

Overview of the Analytical Data Enhancement Process for the Massachusetts Contingency Plan

The Compendium of Quality Assurance and Quality Control Requirements and Performance Standards for Selected Analytical Methods Used in Support of Response Actions for the Massachusetts Contingency Plan (MCP)

WSC - 02 - 320

Preface

This Compendium of Analytical Methods (CAM) provides a series of required protocols for the acquisition, analysis, and reporting of analytical data in support of MCP decisions (a) to satisfy the broad quality assurance (QA) and quality control (QC) requirements of 310 CMR 40.0017 and 40.0191 regarding the scientific defensibility, precision and accuracy, and reporting of analytical data and (b) to meet the requirements and specifications for those parties who wish to obtain "Presumptive Certainty" for analytical data that may be used in a data usability and representativeness assessment, as required in 310 CMR 40.1056(2)(k) and 40.1057(2)(k) for Permanent and Temporary Solution submittals, respectively, consistent with the guidance described in MassDEP Policy #WSC-07-350, *MCP Representativeness Evaluations and Data Usability Assessments*.

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 proceeding with the Commonwealth. The recommendations and guidance in this document provide approaches the Massachusetts Department of Environmental Protection (MassDEP) considers acceptable for conditions and circumstances encountered at the majority of disposal sites to meet the performance standards set forth in sections 310 CMR 40.0017 and 310 CMR 40.0191(2)(c) of the MCP. Parties using this guidance should be aware that there may be other acceptable alternatives for achieving and documenting compliance with the general regulatory requirements and performance standards of the MCP, including those of sections 310 CMR 40.0017, 310 CMR 40.0191(2)(c) and 40.1056(2)(k). The regulatory citations in this document should not be relied upon as a complete list of the applicable regulatory requirements.

Consistent with the Commonwealth's e-Government initiative, the CAM is provided as an electronic document. This format allows access by the Internet to the most recent revision of the individual analytical methods and guidelines that comprise this electronic compendium. This document is posted on the MassDEP's web site at <https://www.mass.gov/guides/compendium-of-analytical-methods-cam-massdep-bwsc>.

It is anticipated that this document will be updated regularly by the MassDEP to reflect changing technical standards, as well as analytical method modifications and additions. Therefore, the MassDEP recommends that analytical methods and/or guidelines be accessed electronically and downloaded, as needed, rather than being kept "on the shelf" as a conventional reference document. This will ensure use of the most recent revision of the analytical methods and guidelines by laboratories and data users. All



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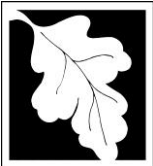
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recent additions and revisions to this electronic document will be maintained on the CAM web page.



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IA OVERVIEW OF THE ANALYTICAL DATA ENHANCEMENT PROCESS FOR THE MASSACHUSETTS CONTINGENCY PLAN

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1.0 Background

Pursuant to 310 CMR 40.0017, “any person undertaking response actions under the provisions of the MCP shall ensure that analytical and environmental monitoring data used in support of recommendations, conclusions, or Licensed Site Professional (LSP) opinions with respect to assessment, removal or containment actions are scientifically valid and defensible, and of a level of precision and accuracy commensurate with its stated or intended use.”

An evaluation of the overall quality and suitability of data utilized to support site characterization decisions and opinions at a disposal site is the responsibility of parties conducting response actions, and is subject to the requirements of the Response Action Performance Standard (RAPS) set forth in 310 CMR 40.0191, 310 CMR 40.1056(2)(k), and 40.1057(2)(k) for Permanent and Temporary Solution submittals, consistent with the guidance described in MassDEP Policy #WSC-07-350, *MCP Representativeness Evaluations and Data Usability Assessments*.

Decisions that may directly impact data quality and suitability include:

- Selection of an analytical service provider;
- Identification of environmental sampling locations and parameters;
- Identification of appropriate analytical methods and Reporting Limits (RLs)/Lower Limits of Quantitation (LLOQs); and
- Specification of QA/QC procedures and performance standards.

To address concerns with site characterization efforts, and otherwise promote improved data quality, the MassDEP initiated an MCP Data Quality Enhancement Program using the successes of the Safe Drinking Water Act (SDWA) laboratory certification process and the revised VPH/EPH analytical and reporting approaches as models. The Program provides guidance and additional certainty for data users, regulators, and laboratories regarding the accuracy, precision and sensitivity of analytical data used in support of MCP Response Actions.

Integral components of the program include:

- Education and training for data users and MassDEP staff; and
- Publication of a Compendium of Analytical Methods (CAM) detailing sampling and analytical guidelines that will enable parties to achieve “Presumptive Certainty” for the acceptability of data submissions.

Specific program elements are described in more detail in the following sections.

2.0 Education and Training for Data Users and MassDEP Staff

Education and training are fundamental components of a comprehensive and effective analytical data QA program. It is recognized that effective evaluation and review of environmental data requires the involvement of highly trained and experienced individuals accomplished in site assessment



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(where and how to collect a representative sample), analytical chemistry (measurement verification), and data interpretation (contaminant fate, transport and risk). Training provided by MassDEP aims to facilitate the development of these skills within both the agency and the regulated community.

3.0 Compendium of Analytical Methods (CAM)

3.1 General

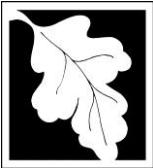
The CAM is a compilation of information found in commonly used analytical methods (e.g., EPA SW-846 Method 8260D). In addition to providing a succinct summary of each method, the CAM further articulates detailed QC provisions and performance standards, analyte lists, reporting formats, appropriate sample containers, preservatives and analytical holding times; and other methodological elements – details that may not have been specified and/or are cited as discretionary in the original publications (e.g., EPA SW-846). Incorporation of all such provisions into a specified analytical method constitutes a “CAM Protocol”. All protocols included in the CAM are considered “methods” published by the MassDEP pursuant to the provisions of 310 CMR 40.0017(2). All CAM Protocols are available in electronic format at the following URL: <https://www.mass.gov/guides/compendium-of-analytical-methods-cam-massdep-bwsc>.

The CAM applies as follows:

- In all cases, parties conducting response actions at MCP sites must consider the information and recommendations provided in CAM publications as *relevant guidance*, in accordance with the provisions of 310 CMR 40.0191(2)(a);
- Electively, parties conducting response actions at MCP sites may choose to conform to all specifications and requirements provided in the CAM publications for the “CAM Protocols” to achieve “Presumptive Certainty” for analytical data and acceptance by agency reviewers for use in a data usability and representativeness assessment, as required in 310 CMR 40.1056(2)(k) for Permanent and Temporary Solution submittals.

3.2 Presumptive Certainty

The term “Presumptive Certainty” as used in Sections I through X of the CAM describes a particular status for analytical or environmental monitoring data used in support of MCP Response Action submittals. Obtaining “Presumptive Certainty” status is just one of a number of options available to satisfy the data quality requirements for MCP submittals described in 310 CMR 40.0017, 40.0191 and 40.1056(2)(k). It should be clearly understood that exercising the “Presumptive Certainty” option is discretionary. However, *parties who elect not to utilize the “Presumptive Certainty” option have an obligation, pursuant to 310 CMR 40.0017 and 40.0191(2)(c), to demonstrate and document an overall level of QA/QC (laboratory and field), data usability, and data representativeness adequate for the intended use of the data.*



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In order to achieve “Presumptive Certainty” for analytical data, parties must:

- (a) Use the analytical method specified for the selected CAM protocol;
- (b) Incorporate **all** required analytical QC elements specified for the selected CAM protocol;
- (c) Implement, as necessary, required corrective actions and analytical response actions for **all** non-conforming analytical performance standards;
- (d) Evaluate and narrate, as necessary, **all** identified CAM protocol non-compliances; and
- (e) Comply with **all** the reporting requirements specified in WSC-CAM-VII A, including retention of reported and unreported analytical data and information for a period of ten (10) years.

In achieving “Presumptive Certainty” status, parties will be assured that analytical data sets:

- ✓ Satisfy the broad QA/QC requirements of 310 CMR 40.0017 and 40.0191 regarding the scientific defensibility, precision and accuracy, and reporting of analytical data; and
- ✓ May be used in a data usability and representativeness assessment, as required in 310 CMR 40.1056(2)(k) for Permanent and Temporary Solution submittals, consistent with the guidance described in MassDEP Policy #WSC-07-350, *MCP Representativeness Evaluations and Data Usability Assessments*.

A logic diagram detailing the “Presumptive Certainty” approach is presented in Figure I A-1.

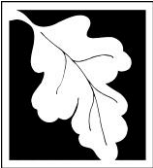
As indicated in Figure I A-1, use of the CAM and achievement of a “Presumptive Certainty” status will produce an analytical data set that will be accepted by agency reviewers for subsequent evaluation of data usability and representativeness.

It is stressed that “Presumptive Certainty” requirements are to be considered minimum requirements. Efforts that go beyond these minimum requirements (e.g., including additional points in a calibration curve) are considered compliant with the “Presumptive Certainty” concept and provisions, and need not be identified and discussed as an “exception”.

3.2.1 Data Usability

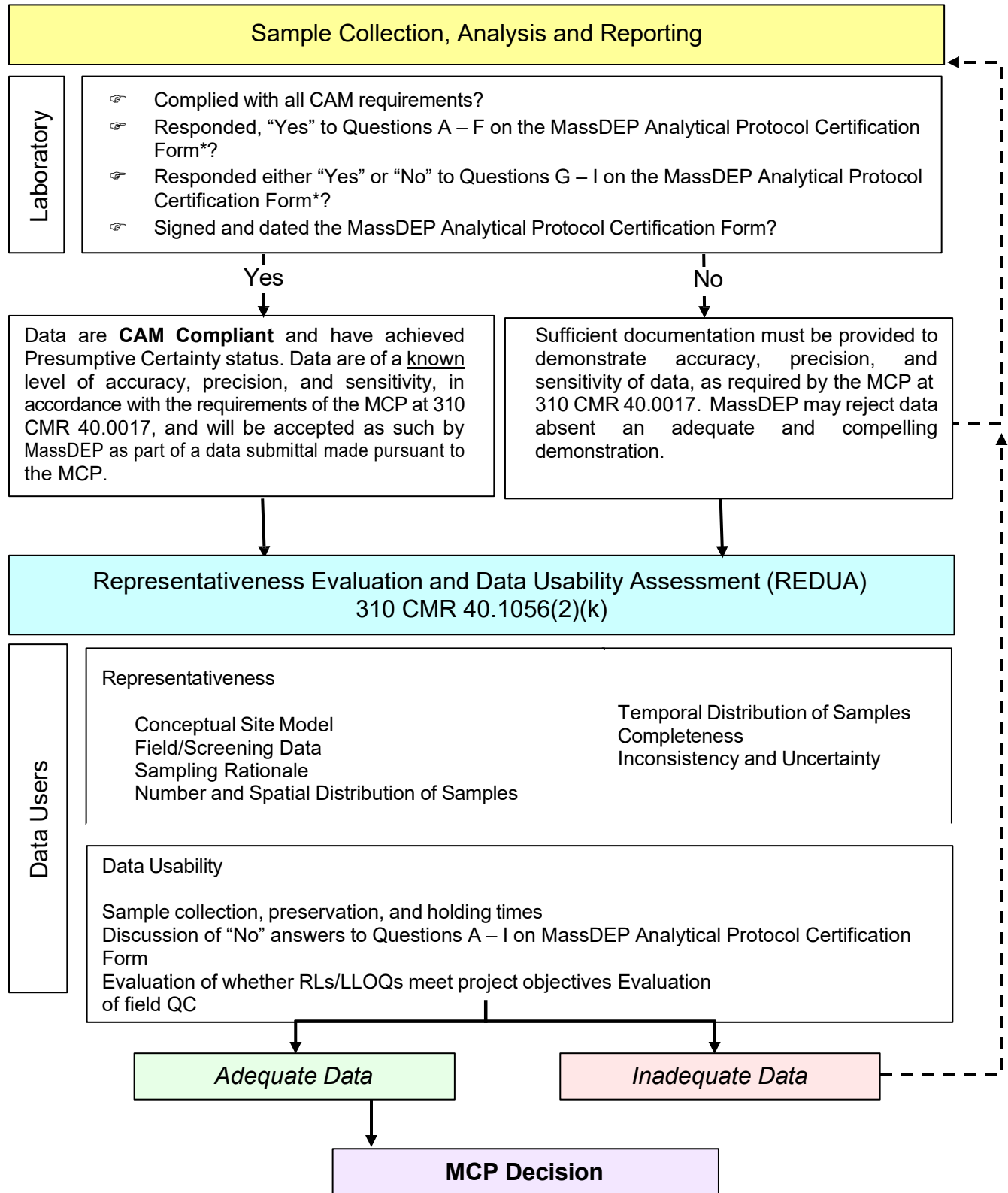
Data usability refers to the extent to which a data set can adequately meet specific site characterization needs and data quality objectives. For example, are the RLs/LLOQs below applicable cleanup standards? Were all method QC measurements within specified limits; if not, can the data still be used to provide useful characterization information?

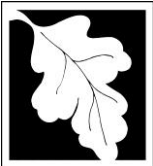
For parties who elect to follow the specifications in the CAM, data will be considered usable for all subsequent data usability evaluations if all provisions and standards of the MCP Analytical Methods are met, including percent recovery limits for (any) method surrogate spikes and achievement of necessary (site-specific) RLs/LLOQs.



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Figure I A-1: MassDEP Presumptive Certainty and REDUA Concept





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In cases where “Presumptive Certainty” is achieved, but where data is qualified as being outside a required QC limit (e.g., low surrogate recoveries), additional evaluation, and possibly additional field sampling and analysis, may be necessary as part of and/or result of the data usability assessment. As stated in WSC-CAM-VII A, Section 1.0, “this document does not provide any specific guidance regarding proper sampling procedures, approaches to achieve representative sampling or the type and frequency of field QC samples required to evaluate overall data representativeness or usability.” Therefore, for example, before a low-recovery surrogate standard can be deemed a “matrix effect,” it may be necessary to obtain and analyze a matrix spike sample.

Overall representativeness and usability of data produced using specific CAM protocols **must** be evaluated for compliance with project-specific data quality objectives pursuant to the requirements of 310 CMR 1056 (2)(k) and as further described in the MassDEP guidance, Policy #WSC-07-350, *MCP Representativeness Evaluations and Data Usability Assessments*.

3.2.2 Data Representativeness

Data representativeness refers to the degree to which site information and data characterizes the types, locations, and concentrations of oil and hazardous materials at a disposal site. Such considerations should consider the totality of information available about a site, the Conceptual Site Model, “laboratory” data, and “field/screening” data.

The “Presumptive Certainty” concept and status articulated in the MCP CAM focuses primarily on the analytical quality of site characterization data – not the quantity or representativeness of site characterization data, which is often the more important of these two elements in a data usability assessment. Nonetheless, absent site-specific information on the likely presence of any given oil or hazardous material, parties who obtain “Presumptive Certainty” status and have adopted the method-specific analyte lists of the CAM can be assured of the acceptability of the scope of testing for each CAM Protocol for each individual environmental sample.

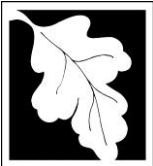
3.3 Laboratory Quality Control

The CAM provides the regulated community with a compilation of recommended laboratory procedures (CAM Protocols) for the most common contaminants of concern that may be used to support MCP Response Actions. These protocols, as described in Sections II through X of this Compendium, include detailed method-specific QC requirements and performance standards needed for achievement of a “Presumptive Certainty” status.

3.4 Field Quality Control

The level of field QC activities should be commensurate with: (a) the complexity of response actions conducted at a disposal site, (b) the potential risks posed to human health and the environment by the contaminants of concern, and (c) the intended use of the data. Data acquired from field QC procedures are used to:

- Estimate the overall quality (precision, accuracy and representativeness) of analytical data;



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- Determine the need for actions to address problems or concerns over the quality of the data;
- Interpret results after actions are implemented to address problems or concerns over the quality of the data; and
- Demonstrate that remedial goals have been achieved.

A total program to produce data of suitable and acceptable quality should include both a QA component, which encompasses the management procedures and controls as well as an operational QC component, to assess the precision, accuracy (bias) and representativeness of the site data set. An effective program should identify and document data quality objectives to support the disposal site's response action requirements and establish sampling design criteria not only to acquire adequate site data but also to acquire the supporting data quality indicators. The disposal site assessment should include an evaluation of the data quality indicators associated with each site data set to determine if the pre-established data quality objectives for the disposal site assessment were achieved.

It should be noted that there are no prerequisites for obtaining "Presumptive Certainty" status with regard to the types and frequency of field QC data with the exception of drinking water samples, as described in Section 2.5 of CAM VII A.

3.5 Reporting Content for Analytical and QC Data

The WSC-CAM-VII A, Section 2.0 describes in detail the reporting content for analytical and QC data for the CAM Protocols but leaves decisions regarding the reporting format of this information to the discretion of the analytical laboratory. The reporting content, specified in WSC-CAM-VII A includes but is not limited to the following elements:

- Sample information (matrix, preservative, temperature on receipt, etc.);
- Analytical results (to include individual RLs/LLOQs for individual analytes, dilutions, extraction/pretreatment, etc.);
- QC results (surrogate recovery, method blanks, etc., as applicable); and
- Laboratory analytical certification (method followed, acceptance criteria met, and documentation of method modifications or anomalies).

3.6 Use of the Words "Shall" or "Must" in the CAM

The use of the words "**shall**" or "**must**" in the CAM is intended to identify specific tasks and/or activities that are **required** to satisfy the QC requirements and performance standards of the individual CAM Protocols in order to achieve "Presumptive Certainty" - *if a party elects to utilize the CAM Protocols to satisfy the performance standards described in 310 CMR 40.0017 and 40.0191(2)(c).*

The use of the words "**shall**" or "**must**" in the CAM in no way implies that the guidance provided is a mandatory regulatory requirement under M.G.L. c. 21E or the MCP.

4.0 Laboratory Accreditation/Certification

The Laboratory Certification Office (LCO), located at the MassDEP Wall Experiment Station (WES), currently provides laboratory certification only for the chemical analysis of potable and non-potable water and microbiological analysis of potable water. The purpose of the Laboratory Certification Program is to



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identify laboratories in both the public and private sectors that are capable of consistently producing valid data. Towards this end, the LCO evaluates laboratories to ensure that they meet and continue to meet the performance and resource criteria set forth in 310 CMR 42.00 regarding laboratory personnel and qualifications, facilities, equipment, methodology employed, and QA/QC practices.

These reviews, which include annual proficiency tests and biennial on-site inspections, help ensure that the data produced by the laboratories are of known and documented quality, and suitable for their intended purpose. It should be clearly understood that certification alone cannot guarantee the “validity” of the data produced by a laboratory.

5.0 Alternative Approaches

Consistent with the provisions of 310 CMR 40.0191, parties may continue to exercise professional judgment regarding the selection of alternative analytical approaches and methods. However, in all cases, sufficient documentation must be provided to support the decision that the selected analytical methods (and laboratory/field QA/QC procedures and results) meet the stated objectives of the plan for assessment of the disposal site, as well as the overall performance standards of 310 CMR 40.0017 and 40.0191(2)(c).