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MCP REPRESENTATIVENESS EVALUATIONS AND DATA USABILITY ASSESSMENTS

Policy #WSC-07-350

This policy provides guidance on conducting Representativeness Evaluations and Data Usability Assessments under the Massachusetts Contingency Plan (MCP).

The information contained in this document is intended solely as guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative or other proceeding with the Commonwealth. Parties using this guidance should be aware that there may be other acceptable alternatives for achieving and documenting compliance with the applicable regulatory requirements and performance standards of the MCP.

September 19 2007
Date

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MCP Representativeness Evaluations and Data Usability Assessments
Policy #WSC-07-350

1.0 Introduction

This guidance may be used to prepare Representativeness Evaluations and Data Usability Assessments required as part of Response Action Outcome (RAO) submittals made pursuant to 310 CMR 40.1056(2)(k) of the Massachusetts Contingency Plan (MCP). This document provides general information regarding the purpose and content of these evaluations as a component of and in support of an RAO submittal.

The information contained in this document is intended solely as guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative or other proceeding with the Commonwealth. Parties using this guidance should be aware that there may be other acceptable alternatives for achieving and documenting compliance with the applicable regulatory requirements and performance standards of the MCP.

2.0 Definitions

Key terms that appear in capital letters in this document that are not otherwise defined in the MCP are defined in **Appendix I**.

3.0 Regulatory Background

The requirement to provide a Representativeness Evaluation and Data Usability Assessment in the documentation that supports an RAO is contained in the MCP at 310 CMR 40.1056(2)(k) and cited below:

> 40.1056: Content of Response Action Outcome Statements
>
> ...
>
> (2) Except where previously submitted, all documentation, plans and/or reports necessary to support the Response Action Outcome shall be submitted to the Department, including, without limitation, the following:
>
> ...
>
> (k) for all Class A, B, or C Response Action Outcomes, a Data Usability Assessment documenting that the data relied upon is scientifically valid and defensible, and of a sufficient level of precision, accuracy, and completeness to support the RAO, and a Representativeness Evaluation, documenting the adequacy of the spatial and temporal data sets used to support the RAO.

The intent of the MCP requirement to provide a Representativeness Evaluation and Data Usability Assessment as part of an RAO Statement is to consolidate and synthesize information **generated and evaluated throughout the response action process** in the documentation that demonstrates achievement of an MCP endpoint (Class A or B RAO) or major milestone (Class C RAO). Documentation in fulfillment of this requirement should be focused on supporting the conclusions that: (1) disposal site conditions are adequately characterized; (2) risks to health, safety, public welfare and the environment have been adequately addressed (i.e., all Exposure Pathways have been identified, Exposure Point

Concentrations meet the applicable cleanup requirements); and (3) all sources have been eliminated or controlled, to the extent required.

Other MCP provisions (310 CMR 40.0017 and 40.0191(2)(c)) define broad performance standards for the acquisition, analysis, and reporting of the analytical and environmental monitoring data used to support MCP response actions. To facilitate the application of these performance standards, MassDEP published a *Compendium of Analytical Methods (CAM),* a series of recommended protocols for the acquisition, analysis, and reporting of MCP-related analytical data. Parties who elect to use and achieve compliance with the CAM will be assured "Presumptive Certainty" for analytical data provided in support of response action submittals.

Analytical data that achieve "Presumptive Certainty" are data for which the precision, accuracy, and sensitivity have been adequately determined. Depending on the nature and use of other analytical data (CAM Non-Compliant, Non-CAM and Pre-CAM), a separate evaluation may be necessary to establish the level of certainty regarding the quality of the data points and to confirm that the quality of data is sufficient for its use in support of a response action decision. Additional discussion on the use of data other than CAM Compliant data is provided in **Section 7** and **Appendix II.** All analytical data (CAM Compliant, CAM Non-Compliant, Non-CAM and Pre-CAM) must also be evaluated against project-specific objectives to determine whether and to what extent it is usable to support the RAO.

310 CMR 40.1056(1)(j) requires that parties conducting response actions indicate whether the analytical data used to support the RAO were generated using MassDEP's CAM. This regulatory requirement is met by providing this information in response to a specific question about use of CAM data on the RAO transmittal form (BWSC-104).

It is important to note that the broad performance standards (310 CMR 40.0017 and 40.0191(2)(c)) for ensuring the adequacy of analytical and other environmental assessment data are applicable to all MCP response actions. As such, ongoing consideration and evaluation of data usability and representativeness are important and appropriate throughout the response action process. These evaluations inform the development of sampling plans, the identification of goals or Data Quality Objectives for each assessment event, and the development and refinement of the disposal site Conceptual Site Model.

Note:	***The specific requirement to provide a Representativeness Evaluation and Data Usability Assessment in an RAO submittal is not intended to preclude evaluation and discussion of data usability and representativeness as they relate to supporting conclusions in other MCP response action submittals***.

Figure 1 outlines the process for conducting a Representativeness Evaluation and Data Usability Assessment to support an RAO. As depicted in Figure 1, the Representativeness Evaluation and Data Usability Assessment should occur contemporaneously and on an ongoing basis. The results of each of these assessments should be used to inform the other. That is, as the analytical and other data become available throughout the course of the site investigation, its quality should be assessed to ensure that the data needed to fully represent disposal site conditions and support response action decisions and conclusions are usable for their intended purpose. The ongoing Representativeness Evaluation will determine whether the site investigation needs to be modified or expanded to test or confirm the

Conceptual Site Model and/or obtain additional analytical or other data to achieve a level of information that is sufficiently representative and of sufficient quality to support the RAO.

4.0 Applicability

This guidance is applicable to all Class A, B or C RAO Statements, including partial RAOs.

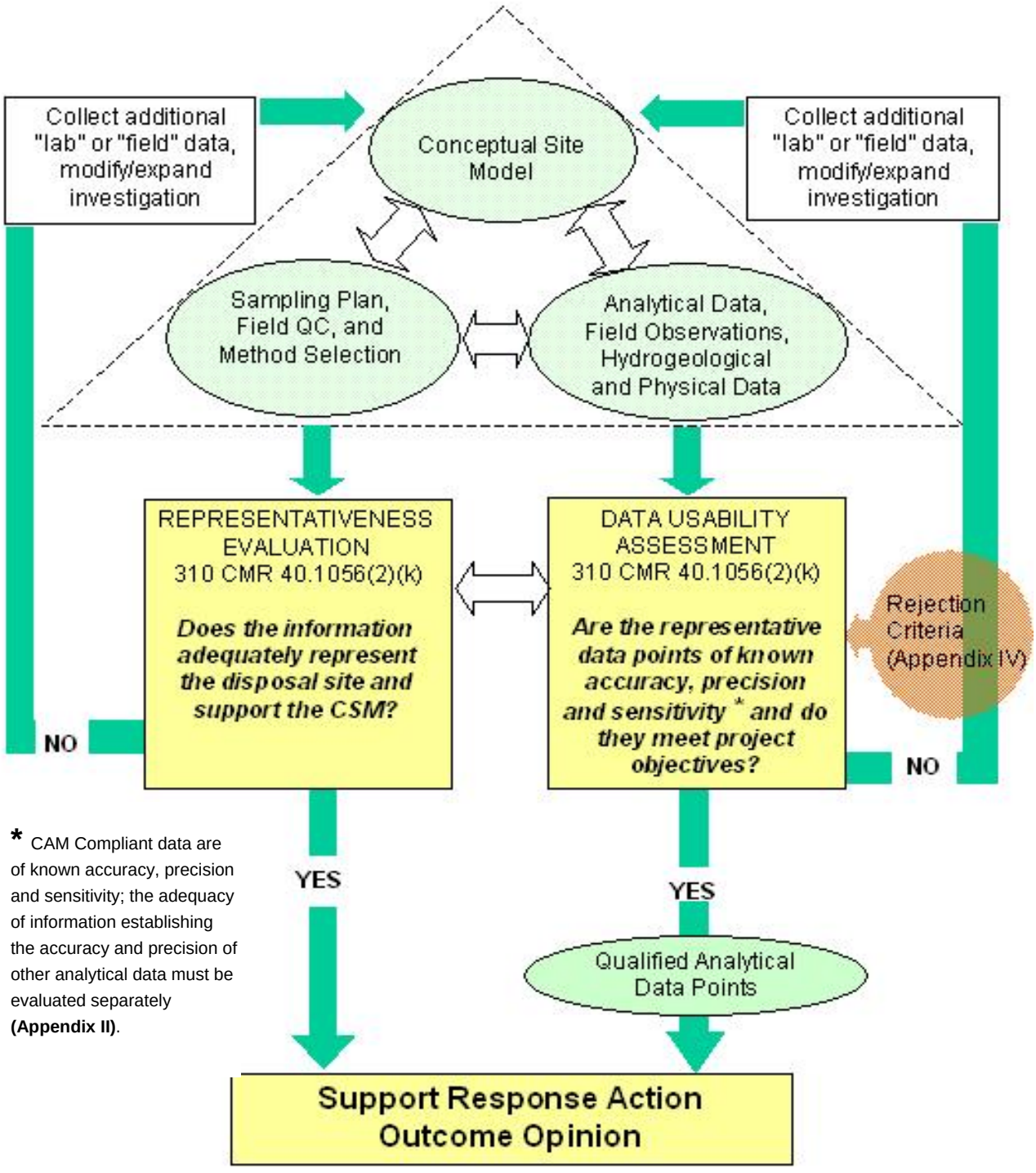
5.0 Response Action Outcome Requirements

In documenting that the data used to support an RAO are representative and usable (i.e., meets the requirement at 310 CMR 40.1056(2)(k)), the Representativeness Evaluation and the Data Usability Assessment must address how the data supports the specific RAO requirements in 310 CMR 40.1000 summarized in **Table 1**:

TABLE 1 SUMMARY OF RESPONSE ACTION OUTCOME REQUIREMENTS

Class A or B RAO	Class C RAO
Delineation of disposal site boundaries	Delineation of disposal site boundaries
Characterization of Risk o Identification of Exposure Pathways and Receptors o Identification of Hot Spots o Calculation of EPCs o Identification of Background	Characterization of Risk o Identification of Exposure Pathways and Receptors o Identification of Hot Spots o Calculation of EPCs o Identification of Background
Elimination/control of OHM source(s)	Elimination/control of OHM source(s), to the extent feasible
Achievement of background, to the extent feasible (for Class A RAOs)	
Achievement of No Significant Risk (NSR)	Achievement of No Substantial Hazard (NSH)

FIGURE 1 REPRESENTATIVENESS EVALUATION AND DATA USABILITY ASSESSMENT PROCESS DIAGRAM



* CAM Compliant data are of known accuracy, precision and sensitivity; the adequacy of information establishing the accuracy and precision of other analytical data must be evaluated separately **(Appendix II)**.

The documentation must support the conclusions that: (1) disposal site conditions are adequately characterized; (2) risks to health, safety, public welfare and the environment have been adequately addressed (i.e., all Exposure Pathways have been identified, Exposure Point Concentrations meet the applicable cleanup requirements); (3) all sources have been eliminated or controlled, to the extent required; and (4) for Class A RAOs, background has been achieved or approached to the extent feasible.

Data generated over the course of conducting response actions should be reviewed and considered in the process of conducting the Representativeness Evaluation and Data Usability Assessment (i.e., sampling results from all assessment and remedial actions, remediation waste characterization information, pilot test results, etc.). The documentation in support of the RAO, however, **should not** simply be a review of this information. Rather, it should be a thoughtful and succinct synthesis of the judgments and findings that are relevant and necessary to support the RAO. Where judgments are made that certain information is more relevant and representative than other information or where inconsistent or contradictory information has been discounted or disregarded entirely, those judgments should be explicitly stated and adequately supported.

6.0 Representativeness Evaluation

The Representativeness Evaluation is an evaluation and demonstration of the adequacy of the spatial and temporal data sets used to support the RAO. In evaluating the adequacy of such data, information such as the site's historical use, hydrogeological and physical characteristics, and field observations should be considered, in addition to analytical data. The Representativeness Evaluation determines whether the data set in total sufficiently characterizes conditions at the disposal site and supports a coherent Conceptual Site Model. The Representativeness Evaluation determines whether there is enough information from the right locations, both spatially and temporally, to support the RAO, specifically the requirements in **Table 1**.

The Representativeness Evaluation should demonstrate the adequacy of cumulative data to characterize the nature and extent of contamination at the disposal site, the risk to health, safety, public welfare and the environment (i.e., the achievement of NSR or NSH) and the elimination/control of OHM sources.

The Representativeness Evaluation should identify inconsistent and incomplete information, and sources of uncertainty, and justify why such inconsistent information, data gaps, or uncertainty are not sufficient to undermine the RAO Opinion (i.e., justify the use of the data to support the RAO).

Sections 6.1 through 6.8 below describe the elements that should be evaluated in a Representativeness Evaluation in support of an RAO pursuant to 310 CMR 40.1056(2)(k).

6.1 Conceptual Site Model

The Representativeness Evaluation should provide a succinct summary of the most current disposal site Conceptual Site Model (CSM). The CSM is a site-specific description of what and how contaminants entered the environment, how they were transported within the system, and routes of exposure to and identification of human and environmental receptors. It provides a framework for assessing risks from contaminants, controlling or eliminating sources, developing response action

strategies, and determining whether those strategies have been effective in achieving the RAO requirements.

The CSM should be modified as necessary to incorporate new information and guide decision-making throughout the site assessment, risk characterization, and remediation of the disposal site. Its complexity is directly related to the complexity of disposal site conditions.

At the point in the response action process that a Representativeness Evaluation is prepared to support a Class A, B, or C RAO, the CSM should be well-developed. The CSM summary should provide the following information **to the extent it is relevant to characterizing disposal site conditions and supporting the RAO**:

- History of the disposal site as applicable to the potential presence of oil and hazardous materials;
- Geologic and hydrogeological setting;
- Description of known/likely source(s) and types of contaminants
- Description of the known/estimated volume/mass of contaminant(s) released;
- The approximate date/time period of the release(s);
- The location(s) of the release(s) and affected media and horizontal and vertical extent of the contamination;
- Description of contaminant fate and transport in the environment, including migration pathways and rates, density and hydrodynamic factors, and contaminant degradation rates and degradation products; and
- Mechanisms/pathways and points of exposure by human and ecological receptors.

Subsequent discussion of all other elements of the Representativeness Evaluation (**Sections 6.2 through 6.8**) should refer to relevant aspects of the CSM.

6.2 Use of Field/Screening Data

Use of field screening methods and EPA's Triad approach can reduce costs, improve decision certainty, and accelerate and improve the cleanup process. MassDEP supports the appropriate use of alternative analytical approaches, including field screening methods, at 21E sites. The Representativeness Evaluation should discuss the manner in which Field/Screening Data were incorporated into decisions about field investigations and sampling, and the comparability of Field/Screening Data results and visual/olfactory observations with laboratory results. In general, Field/Screening Data do not have the same level of analytical quality control, sensitivity and specificity as data produced in fixed laboratories. Consequently, Field/Screening Data should generally be used to augment or complement fixed laboratory data and should seldom be used for characterizing Exposure Point Concentrations without laboratory confirmation of a subset of samples.

6.3 Sampling Rationale

The Representativeness Evaluation should justify that the media and locations (in terms of both area and depth) sampled are appropriate to support the conclusions of the RAO, specifically the requirements identified in **Table 1.** The discussion should indicate the relationship and proximity of the sampling locations to source areas and impacted media; which samples are taken from within impacted areas and which are

taken from outside (adjacent or above/below) impacted areas; and any samples that are considered Critical Samples (i.e., samples identified as Critical Samples in sampling plans). The discussion should support the conclusion that the sampling locations are sufficient to delineate disposal site boundaries, identify background, calculate Exposure Point Concentrations, identify Hot Spots, identify exposure pathways and receptors, and demonstrate source elimination or control.

6.4 Number, Spatial Distribution and Handling of Samples

This component of the Representativeness Evaluation involves justifying that the number and spatial distribution of the samples within a given sampling area (as identified by the discussion under **Section 6.3**) are sufficient to support the RAO, specifically the requirements identified in **Table 1**. This component of the evaluation should include discussion of relevant information on the density of sampling locations and the collection and handling of samples (e.g., compositing, split samples, etc.). If the contamination is distributed in an unknown or random manner due to historical use of the property, justification should be provided as to how the sampling density and distribution took this into account. As appropriate, this discussion may be combined with the discussion related to **Section 6.3**.

6.5 Temporal Distribution of Samples

For disposal site conditions that warrant monitoring over time, the Representativeness Evaluation should justify that the frequency and time period of such temporal sampling is sufficient to support the RAO. Specifically, the evaluation should demonstrate that the requirements identified in **Table 1** are met; that no ongoing or uncontrolled source of contamination remains, that concentrations are stable and/or diminishing over time, that Exposure Point Concentrations accurately reflect disposal site conditions and are consistent over time. Where relevant, the discussion should address the effect of seasonal variability on disposal site conditions and contaminant concentrations and migration.

6.6 Completeness

Data gaps should be identified and their significance discussed. Generally, target completeness for all samples identified as Critical Samples (**Section 6.3**) should be 100%.

6.7 Inconsistency and Uncertainty

The Representativeness Evaluation should justify that inconsistent information and sources of uncertainty are not sufficient to undermine the RAO Opinion. Examples of such information include historical use information that is inconsistent with contaminants found or not found, analytical results that are inconsistent with Field/Screening Data or other observations (e.g., remediation waste data) that indicate contaminants in addition to those evaluated in the risk characterization.

6.8 Information Considered Unrepresentative

Where it is not otherwise apparent or discussed in previous sections, the Representativeness Evaluation should identify information generated during the course of response actions that was not used to support the RAO because it was

determined to be unrepresentative or no longer representative of disposal site conditions (e.g., conditions changed as the result of remedial actions).

7.0 Data Usability Assessment

A Data Usability Assessment has an analytical and a field component. An Analytical Data Usability Assessment is used to evaluate whether analytical data points are scientifically valid and defensible, and of a sufficient level of precision, accuracy, and sensitivity to support the RAO, specifically the requirements specified in **Table 1**. The Analytical Data Usability Assessment evaluates whether the analysis of "What's in the Jar" has yielded a valid result.

The Field Data Usability Assessment evaluates whether the sampling procedure (e.g., sampling method, sample preservation and hold times) ensures that the sample that is collected and delivered to the laboratory is representative of the sampling point.

The rigorousness of a Data Usability Assessment should be proportional to the complexity of the project and the ramifications of risk-related decisions associated with the interpretation of the data. **Sections 7.1 through 7.3** below describe elements of a Data Usability Assessment conducted in support of a Response Action Outcome pursuant to 310 CMR 40.1056(2)(k).

7.1 Analytical Data Usability Assessments

7.1.1 Evaluation for CAM Compliant Data

CAM Compliant data (data with "Presumptive Certainty") is of known accuracy, precision and sensitivity. Any identified analytical quality control performance standard deficiencies for CAM Compliant data must be described in the Laboratory Case Narrative. The Analytical Data Usability Assessment should provide (1) an evaluation of the sensitivity of the CAM Compliant data in comparison with project-specific objectives, and (2) a discussion of how the uncertainty associated with any identified analytical deficiencies may affect the overall accuracy, precision and sensitivity of the analytical data and the achievement of project-specific objectives. This discussion must address any analytical data issues that were included in the Laboratory Case Narrative and provide justification as to why such analytical data are still considered acceptable to support the RAO in light of data qualifications.

7.1.2 Evaluation for CAM Non-Compliant, Non-CAM and Pre-CAM Data

Other types of analytical data (CAM Non-Compliant, Non-CAM, and Pre-CAM), **subsequently referred to as "non-CAM" data**, may require a more in-depth review and evaluation of the accuracy, precision, and sensitivity of these data points. **Table 2** summarizes the different categories of analytical data and how such data may be used in an Analytical Data Usability Assessment. **Appendix II** summarizes the elements that should be considered in evaluating the accuracy, precision, and sensitivity of data points for the "non-CAM" data categories.

TABLE 2 ANALYTICAL DATA USABILITY CONSIDERATIONS FOR DIFFERENT DATA CATEGORIES

	DATA QUALITY CATEGORY	DEFINITION	ANALYTICAL DATA USABILITY CONSIDERATIONS
	CAM Compliant	Analytical results (1) determined using an "MCP Analytical Method" detailed in the CAM; (2) that comply with method-specific QC requirements specified in CAM; (3) that are reported with a narration of method–specific performance standard deficiencies, as necessary; and (4) reported with the required deliverables specified in the CAM for MCP analytical data. **CAM Compliant data are data with "Presumptive Certainty".**	CAM-compliant analytical data meeting method- and project-specific Data Quality Objectives may be used to support an RAO pursuant to 310 CMR 40.1056 (2)(k). The Analytical Data Usability Assessment should discuss how any analytical deficiencies might affect the overall accuracy, precision and sensitivity of the analytical data. The effect of any Laboratory Case Narrative issues must be evaluated in the Data Usability Assessment.
"Non-CAM" Analytical Data	CAM Non-Compliant	Analytical results determined using an "MCP Analytical Method" detailed in the CAM that: (1) are not in compliance with method-specific QC requirements specified in the CAM; (2) do not include a narration of method–specific performance standard deficiencies, as necessary; and/or (3) do not include the required deliverables specified in the CAM for MCP analytical data.	Analytical data other than "CAM Compliant" may be used to support an RAO pursuant to 310 CMR 40.1056 (2)(k), but only after any uncertainties associated with identified data deficiencies, with respect to the overall accuracy, precision and sensitivity of the analytical data, are evaluated. See **Appendix II**.
	Non-CAM	Analytical results determined using an analytical method that is not currently included in the CAM.	
	Pre-CAM	Analytical results determined using any analytical method before August 1, 2003 for methods included in the CAM.	

In addition to supporting the use of "non-CAM" data by an evaluation of the elements in **Appendix II**, other circumstances in which "non-CAM" data may be used to supplement CAM data points include:

- Consistency - where consistency (i.e., consistent concentrations and trends) can be demonstrated between "non-CAM" data and CAM data generated for comparable samples at the disposal site;
- Lack of risk associated with use of the data - where it can be clearly demonstrated that any uncertainties related to the "non-CAM" data are unlikely to affect the conclusions of the RAO or the risk characterization on which it is based.

Under such circumstances, documentation of consistency or lack of risk, as described above, may be sufficient to demonstrate the usability of data to supplement CAM data points, and additional documentation as specified in **Appendix II** would not be necessary.

7.1.3 Data Evaluation Criteria

All data supporting the RAO should be evaluated to determine whether it is usable for that purpose. **Appendix III** summarizes how the PARCSS parameters apply to the evaluation of data usability and any project-specific Data Quality Objectives. Any limitations or qualifications on the use of the data in the RAO should be stated and explained in the Data Usability Assessment documentation.

The Analytical Data Usability Assessment should evaluate whether the Reporting Limits for the analyses are sensitive enough to support the RAO, specifically the requirements identified in **Table 1**. For example, if the analysis is conducted to determine an Exposure Point Concentration (EPC) and compare the EPC to a Method 1 standard, the Reporting Limit must be at/below the standard.

7.2 Field Data Usability Assessment

Use of appropriate sampling methods is a critical component of ensuring sample integrity. In addition, how samples are handled in the field (e.g., split samples, compositing, etc.), as well as the use of proper sampling containers and preservatives, are essential to minimizing any potential loss of contaminants of concern prior to laboratory analysis and ensuring that the sample delivered to the laboratory for analysis is representative of field conditions. The application of field quality control elements should be commensurate with the data's intended use. **Table 3** provides a summary of different field quality control elements to be considered/used both when collecting samples and subsequently in evaluating the quality of analytical results. MassDEP's *Compendium of Analytical Methods Quality Assurance and Quality Control Guidelines for the Acquisition and Reporting of Analytical Data in Support of Response Actions Conducted Under the Massachusetts Contingency Plan (MCP) (WSC–CAM–VIIA)* provides general guidance on the use of field quality control elements for all samples and specifies minimum field quality control requirements for drinking water samples **(See WSC-CAM-VIIA, Section 2.0).** Any field quality control issue identified through field quality control elements that would limit or qualify the use of data presented in support of the RAO should be identified and discussed in the Data Usability Assessment.

7.3 Rejection of Analytical Data as the Result of Gross Failure

Data under consideration for use in support of an RAO should be assessed against the criteria indicative of "gross failure" in quality control as described in **Appendix IV**. Data that are deemed unusable as the result of a gross failure of quality control in the process of sampling or analysis should not be used to support an RAO (see **Figure 1**). Note, data that are not eliminated based on the gross failure criteria may still otherwise be found unusable or of limited use following a data quality assessment.

TABLE 3 FIELD QUALITY CONTROL ELEMENTS TO BE CONSIDERED FOR ALL ANALYTICAL DATA CATEGORIES

Review Element	Field Quality Control Indicators
Sampling Procedure	Field Accuracy/Field Precision
Sample Containers and Sample Preservation	Field Accuracy
Holding Times	Field Accuracy
Field Duplicates	Field Precision
Matrix Spikes/Matrix Spikes Duplicates	Field Accuracy/Field Precision
Equipment Blank/Trip Blank	Field Accuracy/Sensitivity

8.0 Conclusions

In addition to addressing the elements outlined in Sections 6.0 and 7.0, the Representativeness Evaluation and Data Usability Assessment narrative submitted in support of an RAO should contain a conclusions section that summarizes the overall findings of the evaluations.

9.0 Documentation

The Representativeness Evaluation, Data Usability Assessment and Conclusions should be documented in the Response Action Outcome submittals as a distinct section. This documentation should include the information outlined in this guidance. The length and detail of this documentation should be commensurate with the complexity of the disposal site conditions, the amount of analytical and other data collected and evaluated in support of the Response Action Outcome, and issues identified in the Representativeness Evaluation and Data Usability Assessment. Parties are encouraged to use the **Representativeness and Data Usability Worksheet** provided in **Appendix V** in such documentation. **Appendix VI** provides a **Data Summary Table** format that may be used to summarize the analytical data generated in the course of response actions. For many disposal site scenarios, completed worksheets alone may be sufficient to document the information needed to meet the Representativeness Evaluation and Data Usability Assessment requirements.

APPENDIX I DEFINITIONS OF KEY TERMS

Analytical Data Usability Assessment means a systematic evaluation of the uncertainty associated with **analytical data points** in terms of their accuracy and precision conducted pursuant to 310 CMR 40.1056(2)(k). It determines whether an individual analytical data point is indicative of the location sampled and establishes or qualifies to what extent the analytical data for that sampling point meet applicable **Data Quality Objectives,** and are suitable for use in a **Representativeness Evaluation** pursuant to 310 CMR 40.1056(2)(k).

> **Note:** The US Environmental Protection Agency uses the term "Data Usability" to encompass a range of factors used to evaluate the quality and adequacy of data points and data sets. Data Usability as defined by EPA includes consideration of precision, accuracy, representativeness, completeness, comparability and sensitivity (a.k.a. the PARCCS parameters). Under the MCP, the "Representativeness Evaluation" is a distinct evaluation of all data (not just analytical) used to support the RAO. Parties familiar with the EPA's use of the terms related to Data Usability should be aware of the differences in the way EPA and the MCP and this guidance apply these terms. **Appendix III** presents how PARCCS parameters apply to Data Usability Assessments for the MCP process.

CAM Compliant means analytical results: (1) determined using an "MCP Analytical Method" detailed in the CAM; (2) that comply with method-specific QC requirements specified in CAM; (3) that are reported with narration of method–specific performance standard deficiencies, as necessary; and (4) reported with the required deliverables specified in the CAM for MCP analytical data. CAM Compliant data are data with "Presumptive Certainty".

CAM Non-Compliant means analytical results determined using an "MCP Analytical Method" detailed in the CAM that: (1) are not in compliance with method-specific QC requirements specified in the CAM; (2) do not include narration of method–specific performance standard deficiencies, as necessary; and/or (3) do not include the required deliverables specified in the CAM for MCP analytical data.

Compendium of Analytical Methods (CAM) is a MassDEP publication that provides (a) information and guidance to all parties on analytical and data quality issues, and (b) requirements and specifications for those parties who wish to obtain "Presumptive Certainty" for satisfying the data quality requirements of the MCP at 310 CMR 40.0017 and 310 CMR 40.0191(2)(c).

Conceptual Site Model (CSM) is a description of what contaminants are present, how they entered the environment, how they were transported within the system, and routes of exposure to and identification of human and environmental receptors. It provides a framework for assessing risks from contaminants, controlling or eliminating sources, developing response action strategies, and determining whether those strategies have been effective in achieving the RAO requirements.

APPENDIX I DEFINITIONS OF KEY TERMS

Critical Sample means a sample for which a usable result is necessary to support a conclusion that the response action objectives have been met (i.e., absent a usable result for such sample, it cannot otherwise be demonstrated that the objective has been achieved).

Data Quality Objectives are the qualitative and quantitative statements that clarify an assessment's technical and data quality goals, define the appropriate type of data to be obtained, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Usability Assessment means an assessment of whether data are scientifically valid and defensible, and of a sufficient level of precision, accuracy, and sensitivity to support the response action decision. A Data Usability Assessment has an analytical and a field component (see **Analytical Data Usability Assessment** and **Field Data Usability Assessment**).

Field Data Usability Assessment means an evaluation of the sampling procedure (e.g., sampling method, preservation, hold times) and, as appropriate, field quality control elements to ensure the quality of the sample and to identify any issues of concern that may limit or qualify the use of the data.

Field/Screening Data means data produced in the field using test kits, hand-held instruments and/or "portable" laboratory instruments with or without pre-concentration.

Laboratory Case Narrative means a discussion provided by the laboratory of any performance standard non-conformances.

Non-CAM means an analytical result determined using an analytical method that is not currently included in the CAM. (Common examples include dioxins/furans, PCB congeners or homologues, and various wet chemistry analyses.)

Pre-CAM means an analytical result determined using an analytical method conducted prior to August 1, 2003 for methods included in the CAM.

Representativeness Evaluation means a comprehensive evaluation of the adequacy of spatial and temporal data sets in representing disposal site conditions and supporting environmental decision-making. As used in this definition, information for determining whether the data are spatially and temporally adequate includes the site's historical use, hydrogeological and physical characteristics, field observations and similar data in addition to analytical data. The Representativeness Evaluation, pursuant to 310 CMR 40.1056(2)(k), must consider the full range of data gathered over the course of the response action process. The rigorousness of the Representativeness Evaluation should be proportional to the complexity of the project and the CSM and the ramifications of risk-related decisions associated with the evaluation of disposal site conditions.

APPENDIX II ELEMENTS FOR EVALUATING THE ACCURACY, PRECISION AND SENSITIVITY OF CAM NON-COMPLIANT, NON-CAM AND PRE-CAM DATA CATEGORIES

Table II-I	Elements for Evaluating the Accuracy, Precision and Sensitivity of CAM Non-Compliant, Non-CAM and Pre-CAM Data Categories
Review Element	**Data Quality Indicator**
GC/MS Tunes (GC/MS methods only)	Laboratory Accuracy
Endrin/DDT Breakdown (Pesticides only)	Laboratory Accuracy
Initial Calibration (Reporting Limit)	Laboratory Accuracy/Sensitivity
Continuing Calibration	Laboratory Accuracy
Interference Checks (Metals only)	Laboratory Accuracy
Method Blanks	Laboratory Sensitivity and Laboratory Cross-Contamination Evaluation
Laboratory Control Spikes (LCS)	Laboratory Accuracy
Laboratory Control Spike Duplicate (LCSD)	Laboratory Accuracy and Precision
Matrix Spikes (MS)	Method Accuracy in Sample Matrix
Matrix Duplicate (MD) and Matrix Spike Duplicates (MSD)	Method Accuracy and Precision in Sample Matrix
Surrogate Spike Recovery (Organics only)	Accuracy in Sample Matrix
Internal Standards	Laboratory Accuracy and Method Accuracy in Sample Matrix
Fractionation Check Standard (EPH only)	Laboratory Accuracy
Laboratory Case Narrative and Data Report	Ensures Consistent Reporting and Compliance with CAM and/or Sufficient Information Available to Perform Analytical Data Usability Assessment

Table II-II	Additional Elements to Consider for Analytical Data Usability Assessment of Non-CAM, Pre-CAM, and Field/Screening Data
Review Element	**Data Quality Objective**
Standard Operating Procedure (SOP)	Overall Method Consistency and Reproducibility
Initial Demonstration of Proficiency	Overall Analytical Performance
Additional Elements Which May be Required for Non-CAM, Pre-CAM and Field Screening methods Based on Review of SOP or Method Requirements	To Be Determined Based on SOP or Method Review

APPENDIX III USE OF PARCCS PARAMETERS FOR MCP DATA USABILITY ASSESSMENT[1]			
QC Element	**Laboratory Measures**	**Field Measures**	**Basis of Evaluation**
Precision	Laboratory Control Sample (LCS) LCS Duplicates (LCSD) Matrix Duplicates Historical Data Trends	Field Duplicates Matrix Spike Duplicates Matrix Duplicates Appropriate Sampling Procedure	Evaluation of Project **Precision** Data Quality Indicators by Media Type. Evaluation of Compliance with Project's Data Quality Objectives.
Accuracy	LCSs Matrix Spikes Internal Standards Surrogate Recovery Initial Calibration Continuing Calibration Standard Reference Material	Matrix Spikes/Matrix Spike Duplicates Inclusion of "Blind" Samples Appropriate Sampling Procedures Appropriate Sample Containers Appropriate Sample Preservation Holding Times Equipment Blank/Field Blank	Evaluation of Project **Accuracy** Data Quality Indicators by Media Type. Evaluation of Compliance with Project's Data Quality Objectives
Representativeness	Laboratory Homogenization Appropriate Sub-sampling Appropriate Dilutions "As Received" Sample Preservation Meeting Hold Times	Appropriate Sampling Procedures Appropriate Sample Containers Appropriate Sample Preservation Incorporation of Field Screening Data	Evaluation of consistency of data with Conceptual Site Model Evaluation of consistency of analytical data with field data and hydrogeological site data Evaluation of spatial and temporal variabilities
Comparability	GC/MS Tuning Calibration Analytical Method Followed	Comparison to Previous Data Points Comparison to Similar Data Points	Evaluation of inter-comparability of all site data and information by media type
Completeness	% Sample Per Batch Analyzed and Reported All Critical Samples Reported and Unqualified	% Planned Samples Collected All Critical Samples Collected	Analyte list consistent with site history Number of data points adequate to describe the magnitude and areal extent of release
Sensitivity	Method Blanks Instrument Blanks Reporting Limit (Lowest Calibration Standard) Appropriate Analytical Method	Equipment Blank/Field Blanks Appropriate Sample Volume or Weight	Evaluate whether reporting limits for data adequate to demonstrate compliance with applicable standards

[1] Note: Some of these PARCCS measures are not required deliverables for CAM data. CAM data require reporting of LCS/LCSD, Method blanks, and surrogates. MS/MSD/MD are performed upon project-specific/LSP request.

APPENDIX IV REJECTION CRITERIA – ANALYTICAL DATA USABILITY ASSESSMENTS

Purpose: To determine if data are unusable for supporting an RAO due to gross failure of quality control.

References:

EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses, December 1996 (updated in February 2004 for pesticides/PCBs).

Region I Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analyses, February 1989.

Definition of Rejected Data: The data are unusable (analyte/compound may or may not be present) due to gross failure of quality control criteria and cannot be used to support project objectives.

Inorganic Criteria for Rejection of Data: Applicable to metals, hexavalent chromium, cyanide, and other inorganic parameters.

- Holding Time (HT): "Gross" violation of HT; "gross" = greater than two times the allowable HT: reject all non-detected results
- Laboratory Control Sample (LCS) and LCS Duplicate Recoveries:
    - Aqueous samples only: recovery < 50%: reject all results for affected analyte (professional judgment commonly used if LCS < 50% but MS shows acceptable recovery to determine result as usable; professional judgment may be used to reject non-detected results only)
    - Soil: solid LCS or Standard Reference Material recoveries compared to vendor control limits: use professional judgment on rejection of data
- Matrix Spike (MS) Recovery: recovery < 30%: reject non-detected results for affected analyte in all associated samples in batch (up to 20 associated samples). Exception: Low recovery of hexavalent chromium in soils may be acceptable if supported by pH and ORP data which demonstrate reducing conditions
- Professional Judgment: Example – severely poor overall instrument performance may cause all associated data to be rejected; if percent solids content very low (<10%), may reject data

Organic Criteria for Rejection of Data: Applicable to VOCs, SVOCs, Pesticides, PCBs, and herbicides, and can also be applied to VPH/EPH.

- Holding Time (HT): "Gross" violation of HT; "gross" = greater than two times the allowable HT: reject all non-detected results
- Sample Preservation (VOCs only): Soil/sediment samples without methanol or water (alternative for low level VOCs only) preservation: reject all non-detected results
- Laboratory Control Sample (LCS) and LCS Duplicate Recoveries: recovery < 10%: reject non-detected results for affected compound
- Surrogate Recovery: recovery < 10%: reject associated non-detected results (see CAM method for compounds associated with surrogate by class), except if low recovery is due to necessary analytical dilution(s)
- Matrix Spike/Matrix Spike Duplicate Recoveries: recovery < 10%: reject non-detected results for affected compound in unspiked field sample only (i.e., field sample used for MS/MSD only)

APPENDIX IV REJECTION CRITERIA – ANALYTICAL DATA USABILITY ASSESSMENTS

Organic Criteria for Rejection of Data, continued

- Calibrations: RRF < 0.05 (with no technical justification for RRF being lower): reject non-detected results for affected compound in all associated samples
- Internal Standards: Area Counts < 20% of associated Calibration Standard: reject associated non-detected results, depending on which compounds are quantitated with the affected internal standard
- Fractionation Check Standard Recoveries (EPH only): recovery < 10%: reject non-detected results for affected compound
- Dual Column Precision: %D > 100% for single-component pesticides and herbicides: reject positive and non-detected results; % D > 500% for multicomponent pesticides and Aroclors: reject positive and non-detected results
- Endrin/DDT Breakdown: Breakdown >20%: reject non-detected results for endrin or DDT, whichever is affected
- Professional Judgment: Example – severely poor overall instrument performance may cause all associated data to be rejected; if percent solids content very low (<10%), may reject data

APPENDIX V REPRESENTATIVENESS AND DATA USABILITY WORKSHEET

A. <u>Representativeness Evaluation</u> *(Specific to information/samples used to support the RAO. Refer to Section 6.0 through 6.8.)*	
A-1 Provide a succinct summary of the Conceptual Site Model (CSM) for the disposal site. Discussion should include: - Disposal site history - Geologic/hydrogeological setting - Contaminant Source(s) and Type(s) - Description of the volume/mass and types of contaminants released to the environment - Date/time period of release(s), if known - Release location, affected media, and horizontal and vertical extent of the contamination - Contaminant migration pathways - Mechanism/pathways and points of exposure by human and ecological receptors ***(Refer to Section 6.1)***	
A-2 Discuss use of Field/Screening Data in response action decision making, including: - Contaminant of Concern screening/elimination - Selection of sampling locations - Comparison to laboratory results - Comparison to visual/olfactory observations ***(Refer to Section 6.2)***	( ) No Field/Screening Data were used to directly support this RAO. ( ) Field/Screening Data were used, as follows:
A-3 Discuss and justify sampling locations and depths collected in support of RAO regarding: <u>For Class A or B RAOs</u> -Delineation of disposal site boundaries (horizontal and vertical) -Elimination/control of OHM source(s) -Characterization of Risk (Exposure Pathways/Receptors, Hot Spots, samples included in EPCs, Background) -Achievement of No Significant Risk (NSR) <u>For Class C RAOs</u> -Delineation of disposal site boundaries (horizontal and vertical) -Elimination/control of OHM source(s) -Characterization of Risk (Exposure Pathways/Receptors, Hot Spots, samples included in EPCs, Background) -Achievement of No Substantial Hazard (NSH) ***(Refer to Table1 and Section 6.3; A-3 and A-4 of the worksheet may be combined, as appropriate.)***	

A. <u>Representativeness Evaluation</u> *(Specific to information/samples used to support the RAO. Refer to Section 6.0 through 6.8.)*	
A-4 Discuss and justify the density, spatial distribution, collection methods, and handling (compositing, split sampling) of samples collected in support of RAO (in relation to the justification provided in A-3 for meeting the RAO requirements) ***(Refer to Table 1 and Section 6.4)***	
A-5 Identify disposal site conditions, if any, that warrant the collection and analysis of temporal samples. For disposal sites that require monitoring over an extended time period, discuss and justify the number and time interval for sampling rounds conducted in support of the RAO for the following: <u>For Class A or B RAOs</u> - Delineation of disposal site boundaries (horizontal and vertical) - Characterization of Risk (Exposure Pathways/Receptors, Hot Spots, samples included in EPCs, Background) - Elimination/control of OHM source(s) - Achievement of No Significant Risk (NSR) <u>For Class C RAOs</u> - Delineation of disposal site boundaries (horizontal and vertical) - Characterization of Risk (Exposure Pathways/Receptors, Hot Spots, samples included in EPCs, Background) - Elimination/control of OHM source(s) - Achievement of No Substantial Hazard (NSH) ***(Refer to Table 1 and Section 6.5)***	( ) Temporal sampling not warranted for this disposal site.
A-6 Field Completeness of Data: Discuss data gaps identified in sampling and analytical information used to support RAO and their significance. ***(Refer to Section 6.6)***	
A-7 Identify any inconsistent information or uncertainty and justify disregarding such information or uncertainty (e.g., site assessment data inconsistent with historical information, field screening data/observations inconsistent with analytical data, use of data to support the RAO in spite of identified analytical or other deficiencies, etc.) in rendering the RAO Opinion. ***(Refer to Section 6.7)***	

A. <u>Representativeness Evaluation</u> *(Specific to information/samples used to support the RAO. Refer to Section 6.0 through 6.8.)*	
A-8 Where it is not otherwise apparent or discussed in previous sections, identify/discuss information generated during the course of response actions that was not used to support the RAO because it was determined to be unrepresentative or no longer representative of disposal site conditions. ***(Refer to Section 6.8)***	

B. <u>Data Usability Assessment</u> *(Specific to samples used to support the RAO. Refer to Table 1, Section 7.0 through 7.3, and Appendices I, II, III and IV.)*	
B-1 List all MCP activities that provided the analytical data reviewed in the course of conducting the Data Usability Assessment in support of the RAO. Include the media sampled and the month and year the data were acquired.	( ) Listed below. ( ) Attached separately (provide attachment reference).
B-2 Discuss appropriateness of selected analytical methods to quantitatively support the RAO.	
B-3 Discuss appropriateness of selected analytical methods' Reporting Limits (RL) to quantitatively support the RAO.	( ) All Reporting Limits were at or below applicable standards.
B-4 Discuss laboratory performance criteria and data quality indicators used to assess overall <u>Analytical Accuracy</u> (continuing calibration, laboratory control spikes, etc.) and <u>Analytical Precision</u> (laboratory duplicates, laboratory control spike duplicates, etc.). For CAM data, see MCP Analytical Method Report Certification Form and Laboratory Case Narrative.	( ) Met all CAM requirements and performance standards without qualification. ( ) If not, discuss data usability implications.
B-5 Discuss performance criteria and data quality indicators used to assess overall <u>Field Data Usability</u> (sample preservation compliance, sample sub sampling/compositing, etc.).	
B-6 Discuss any data rejected pursuant to **Appendix IV**, Rejection Criteria – Analytical Data Usability Assessments.	( ) No data rejected pursuant to **Appendix IV**.

C. <u>Representativeness Evaluation and Data Usability Assessment Summary and Conclusions</u> *(Refer to Section 8.0)*	
Provide a summary declaration that the data set relied upon to support the RAO is: 1. Scientifically valid and defensible, and of sufficient accuracy, precision and completeness; and 2. Representative with regards to the spatial and temporal distribution of sampling points.	

APPENDIX VI DATA SUMMARY TABLE

Sample ID or Series	Parameters	Date	Soil	Groundwater	Surface Water	Sediment	Air	Site Characterization	Background	EPCs	Hazard Elimination	CAM Compliant	Data Qualifications, if any (*brief explanation*)
												Yes ( ) NO ( )	
												Yes ( ) NO ( )	
												Yes ( ) NO ( )	
												Yes ( ) NO ( )	
												Yes ( ) NO ( )	
												Yes ( ) NO ( )	
												Yes ( ) NO ( )	
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												Yes ( ) NO ( )	