analytical detection limits above applicable health-based cleanup levels for certain COCs. Remediating parties typically recognize the need to continue monitoring for such chemicals while deferring further discussion of the detection limit issue until such time as the other COCs that are present (those that can be analytically quantified) are approaching their respective cleanup levels. At that time, the detection limit issue for the problem chemicals with low health- or ecological-based limits would need to be addressed in more detail.

A long-term approach to this issue is to establish an interim target cleanup level corresponding to the site-specific laboratory's method detection limit (assuming that limit is acceptable to the department). This approach would typically be accompanied by a listing or acknowledgement of the lower health-based limit and a contingency that

requires remediating parties to change to new, more "sensitive" analytical methods, and therefore updated target levels, if such analytical methods become available during the course of cleanup. Sample language for this approach, as might be included in a work plan, follows:

> The risk-based groundwater cleanup target level for some of the COCs is below the lowest, reasonably achievable method detection limit due to limitations of current analytical technology. The interim groundwater cleanup target level has therefore been set at the method detection limit for those chemicals. A list of the corresponding risk-based concentrations for those chemicals is also provided.
>
> The allowable maximum detection limit for the referenced COCs can never be greater than the interim groundwater cleanup target levels. If the allowable maximum detection limit for specific COCs cannot be achieved due to matrix interferences or other reasonable analytical limitations (appropriate supporting documentation must be provided), the affected sample and associated chemical analyses will be exempted from this requirement. However, such an exemption does not in any way relieve the remediating party from complying with the interim groundwater cleanup target levels.
>
> The department reserves the right to modify the interim groundwater cleanup target levels based on future advances in analytical technology. Any such modifications would be to facilitate comparison of residual concentrations of chemicals in groundwater with then current risk-based groundwater cleanup target levels.

The above approach will most often apply in situations where the remediating party initially chooses to use the DTL or Tier 1 risk based target levels as the interim target cleanup level. The Tier 3 analysis may resolve this issue as more site-specific target cleanup levels are developed, in that it will result in the establishment of final cleanup target levels that are above the method detection limits.

If any disparity between target levels and analytical detection limits occurs when determining representative concentrations, see Appendix C, Section C.1 for guidance on handling non-detect values.

10.6 STEP 5: DETERMINE THE NEXT COURSE OF ACTION

After completion of the Tier 3 risk assessment, one of the following two alternatives is available:

Alternative 1: The remediating party may request a Letter of Completion from the department if the calculated risks for each COC and the cumulative site-wide risk do not exceed the target risk levels and the following four conditions are met.

Condition 1: The plume, if one exists, is stable or decreasing (refer to Section 6.13.2 for discussion of plume stability). If this condition is not satisfied, the remediating

party must continue groundwater monitoring until the plume is demonstrably stable. Actions may be taken to hasten plume stability. This recommendation must include a sampling plan with specifics such as:

- Wells to be sampled,
- Frequency of sampling,
- Laboratory analysis method,
- Method to be used to demonstrate that the plume is stable or shrinking, and
- The format and frequency of reporting requirements.

Condition 2: The maximum concentration of any COC is less than ten times the representative concentration of that COC for any exposure pathway. Note the maximum concentration here refers to the maximum concentration of a chemical in the exposure domain, not the site-wide maximum concentration. This condition can be met if an exceedance can be justified by any of the following and/or appropriate actions taken:

- The maximum concentration is an outlier,
- The average concentration was inaccurately calculated,
- The site is not adequately characterized,
- A hot spot may not have been adequately characterized, or
- Other explanation satisfactory to the department.

Any exceedance of this condition must be documented and the possible rationale, if any, submitted to the department. The department will determine what actions, if any, will be necessary to address the situation.

Condition 3: Prior to issuance of a letter of completion, adequate assurance is provided that the land use assumptions used in the MRBCA evaluation are not violated for current or reasonably anticipated future use conditions. This condition may require that one or more activity and use limitations (AULs) are placed on the site and plans are in place to maintain long-term stewardship (LTS) for as long as needed to protect human health, public welfare and the environment.

Condition 4: There are no ecological concerns at the site, as determined by confirmation that the maximum or representative concentrations are below levels protective of ecological receptors or completion of the Ecological Risk Assessment. . If this condition is not met, the remediating party must provide recommendations to the department to manage the ecological risk. If the department approves the recommendations, their implementation and effectiveness, then this condition would be met.

Alternative 2: The remediating party must develop site-specific target levels and propose remedial actions to achieve these levels if the analysis finds that either:

1. The total risk for each COC (all pathways, $IELCR_{Ci}$ and HI_{Ci}) is unacceptable for any of the human or ecological receptors, or
2. The cumulative site-wide risk (all COCs and all complete pathways, $IELCR_T$ and HI_T) is unacceptable for any of the human or ecological receptors.

The site-specific target levels and the methodologies used to achieve these levels must be included in the Risk Management Plan.

The chart below summarizes several combinations of outcomes and necessary actions when cumulative site-wide risk is considered.

Action vs. Calculated Risk

Carcinogenic Risk		Non-carcinogenic Risk		Action
Individual Chemical of Concern	**Cumulative Site-wide Risk**	**Individual Chemical of Concern**	**Cumulative Site-wide Risk**	
NE	NE	NE	NE	No need to calculate any SSTLs.
E	E	E	E	Both carcinogenic and non-carcinogenic SSTLs must be developed.
NE	E	NE	E	Both carcinogenic and non-carcinogenic SSTLs must be developed.
E	NE	E	NE	Both carcinogenic and non-carcinogenic SSTLs must be developed.
NE	NE	E	NE	Non-carcinogenic SSTLs must be developed.
NE	NE	NE	E	Non-carcinogenic SSTLs must be developed.
E	NE	NE	NE	Carcinogenic SSTLs must be developed.
NE	E	NE	NE	Carcinogenic SSTLs must be developed.

Notes:
E: Exceeds acceptable risk level (refer to Appendix B)
NE: Does not exceed acceptable risk level
SSTL: Site-specific target level

10. 7 STEP 6: DOCUMENT TIER 3 RISK ASSESSMENT AND RECOMMENDATIONS

Because a Tier 3 risk assessment is very site-specific, the remediating party must submit a report that clearly describes the data used, methodology and key assumptions, results,

and recommendations regarding the path forward. Any deviation from the approved scope of work, the rationale for the deviation, and the date when the deviation was approved by the department must be clearly documented in the report. At a minimum the report must include:

- Site background and chronology of events,
- Data used to perform the evaluation,
- Documentation of the exposure model and its assumptions,
- Documentation and justification of all input parameters used,
- Estimated risk for each COC, each exposure pathway, each receptor, and the site-wide risk for each receptor and media,
- Recommendations based on the Tier 3 risk assessment, and
- If a Letter of Completion is requested, documentation that all the conditions in Section 10.5, Alternative 1, have been met.

The effort required to prepare the final report can be significantly reduced by preparing a detailed work plan up front.