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Top Ten Most Common MCP Risk Characterization Problems

Bureau of Waste Site Cleanup and Office of Research and Standards

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Ten issues to consider before submitting an MCP Risk Characterization document. Based upon audit results and inquiries to the MCP HelpLine

1. **The extent of contamination at the disposal site has not been adequately delineated.**

   In order to conclude that a site poses No Significant Risk, a detailed understanding of the source and migration of the contaminants must be obtained. Gaps in the site assessment translate directly to uncertainty in the risk assessment.

   The MCP identifies site information that is required for the risk characterization at 310 CMR 40.0904. Included in this list is information on the extent of the release. The conclusions of the risk characterization are only valid if the extent of the release has been properly defined and all possible affected media and migration pathways have been considered. The Guidance for Disposal Site Risk Characterization (July, 1995) addresses this topic in greater detail in Section 2.2.

2. **Analytical data has not been reviewed prior to use in the risk assessment.**

   The analytical data which is used in the risk characterization will ultimately determine the outcome. It is therefore imperative that the quality of the data be reviewed prior to its use. The sampling and analytical methods employed should be evaluated to ensure that the methods selected were appropriate and the method detection limits achieved were sufficiently sensitive. For example, in an area categorized as GW-1, the analytical methods selected for groundwater analysis should be sufficiently sensitive to meet the Drinking Water Standards (310 CMR 22.00). Further discussion of data considerations may be found in the Guidance for Disposal Site Risk Characterization in Section 2.2.

3. **Soil and groundwater have not been categorized or have been categorized improperly.**

   The MCP (310 CMR 40.0930) requires that soil and groundwater be categorized at all sites, regardless of the risk characterization method selected - including Method 3. Categorization of soil and groundwater determines the applicability of standards (for all 3 Methods). For example, in a Method 3 Risk Characterization, the Massachusetts Drinking Water Standards (310 CMR 22) are considered Applicable and Suitably Analogous Standards in GW-1 areas. In addition, categorization provides a rough estimate of exposure potential under Method 3, which is useful to gauge the appropriateness of the exposure assumptions chosen. The categorization process is fairly straightforward, but is often overlooked or addressed in only a cursory fashion. Additional details on both soil and groundwater categorization may be found in the Guidance for Disposal Site Risk Characterization in Section 2.1, with particular emphasis on Section 2.1.4.

4. **Contaminants have been inappropriately eliminated from the risk characterization process.**

   The contaminants present at the site will in large part determine the risk posed by possible exposures at the site. It is up to the risk assessor to provide sufficiently detailed justification for eliminating any chemical detected at the site from the Risk Characterization. Factors which are considered in eliminating chemicals from the list of Contaminants of Concern include background levels, frequency of detection and concentration levels, and laboratory or field contamination. Reportable Concentrations (RCs) should never be used a means of screening chemicals from the Risk Characterization. Specific guidance in this area may be found in Section 2.4 of the Guidance for Disposal Site Risk Characterization.

5. **Background concentrations at the site have not been established or have been improperly identified.**

   "Background" has a specific regulatory definition in the Massachusetts Contingency Plan (310 CMR 40.0006, and Section 2.3 of the Guidance for Disposal Site Risk Characterization), which may be different from the lay understanding of the term. For example, the definition of background in the MCP does not include contamination migrating from an upgradient source -- something which can be addressed through the "Downgradient Property Status" provisions of the MCP (310 CMR 40.0180). Establishing background conditions is important to determine if a Class A1 Response Action Outcome is appropriate for a site, when the feasibility of achieving or approaching background must be evaluated, or when background levels prevent the achievement of "No Significant Risk" conditions at a site. See also Section 9.4.2.1 for a discussion of "local conditions" as it applies to ecological risk characterizations.

6. **Exposure Point Concentrations have been calculated improperly or it is uncertain how they were calculated. The MCP numerical standards and risk limits are based upon the site Exposure Point Concentrations (EPCs), not the raw analytical results received from a laboratory. Thoughtful analysis of the data is required to develop the EPCs.**

   The method used for calculating Exposure Point Concentrations (EPCs) should be clearly stated in the report, with sufficient detail to allow a reviewer to replicate the calculations. Specific guidance is available on important aspects of developing Exposure Point Concentrations, including the treatment of Non-Detect values, spacial and temporal averaging, when average concentrations are not appropriate, and how to address "Hot Spots." (See Sections 5.8 and 7.3 of the Guidance for Disposal Site Risk Characterization.)

7. Risk characterization methods have been selected which are inappropriate for the site.

Each Risk Characterization must affirm and document the applicability of the chosen Method to the disposal site (310 CMR 40.0971(4) and 310 CMR 40.0988(1)). An important limitation on the applicability of Methods 1 and 2 is that the environmental media contaminated by the oil or hazardous material must be limited to soil and groundwater. Combinations of Methods (e.g., using Method 1 for soil contamination and Method 3 for sediment contamination at a site) can only be used under special circumstances. Method 1 standards are never used as screening criteria or as "applicable or suitably analogous standards" in a Method 3 Risk Characterization.

8. An Environmental Risk Characterization has not been conducted or is inadequate.

The MCP requires that a Method 3 (site specific) risk characterization be based upon site-specific exposure information (310 40.0995(1)) and receptor identification (310 40.0922). The Guidance for Disposal Site Risk Characterization (Chapter 9 - Environmental Risk Characterization) specifies that risk assessments should focus on receptors that are most susceptible to the contamination in question. Thus, the risk assessment report should document that the combination of effects evaluated in the assessment represent potential effects from all pathways of concern and are relatively sensitive indicators of risk.

The spatial scale of an Environmental Risk Characterization should be consistent with the site-specific exposures, receptors and impacts of concern. Portions of sites being evaluated separate from the rest of the site (e.g. as an "operable units" under federal programs) are not likely lend themselves to a valid or meaningful environmental risk characterization.

9. Inadequate documentation of exposure factor assumptions and models used to estimate exposures.

The frequency, duration and intensity of exposure to site contamination for each receptor must be described and documented, with particular consideration given to both the current and reasonably foreseeable Site Activities and Uses identified for the disposal site. The magnitude of each receptor's total exposure to the oil and/or hazardous material is calculated in a manner which provides a conservative (i.e., "health-protective") estimate of the potential exposures (310 CMR 40.0993(4)). The Risk Characterization report must contain sufficient discussion of who the receptors are and how the receptors are exposed to justify the selection of exposure factors used in the risk assessment.

In many instances it is impossible to directly measure environmental concentrations. The regulations recognize this and allow for the development of Exposure Point Concentrations using monitoring data gathered during the site investigation or, when appropriate, through the use of fate and transport models generally accepted by the environmental modeling community. While direct measurement is preferred, modeling may be acceptable when direct measurement is impossible or extremely impractical. If a model is used, modeling methods, input parameters and assumptions, and model validation should be fully referenced and described. The uncertainties associated with any model used should be discussed in detail in the risk assessment report.

10. Conclusions are not supported by the risk assessment.

When the risk characterization does not demonstrate that a condition of "No Significant Risk of harm" exists, the conclusion of the risk characterization should clearly state that fact, and should acknowledge that remediation would be necessary to achieve a permanent solution. In particular, the conclusion must recognize conditions that constitute a significant risk of harm by definition, for example, an exceedance of UCLs or applicable standards under a Method 3 Risk Characterization.