TNI VERSION 2009 and DoD/DOE QSM VERSION 5.4 CHECKLIST

THIS CHECKLIST IS ONLY A TOOL, AND NOT CONSIDERED AS THE REQUIREMENTS OF THE STANDARD(S)!

IF THERE IS A DISAGREEMENT BETWEEN THIS CHECKLIST AND THE STANDARD(S), THE STANDARD(S) SHALL PREVAIL.

Organization Name:	
Address: (Mailing)	
Address: (Physical Location)	
Telephone:	
Fax:	
E-mail:	
Web Address:	
Assessment Location (If different):	
Assessment Date(s):	
Assessment Organization:	Perry Johnson Laboratory Accreditation, inc. (PJLA)
Assessors(s):	
Signature(s):	
Receipt acknowledgment by Laboratory:	
Notes:	

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1	**Volume 1 Module 1**				
M1	**Proficiency Testing (PT)**				
M1 2.0	**Requirements for Accreditation (Section 2: DoD Only)**				
M1 2.1	**Initial Accreditation (Section 2.1 DoD Only)**				
M1 2.1.1	**Initial Accreditation for DoD ELAP (DoD Only)**				
M1 2.1.1	Does the laboratory analyze at least two (2) PT samples for each combination of analyte-matrix-method that corresponds to their scope of accreditation? Note: Laboratories that combine multiple methods into one SOP (e.g., SOP that combines Method 624 volatiles & Method 8260 volatiles) can report those methods with a single PT sample. All other analyte-matrix-method combinations require unique PT samples.				
M1 2.1.2	**PT Samples for Initial Accreditation (DoD Only)**				
M1 2.1.2	Are PT samples used for initial accreditation obtained from PT providers that are accredited under ISO/IEC 17043 (General Requirements for PT) from an ILAC approved signatory AB?				
M1 2.1.3	**PT Samples not from ISO/IEC 17043:2010(E) Accredited PT Provider (DoD Only)**				
M1 2.1.3	For PT samples that were not obtained by an ISO 17043 accredited PT provider, does the laboratory have special permission to use the non-ISO/IEC 17043 provider from the AB? Note: The requirements and criteria from the PT provider must be met by the laboratory for the PT sample to be considered successful.				
M1 2.1.4	**PT Samples for Analyte-matrix-method not from PT Provider (DoD Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 2.1.4	Does the laboratory submit, in writing, to the AB, when PT samples for an analyte-matrix-method combination cannot be obtained from any PT provider and the analyte-matrix-method combination is required for a scope of accreditation? Note: Other measures (e.g., precision, bias, and selectivity) as outlined in the 2009 TNI Standard Test Modules 3-7 must be performed to satisfy the PT requirement until those PT samples are available.				
M1 2.1.5	**Analysis Date of PT Samples (DoD Only)**				
M1 2.1.5	Are the PT samples analyzed by the laboratory for initial DoD ELAP accreditation no more than twelve (12) months old?				
M1 2.1.5	If two or more successive PT samples are performed, is the analysis date between PT samples at least fifteen (15) calendar days apart?				
M1 2.1.6	**PT Study Determination (DoD Only)**				
M1 2.1.6	Is the success or failure of the analyte-matrix-method combination determined by the PT provider under the requirements of the governing regulatory or ISO/IEC 17043:2010(E) statistically derived program?				
M1 2.1.7	**PT Samples Same as Regular Environmental Samples (DoD Only)**				
M1 2.1.7	Are PT samples analyzed and evaluated in the same was as regular environmental samples?				
M1 2.1.7	Does the laboratory employ the same QC, sequence of analytical steps, and replicates as when analyzing routine analytical samples?				
M1 2.2	**Continuing Accreditation (Section 2.2 DoD Only)**				
M1 2.2.1	**Maintaining Accreditation (DoD Only)**				
M1 2.2.1	Has the laboratory successfully analyze at least two (2) PT samples per calendar year for each analyte-matrix-method combination on their scope of accreditation? Note: A PT sample for Whole Effluent Toxicity (WET) testing is required at least once per year.				
M1 2.2.1	Is each PT sample analyzed not less than 4 months and not to exceed 8 months apart?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 2.2.2	**Laboratory PT History (DoD Only)**				
M1 2.2.2	Does the laboratory maintain a history of at least two (2) successful PT rounds out of the most recent three (3) attempts for each analyte-matrix-method combination on their scope of accreditation.				
M1 2.2.2	If PT samples are required for corrective action to reestablish history of successful PT rounds, are the analysis dates of successive corrective action PT samples at least fifteen (15) calendar days apart?				
M1 2.2.3	**Failure to Meet Criteria (DoD Only)**				
M1 2.2.3	Are analyte-matrix-method combinations that do not meet the above criteria removed from the DoD ELAP scope of accreditation?				
M1 2.2.4	Are PT samples analyzed and evaluated in the same manner as regular environmental samples?				
M1 2.2.4	Does the laboratory employ the same quality control, sequence of preparation and analytical steps, and replicates as used when analyzing routine samples?				
M1 3.0	**Requirements for Participation (Section 3: DOE Only)**				
M1 3.1	**Initial Inclusion (Section 3.1 DOE Only)**				
M1 3.1.1	**Initial Inclusion into the DOECAP Program (DOE Only)**				
M1 3.1.1	Does the laboratory analyze at least two (2) PT samples for each combination of analyte-matrix-method that corresponds to their scope of accreditation? Note: Laboratories that combine multiple methods into one SOP (e.g., SOP that combines Method 624 volatiles & Method 8260 volatiles) can report those methods with a single PT sample provided the strictest Quality Control (QC) criteria are applied. All other analyte-matrix-method combinations may require other applicable PT samples as discussed under Section 3.1.2 below.				
M1 3.1.1	Has the laboratory demonstrated successful participation for a minimum of one year in an ISO/IEC 17043:2010(E) accredited PT program?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 3.1.1	Are single blind studies related to regulatory or environmental programs, analytes, matrix types, and methods for each of the analytical disciplines (i.e., inorganic, organic, radiochemistry, biological, etc.) that each laboratory will perform in support of DOE sites. Note: A laboratory is required to analyze PT samples in matrices containing analytes listed on the accreditation scope using methodology applicable to data they report under DOE contracts, where available.				
M1 3.1.1	Are PT samples tested and evaluated in the same manner as regular environmental samples?				
M1 3.1.2	**PT Samples for Initial Inclusion (DOE Only)**				
M1 3.1.2	**MAPEP**				
M1 3.1.2	Are PT samples used for initial accreditation obtained from PT providers that are accredited under ISO/IEC 17043 (General Requirements for PT) from an ILAC approved signatory AB?				
M1 3.1.2	Does the laboratory possess a radioactive materials license from the Nuclear Regulatory Commission, an Agreement State, or a DOE exemption authorized by the contract holder to receive PT samples that contain radiological materials?				
M1 3.1.2	Does the laboratory use the following required ISO/IEC 17043:2010(E) PT providers for other programs (such as Drinking Water) require program-specific PT samples? - RadCheM™ by ERA (or other equivalent ISO/IEC 17043:2010(E) provider), for radioactivity measurements in drinking water. - NELAC Fields of Testing for CWA-Water (formerly known as WP) - NELAC Fields of Testing for SDWA-Water (formerly known as WS) - AIHA Proficiency accreditation for Asbestos and Beryllium (if applicable) Note: Other Recommended Programs include: - DMR-QA, for NPDES analysis - NELAC Fields of Testing for RCRA Solid				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 3.1.3	For PT samples that were not obtained by an ISO 17043 accredited PT provider, does the laboratory have special permission to use the non-ISO 17043 provider from the AB? Note: The requirements and criteria from the PT provider must be met by the laboratory for the PT sample to be considered successful.				
M1 3.1.4	For PT samples that were not obtained by an ISO 17043 accredited PT provider, does the laboratory have special permission to use other measures from the AB? Note 1: The requirements and criteria from the PT provider must be met by the laboratory for the PT sample to be considered successful. Note 2: Other measures (e.g., precision, bias, and selectivity) as outlined in the appropriate 2009 TNI Standard Test Modules must be performed to satisfy the PT requirement until those PT samples are available.				
M1 3.1.5	Are the PT sample analysis dates by the laboratory for initial DOECAP-AP accreditation no more than 12 months old?				
M1 3.1.5	Are the analysis date between PT samples at least 7 calendar days apart if two or more successive PT samples are performed?				
M1 3.1.6	Is the success or failure of any analyte-matrix-method combination for a PT study determined by the PT provider under the requirements of the governing regulatory or ISO/IEC 17043:2010(E) statistically derived program?				
M1 3.1.7	Are PT samples tested and evaluated in the same manner as regular environmental samples? Note: A laboratory shall employ the same quality control, sequence of preparation and analytical steps, and replicates as used when analyzing routine samples from DOE sites for the purposes of achieving accreditation.				
M1 3.2	**Continued Participation (Section 3.2 DOE Only)**				
M1 3.2.1	**Maintaining Participation (DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 3.2.1	Does the laboratory continue to participate in all applicable rounds of external PT programs?				
M1 3.2.1	Does the laboratory successfully analyze at least two PT samples, where available, per calendar year for each analyte-matrix-method combination on their scope of accreditation?				
M1 3.2.1	Is each PT sample analyzed approximately six months apart (any time frame from four to eight months apart is considered acceptable) if two PT samples are analyzed?				
M1 3.2.2	**Laboratory PT History (DOE Only)**				
M1 3.2.2	Does the laboratory maintain a history of at least two (2) successful PT rounds out of the most recent three (3) attempts for each analyte-matrix-method combination on their scope of accreditation?				
M1 3.2.3	**Reporting Requirements to DOE Sites (DOE Only)**				
M1 3.2.3	Note: The results of all PT programs will be utilized in the reports produced for DOE and the sites that have contracts with the laboratory. PT results from commercial PT studies will be provided to the Laboratory's applicable DOE contract holder sites no later than 10 days of receipt of results from the PT provider from the most recent PT study.				
M1 3.2.4	**Failure to Meet Criteria (DOE Only)**				
M1 3.2.4	Note: Any applicable analyte for which individual laboratory results are entered as NR or "not reported" will not be considered an acceptable result unless it is a remedial PT study.				
M1 3.2.4	Is the success or failure of any analyte-matrix-method combination for a PT study determined by the PT provider under the requirements of the governing regulatory or ISO/IEC 17043:2010(E) statistically derived program?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 3.2.4	If the laboratory fails two consecutive evaluations or two (2) out of three (3) attempts, does the laboratory receive samples for analysis by the failed analyte-matrix-method combination until acceptable PT performance has been achieved? Note: The decision to withhold sample shipments will be at the discretion of the individual DOE contract holder.				
M1 3.2.4	Are analyte-matrix-method combinations that do not meet the above criteria removed from the DOECAP-AP scope of accreditation by the Accrediting Body?				
M1 3.2.4	Note: The laboratory can demonstrate proficiency in remedial PT studies by acceptable performance in an unscheduled evaluation by the same PT program or by participation in the next regularly scheduled study. The use of quick turnaround and remedial samples will be acceptable, but the PT samples are included in the number of possible attempts at maintaining proficiency (i.e., receiving acceptable performance in two out of the last three rounds by analyte-matrix-method of proficiency testing reported). PT samples are required for corrective action to reestablish history of successful PT performance.				
M1 3.2.4	Is the analysis dates of successive corrective action PT samples at least 15 calendar days apart?				
M1 3.2.5	Are PT samples analyzed and evaluated in the same manner as regular environmental samples?				
M1 3.2.5	Does the laboratory employ the same quality control, sequence of preparation and analytical steps, and replicates as used when analyzing routine samples?				
M1 4.0	**Requirements for Accreditation (Section 4.0 TNI Only)**				
M1 4.1	**Initial Accreditation (Section 4.1 TNI Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 4.1.1	Does the laboratory successfully analyze two unique TNI compliant PT samples for each accreditation FoPT that correspond to the fields of accreditation for which it seeks accreditation. Note1: The requirements for successful PT performance are described in Volume 2, Module 2, and in Volume 3. Note2: Accreditation and experimental FoPT are established by the TNI PT Board. The official Tables of FoPT are posted to the TNI website.				
M1 4.1.2	Are the PT samples used for initial accreditation obtained from a PTPA-accredited PTP as part of a TNI-compliant study.				
M1 4.1.2	If a PT sample for an accreditation FoPT is not available from any accredited PTP, does the laboratory obtain the PT sample from a non-PTPA-accredited PTP.				
M1 4.1.3	When the PT samples used for initial accreditation were analyzed by the laboratory prior to the date of application, are the analysis dates of the PT samples for the same accreditation FoPT no more than eighteen (18) months prior to the application date of accreditation, with the analysis date of the most recent PT sample having been no more than six (6) months prior to the application date for accreditation? Otherwise, there shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the same accreditation FoPT.				
M1 4.2	**Continued Accreditation (Section 4.2 TNI Only)**				
M1 4.2.1	To maintain accreditation, does the laboratory:				
M1 4.2.1	a) Analyze at least two TNI-compliant PT samples per calendar year for each accreditation FoPT for which the laboratory is accredited?				
M1 4.2.1	a) If TNI-compliant PT samples are not available from any PTPA approved PT provider at least twice per year, does the laboratory analyze the PT samples in the minimum time frame in which the PT samples are available?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 4.2.1	a) Are the analysis dates of successive PT samples for the same accreditation FoPT at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation, or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive?				
M1 4.2.1	a) are successive PT samples for the same accreditation FoPT at least fifteen (15) days apart?				
M1 4.2.1	b) Maintain a history of at least two (2) successful performances out of the most recent three (3) attempts; for each accreditation FoPT?				
M1 4.2.1	c) Obtain the PT samples from any PTPA-accredited PTP?				
M1 4.2.1	c) If a PT sample for a FoPT is not available from any accredited PTP, does the laboratory obtain the PT sample from any non- PTPA-accredited PTP?				
M1 4.2.2	When a laboratory is accredited for a field of accreditation for which the FoPT is an experimental FoPT, does the laboratory analyze two (2) PT samples for the experimental FoPT per year within the same time frames specified for accreditation FoPT. Note: Successful performance of the experimental PT is not a requisite for continued accreditation.				
M1 5.0	**Requirements for PT Sample Handling, Analysis & Reporting (Section 5.0 TNI Only)**				
M1 5.1	**PT Sample Analysis Requirements (Section 5.1 TNI Only)**				
M1 5.1.1	Does the laboratory analyze PT samples in the same manner as used for routine environmental samples using the same: - staff? - sample tracking? - sample preparation and analysis methods? - standard operating procedures? - calibration techniques? - quality control procedures? - acceptance criteria?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 5.1.2	Prior to the closing date of a study, does the laboratory personnel, including corporate personnel, not:				
M1 5.1.2	a) Subcontract the analysis of any PT sample or a portion of a PT sample to another laboratory for any accreditation or experimental FoPT?				
M1 5.1.2	b) Knowingly receive and analyze any PT sample or portion of a PT sample from another laboratory for which the results of the PT sample are intended for use for initial or continued accreditation?				
M1 5.1.2	c) Communicate with any individual at another laboratory concerning the analysis of the PT sample prior to the closing date of the study?				
M1 5.1.2	d) Attempt to obtain the assigned value of any accreditation or experimental FoPT from the PTP?				
M1 5.2	**PT Sample Reporting Requirements (Section 5.2 TNI Only)**				
M1 5.2.1	Does the laboratory evaluate and report the analytical result for accreditation or experimental FoPT as follows:				
M1 5.2.1	a) For instrument technology that employs a multi-point calibration, does the laboratory evaluate the analytical result to the value of the lowest calibration standard established for the test method used to analyze the PT sample?				
M1 5.2.1	a) Is the working range of the calibration under which the PT sample is analyzed the same range as used for routine environmental samples?				
M1 5.2.1	i. Is a result for any FoPT at a concentration above or equal to the lowest calibration standard reported as the resultant value?				
M1 5.2.1	ii. Is a result for any FoPT at a concentration less than the lowest calibration standard reported as less than the value of the lowest calibration standard?				
M1 5.2.1	b) For instrument technology (such as ICP-AES or ICP-MS) that employ standardization with a zero point and a single point calibration standard, does the laboratory evaluate the analytical result to the LOQ established for the test method used to analyze the PT sample?				
M1 5.2.1	b) Is the LOQ for the FoPT the same as used for routine environmental samples?				
M1 5.2.1	i. Is a result for any FoPT at a concentration above or equal to the LOQ reported as the resultant value?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 5.2.1	ii. Is a result for any FoPT at a concentration less than the LOQ reported as less than the value of the LOQ?				
M1 5.2.2	Does the laboratory report the analytical results for accreditation and experimental FoPTs to the PTP on or before the closing date of the study using the reporting format specified by the PTP?				
M1 5.2.3	On or before the closing date of the study, does the laboratory authorize the PTP to release the laboratory's final evaluation report directly to the laboratory's Primary AB?				
M1 5.3	**PT Sample Record Retention Requirements (Section 5.3 TNI Only)**				
M1 5.3.1	Does the laboratory retain all records necessary to facilitate historical reconstruction of the analysis and reporting of analytical results for PT samples for a minimum of five years?				
M1 5.3.2	Do the historical records include a copy of the reporting forms used by the laboratory to report the analytical results for PT samples to the PTP?				
M1 5.3.2	If the analytical results for the PT samples were entered or uploaded electronically to a PTP website, does the laboratory retain a copy of the on-line data entry summary or similar documentation of entry of the PT results from the PTP's website?				
M1 5.3.3	Does the laboratory make these records available for review upon request by the Primary AB?				
M1 6.0	**Requirements for Corrective Action (Section 6.0 TNI Only)**				
M1 6.1	When the laboratory receives a "not acceptable" performance score from a PTP or a Primary AB, does the laboratory perform corrective action?				
M1 6.1	When the laboratory receives an evaluation of not acceptable for an accreditation FoPT in any study, does the laboratory choose to re-establish successful history for the accreditation FoPT with a PT sample from any study?				
M1 6.1	Do the following requirements apply to the PT sample used to reestablish successful history:				
M1 6.1	a) Is the PT sample obtained from any PTPA–accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample is purchased from any PTP?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 6.1	a) Does the laboratory notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample supplied meets the requirements for supplemental PT as defined in Volume 3 of this standard?				
M1 6.1	b) Does the laboratory ensure that there are at least fifteen (15) calendar days between the analysis dates of successive PT samples for the same accreditation FoPT?				
M1 6.1	c) Is the PT sample analyzed and reported in accordance with the requirements described this Module?				
M1 7.0	**Requirements for Complaint Resolution (Section 7.0 TNI Only)**				
M1 7.1	Does the laboratory submit questions about PT samples or performance evaluations made by the PTP to the PTP?				
M1 7.1	If the PTP is not able or is unwilling to resolve the question to the satisfaction of the laboratory, does the laboratory refer those questions to the PTP's PTPA?				
M1 8.0	**Requirements for Reinstatement of Accreditation after Suspension or Revocation (Section 8.0 TNI Only)**				
M1 8.1	To reinstate accreditation for an accreditation FoPT after suspension, does the laboratory meet the requirements for continued accreditation as described in Section 4.2 of this module?				
M1 8.2	To reinstate accreditation for an accreditation FoPT after revocation, does the laboratory meet the requirements for initial accreditation as described in Section 4.1 of this module.				
M2	**Volume 1 Module 2**				
M2	**Quality Systems (QS) General Requirements**				
M2 4.0	**Management Requirements**				
M2 4.1	**Organization**				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.1) Are laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.2) Is laboratory management committed to impartiality?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.3) Is the laboratory responsible for impartiality of its laboratory activities?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.3) Does the laboratory not allow commercial, financial or other pressures to compromise impartiality?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.4) Does the laboratory identify risks to its impartiality on an ongoing basis?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.4) Do identified risks to its impartiality include those risks that arise from the laboratory's activities, or from its relationships, or from the relationships of its personnel? Note1: Such relationships do not necessarily present a laboratory with a risk to impartiality. Note2: A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.1.5) If a risk to impartiality is identified, does the laboratory demonstrate how it eliminates or minimizes such risk?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.1) Is the laboratory responsible, through legally enforceable commitments, for the management of all information attained or created during the performance of laboratory activities?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.1) Does the laboratory inform the customer in advance of information it intends to place in the public domain?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.1) Except for information that the customer makes publicly available, or when agreed between the laboratory and customer (e.g., for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.2) When the laboratory is required by law or authorized by contractual arrangements to release confidential information, unless prohibited by law, is the customer or individual concerned notified of the information provided?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.3) Is information about the customer obtained from sources other than the customer (e.g., complainant, regulators) maintained confidential between the customer and the laboratory?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.3) Is the provider (source) of the information maintained confidential by the laboratory and not shared with the customer, unless agreed by the source?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 4.2.4) Do personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities, except as required by law?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 5.3) Does the laboratory define and document the range of laboratory activities for which it conforms with the standard?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 5.3) Does the laboratory only claim conformity with the standard for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 5.4) Are laboratory activities carried out in such a way as to meet the requirements of the standard, the laboratory's customers, regulatory authorities and organizations providing recognition?				
M2 4.1 Grey Box 4	(ISO/IEC 17025:2017 5.4) Does this include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility?				
M2 4.1.1	Does the laboratory or the organization of which it is part, an entity that can be held legally responsible?				
M2 4.1.2	Does the laboratory uphold its responsibility to carry out its testing and/or calibration activities in such a way as to meet the requirements of this standard?				
M2 4.1.2	Does the laboratory carry out its testing and/or calibration activities in such a way as to meet the requirements of the customer, the regulatory authorities or organizations providing recognition?				
M2 4.1.3	Does the laboratory management system cover work carried out in the laboratory’s permanent facilities, at sites away from its permanent facilities, and/or in its associated temporary or mobile facilities?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities defined in order to identify potential conflicts of interest?				
M2 4.1.4	Note1: Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.				
M2 4.1.4	Note2: If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.				
M2 4.1.5 Grey Box 5	(ISO/IEC 17025:2017 6.2.3) Does the laboratory ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations?				
M2 4.1.5 Grey Box 5	(ISO/IEC 17025:2017 6.2.4) Does the management of the laboratory communicate to personnel their duties, responsibilities and authorities?				
M2 4.1.5 Grey Box 5	(ISO/IEC 17025:2017 6.2.5.d) Does the laboratory have procedure(s) and retain records for supervision of personnel?				
M2 4.1.5	a) Does the laboratory managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to:				
M2 4.1.5	• Carry out their duties, including the implementation, maintenance and improvement of the management system?				
M2 4.1.5	• identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations?				
M2 4.1.5	• initiate actions to prevent or minimize such departures (see also Section 5.2)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.5	b) Does the laboratory have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?				
M2 4.1.5	c) Does the laboratory have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?				
M2 4.1.5	d) Does the laboratory have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?				
M2 4.1.5	e) Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management technical operations and support services?				
M2 4.1.5	f) Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations?				
M2 4.1.5	g) Does the laboratory provide adequate supervision of testing and/or calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results?				
M2 4.1.5	h) Does the laboratory have technical management which has overall responsibility for the technical operations and the provision of the resources needed, ensure the required quality of laboratory operations?				
M2 4.1.5	i) Does the laboratory appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, has:				
M2 4.1.5	• defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times?				
M2 4.1.5	• direct access to the highest level of management at which decisions are made on laboratory policy or resources?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.5	j) Does the laboratory appoint deputies for key managerial personnel? Note: Individuals may have more than one function and it may be impractical to appoint deputies for every function.				
M2 4.1.5	j) At a minimum, is the following laboratory management staff (however named) considered key managerial personnel:				
M2 4.1.5	i. Management (e.g., President, CEO, COO, Laboratory Director)? ii. Technical managers (e.g., Technical Director, Section Supervisors)? iii. Quality managers;? iv. Support systems and administrative managers (e.g., LIMS manager, purchasing manager, project managers)? v. Customer services managers?				
M2 4.1.5	k) Does the laboratory ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system?				
M2 4.1.6	Does top management ensure that appropriate communication processes are established and that communication takes place regarding the effectiveness of the management system?				
M2 4.1.7.1	Does the laboratory's quality manager and/or his/her designee(s): Note: Where staffing is limited, the quality manager may also be the technical manager.				
M2 4.1.7.1	a) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data?				
M2 4.1.7.1	b) have functions independent from laboratory operations for which they have quality assurance oversight?				
M2 4.1.7.1	c) have ability to evaluate data objectively and perform assessments without outside (e.g. Managerial) influence?				
M2 4.1.7.1	d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system?				
M2 4.1.7.1	e) have a general knowledge of the analytical methods for which data review is performed?				
M2 4.1.7.1	f) arrange for or conduct internal audits as per Section 4.14 annually?				
M2 4.1.7.1	g) notify laboratory management of deficiencies in the quality system?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.7.1	h) monitor corrective actions?				
M2 4.1.7.1	i. implement, maintain, and improve the management system by using available tools such as audit and surveillance results, control charts, PT results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends?				
M2 4.1.7.1	Is the laboratory's technical manager(s) and/or his/her designee(s):				
M2 4.1.7.2	a) a member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results?				
M2 4.1.7.2	b) experienced in the fields of accreditation for which the laboratory is seeking accreditation?				
M2 4.1.7.2	c) have duties that include:				
M2 4.1.7.2	i. monitoring standards of performance in quality control and quality assurance?				
M2 4.1.7.2	ii. monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data?				
M2 4.1.7.2	d) not the technical manager(s) of more than one accreditation environmental laboratory without authorization from the primary Accreditation Body?				
M2 4.1.7.2	e) If absent for a period of time exceeding fifteen (15) consecutive calendar days, designates another full-time staff member meeting the qualifications of the technical manager(s) to temporarily perform this function?				
M2 4.1.7.2	e) If absent for a period of time exceeding thirty-five (35) consecutive calendar days, the primary accreditation body notified in writing?				
M2 4.1.7.2	f) meets the requirements as specified in Section 5.2.6.1?				
M2 4.2	**Management**				
M2 4.2.1	Has the laboratory established, implemented, & maintained a management system appropriate to the scope of its activities?				
M2 4.2.1	Has the laboratory documented its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.1	Is the laboratory system's documentation communicated to, understood by, available to, and implemented by the appropriate personnel?				
M2 4.2.1	Are copies of all management system documentation provided to DoD ELAP ABs, DOECAP-AP, or to personnel on behalf of DoD/DOE provided in English?				
M2 4.2.2 Grey Box 6	(ISO/IEC 17025:2017 8.2.2) Do policies and objectives address the competence, impartiality and consistent operation of the laboratory?				
M2 4.2.2	Are the laboratory's management system policies related to quality, including a quality policy statement, defined in a quality manual (however named)?				
M2 4.2.2	Has the laboratory established overall objectives and reviewed objectives during management review?				
M2 4.2.2	Is the laboratory's quality policy statement issued under the authority of top management?				
M2 4.2.2	Does the laboratory's quality policy statement include at least the following:				
M2 4.2.2	a) the laboratory management's commitment to good professional practice and to the quality of its environmental testing in servicing its customers?				
M2 4.2.2	b) the management’s statement of the laboratory's standard of service?				
M2 4.2.2	c) the purpose of the management system related to quality?				
M2 4.2.2	d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work?				
M2 4.2.2	e) the laboratory management's commitment to:				
M2 4.2.2	• compliance with this Standard?				
M2 4.2.2	• continually improve the effectiveness of the management system?				
M2 4.2.2	Note: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.				
M2 4.2.3	Does top management provided evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.3	Is top management (including 4.1.5 j) i) through iii)) responsible for:				
M2 4.2.3	a) Defining the minimum qualifications, experience, and skills necessary for all positions in the laboratory?				
M2 4.2.3	b) Ensuring that all laboratory technical staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be recorded?				
M2 4.2.3	c) Ensuring that the training of each member of the technical staff is kept up-to-date (ongoing) by the following:				
M2 4.2.3	i. ensuring each employee training file contains a certification that the employee has read, understands, and is using the latest version of the management system records relating to his/her job responsibilities?				
M2 4.2.3	ii. ensuring training courses or workshops on specific equipment, analytical techniques, or laboratory procedures are recorded?				
M2 4.2.3	iii. ensuring review of analyst work by relevant technical managers on an on-going basis is recorded or another annual DOC is performed by one of the following?				
M2 4.2.3	a) acceptable performance of a blind sample (single or double blind to the analyst); b) at least four consecutive laboratory control samples with acceptable levels of precision and bias. The laboratory must determine the acceptable levels of precision and bias prior to analysis; or c) if the above cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.				
M2 4.2.3	d) Ensuring recording all analytical and operational activities of the laboratory?				
M2 4.2.3	e) Ensuring adequate supervision of all personnel employed by the laboratory?				
M2 4.2.3	f) Ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored?				
M2 4.2.3	g) Ensuring recording of the quality of all data reported by the laboratory?				
M2 4.2.4	Does top management communicate to the organization the importance of meeting customer, statutory and regulatory requirements?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.5	Does the quality manual:				
M2 4.2.5	• include or make reference to supporting and technical procedures?				
M2 4.2.5	• outline the structure of the documentation used in the management system?				
M2 4.2.6	• define the roles and responsibilities of technical management and the quality manager, including their responsibilities for ensuring compliance with this standard?				
M2 4.2.7	Does Top Management ensure that the integrity of the management system is maintained when changes are planned and implemented?				
M2 4.2.8.1	Has the laboratory established and maintained a documented data integrity system?				
M2 4.2.8.1	Does the laboratory's data integrity system include the following four required elements:				
M2 4.2.8.1	• data integrity training?				
M2 4.2.8.1	• signed data integrity documentation for all laboratory employees?				
M2 4.2.8.1	• in-depth, periodic monitoring of data integrity?				
M2 4.2.8.1	• data integrity procedure documentation?				
M2 4.2.8.1	Are the data integrity procedures signed and dated by top management?				
M2 4.2.8.1	Are the requirements for data integrity investigation identified in Section 4.16 listed in the data integrity documentation?				
M2 4.2.8.1	Note: The requirements for data integrity training and documentation are listed in Section 5.2.7				
M2 4.2.8.1	Does management annually review data integrity procedures and update as needed?				
M2 4.2.8.1	a) Does the laboratory have a procedure for confidential reporting of data integrity issues in their laboratory?				
M2 4.2.8.1	a) Does the procedure assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern?				
M2 4.2.8.1	b) Where there is ethical concern, does the procedure include a process whereby laboratory management is to be informed of the need for any further detailed investigation?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.1	c) Does the laboratory have a documented program to detect and deter improper or unethical actions?				
M2 4.2.8.1	c) Is Data produced according to the project-specific requirements as specified in the final, approved project-planning documents, such as the approved Quality Assurance Project Plan (QAPP), when these documents are provided to the laboratory?				
M2 4.2.8.1	c) Does the laboratory have the following minimum elements for an acceptable program for detecting and deterring improper or unethical actions:				
M2 4.2.8.1	i) An ethics policy that must be read and signed by all personnel?				
M2 4.2.8.1	ii) Initial and annual ethics training conducted as described in Section 5.2.7?				
M2 4.2.8.1	iii) Analysts records of an explanation and signing off on all manual changes to data?				
M2 4.2.8.1	iv) Where available in the instrument software, all electronic tracking and audit functions are enabled?				
M2 4.2.8.2	Is the quality manager responsible for maintaining the currency of the quality manual?				
M2 4.2.8.2	Does the quality manager review (or oversee the review of) the quality manual at least annually, and update it if needed?				
M2 4.2.8.3	Does the quality manual contain the following:				
M2 4.2.8.3	a) document title?				
M2 4.2.8.3	b) laboratory's full name and address?				
M2 4.2.8.3	c) name, address (if different from above), and telephone number of individual(s) responsible for the laboratory?				
M2 4.2.8.3	d) identification of all major organizational units which are to be covered by this quality manual and the effective date of the version?				
M2 4.2.8.3	e) identification of the laboratory's approved signatories?				
M2 4.2.8.3	f) the signed and dated concurrence (with appropriate names and titles), of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.3	g) the objectives of the quality system and contain or reference the laboratory's policies and procedures?				
M2 4.2.8.3	h) the laboratory's official quality policy statement, including quality system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard?				
M2 4.2.8.3	i) a table of contents, and applicable lists of references, glossaries and appendices?				
M2 4.2.8.4	Does the quality manual contain or reference:				
M2 4.2.8.4	a) all maintenance, calibration and verification procedures used by the laboratory in conducting tests?				
M2 4.2.8.4	b) major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests?				
M2 4.2.8.4	c) verification practices, which may include inter-laboratory comparisons, PT programs, use of reference materials and internal quality control schemes?				
M2 4.2.8.4	d) procedures for reporting analytical results?				
M2 4.2.8.4	e) the organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts?				
M2 4.2.8.4	f) procedures to ensure that all records required under this Standard are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force?				
M2 4.2.8.4	g) job descriptions of key staff and reference to the job descriptions of other laboratory staff?				
M2 4.2.8.4	h) procedures for achieving traceability of measurements?				
M2 4.2.8.4	i) a list of all methods under which the laboratory performs its accredited testing?				
M2 4.2.8.4	j) procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work?				
M2 4.2.8.4	k) procedures for handling samples?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.4	l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur?				
M2 4.2.8.4	m) policy for permitting departures from documented policies and procedures or from standard specifications?				
M2 4.2.8.4	n) procedures for dealing with complaints?				
M2 4.2.8.4	o) procedures for protecting confidentiality (including national security concerns), and proprietary rights?				
M2 4.2.8.4	p) procedures for audits and data review?				
M2 4.2.8.4	p) Do the procedures for audits and data reviews specify which records must be included in the review?				
M2 4.2.8.4	p) Do internal data reviews consist of a tiered or sequential system of verification, consisting of at least three tiers - 100% review by the analyst - 100% verification review by a technically qualified supervisor or data review specialist - a final administrative review?				
M2 4.2.8.4	p) Do the analyst and verification review include at least the following procedures:				
M2 4.2.8.4	i) determination of whether the results meet the laboratory-specific quality control criteria?				
M2 4.2.8.4	ii) checks to determine consistency with project-specific measurement performance criteria (MPCs) if available?				
M2 4.2.8.4	iii) checks to ensure that the appropriate sample preparatory and analytical SOPs and methods were followed and that chain of custody and holding time requirements were met?				
M2 4.2.8.4	Note: For a test with a recommended maximum holding time measured in hours, the holding time shall be tracked by the hour. For a test with a recommended holding time measured in days, the holding time shall be tracked by the day. For a test with a recommended maximum holding time measured in months, the holding time shall be tracked by the month. One month is defined as 30 days.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.4	Note: For example, an exceedance of holding time for a sample with a 48-hour holding time will occur when the 49th hour is reached (e.g., a sample with a 48-hour holding time collected at 830 AM on April 4th must be analyzed or extracted by 9 AM on April 6th, or an exceedance will be considered to have occurred). An exceedance of holding time for a sample with a 14-day holding time will occur when the 15th day is reached (e.g., a sample with a 14-day holding time collected at 840 AM on April 4th must be analyzed or extracted by 12AM on April 19th, or an exceedance will be considered to have occurred). An exceedance of holding time for a sample with a 6-month holding time will occur when 6 months have passed (e.g., a sample with a 6-month holding time collected at 830 AM on April 5th must be analyzed or extracted by 12AM on October 2nd, or an exceedance will be considered to have occurred);				
M2 4.2.8.4	iv) checks to ensure that all calibration and quality control requirements were met?				
M2 4.2.8.4	v) checks for complete and accurate explanations of anomalous results, corrections, and the use of data qualifiers in the case narrative?				
M2 4.2.8.4	v) Does the final administrative review verify that previous reviews were recorded properly and that the data package is complete?				
M2 4.2.8.4	v) In addition, does the quality manager or designee review a minimum of 10% of all data packages for technical completeness and accuracy on a quarterly basis? Note: This review is considered a part of overall data review and does not need to be completed before the data package is issued to the customer.				
M2 4.2.8.4	v) If data quality issues are discovered during the review, is the client notified within fifteen (15) business days of the discovery of the issue?				
M2 4.2.8.4	v) If electronic audit trail functions are available, are they in use at all times, and associated data accessible?				
M2 4.2.8.4	v) If the instrument does not have an audit trail, does the laboratory have procedures to record the integrity of the data?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.4	q) procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training?				
M2 4.2.8.4	r) policy addressing the use of unique electronic signatures, where applicable?				
M2 4.2.8.4	s) procedures for procurement of standards?				
M2 4.2.8.4	t) procedures for data management including validation, verification, and purging of electronic data and data systems?				
M2 4.2.8.4	u) procedures for manual entry of raw data from analytical measurements that are not interfaced to LIMS and the verification and records of the accuracy of manually entered data?				
M2 4.2.8.4	v) procedures for making changes to electronic data (including establishing the requirements for a hardcopy or electronic log to record all changes to electronic data that affect data quality)?				
M2 4.2.8.4	w) procedures for how electronic data are processed, maintained, and reported?				
M2 4.2.8.4	x) procedures for ensuring that data review includes all quality-related steps in the analytical process, including sample preparation, dilution calculations, chromatography evaluation, and spectral interpretations?				
M2 4.2.8.4	x) Does the SOP for data review require that records of the review be maintained and available for external review?				
M2 4.2.8.4	y) a list of all current certifications and accreditations that the laboratory holds and the scope of certification or accreditation (with expiration date) for each?				
M2 4.2.8.4	z) health and safety (e.g., Chemical Hygiene Plan)?				
M2 4.2.8.4	aa) materials (Waste) management?				
M2 4.2.8.5	Does the laboratory maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods?				
M2 4.2.8.5	a) Do these documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents with adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.5	b) Are the relevant SOPs readily accessible to all personnel?				
M2 4.2.8.5	c) Does each SOP clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority?				
M2 4.2.8.5	d) If the documents do not contain sufficient information to perform the tests, are they supplemented or rewritten as internal procedures if written in a way that they can be used as written?				
M2 4.2.8.5	d) Are any changes, including the use of a selected option, documented and included in the laboratory's method records?				
M2 4.2.8.5	e) Does the laboratory have and maintain an SOP for each accredited analyte or method?				
M2 4.2.8.5	f) The SOP may be a copy of a published or referenced method or may be written by the laboratory.				
M2 4.2.8.5	f) In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, are these changes or clarifications clearly described?				
M2 4.2.8.5	f) Each method includes or references the following topics where applicable:				
M2 4.2.8.5	i. Identification of the method?				
M2 4.2.8.5	ii. Applicable matrix or matrices?				
M2 4.2.8.5	iii. Limits of detection and quantitation?				
M2 4.2.8.5	iv. Scope and application, including parameters to be analyzed?				
M2 4.2.8.5	v. Summary of the method?				
M2 4.2.8.5	vi. Definitions?				
M2 4.2.8.5	vii. Interferences?				
M2 4.2.8.5	viii. Safety?				
M2 4.2.8.5	ix. Equipment and supplies?				
M2 4.2.8.5	x. Reagents and standards?				
M2 4.2.8.5	xi. Sample collection, preservation, shipment and storage?				
M2 4.2.8.5	xii. Quality control?				
M2 4.2.8.5	xiii. Calibration and standardization?				
M2 4.2.8.5	xiv. Procedure?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.5	xv. Data analysis and calculations?				
M2 4.2.8.5	xvi. Method performance?				
M2 4.2.8.5	xvii. Pollution prevention?				
M2 4.2.8.5	xviii. Data assessment and acceptance criteria for quality control measures?				
M2 4.2.8.5	xix. Corrective actions for out-of-control data?				
M2 4.2.8.5	xx. Contingencies for handling out-of-control or unacceptable data?				
M2 4.2.8.5	xxi. Waste management?				
M2 4.2.8.5	xxii. References?				
M2 4.2.8.5	xxiii. Any tables, diagrams, flowcharts and validation data?				
M2 4.2.8.5	xxiv. Equipment/instrument maintenance?				
M2 4.2.8.5	xxv. Computer hardware and software?				
M2 4.2.8.5	xxvi. Troubleshooting?				
M2 4.2.8.5	g) Are all technical SOPs (e.g., sample preparation, analytical procedures, sample storage, or sample receipt) reviewed for accuracy and adequacy at least annually, and updated if necessary? Guidance: Non-technical SOPs that are not required elements of the quality manual (e.g., personnel policies, timekeeping procedures, or payroll) are considered administrative SOPs and do not require an annual review.				
M2 4.2.8.5	g) Are all SOP reviews conducted by personnel having the pertinent background, recorded, and made available for assessment?				
M2 4.2.8.5	h) Has the laboratory developed, maintained, and implemented procedures, however named, for Chemical Hygiene, Waste Management, and Radiation Protection (as applicable)?				
M2 4.3	**Document Control**				
M2 4.3.1	Has the laboratory established and maintained procedures to control all documents that form part of its management system (internally generated or from external sources) such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.3.1	Note1: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.				
M2 4.3.1	Note2: The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.				
M2 4.3.2	**Document Approval and Issue**				
M2 4.3.2.1	Has the laboratory established a master list (or equivalent document control procedure):				
M2 4.3.2.1	• identifying the current revision status and distribution of documents in the management system?				
M2 4.3.2.1	• that is readily available to preclude the use of invalid and/or obsolete documents?				
M2 4.3.2.2	Does the document control procedure(s) adopted ensure that:				
M2 4.3.2.2	a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed?				
M2 4.3.2.2	b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements?				
M2 4.3.2.2	c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?				
M2 4.3.2.2	d) obsolete documents retained for either legal or knowledge presentation purposes are suitable marked?				
M2 4.3.2.2	e) Are affected personnel notified of changes to management systems documents and supporting procedures, including technical documents?				
M2 4.3.2.2	f) Are reviews (internal or external) of management system documentation maintained and made available for assessment?				
M2 4.3.2.2	g) Are any documents providing instructions to laboratory personnel (e.g., operator aids) considered part of the management system and are subject to document control procedures?				
M2 4.3.2.3	Are management system documents generated by the laboratory uniquely identified?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.3.2.3	Does this identification include:				
M2 4.3.2.3	• the date of issue and/or revision identification?				
M2 4.3.2.3	• page numbering?				
M2 4.3.2.3	• the total number of pages or a mark to signify the end of the document?				
M2 4.3.2.3	• the issuing authority(ies)?				
M2 4.3.3	**Document Changes**				
M2 4.3.3.1	Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise?				
M2 4.3.3.1	Does designated personnel have access to pertinent background upon which to base their review and approval?				
M2 4.3.3.2	Where practicable, is altered or new text identified in the document or the appropriate attachments?				
M2 4.3.3.3	If the laboratory's document control system allows for the amendment of documents by hand, pending the re-issue of the documents, are their procedures and authorities for such amendments defined?				
M2 4.3.3.3	Are amendments to documents clearly marked, initialed and dated?				
M2 4.3.3.3	Is a revised document formally re-issued as soon as practicable?				
M2 4.3.3.4	Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?				
M2 4.4	**Review of Requests, Tenders and Contracts**				
M2 4.4 Grey Box 7	(ISO/IEC 17025:2017 7.1.3) When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g., pass/fail, in-tolerance/out-of-tolerance), is the specification or standard and the decision rule clearly defined? Note: For further guidance on statements of conformity, see ISO/IEC Guide 98-4.				
M2 4.4 Grey Box 7	(ISO/IEC 17025:2017 7.1.3) Unless inherent in the requested specification or standard, is the decision rule selected communicated to, and agreed with, the customer?				
M2 4.4.1	Has the laboratory established and maintained procedures for the review of requests, tenders and contracts?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.4.1	Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that:				
M2 4.4.1	a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2)?				
M2 4.4.1	b) the laboratory has the capability and resources to meet the requirements?				
M2 4.4.1	c) the appropriate test and/or calibration method is selected and is capable of meeting the customer's requirements (see 5.4.2)?				
M2 4.4.1	Are any differences between the request or tender and the contract resolved before any work commences?				
M2 4.4.1	Is each contract acceptable both to the laboratory and the customer?				
M2 4.4.1	Note1: The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.				
M2 4.4.1	Note2: The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or PT and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.				
M2 4.4.1	Note3: A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.				
M2 4.4.2	Are records of reviews maintained, including any significant changes?				
M2 4.4.2	Are records of reviews also maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.4.2	Note: For review of routine and other simple tasks, the date and the identification (e. g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced environmental testing and/or calibration tasks, a more comprehensive record should be maintained.				
M2 4.4.3	Does the review cover any work that is subcontracted by the laboratory?				
M2 4.4.4	Is the customer informed of any deviation from the contract?				
M2 4.4.4 Grey Box 8	(ISO/IEC 17025:2017 7.1.4) Are any differences between the request or tender and the contract resolved before the laboratory activities commence?				
M2 4.4.4 Grey Box 8	(ISO/IEC 17025:2017 7.1.4) Is each contract acceptable both to the laboratory and the customer?				
M2 4.4.4 Grey Box 8	(ISO/IEC 17025:2017 7.1.4) Do deviations requested by the customer not impact the integrity of the laboratory or the validity of the results?				
M2 4.4.4.1	Are waivers from QSM requirements requested in writing from the appropriate DoD or DOE Chemist or Contractor Project Chemist (however named) on a project-specific basis and does it include technical justification relating to the specific project for the waiver. Is documentation of approval for the waiver maintained by the laboratory and is it readily available for review?				
M2 4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated ?				
M2 4.4.5	Are any contract amendments communicated to all affected personnel?				
M2 4.5	**Subcontracting of Environmental Tests**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.5 Grey Box 9	(ISO/IEC 17025:2017 6.6.1) Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products services: (a) are intended for incorporation into the laboratory's own activities; (b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; (c) are used to support the operation of the laboratory?				
M2 4.5 Grey Box 9	(ISO/IEC 17025:2017 6.6.1 Note): Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.				
M2 4.5 Grey Box 9	(ISO/IEC 17025:2017 6.6.2) Does the laboratory have a procedure and retain records for:				
M2 4.5 Grey Box 9	a) defining, reviewing and approving the laboratory's requirements for externally provided products and services?				
M2 4.5 Grey Box 9	b) defining the criteria for evaluation, selection, monitoring and performance and re-evaluation of the external providers?				
M2 4.5 Grey Box 9	c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of the standard, before they are used or directly provided to the customer?				
M2 4.5 Grey Box 9	d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers?				
M2 4.5 Grey Box 9	(ISO/IEC 17025:2017 6.6.3) Does the laboratory communicate its requirements to external providers for:				
M2 4.5 Grey Box 9	(ISO/IEC 17025:2017 7.1.1.c) Does the laboratory procedure ensure that, where external providers are used, the requirements of ISO/IEC 17025:2017, section 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.5 Grey Box 9	(ISO/IEC 17025:2017 7.1.1.c) Note: It is recognized that externally provided laboratory activities occur when: - the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full; - the laboratory does not have the resources or competence to perform the activities.				
M2 4.5	a) the products and services to be provided?				
M2 4.5	b) the acceptance criteria?				
M2 4.5	c) competence, including any required qualification of personnel?				
M2 4.5	d) activities that the laboratory, or its customer, intends to perform at the external provider's premises?				
M2 4.5.1	When a laboratory subcontracts work, whether because of unforeseen reasons (workload, need for further expertise or temporary incapacity) or on a continuing basis (permanent subcontracting, agency or franchising arrangements), is this work placed with a competent subcontractor (for example, complies with this standard for the work in question)?				
M2 4.5.2	Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer preferably in writing?				
M2 4.5.3	Does the laboratory accept responsibility to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specified which subcontract was to be used?				
M2 4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations?				
M2 4.5.4	Does the laboratory maintain a record of evidence of compliance with this standard for the work in question?				
M2 4.5.5	When a laboratory subcontracts work, is the work placed with a laboratory accredited to this standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed?				
M2 4.5.5	Is the laboratory performing the subcontracted work indicated in the final report?				
M2 4.5.5	Is a copy of the subcontractor’s report available when requested?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.5.6	Does the laboratory ensure and document that subcontracted (sub-tier) laboratories meet the requirements of this standard?				
M2 4.5.7	Are subcontracted laboratories performing analytical services accredited in accordance with the the project?				
M2 4.5.8	Do subcontracted laboratories receive project-specific approval from the DoD or DOE customer before any samples are analyzed?				
M2 4.5.9	Are the requirements for subcontracting laboratories also applied to the use of any laboratory under the same corporate umbrella, but at a different facility or location?				
M2 4.5.10	Do all subcontracted or outsourced management systems elements (such as data review, data processing, project management, and IT support) or outsourced personnel: - comply with the laboratory's overall management system, - comply with the requirements of this standard, and - receive prior written approval and authorization from the DoD/DOE customer?				
M2 4.6	**Purchasing Services and Supplies**				
M2 4.6 Grey Box 10	Note: The ISO/IEC 17025:17025, sections 6.6 and 7.1.1 c requirements identified in M2 4.5 above also apply to clause 4.6.				
M2 4.6.1	Does the laboratory have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations?				
M2 4.6.1	Do procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations?				
M2 4.6.1	Do records for services and supplies that may affect the quality of environmental tests include the following, where applicable: Guidance: Examples of services and supplies that may affect the quality of environmental tests include but are not limited to: balance or pipette calibration, solvents, standards, reagents, and sample containers.				
M2 4.6.1	a) Date of receipt?				
M2 4.6.1	b) Expiration date?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.6.1	c) Source?				
M2 4.6.1	d) Lot or serial number?				
M2 4.6.1	e) Calibration and verification records?				
M2 4.6.1	f) Accreditation or certification scopes/certificates?				
M2 4.6.1	g) date opened?				
M2 4.6.2	Does the laboratory ensure that purchased supplies and reagents and consumable materials that affect quality or tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned?				
M2 4.6.2	Are the services and supplies used compliant with specified requirements?				
M2 4.6.2	Are records maintained of action taken to check compliance?				
M2 4.6.3	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered?				
M2 4.6.3	Are these purchasing documents reviewed and approved for technical content prior to release?				
M2 4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration?				
M2 4.6.4	Are records maintained of the supplier evaluations?				
M2 4.6.4	Is a list of approved suppliers maintained?				
M2 4.7	**Service to the Client**				
M2 4.7.1	Does the laboratory afford customers or their representative's cooperation to clarify the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.7.1	DoD/DOE Clarification: Examples of situations for which immediate clarification or feedback shall be sought from the customer include the following: a) the customer has specified incorrect, obsolete, or improper methods; b) methods require modifications to ensure achievement of project-specific objectives contained in planning documents (e.g., difficult matrix, poor performing analyte); c) project planning documents (e.g., QAPP or Sampling and Analysis Plan (SAP)) are missing or requirements (e.g., action levels, detection and quantification capabilities) in the documents require clarification; or d) the laboratory has encountered problems with sampling or analysis that may impact results (e.g., improper preservation of sample).				
M2 4.7.1	Note1: Such cooperation may include: a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer; b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.				
M2 4.7.1	Note2: Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.				
M2 4.7.2	Does the laboratory seek feedback, both positive and negative, from its customers?				
M2 4.7.2	Is the feedback used and analyzed to improve the management system, testing and calibration activities and customer service?				
M2 4.7.2	Note: Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.				
M2 4.8	**Complaints**				
M2 4.8	Does the laboratory have a policy and procedure for the resolution of complaints received from customers or other parties?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.8	Are records maintained of all complaints and of the investigations and corrective actions taken (see also 4.11)?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.2) Is a description of the handling process for complaints available to any interested party upon request?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.2) Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to the laboratory activities that it is responsible for and, if so, deal with it?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.2) Is the laboratory responsible for all decisions at all levels of the handling process for complaints?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.3) Does the process for handling complaints include at least the following elements and methods?				
M2 4.8 Grey Box 11	a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it?				
M2 4.8 Grey Box 11	b) tracking and recording complaints, including aactions undertaken to resolve them?				
M2 4.8 Grey Box 11	c) ensuring that any appropriate action is taken?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.4) Is the laboratory receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.5) Wherever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.6) Are the outcomes to be communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original labortory activities in question? Note: This can be performed by external personnel.				
M2 4.8 Grey Box 11	(ISO/IEC 17025:2017 7.9.7) Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant?				
M2 4.9	**Control of Nonconforming Environmental Testing Work**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.9.1 Grey Box 12	(ISO/IEC 17025:2017 7.10.1) Does the laboratory have a procedure that is implemented when any aspect of its laboratory activities or results of this work do not confirm to its own procedure or the agreed requirement of the customer (e.g., equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)?				
M2 4.9.1	Does the laboratory procedure ensure that:				
M2 4.9.1	a) the responsibilities and authorities for the management of nonconforming work are defined?				
M2 4.9.1	b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory?				
M2 4.9.1	c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results?				
M2 4.9.1	d) a decision is taken on the acceptability of the nonconforming work?				
M2 4.9.1	e) where necessary, the customer is notified and work is recalled?				
M2 4.9.1	f) the responsibility for authorizing the resumption of work is defined?				
M2 4.9.1 Grey Box 12	(ISO/IEC 17025:2017 7.10.2) Does the laboratory retain records of nonconforming work and actions as specified in ISO/IEC 17025:2017, section 7.10.1, bullets b) to f), above?				
M2 4.9.1	Does the laboratory have a policy and procedures that are implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer?				
M2 4.9.1	Do the policy and procedures for nonconforming work ensure that:				
M2 4.9.1	a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified?				
M2 4.9.1	b) an evaluation of the significance of the nonconforming work is made?				
M2 4.9.1	c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work?				
M2 4.9.1	d) where necessary, the customer is notified and work is recalled?				
M2 4.9.1	e) the responsibility for authorizing the resumption of work is defined?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.9.1	Note: Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.				
M2 4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are the corrective action procedures given in 4.10 promptly followed?				
M2 4.9.3	Does the laboratory upon discovery, notify all affected customers of potential data quality issues resulting from nonconforming work within fifteen (15) business days?				
M2 4.9.3	Is a notification performed according to a written procedure?				
M2 4.9.3	Are records of corrections taken to resolve the nonconformance submitted to the customer(s) within thirty (30) business days of discovery?				
M2 4.9.4	Does the laboratory report any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7, to the AB within fifteen (15) business days of discovery? **See also M2 4.16 and 4.14.2** Note: Discovery includes findings of such inappropriate practices by laboratory staff or customer stakeholders.				
M2 4.9.4	Does the laboratory submit records of associated corrections taken or proposed corrective actions to the AB within thirty (30) business days of discovery? Note: Rev 5.1.1 requirement revision failed to remove "DoD ELAP Laboratories". Since rest of requirement incorporated both DoD and DOECAP, this requirement should have, too.				
M2 4.9.4	Note1: The respective AB will then have the responsibility of informing the EDQW and ASPM of the laboratory's deviation from the requirements of the QSM.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.9.4	Note2: If the AB is not notified within fifteen (15) business days, the AB will immediately suspend the laboratory's DoD ELAP accreditation and/or their DOECAP-AP accreditation, as applicable. The respective ABs, DOE, and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties.				
M2 4.10	**Improvement**				
M2 4.10	Has the laboratory continually improved the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?				
M2 4.11	**Corrective Action**				
M2 4.11 Grey Box 13	(ISO/IEC 17025:2017 8.7.1) When a nonconformity occurs, does the laboratory:				
M2 4.11 Grey Box 13	a) react to the nonconformity and, as applicable: - take action to control and correct it; - address the consequences?				
M2 4.11 Grey Box 13	b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: - reviewing and analyzing the nonconformity; - determining the causes of the nonconformity; - determining if similar nonconformities exist, or could potentially occur?				
M2 4.11 Grey Box 13	e) update risks and opportunities determined during planning, if necessary?				
M2 4.11 Grey Box 13	f) make changes to the management system, if necessary?				
M2 4.11.1	Does the laboratory have an established policy and procedure for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified?				
M2 4.11.1	Has the laboratory designated appropriate authorities for implementing corrective action in the above situations?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.11.1	Note: A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, and feedback from customers and from staff observations.				
M2 4.11.2	**Cause Analysis**				
M2 4.11.2	Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?				
M2 4.11.2	Note: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.				
M2 4.11.3	**Selection and Implementation of Corrective Actions**				
M2 4.11.3	Where corrective action is needed, does the laboratory identify potential corrective actions?				
M2 4.11.3	Does the laboratory select and implement the action(s) most likely to eliminate the problem and prevent recurrence?				
M2 4.11.3	Are corrective actions made to a degree appropriate to the magnitude and the risk of the problem?				
M2 4.11.3	Does the laboratory document and implement any required changes resulting from corrective action investigations?				
M2 4.11.4	**Monitoring of Corrective Actions**				
M2 4.11.4	Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?				
M2 4.11.5	**Additional Audits**				
M2 4.11.5	Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.11.5	Note: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.				
M2 4.11.6	Does the laboratory documented procedure(s) address 4.11.1 and 4.11.3 through 4.11.5?				
M2 4.11.6	Do the procedure(s) include:				
M2 4.11.6	a) Which individual(s) or positions are responsible for assessing each QC data type?				
M2 4.11.6	b) Which individual(s) or positions are responsible for initiating and/or recommending corrective actions?				
M2 4.11.7	Does the cause analysis described in Section 4.11.2 apply to failures that indicate a systematic error?				
M2 4.11.8 Grey Box 14	(ISO/IEC 17025:2017 8.7.3) Does the laboratory retain records as evidence of:				
M2 4.11.8 Grey Box 14	a) the nature of the nonconformities, cause(s) and any subsequent actions taken?				
M2 4.11.8 Grey Box 14	b) the results of any corrective action?				
M2 4.11.8	Does the laboratory have and use a record system for tracking corrective actions to completion and for analyzing trends to prevent the recurrence of the nonconformance?				
M2 4.11.8	Are corrective actions developed to address findings during DoD ELAP or DOECAP-AP assessments implemented?				
M2 4.11.8	DoD/DOE Guidance: Willful avoidance of approved corrective action implementation may result in loss of accreditation. As a result, work may be discontinued until implementation is verified by the DoD ELAP AB or DOECAP-AP AB, as appropriate.				
M2 4.11.8	Are corrective actions developed to address findings during DoD ELAP or DOECAP-AP assessments implemented?				
M2 4.11.8	Are any changes to reviewed corrective action plans approved by the DoD ELAP AB or the ASPM, as appropriate?				
M2 4.12	**Preventive Action**				
M2 4.12 Grey Box 15	(ISO/IEC 17025:2017 8.5.1) Does the laboratory consider the risks and opportunities associated with the laboratory activities in order to:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.12 Grey Box 15	a) give assurance that the management system achieves its intended results?				
M2 4.12 Grey Box 15	b) enhance opportunities to achieve the purpose and objectives of the laboratory?				
M2 4.12 Grey Box 15	c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities?				
M2 4.12 Grey Box 15	d) achieve improvement?				
M2 4.12 Grey Box 15	(ISO/IEC 17025:2017 8.5.2) Does the laboratory plan:				
M2 4.12	a) actions to address these risks and opportunities?				
M2 4.12	b) how to: - integrate and implement these actions into its management system; - evaluate the effectiveness of these actions?				
M2 4.12 Grey Box 15	(ISO/IEC 17025:2017 8.5.2) Note: Although the standard specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this standard, e.g., through the application of other guidance or standards.				
M2 4.12 Grey Box 15	(ISO/IEC 17025:2017 8.5.3) Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results.				
M2 4.12 Grey Box 15	(ISO/IEC 17025:2017 8.5.3) Note1: Options to address risks can include identifying and avoiding threats, taking risks in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.				
M2 4.12 Grey Box 15	(ISO/IEC 17025:2017 8.5.3) Note2: Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.				
M2 4.12.1	Are needed improvements and potential sources of nonconformities, either technical or concerning the management system, identified?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.12.1	When improvement opportunities are identified or if preventive action is required, are action plans developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement?				
M2 4.12.1	Are records of preventive actions maintained for review?				
M2 4.12.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?				
M2 4.12.2	Note1: Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.				
M2 4.12.2	Note2: Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.				
M2 4.13	**Control of Records**				
M2 4.13.1.1	Has the laboratory established and maintained procedures for: - identification? - collection? - indexing? - access? - filing? - storage? - maintenance? - disposal? of quality and technical records.				
M2 4.13.1.1	Do the quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?				
M2 4.13.1.2	Are all records:				
M2 4.13.1.2	• legible?				
M2 4.13.1.2	• retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?				
M2 4.13.1.2	Are the retention times of records established?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.1.2	DoD/DOE Clarification: Dual storage of records at separate locations is considered an acceptable option for the purpose of protecting records against fire, theft, or loss.				
M2 4.13.1.2	Note: Records may be in any media, such as hard copy or electronic media.				
M2 4.13.1.3	Are all records held secure and in confidence?				
M2 4.13.1.4	Does the laboratory have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records?				
M2 4.13.2	**Technical Records**				
M2 4.13.2 Grey Box 16	(ISO/IEC 17025:2017 7.5.2) Does the laboratory ensure that amendments to technical records can be tracked to previous versions or to the original observations?				
M2 4.13.2 Grey Box 16	(ISO/IEC 17025:2017 7.5.2) Are both the original and amended data and files retained, including the date of alteration, and indication of the altered aspects and the personnel responsible for the alterations?				
M2 4.13.2.1	Does the laboratory retain the following records for a defined period: - original observations? - derived data? - sufficient information to establish an audit trail? - calibration records? - staff records? - a copy of each test report or calibration certificate issued?				
M2 4.13.2.1	Do the records for each test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original?				
M2 4.13.2.1	Do the records include the identity of personnel responsible for the - sampling? - performance of each test and/or calibration? - and checking of results?				
M2 4.13.2.1	Note1: In certain fields it may be impossible or impractical to retain records of all original observations.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.2.1	Note2: Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.				
M2 4.13.2.2	Are observations, data and calculations: - recorded at the time they are made? - identifiable to the specific task?				
M2 4.13.2.3	When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and the correct value entered alongside?				
M2 4.13.2.3	Are all such alterations to records signed or initialed by the person making the correction?				
M2 4.13.2.3	In the case of electronic records, are equivalent measures taken to avoid loss or change of original data?				
M2 4.13.3	**Additional Requirements**				
M2 4.13.3	a) Has the laboratory established a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation?				
M2 4.13.3	a) Does the system produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts?				
M2 4.13.3	b) Does the laboratory retain all records for a minimum of five (5) years from generation of the last entry in the records?				
M2 4.13.3	c) Are records available to the accreditation body?				
M2 4.13.3	d) Are records that are stored only on electronic media supported by the hardware and software necessary for their retrieval?				
M2 4.13.3	e) Is the access to archived information documented with an access log?				
M2 4.13.3	f) Does the laboratory maintain the following information necessary for the historical reconstruction of data:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.3	i. all raw data, whether hard copy or electronic, for calibrations, samples and quality control measures including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records)?				
M2 4.13.3	ii. a written description or reference to the specific method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value?				
M2 4.13.3	iii. laboratory sample ID code?				
M2 4.13.3	iv. date of analysis?				
M2 4.13.3	v. time of analysis if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations)?				
M2 4.13.3	vi. Instrumentation identification and instrument operating conditions/parameters (or Reference to such data)?				
M2 4.13.3	vii. all manual calculations?				
M2 4.13.3	viii. Analyst's or operator's initials/signature or electronic identification?				
M2 4.13.3	ix. sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents?				
M2 4.13.3	x. test results?				
M2 4.13.3	xi. standard and reagent origin, receipt, preparation, and use?				
M2 4.13.3	xii. calibration criteria, frequency and acceptance criteria?				
M2 4.13.3	xiii. data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions?				
M2 4.13.3	xiv. quality control protocols and assessment?				
M2 4.13.3	xv. electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries?				
M2 4.13.3	xvi. method performance criteria including expected quality control requirements?				
M2 4.13.3	xvii. proficiency test results?				
M2 4.13.3	xviii. records of demonstration of capability for each analyst?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.3	xix. a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record?				
M2 4.13.3	g) Are all generated data, except those that are generated by automated data collection systems, recorded legibly in permanent ink?				
M2 4.13.3	i. Is the individual making corrections to records recording date and initials to the correction?				
M2 4.13.3	ii. Do corrections due to reasons other than transcription errors specify the reason for the correction?				
M2 4.13.3	iii) Do records for changes made to data (either hardcopy or electronic) include the identification of the person who made the change and the date of change?				
M2 4.13.3	h) Does the laboratory have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business?				
M2 4.13.3	h) Are appropriate regulatory and state legal requirements concerning laboratory records followed?				
M2 4.13.4	Do the permanent, bound laboratory notebooks (logbooks) or notebooks have measures in place to prevent the removal or addition of pages?				
M2 4.13.4	Do the permanent, bound logbooks, does the laboratory have:				
M2 4.13.4	a) Pre-numbered laboratory notebook pages?				
M2 4.13.4	a) All entries signed or initialed and dated by the person responsible for performing the activity at the time the activity is performed?				
M2 4.13.4	a) All entries recorded in chronological order?				
M2 4.13.4	b) All notebook pages closed when the activities recorded are completed or carried over to another page?				
M2 4.13.4	b) The person responsible for performing the closure be the one who performed the last activity recorded?				
M2 4.13.4	b) Closure occur at the end of the last activity recorded on a page, as soon as practicable, thereafter. Note: Satisfactory records of closure include analyst initials and date.				
M2 4.13.4	c) Does each laboratory notebook have a unique serial number clearly displayed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.5	Does the laboratory have procedures for the independent review of technical and quality records to ensure they are legible, accurate, and complete?				
M2 4.13.6	Has the laboratory established a review frequency for all records such as laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, verification, validation, and archival?				
M2 4.13.6	Are records of the reviews maintained and made available for review?				
M2 4.13.7	If not self-explanatory (e.g., a typo or transposed number), do corrections to technical and quality records include a justification for the change?				
M2 4.13.8	Does the records control system SOP address the requirements for access to and control of the files including accountability for any records removed from storage?				
M2 4.13.9	Are all SOPs archived for historical reference, per regulatory or customer requirements?				
M2 4.13.9	Does the laboratory have a procedure for permanent laboratory closure and disposal of any remaining records associated with DoD/DOE analytical data.				
M2 4.14	**Internal Audits**				
M2 4.14 Grey Box 17	(ISO/IEC 17025:2017 8.8.2) Does the laboratory:				
M2 4.14 Grey Box 17	a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits?				
M2 4.14 Grey Box 17	b) define the audit criteria and scope for each audit?				
M2 4.14 Grey Box 17	c) ensure that the results of the audits are reported to relevant management?				
M2 4.14 Grey Box 17	d) implement appropriate correction and corrective actions without undue delay?				
M2 4.14 Grey Box 17	e) retain records as evidence of the implementation of the audit programme and the audit results?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.14 Grey Box 17	Note: ISO 19011 provides guidance for internal audits.				
M2 4.14.1	Does the laboratory periodically, in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this standard?				
M2 4.14.1	Note: The cycle for internal auditing should normally be completed in one year.				
M2 4.14.1	Does the internal audit program address all elements of the management system, including the testing and/or calibration activities?				
M2 4.14.1	Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management?				
M2 4.14.1	Are such audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited?				
M2 4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, does the laboratory take timely corrective action?				
M2 4.14.2	Does the laboratory notify customers in writing if investigations show that the laboratory results may have been affected?				
M2 4.14.2	Does the laboratory notify DoD/DOE clients within fifteen (15) business days of discovery of any investigation that casts doubt upon the validity of test results?				
M2 4.14.3	Are the following recorded? - area of activity audited? - audit findings? - corrective actions that arise?				
M2 4.14.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?				
M2 4.14.5	a) Does the laboratory have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results?				
M2 4.14.5	b) Does the laboratory management ensure that these actions are discharged within the agreed time frame?				
M2 4.14.5	c) Is the Internal audit schedule completed annually?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.14.6	Does the audit schedule ensure that all areas of the laboratory are reviewed over the course of one year?				
M2 4.14.6	Does the review include both technical and quality systems areas?				
M2 4.14.6	Does the review include raw electronic data files derived from test reports?				
M2 4.14.7	Are audit personnel trained and qualified in the specific management system element or technical area under review?				
M2 4.14.7	Has the laboratory determined the training and qualification requirements for audit personnel, including quality managers?				
M2 4.14.7	Has the laboratory established procedures to ensure that audit personnel are trained and qualified (i.e., have the necessary education or experience required for their assigned positions)?				
M2 4.14.7	Are these requirements and procedures recorded?				
M2 4.14.8	Does Management ensure that sufficient resources are available so that all internal audits are conducted by personnel independent of the activity to be audited?				
M2 4.14.8	Do personnel conducting independent assessments have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management?				
M2 4.15	**Management Reviews**				
M2 4.15 Grey Box 18	(ISO/IEC 17025:2017 8.9.2) Are the inputs to management review recorded?				
M2 4.15 Grey Box 18	(ISO/IEC 17025:2017 8.9.2) Do the inputs to management review include information related to the following?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.15 Grey Box 18	a) changes in internal and external issues that are relevant to the laboratory? b) fulfilment of objectives? c) suitability of policies and procedures? d) status of actions from previous management reviews? e) outcome of recent internal audits? f) corrective actions g) assessments by external bodies? h) changes in the volume and type of the work or in the range of laboratory activities? i) customer and personnel feedback? j) complaints? j) complaints? k) effectiveness of any implemented improvements? l) adequacy of resources? m) results of risk identification? n) outcomes of the assurance of the validity of results? o) any need for change?				
M2 4.15 Grey Box 18	(ISO/IEC 17025:2017 8.9.3) Are the outputs from the management review recorded?				
M2 4.15 Grey Box 18	(ISO/IEC 17025:2017 8.9.3) Do the outputs include all decisions and actions related to at least:				
M2 4.15 Grey Box 18	a) the effectiveness of the management system and its processes?				
M2 4.15 Grey Box 18	b) improvement of the laboratory activities related to the fulfilment of the requirements of the standard?				
M2 4.15 Grey Box 18	c) provision of required resources?				
M2 4.15 Grey Box 18	d) any need for change?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.15.1	In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?				
M2 4.15.1	DoD/DOE Clarification: Management reviews and internal audits are separate activities. The management review shall not be performed in lieu of an internal audit. It is an independent, executive review of the laboratory's management system.				
M2 4.15.1	Does the review take account of: - the suitability of policies and procedures? - reports from managerial and supervisory personnel? - the outcome of recent internal audits? - corrective and preventive actions? - assessments by external bodies? - the results of inter-laboratory comparisons or proficiency tests? - changes in the volume and type of work? - customer feedback? - complaints? - recommendations for improvement? - other relevant factors, such as quality control activities, resources and staff training?				
M2 4.15.1	Do management reviews also include laboratory radiation health and safety, radioactive hazardous waste, and radioactive materials management functions, where applicable (i.e., when radioactive samples are analyzed)?				
M2 4.15.1	Note1: A typical period for conducting a management review is once every 12 months.				
M2 4.15.1	Note2: Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.				
M2 4.15.1	Note3: A management review includes consideration of related subjects at regular management meetings.				
M2 4.15.2	Are findings from management reviews and the actions that arise from them recorded?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.15.2	Does management ensure that those actions are carried out within an appropriate and agreed timescale?				
M2 4.15.3	Is the Management review completed on an annual basis?				
M2 4.16	**Data Integrity Investigations**				
M2 4.16	Are all investigations resulting from data integrity issues conducted in a confidential manner until they are completed?				
M2 4.16	Are these investigations documented, as well as any notifications made to clients receiving any affected data.				
M2 4.16	Does the laboratory report any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7, to their AB within fifteen (15) business days of discovery? **See also M2 4.9.4 and 4.14.2** Note: Discovery includes findings of such inappropriate practices by laboratory staff or customer stakeholders.				
M2 4.16	Does the laboratory submit records of associated corrections taken or proposed corrective actions to their AB within thirty (30) business days of discovery?				
M2 4.16	Note: The AB will then have the responsibility of informing the EDQW (for DoD-ELAP) and/or ASPM (for DOECAP-AP) of the laboratory's deviation from the requirements of the QSM. The AB, DOE, and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties.				
M2 5.0	**TECHNICAL REQUIREMENTS**				
M2 5.1	**General**				
M2 5.1 Grey Box 19	(ISO/IEC 17025:2017 6.1) Does the laboratory have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.1.1	Does the laboratory determine correctness and reliability of the environmental tests include contributions from: - human factors (5.2)? - accommodation and environmental conditions (5.3)? - test and calibration methods and method validation (5.4)? - equipment (5.5)? - measurement traceability (5.6)? - sampling (5.7)? - the handling of test and calibration items (5.8)?				
M2 5.1.2	Does the laboratory take account of the factors that contribute to the total uncertainty of measurement in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses?				
M2 5.2	**Personnel**				
M2 5.2 Grey Box 20	(ISO/IEC 17025:2017 6.2.1) Do all personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system?				
M2 5.2 Grey Box 20	(ISO/IEC 17025:2017 6.2.2) Does the laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience?				
M2 5.2 Grey Box 20	(ISO/IEC 17025:2017 6.2.3) Does the laboratory ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations?				
M2 5.2 Grey Box 20	(ISO/IEC 17025:2017 6.2.4) Does management of the laboratory communicate to personnel their duties, responsibilities and authorities?				
M2 5.2 Grey Box 20	(ISO/IEC 17025:2017 6.2.5) Does the laboratory have procedure(s) and retain records for:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2 Grey Box 20	a) determining the competence requirements? b) selection of personnel? c) training of personnel? d) supervision of personnel? e) authorization of personnel? f) monitoring competence of personnel?				
M2 5.2 Grey Box 20	(ISO/IEC 17025:2017 6.2.6) Does the laboratory authorize personnel to perform specific laboratory activities, including but not limited to, the following?				
M2 5.2 Grey Box 20	a) development, modification, verification and validation of methods? b) analysis of results, including statements of conformity or opinions and interpretations? c) report, review and authorization of results?				
M2 5.2.1	Does the laboratory management ensure the competence of all who: - operate specific equipment? - perform tests and/or calibrations? - evaluate results? - sign test reports and calibration certificates?				
M2 5.2.1	When using staff undergoing training, is appropriate supervision provided?				
M2 5.2.1	Are those personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required?				
M2 5.2.1	Note1: In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.1	Note2: The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: - relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; - knowledge of the general requirements expressed in the legislation and standards; and - an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.				
M2 5.2.2	Does the management formulate goals with respect to the education, training and skills of the laboratory personnel?				
M2 5.2.2	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?				
M2 5.2.2	Does the laboratory have a training program relevant to the present and anticipated tasks of the laboratory?				
M2 5.2.2	Is the effectiveness of the training actions taken evaluated?				
M2 5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory?				
M2 5.2.3	DoD/DOE Clarification: The laboratory shall ensure that all personnel, including part-time, temporary, contracted, and administrative personnel, are trained in the basic laboratory quality assurance (QA) and health and safety programs.				
M2 5.2.3	Where contracted and additional technical and key support personnel are used, does the laboratory ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system?				
M2 5.2.4	Does the laboratory maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.4	Note: Job descriptions can be defined in many ways. As a minimum, the following should be defined: - the responsibilities with respect to performing tests and/or calibrations; - the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results; - the responsibilities for reporting opinions and interpretations; - the responsibilities with respect to method modification and development and validation of new methods; - expertise and experience required; - qualifications and training programs; - managerial duties.				
M2 5.2.4	Are the job description elements itemized in the note above for 5.2.4 minimum requirements?				
M2 5.2.5	Does management authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment?				
M2 5.2.5	Does the laboratory maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel?				
M2 5.2.5	Is this information readily available and include the date on which authorization and/or competence was confirmed?				
M2 5.2.5	Note: All references to Calibration Certificates in ISO/IEC 17025:2005(E) are not applicable to environmental testing.				
M2 5.2.6	**Additional Personnel Requirements**				
M2 5.2.6.1	**Technical Manager Qualifications**				
M2 5.2.6.1	Does the laboratory meet the applicable requirements for technical managers as listed below?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.6.1	a) Any technical manager of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.				
M2 5.2.6.1	b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis.				
M2 5.2.6.1	c) Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.6.1	d) Any technical manager of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor's degree in chemistry, environmental, biological sciences, physical sciences or engineering with twenty-four (24) college semester credit hours of chemistry with two (2) or more years of experience in the radiological analysis of environmental samples. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.				
M2 5.2.6.1	e) The technical manager(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements?				
M2 5.2.6.1	i. For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of courses in the use of the instrument, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.				
M2 5.2.6.1	ii. For procedures requiring the use of a polarized light microscope, an associate's degree or two (2) years of college study, successful completion of formal coursework in polarized light microscopy, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.				
M2 5.2.6.1	iii. For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two (2) years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one (1) year of experience, under supervision, in the use of the instrument.				
M2 5.2.6.1	f) Any technical manager of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate's degree or two (2) years of college and one (1) year of experience in radiation measurements, including at least one (1) year of experience in the measurement of radon and/or radon progeny.				
M2 5.2.6.2	**Technical Manager Qualification Exceptions**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.6.2	a) Notwithstanding any other provision of this Section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational requirements as the technical manager. A technical manager shall have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.				
M2 5.2.6.2	b) A full-time employee of an industrial waste treatment facility with a minimum of two (2) years of experience under supervision in testing of environmental samples taken within such facility for the scope of that facility's regulatory permit shall be deemed to meet the requirements for serving as the technical manager of an accredited laboratory. Such accreditation for an industrial waste treatment facility shall be limited to the scope of that facility's regulatory permit.				
M2 5.2.6.2	c) Persons who do not meet the education credential requirements but possess the requisite experience of Section 5.2.6.1 shall qualify as technical manager(s) subject to the following conditions.				
M2 5.2.6.2	i. The person shall be a technical manager of the laboratory on the date the laboratory applies for accreditation and/or becomes subject to accreditation under this Standard, and shall have been a technical manager in that laboratory continuously for the previous twelve (12) months or more.				
M2 5.2.6.2	ii) The person will be approved as a technical manager for only those fields of accreditation for which he/she has been technical manager in that laboratory for the previous twelve (12) months or more.				
M2 5.2.6.2	iii. A person who is admitted as a technical manager under these conditions, and leaves the laboratory, will be eligible for hire as a technical manager for the same fields of accreditation in another accredited laboratory.				
M2 5.2.7	**Data Integrity Training**				
M2 5.2.7	Is data integrity training provided as a formal part of new employee and is it provided on an annual basis for all current employees?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.7	Are employees required to understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution?				
M2 5.2.7	Does the initial data integrity training and the annual refresher training have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity?				
M2 5.2.7	Does data integrity training require emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient?				
M2 5.2.7	Are the topics covered in such training documented in writing (such as an agenda) and provided to all trainees?				
M2 5.2.7	At a minimum, are the following topics and activities included:				
M2 5.2.7	a) organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping?				
M2 5.2.7	b) training, including discussion regarding all data integrity procedures?				
M2 5.2.7	c) data integrity training documentation?				
M2 5.2.7	d) in-depth data monitoring and data integrity procedure documentation?				
M2 5.2.7	e) specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards?				
M2 5.2.7	The data integrity procedures may also include written ethics agreements, examples of improper practices, examples of improper chromatographic manipulations, requirements for external ethics program training, and any external resources available to employees.				
M2 5.2.7.1	Does top management acknowledge its support for data integrity by implementing the specific requirements of the laboratory's data integrity program?				
M2 5.2.7.1	To facilitate the implementation of this program, are following practices prohibited:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.7.1	a) Fabrication, falsification, or misrepresentation of data?				
M2 5.2.7.1	i. Creating data for an analysis that was not performed (dry lab)?				
M2 5.2.7.1	ii. Creating information for a sample that was not collected (dry lab)?				
M2 5.2.7.1	iii. Using external analysts, equipment, and/or laboratories to perform analyses when not allowed by contract?				
M2 5.2.7.1	b) Improper clock setting (time traveling) or improper date/time recording?				
M2 5.2.7.1	i. Resetting the internal clock on an instrument to make it appear that a sample was analyzed within holding time when in fact it was not?				
M2 5.2.7.1	ii. Changing the actual time or recording a false time to make it appear that holding times were met, or changing the times for sample collection, extractions or other steps to make it appear that holding times were met?				
M2 5.2.7.1	c) Unwarranted manipulation of samples, software, or analytical conditions?				
M2 5.2.7.1	i. Unjustified dilution of samples?				
M2 5.2.7.1	ii. Manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria?				
M2 5.2.7.1	iii. Changing the instrument conditions for sample analysis from the conditions used for standard analysis (e.g., changing EM voltage)?				
M2 5.2.7.1	iv. Unwarranted manipulation of computer software (e.g., forcing calibration or QC data to meet criteria, removing computer operational codes such as the M" flag, inappropriately subtracting background, or improperly manipulating the chromatographic or spectrophotometric baseline)?				
M2 5.2.7.1	v. Turning off, or otherwise disabling, electronic instrument audit/tracking functions?				
M2 5.2.7.1	d) Misrepresenting or misreporting field or QC samples?				
M2 5.2.7.1	i. Representing spiked samples as being digested or extracted when this has not been done?				
M2 5.2.7.1	ii. Substituting previously generated runs for a non-compliant calibration or QC run to make it appear that an acceptable run was performed?				
M2 5.2.7.1	iii. Failing to prepare or analyze MBs and the LCS in the same manner that samples were prepared or analyzed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.7.1	iv. Tampering with QC samples and results, including over spiking and adding surrogates after sample extraction?				
M2 5.2.7.1	v. Performing multiple calibrations or QC runs (including CCVs, LCSs, spikes, duplicates, and blanks) until one meets criteria, rather than taking needed, corrective action, and not documenting or retaining data for the other unacceptable data?				
M2 5.2.7.1	vi. Deleting or failing to record non-compliant QC data to conceal the fact that calibration or other QC analyses were non-compliant?				
M2 5.2.7.1	e) Improper calibrations?				
M2 5.2.7.1	i. Discarding points in the initial calibration to force the calibration to be acceptable?				
M2 5.2.7.1	ii. Discarding points from an MDL study to force the calculated MDL to be higher or lower than the actual value?				
M2 5.2.7.1	iii. Using an initial calibration that does not correspond to the actual run sequence to make continuing calibration data look acceptable when in fact it was not?				
M2 5.2.7.1	iv. Performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to meet QC criteria or to avoid corrective action?				
M2 5.2.7.1	f) Concealing a known analytical or sample problem?				
M2 5.2.7.1	g) Concealing a known improper or unethical behavior or action?				
M2 5.2.7.1	h) Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official?				
M2 5.3	**Accommodation and Environmental Conditions**				
M2 5.3 Grey Box 21	(ISO/IEC 17025:2017 6.3.5) When the laboratory performs laboratory activities at sites or facilities outside its permanent control, does it ensure that the requirements related to facilities and environmental conditions of the standard are met?				
M2 5.3.1	Are laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, such as to facilitate correct performance of the tests and/or calibrations?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.3.1	Does the laboratory ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement?				
M2 5.3.1	Is particular care taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility?				
M2 5.3.1	Are the technical requirements for accommodation and environmental conditions that can affect the results of environmental tests documented?				
M2 5.3.2	Does the laboratory monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of results?				
M2 5.3.2	Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned?				
M2 5.3.2	Are tests and calibrations stopped when the environmental conditions jeopardize the results of the tests and/or calibrations?				
M2 5.3.3	Is there effective separation between neighboring areas in which there are incompatible activities?				
M2 5.3.3	Are measures taken to prevent cross-contamination?				
M2 5.3.3	a) When cross-contamination is a possibility, are samples suspected of containing high concentrations of analytes isolated from other samples?				
M2 5.3.3	b) Are storage blanks stored with all volatile organics samples, regardless of suspected concentration levels?				
M2 5.3.3	b) Are storage blanks used to determine if cross-contamination may have occurred?				
M2 5.3.3	b) Does the laboratory have documented procedures and criteria for evaluating storage blanks, appropriate to the types of samples being stored?				
M2 5.3.3	b) Are storage blanks stored in the same manner as the customer samples?				
M2 5.3.3	b) Are storage blanks analyzed and reviewed at a minimum, every fourteen (14) days?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.3.3	c) If contamination is discovered, does the laboratory have corrective action plan in place to identify the root cause and eliminate the source; determine which samples may have been impacted and implement measures to prevent recurrence?				
M2 5.3.4	Is access to and use of areas affecting the quality of the tests and/or calibrations controlled?				
M2 5.3.4	Does the laboratory determine the extent of control based on its particular circumstances?				
M2 5.3.5	Are measures taken to ensure good housekeeping in the laboratory?				
M2 5.3.5	Are special procedures prepared where necessary?				
M2 5.4	**Environmental Methods and Method Validation**				
M2 5.4 Grey Box 24	(ISO/IEC 17025:2017 7.2.2.2) When changes are made to a validated method, is the influence of such changes determined and where they are found to affect the original validation, a new method validation is performed?				
M2 5.4 Grey Box 24	(ISO/IEC 17025:2017 7.2.2.4) Does the laboratory retain the following records of validation?				
M2 5.4 Grey Box 24	a) the validation procedure used? b) specification of the requirements? c) determination of the performance characteristics of the method? d) results obtained? e) a statement on the validity of the method, detailing its fitness for the intended use?				
M2 5.4	Note: All references to Calibration Laboratories and Calibration Methods in ISO/IEC 17025:2005(E) in these Clauses are not applicable to environmental testing.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.1	Does the laboratory use appropriate methods and procedures for all tests and/or calibrations within its scope, including: - sampling - handling - transport - storage - preparation of items to be tested and/or calibrated, and where appropriate - an estimation of the measurement uncertainty - statistical techniques for analysis of test and/or calibration data?				
M2 5.4.1	Does the laboratory have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations?				
M2 5.4.1	Are all instructions, standards, manuals and reference data relevant to the work of the laboratory kept up to date and made readily available to personnel (see 4.3)?				
M2 5.4.1	Do deviations from test and calibration methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?				
M2 5.4.1	Note: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.				
M2 5.4.2	**Selection of Methods**				
M2 5.4.2 Grey Box 22	(ISO/IEC 17025:2017 7.2.1.5) Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance?				
M2 5.4.2 Grey Box 22	(ISO/IEC 17025:2017 7.2.1.5) Are records of the verification retained?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.2 Grey Box 22	(ISO/IEC 17025:2017 7.2.1.5) If the method is revised by the issuing body, is verification repeated to the extent necessary?				
M2 5.4.2	Does the laboratory use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the test and/or calibrations it undertakes?				
M2 5.4.2	Are methods published in international, regional or national standards used if possible?				
M2 5.4.2	Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so?				
M2 5.4.2	When necessary, is the standard supplemented with additional details to ensure consistent application?				
M2 5.4.2	When the customer does not specify the method to be used, does the laboratory select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment? Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.				
M2 5.4.2	Is the customer informed as to the method chosen?				
M2 5.4.2	Does the laboratory confirm that it can properly operate standard methods before introducing the tests or calibrations and if the standard method changes, the confirmation is repeated?				
M2 5.4.2	Does the laboratory inform the customer when the method proposed by the customer is considered to be inappropriate or out of date?				
M2 5.4.3	**Laboratory-Developed Methods**				
M2 5.4.3 Grey Box 23	(ISO/IEC 17025:2017 7.2.1.6) When method development is required, is it a planned activity and assigned to competent personnel equipped with adequate resources?				
M2 5.4.3 Grey Box 23	(ISO/IEC 17025:2017 7.2.1.6) As method development proceeds, is a periodic review carried out to confirm that the needs of the customer are still being fulfilled?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.3 Grey Box 23	(ISO/IEC 17025:2017 7.2.1.6) Are any modifications to the development plan approved and authorized?				
M2 5.4.3	Is the introduction of test and calibration methods:				
M2 5.4.3	• developed by the laboratory for its own use a planned activity?				
M2 5.4.3	• assigned to qualified personnel equipped with adequate resources?				
M2 5.4.3	Are plans updated as development proceeds and effective communication amongst all personnel involved ensured?				
M2 5.4.4	**Non-Standard Methods**				
M2 5.4.4	Non-Standard Methods (ISO/IEC 17025:2005(E), Clause 5.4.4) is not applicable in this module and is addressed in specific technical modules based on technology.				
M2 5.4.4	When it is necessary to use methods not covered by standard methods, are these methods subject to agreement with the customer and include a clear specification of the customer's requirements and the purpose of the test and/or calibration?				
M2 5.4.4	Is the method developed validated appropriately before use?				
M2 5.4.4	Note: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:				

Section Reference	Question	Compliant? Yes	Compliant? No	Compliant? NA	Comments
M2 5.4.4	a) appropriate identification; b) scope; c) description of the type of item to be tested or calibrated; d) parameters or quantities and ranges to be determined; e) apparatus and equipment, including technical performance requirements; f) reference standards and reference materials required; g) environmental conditions required and any stabilization period needed; h) description of the procedure, including - affixing of identification marks, handling, transporting, storing and preparation of items, - checks to be made before the work is started, - checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use, - the method of recording the observations and results, - any safety measures to be observed; i) criteria and/or requirements for approval/rejection; j) data to be recorded and method of analysis and presentation; k) the uncertainty or the procedure for estimating uncertainty.				
M2 5.4.5	**Validation of Methods**				
M2 5.4.5	Validation of Methods (ISO/IEC 17025:2005(E), Clause 5.4.5) is not applicable in this module and is addressed in specific technical modules based on technology.				
M2 5.4.5.1	Is validation confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled?				
M2 5.4.5.2	The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.5.2	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
M2 5.4.5.2	Does the laboratory:				
M2 5.4.5.2	• record the results obtained? • record the procedure used for the validation? • record a statement as to whether the method is fit for the intended use?				
M2 5.4.5.2	Note1: Validation may include procedures for sampling, handling and transportation.				
M2 5.4.5.2	Note2: The techniques used for the determination of the performance of a method should be one of, or a combination of, the following: - calibration using reference standards or reference materials; - comparison of results achieved with other methods; - interlaboratory comparisons; - systematic assessment of the factors influencing the result; - assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.				
M2 5.4.5.2	Note3: When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.				
M2 5.4.5.3	Are the range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, relevant to the customers' needs?				
M2 5.4.5.3	Note1: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.				
M2 5.4.5.3	Note2: As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.5.3	Note3: Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.				
M2 5.4.6	**Estimation of Analytical Uncertainty**				
M2 5.4.6	Clause 5.4.6 of the ISO/IEC/IEC 17025:2005(E) concerning calibration testing does not apply. The following requirement replaces the ISO/IEC Clause.				
M2 5.4.6 Grey Box 25	(ISO/IEC 17025:2017 7.6.1) Does the laboratory identify the contributions to measurement uncertainty?				
M2 5.4.6 Grey Box 25	(ISO/IEC 17025:2017 7.6.1) When evaluating measurement uncertainty, are all contributions that are of significance, including those arising from sampling, taken into account using appropriate methods of analysis?				
M2 5.4.6	Does the laboratory have a procedure(s) for estimating analytical uncertainty? Note: Quality control measurement data may be used to determine analytical uncertainty.				
M2 5.4.6	a) Does the laboratory attempt to identify all components of analytical uncertainty and make a reasonable estimation?				
M2 5.4.6	a) Does the laboratory ensure that the form of data reporting does not give a wrong impression of the uncertainty?				
M2 5.4.6	a) Is the reasonable estimation of uncertainty based on knowledge of method performance and previous experience?				
M2 5.4.6	a) When estimating the analytical uncertainty, are all uncertainty components which are of importance in the given situation taken into account?				
M2 5.4.6	b) In those cases where a well-recognized test method specifies limits to the values of the major source of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the requirements on analytical uncertainty by following the test method and reporting instructions?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.6	c) Is laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control?				
M2 5.4.6	c) As stated in Section 5.10.3.1.c, do the test reports include a statement of the estimated uncertainty of measurement only when required by the customer?				
M2 5.4.6	c) If a project requires analytical uncertainty to be reported, does the laboratory report the estimated uncertainty based on project-specific procedures or, if not available, any other scientifically valid procedures?				
M2 5.4.6	Note: A laboratory may report the in-house, statistically-derived LCS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to analytical uncertainty at a 99% confidence level.				
M2 5.4.6	c) For testing laboratories, do they ensure that the equipment used can provide the analytical portion of measurement uncertainty needed by the customer?				
M2 5.4.7	**Control of Data**				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.1) Does the laboratory have access to the data and information needed to perform laboratory activities?				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.2) Is the laboratory information management system(s) (LIMS) used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces within the LIMS) by the laboratory before introduction?				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.2) Whenever there are changes to the LIMS, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation?				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.2) Note1: LIMS includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.2) Note2: Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.3) Is the LIMS:				
M2 5.4.7 Grey Box 26	a) protected from unauthorized access? b) safeguarded against tampering and loss? c) operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription? d) include recording system failures and the appropriate immediate and corrective actions?				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.4) When a LIMS is managed and maintained off-site or through an external provider, does the laboratory ensure the provider or operator of the system complies with all applicable requirements of this standard?				
M2 5.4.7 Grey Box 26	(ISO/IEC 17025:2017 7.11.5) Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel?				
M2 5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner?				
M2 5.4.7.1	a) Does the laboratory have established SOPs to:				
M2 5.4.7.1	a) Ensure that the reported data are free from transcription and calculation errors?				
M2 5.4.7.1	b) Ensure that all quality control measures are reviewed, and evaluated before data are reported?				
M2 5.4.7.1	c) Address manual calculations?				
M2 5.4.7.1	d) Address manual integrations?				
M2 5.4.7.1	When manual integrations are performed, do raw data records include a complete audit trail for those manipulations (i.e., the chromatograms obtained before and after the manual integration must be retained to permit reconstruction of the results)?				
M2 5.4.7.1	Note: This requirement applies to all analytical runs including calibration standards and QC samples.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.7.1	Does the person performing the manual integration - sign and date each chromatogram (electronic signature is acceptable)? - record the rationale for performing manual integration? Note: Records for manual integrations may be maintained electronically as long as all requirements, including signature requirements, are met and the results can be historically reconstructed.				
M2 5.4.7.2	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the laboratory ensure that):				
M2 5.4.7.2	a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use?				
M2 5.4.7.2	b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, - integrity and confidentiality of data entry or collection? - data storage? - data transmission? - data processing?				
M2 5.4.7.2	c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data?				
M2 5.4.7.2	Note: Commercial off-the-shelf software (e.g. word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).				
M2 5.4.7.2	d) Does the laboratory have a procedure to ensure individual user names and passwords are required for all LIMS users?				
M2 5.4.7.2	d) Are LIMS passwords changed on a regular basis, at a minimum annually?				
M2 5.4.7.2	e) Upon employment, are laboratory employees given initial training in computer security awareness and have ongoing refresher training on an annual basis?				
M2 5.4.7.2	e) Are records of the training maintained and available for review?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.7.2	f) Are periodic inspections (at least annually) of the LIMS being performed by the Quality Manager or designee to ensure the integrity of electronic data?				
M2 5.4.7.2	f) Does the Quality Manager or designee maintain records of inspections and submit reports to laboratory management, noting any problems identified with electronic data processing stating the corrective actions taken?				
M2 5.4.7.2	g) Does the laboratory have a procedure to notify the customer prior to changes in LIMS software or hardware configuration that will adversely affect customer electronic data?				
M2 5.4.7.2	h) Are spreadsheets used for calculations verified before initial use and after any changes to equations or formulas, including software revision upgrades?				
M2 5.4.7.2	h) Are the verification records available for review?				
M2 5.4.7.2	h) Are formula cells write-protected to minimize inadvertent changes to the formulas?				
M2 5.4.7.2	h) Do printouts from any spreadsheets include all information used to calculate the data?				
M2 5.4.7.2	i) Does the laboratory have SOPs for:				
M2 5.4.7.2	i. Software development methodologies that are based on the size and nature of the software being developed?				
M2 5.4.7.2	ii. Testing and QC methods to ensure that all software accurately performs its intended functions, including:				
M2 5.4.7.2	a) Acceptance criteria?				
M2 5.4.7.2	b) Tests to be used?				
M2 5.4.7.2	c) Personnel responsible for conducting the tests?				
M2 5.4.7.2	d) Records of test results?				
M2 5.4.7.2	e) Frequency of continuing verification of the software?				
M2 5.4.7.2	f) Test review and approvals?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.7.2	iii. Software change control methods that include instructions for requesting, authorizing, testing (to include quality control), approving, implementing and establishing the priority of software changes and require the requirements to be met by each software change to be documented?				
M2 5.4.7.2	iv. Software version control methods that record the software version currently used and ensure data sets are recorded with the date and time of generation and/or the software version used to generate the data set?				
M2 5.4.7.2	v. Maintaining a historical file of software, software operating procedures, software changes, and software version numbers?				
M2 5.4.7.2	vi. Defining the acceptance criteria, testing, records, and approval required for changes to LIMS hardware and communication equipment?				
M2 5.4.7.2	j) Are records available in the laboratory to demonstrate the validity of laboratory generated software, that include:				
M2 5.4.7.2	i. Software description and functional requirements?				
M2 5.4.7.2	ii. Listing of algorithms and formulas?				
M2 5.4.7.2	iii. Testing and QA records?				
M2 5.4.7.2	iv. Installation, operation and maintenance records?				
M2 5.4.7.2	k) Do Electronic Data Security measures ensure the following:				
M2 5.4.7.2	i. Individual user names and passwords have been implemented?				
M2 5.4.7.2	ii. Operating system privileges and file access safeguards are implemented to restrict the user of the LIMS data to users with authorized access?				
M2 5.4.7.2	iii. All LIMS Users are trained in computer awareness security on an annual basis?				
M2 5.4.7.2	iv. System events, such as log-on failures or break-in attempts are monitored?				
M2 5.4.7.2	v. The electronic data management system is protected from the introduction of computer viruses?				
M2 5.4.7.2	vi. System backups occur on a regular and published schedule and can be performed by more than one person within an organization?				
M2 5.4.7.2	vii. Testing of the system backups must be performed and recorded to demonstrate that the backup systems contain all required data?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.7.2	viii. Physical access to the servers is limited by security measures such as locating the system within a secured facility or room, and/or utilizing cipher locks or key cards?				
M2 5.5	**Calibration Requirements**				
M2 5.5.1 Grey Box 27	(ISO/IEC 17025:2017 6.4.1) Does the laboratory have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and than can influence the results?				
M2 5.5.1 Grey Box 27	(ISO/IEC 17025:2017 6.4.1) Note1: A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties and certified values, their associated measurement uncertainty and metrological traceability.				
M2 5.5.1 Grey Box 27	(ISO/IEC 17025:2017 6.4.1) Note2: ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.				
M2 5.5.1	Is the laboratory furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data)?				
M2 5.5.1	In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of this standard are met?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.2 Grey Box 28	(ISO/IEC 17025:2017 6.4.6) Measurement equipment is calibrated when: - the measurement accuracy or measurement uncertainty affects the validity of the reported results? and/or - calibration of the equipment is required to establish the metrological traceability of the reported results?				
M2 5.5.2 Grey Box 28	(ISO/IEC 17025:2017 6.4.6) Note: Types of equipment having an effect on the validity of the reported results can include: - those used for the direct measurement of the measured value, e.g. use of a balance to perform a mass measurement; - those used to make corrections to the measured value, e.g. temperature measurements; - those used to obtain a measurement result calculated from multiple quantities.				
M2 5.5.2	Is equipment and its software used for testing, calibration and sampling - capable of achieving the accuracy required? - comply with specifications relevant to the tests and/or calibrations concerned?				
M2 5.5.2	Have calibration programs been established for key quantities or values of the instruments where these properties have a significant effect on the results?				
M2 5.5.2	Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications?				
M2 5.5.2	Is equipment checked and/or calibrated before use (see 5.6)?				
M2 5.5.3	Is equipment operated by authorized personnel?				
M2 5.5.3	Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate laboratory personnel?				
M2 5.5.4	Is each item of equipment and its software used for testing and calibration that is significant to the result uniquely identified, when practicable?				
M2 5.5.5 Grey Box 29	(ISO/IEC 17025:2017 6.4.13) Do records retained for equipment which can influence laboratory activities include:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.5 Grey Box 29	a) the identity of equipment, including software and firmware version?				
M2 5.5.5 Grey Box 29	f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity?				
M2 5.5.5	Are records of each item of equipment and its software significant to the tests and/or calibrations performed maintained?				
M2 5.5.5	Do the equipment records include at least the following:				
M2 5.5.5	a) the identity of the item of equipment and its software?				
M2 5.5.5	b) the manufacturer's name, type identification, and serial number or other unique identification?				
M2 5.5.5	c) checks that equipment complies with the specification (see 5.5.2)?				
M2 5.5.5	d) the current location, where appropriate?				
M2 5.5.5	e) the manufacturer's instructions, if available, or reference to their location?				
M2 5.5.5	f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?				
M2 5.5.5	g) the maintenance plan, where appropriate, and maintenance carried out to date?				
M2 5.5.5	h) any damage, malfunction, modification or repair to the equipment?				
M2 5.5.5	i) Date placed in service?				
M2 5.5.5	j) Condition when received (e.g., new, used, reconditioned)?				
M2 5.5.5	k) Operational status?				
M2 5.5.5	l) Instrument configuration and settings?				
M2 5.5.6	Does the laboratory have procedures for measuring equipment covering the following to ensure proper functioning and in order to prevent contamination or deterioration: - safe handling? - transport? - storage? - use? - planned maintenance?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.6	Note: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.				
M2 5.5.7	Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits - taken out of service? - isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly?				
M2 5.5.7	Does the laboratory examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and institute the "Control of nonconforming work" procedure (see 4.9)?				
M2 5.5.8 Grey Box 30	(ISO/IEC 17025:2017 6.4.8) Is all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity?				
M2 5.5.8	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded or otherwise identified to indicate the status of calibration including the date when last calibrated and the date or expiration criteria when recalibration is due?				
M2 5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?				
M2 5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined procedure?				
M2 5.5.11 Grey Box 31	(ISO/IEC 17025:2017 6.4.11) When calibration and reference material data include reference values or correction factors, does the laboratory ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.11	Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer software) are correctly updated?				
M2 5.5.12	Is test and calibration equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test and/or calibration results?				
M2 5.5.12	Note: ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories.				
M2 5.5.13	**Additional Requirements and Clarifications**				
M2 5.5.13	Calibration requirements for analytical support equipment are included in this Section while requirements for instrument (testing) calibration are included in technical modules (i.e., Asbestos, Chemistry, Microbiology, Radiochemistry and Toxicology).				
M2 5.5.13.1	**Support Equipment**				
M2 5.5.13.1	Support Equipment: Are all devices that may not be the actual test instrument, but are necessary to support laboratory operations, including, but are not limited to:				
M2 5.5.13.1	- balances - ovens - refrigerators - freezers - incubators - water baths - temperature measuring devices (including thermometers and thermistors) - thermal/pressure sample preparation devices - volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices) that have quantitative results that are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.				
M2 5.5.13.1	a) Are all support equipment maintained in proper working order?				
M2 5.5.13.1	a) Are the records of all support equipment repair and maintenance activities, including service calls, kept?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.13.1	a) Does the laboratory have procedures for recording catastrophic failure of support equipment (e.g., refrigerators, freezers) and addresses identification of affected samples and customer notification?				
M2 5.5.13.1	b) Are all support equipment calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use?				
M2 5.5.13.1	b) Are the results of such calibration or verification within the specifications required of the application for which this equipment is used or:				
M2 5.5.13.1	i. the equipment is removed from service until repaired?				
M2 5.5.13.1	ii. the laboratory maintains records of established correction factors to correct all measurements?				
M2 5.5.13.1	c) Are raw data records retained to document equipment performance?				
M2 5.5.13.1	d) On each day the equipment is used, balances, ovens, refrigerators, freezers and water baths are checked and documented?				
M2 5.5.13.1	d) Is the acceptability for use or continued use documented according to the needs of the analysis or application for which the equipment is being used?				
M2 5.5.13.1	d) Are checks performed in the expected use range using reference standards that are obtained, where available, from an accredited third party or a NMI (e.g., NIST) traceable to the International System of Units (SI)?				
M2 5.5.13.1	e) Are Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) checked for accuracy on a quarterly basis?				
M2 5.5.13.1	f) Are results of calibration and verification of support equipment within the specifications required of the application for which this equipment is used and/or the equipment is removed from service until repaired?				
M2 5.5.13.1	f) Are calibration and verification records, including those of established correction factors maintained?				
M2 5.5.13.1	f) In the absence of method-specific requirements, the following minimum performance check requirements apply:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.13.1 Table 5-1	Balance verification check (Using two standard weights that bracket the expected mass) Frequency: Daily prior to use Acceptance Criteria: - Top-loading balance: ± 2% or ± 0.02 g, whichever is greater - Analytical balance: ±0.1% or ±0.5 mg, whichever is greater				
M2 5.5.13.1 Table 5-1	Balance Calibration Frequency: Annual Acceptance Criteria: Certificate of Calibration from ISO/IEC 17025 accredited calibration laboratory				
M2 5.5.13.1 Table 5-1	Calibration of standard mass (Using weights traceable to the SI through a NMI) Frequency: Every 5 years Acceptance Criteria: Certificate of Calibration from ISO/IEC 17025 accredited calibration laboratory				
M2 5.5.13.1 Table 5-1	Monitoring of refrigerator/freezer temperature Frequency: Daily (i.e. 7 days per week) Acceptance Criteria: - Refrigerators: 0˚C to 6˚C - Freezers: ≤-10˚C Note: Use MIN/MAX thermometers or data loggers equipped with notification of out of control event capabilities if personnel not available to record daily. If a notification has been sent to laboratory personnel for out of control conditions, the laboratory is expected to respond with corrective actions within 24 hours of sent notification or the client of the affected samples will be notified.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.13.1 Table 5-1	Thermometer verification check (Using a thermometer traceable to the SI through an NMI) - Performed at two temperatures that bracket the target temperature(s). - Assume linearity between the two bracketing temperatures. - If only a single temperature is used, verify at the temperature of use. Frequency: - Liquid in glass: Before first use and annually - Electronic: Before first use and quarterly - Traceable thermometers shall be verified as required and correction foactors used when appropriate Acceptance Criteria: Apply correction factors or replace thermometer				
M2 5.5.13.1 Table 5-1	Volumetric labware Frequency: - Class B: By lot before first use - Class A and B: Upon evidence of deterioration Acceptance Criteria: Bias: Mean within ±2% of nominal volume Precision: RSD ≤1% of nominal volume (based on 10 replicate measurements)				
M2 5.5.13.1 Table 5-1	Non-volumetric labware (Applicable only when used for measuring initial sample volume and final extract/ digestates volume) - Frequency: By lot before first use and upon evidence of deterioration - Bias: Mean within ±3% of nominal volume - Precision: RSD ≤3% of nominal volume (based on 10 replicate measurements)				
M2 5.5.13.1 Table 5-1	Mechanical volumetric pipette Frequency: Daily before use Bias: Mean within ±2% of nominal volume Precision: RSD ≤1% of nominal volume (based on minimum of 3 replicate measurements) Note: Ffor variable volume pipettes, verify at the volume of use or using two volumes that bracket the range of use.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.13.1 Table 5-1	Glass microliter syringe Frequency: Upon receipt and upon evidence of deterioration General Certificate of Bias & Precision upon receipt Replace if deterioration is evident				
M2 5.5.13.1 Table 5-1	Drying oven temperature check Frequency: Daily prior to and after use Acceptance Criteria: Within ±5% of set temperature				
M2 5.5.13.1 Table 5-1	Water purification system Frequency: Daily prior to use Acceptance Criteria: Per Laboratory SOP				
M2 5.5.13.1 Table 5-1	Radiological Survey Equipment Frequency: Daily prior to use (The battery is checked; the physical integrity of the unit and high voltage is checked; a background reading is taken; and verified with a radiological source) Acceptance Criteria: Per Laboratory SOP				
M2 5.5.13.1 Table 5-1	Timer Frequency: Timer traceable to NIST where time is critical to the performance of a test Acceptance Criteria: Per Laboratory SOP				
M2 5.5.13.1 Table 5-1	Note: The table above does not replace the requirement for the laboratory to maintain traceability per their respective Accreditation Body requirements.				
M2 5.6	**Measurement Traceability**				
M2 5.6.1	**General**				
M2 5.6.1	General (ISO/IEC 17025:2005(E), Clause 5.6.1) is not applicable to.				
M2 5.6.1	General ISO/IEC 17025:2005(E), Clause 5.6.1 is applicable.				
M2 5.6.1	Is all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling calibrated before being put into service?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.1	Does the laboratory shall have an established program and procedure for the calibration of its equipment? Note: Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.				
M2 5.6.2	**Specific Requirements**				
M2 5.6.2	Specific Requirements (ISO/IEC 17025:2005(E), Clause 5.6.2) is not applicable.				
M2 5.6.2	Specific Requirements ISO/IEC 17025:2005(E), Clause 5.6.2 is applicable.				
M2 5.6.2.1	**Calibration**				
M2 5.6.2.1	Note. See 5.6.2.2.1 regarding the requirements given in 5.6.2.1 apply for testing laboratories for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.				
M2 5.6.2.1.1	Does the laboratory ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI)?				
M2 5.6.2.1.1	Does a calibration laboratory establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI measurement units?				
M2 5.6.2.1.1	Is the link to SI units achieved by reference to national measurement standards?				
M2 5.6.2.1.1	Are the national measurement standards primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or are they secondary standards (standards calibrated by another national metrology institute)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.2.1.1	When using external calibration services, is traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability? Note1: Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.				
M2 5.6.2.1.1	Do the calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see 5.10.4.2)?				
M2 5.6.2.1.2	When certain calibrations cannot be strictly made in SI units, does calibration provide confidence in measurements by establishing traceability to appropriate measurement standards such as:				
M2 5.6.2.1.2	- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material?				
M2 5.6.2.1.2	- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned?				
M2 5.6.2.1.2	Does the laboratory participate in a suitable program of PT?				
M2 5.6.2.2	**Testing**				
M2 5.6.2.2.1	For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. Note: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.				
M2 5.6.2.2.1	Does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, are the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, required as for calibration laboratories (see 5.6.2.1.2)?				
M2 5.6.3	**Reference Standards and Reference Materials**				
M2 5.6.3.1	**Reference Standards**				
M2 5.6.3.1	Does the laboratory have a program and procedure for the calibration of its reference standards?				
M2 5.6.3.1	Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1?				
M2 5.6.3.1	Are such reference standards of measurement held by the laboratory used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated?				
M2 5.6.3.1	Are reference standards calibrated before and after any adjustment?				
M2 5.6.3.2	**Reference Materials**				
M2 5.6.3.2	Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?				
M2 5.6.3.2	Are internal reference materials checked as far as is technically and economically practicable?				
M2 5.6.3.3	**Intermediate Checks**				
M2 5.6.3.3	Are checks carried out to maintain confidence in the status of reference, primary, transfer or working standards and reference materials according to defined procedures and schedules?				
M2 5.6.3.4	**Transport and Storage**				
M2 5.6.3.4	Does the laboratory have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity?				
M2 5.6.3.4	Note: Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.				
M2 5.6.4	**Additional Requirements and Clarifications**				
M2 5.6.4.1	**Reference Standards and Reference Materials**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.4.1	Does the laboratory provide satisfactory evidence of correlation of results, for example, by participation in a suitable program of inter-laboratory comparisons, PT, or independent analysis?				
M2 5.6.4.1	a) Reference Standards: Where commercially available, is there traceability to a national standard of measurement?				
M2 5.6.4.1	b) Reference Materials: Where possible, is there traceability to national or international standards of measurement or to national or international standard reference materials? Are Internal reference materials checked as far as is technically and economically practicable?				
M2 5.6.4.2	**Documentation and Labeling of Standards, Reagents, and Reference Materials**				
M2 5.6.4.2	Does the laboratory have documented procedures for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory?				
M2 5.6.4.2	a) Does the laboratory retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions?				
M2 5.6.4.2	a) Do records for standards, reagents, and reference materials include lot numbers?				
M2 5.6.4.2	a) Is the documentation for reagents and solvents checked to ensure that the stated purity will meet the intended use and do the supporting records of the checks filed in a manner that is retrievable?				
M2 5.6.4.2	b) For original containers, if an expiration date is provided by the manufacturer or vendor is it recorded on the container? Note: If an expiration date is not provided by the manufacturer or vendor it is not required.				
M2 5.6.4.2	c) Are Records maintained on standard, reference material, and reagent preparation?				
M2 5.6.4.2	c) Do these records indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.4.2	d) Do all containers of prepared standards, reference materials, and reagents bear a unique identifier and expiration date?				
M2 5.6.4.2	d) Do expiration date of the prepared standard not exceed the expiration date of the primary standard?				
M2 5.6.4.2	d) Do all containers of prepared standards bear a preparation date?				
M2 5.6.4.2	e) Are procedures in place to ensure prepared reagents meet the requirements of the method?				
M2 5.6.4.2	f) Are standards, reference materials, and reagents used after their expiration dates only if their reliability is verified by the laboratory?				
M2 5.6.4.2	f) If a standard exceeds its expiration date and is not re-certified, does the laboratory remove the standard or clearly designate it as acceptable for qualitative purposes only?				
M2 5.6.4.2	g) Are Standards and reference materials stored separately from samples, extracts, and digestates and protected in an appropriate cabinet or refrigerator?				
M2 5.7	**Collection of Samples**				
M2 5.7.1 Grey Box 32	(ISO/IEC 17025:2017 7.3.2) Does the sampling method describe:				
M2 5.7.1 Grey Box 32	a) the selection of samples or sites? b) the sampling plan? c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration?				
M2 5.7.1 Grey Box 32	(ISO/IEC 17025:2017 7.3.2) Note: When received into the laboratory, further handling can be required as specified in section 7.4 for the ISO/IEC 17025:2017 standard.				
M2 5.7.1 Grey Box 32	(ISO/IEC 17025:2017 7.3.2) Note: For the purpose of the QSM standard, a sampling method and a sampling procedure are equivalent.				
M2 5.7.1	Does the laboratory have a sampling plan and procedure for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration?				
M2 5.7.1	Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken?				
M2 5.7.1	Are sampling plans, whenever reasonable, based on appropriate statistical methods?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the environmental test and calibration results?				
M2 5.7.1	Note1: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but is determined by availability.				
M2 5.7.1	Note2: Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.				
M2 5.7.1	Does the sample handling procedures address laboratory practices for recording the presence of extraneous materials (e.g., rocks, twigs, vegetation) present in samples in the case of heterogeneous materials?				
M2 5.7.1	To avoid preparing non-representative samples, does the laboratory not "target" within a relatively small mass range (e.g., 1.00 ± 0.01 g) because such targeting will produce non-representative subsamples if the sample has high heterogeneity?				
M2 5.7.1	Does the laboratory not manipulate the sample material so the sample aliquot weighs exactly 1.00g ± 0.01g, as an example?				
M2 5.7.1	Does the laboratory's sampling procedures comply with recognized consensus standards (for example, ASTM standards or EPA's Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples (EPA/600/R-03/027)) where available?				
M2 5.7.2	Are customer required deviations, additions or exclusions from the documented sampling procedure - recorded in detail with the appropriate sampling data? - included in all documents containing test and/or calibration results? - communicated to the appropriate personnel?				
M2 5.7.3	Does the laboratory have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.7.3	Do these records include: - the sampling procedure used? - the identification of the sampler? - environmental conditions (if relevant)? - diagrams or other equivalent means to identify the sampling location as necessary? - if appropriate, the statistics the sampling procedures are based upon?				
M2 5.7.4	a) Does the documentation include the date and time of sampling?				
M2 5.7.4	b) Are any deviations from sampling procedures documented?				
M2 5.8	**Handling Samples and Test Items**				
M2 5.8.1	Does the laboratory have procedures for the - transportation - receipt - handling - protection - storage - retention - and/or disposal of samples including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the customer.				
M2 5.8.1	Are the personnel dealing with radioactive samples trained in - radioactive sample receipt - radioactive waste management - radioactive materials shipping (49 CFR 172) - handling, and radioactive material control?				
M2 5.8.2	Does the laboratory have a system for identifying test and/or calibration items?				
M2 5.8.2	Is the sample identification retained throughout the life of the item in the laboratory?				
M2 5.8.2	Is the system designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents?				
M2 5.8.2	Does the system, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.3 Grey Box 33	(ISO/IEC 17025:2017 7.4.3) Upon receipt of the test or calibration item, are deviations from specified conditions recorded?				
M2 5.8.3 Grey Box 33	(ISO/IEC 17025:2017 7.4.3) Where there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding and record the results of this consultation?				
M2 5.8.3 Grey Box 33	(ISO/IEC 17025:2017 7.4.3) When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the laboratory include a disclaimer in the report indicating which results may be affected by the deviation?				
M2 5.8.3	Upon receipt of the test or calibration item, are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded?				
M2 5.8.3	When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, does the laboratory consult the customer for further instructions before proceeding?				
M2 5.8.3	Is the discussion recorded?				
M2 5.8.3	Does the laboratory have a procedure addressing instances when it receives samples that require non-routine or additional sample preparation steps?				
M2 5.8.4	Does the laboratory have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation?				
M2 5.8.4	Are handling instructions provided with the item followed?				
M2 5.8.4	When items have to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?				
M2 5.8.4	Where a test or calibration item or a portion of an item is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.4	Note1: Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.				
M2 5.8.4	Note2: A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.				
M2 5.8.4	Note3: Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.				
M2 5.8.4	a) Does the laboratory have SOP(s) in place to address the use of ventilation hoods or suitable containment for opening shipping containers, radiation screening of samples, laboratory notification, and labeling requirements for radioactive samples?				
M2 5.8.4	b) Does the laboratory have a procedure and records to verify ventilation hood contamination control on a semiannual basis, such as a smoke test or flow meter measurements?				
M2 5.8.4	b) Are materials submitted for industrial hygiene or asbestos analysis opened in an established manner to prevent worker exposure?				
M2 5.8.4	b) Have receiving practices been developed and implemented for the receipt of beryllium, beryllium oxide, and asbestos?				
M2 5.8.4	c) Are shipping containers and packages opened inside a ventilation hood or other designated area that provides adequate ventilation for personnel?				
M2 5.8.4	c) Are all shipping containers from known radiological areas surveyed for radiological contamination on all external surfaces?				
M2 5.8.4	c) Has the laboratory developed and implemented administrative policies for the receipt of radiological shipping containers and samples?				
M2 5.8.4	c) Are radiological surveys of sample shipping containers performed as soon as possible from the time of receipt by the laboratory?				
M2 5.8.4	d) Are Instrumentation and equipment used for monitoring:				
M2 5.8.4	i. Maintained and calibrated on an established frequency?				
M2 5.8.4	ii. Appropriate for the type(s), levels, and energies of the radiation encountered?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.4	iii. Appropriate for existing environmental conditions?				
M2 5.8.4	iv. Routinely tested for operability (10 CFR 835.401(b))?				
M2 5.8.4	e) Does the laboratory have a system in place to record incidents involving spillage of customer samples or significant spillage of chemicals?				
M2 5.8.5	Are the following followed to ensure the validity of the laboratory's data:				
M2 5.8.5	a) Does the laboratory have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time? Does the system include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates?				
M2 5.8.5	b) Does the laboratory code maintain an unequivocal link with the unique field ID code assigned to each sample?				
M2 5.8.5	c) Is the laboratory ID code placed as a durable mark on the sample container?				
M2 5.8.5	d) Is the laboratory ID code entered into the laboratory records and does the link associate the sample with related laboratory activities such as sample preparation?				
M2 5.8.5	e) In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.				
M2 5.8.6	Does the laboratory have a written sample acceptance policy, that includes the following?				
M2 5.8.6	a) proper, full, and complete documentation, which includes sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample?				
M2 5.8.6	b) proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink?				
M2 5.8.6	c) use of appropriate sample containers?				
M2 5.8.6	d) adherence to specified holding times?				
M2 5.8.6	e) sufficient sample volume to perform the necessary tests?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.6	f) procedures to be used when samples show signs of damage, contamination or inadequate preservation?				
M2 5.8.6	g) qualification of any data that do not meet the above requirements?				
M2 5.8.6	h) a clear outline or the circumstances under which samples shall be accepted or rejected?				
M2 5.8.7.1	Has the laboratory implement procedures for verifying and documenting preservation?				
M2 5.8.7.1	a) Is sample temperature measurement verified through the use of one or more temperature blanks for each shipping container, if provided?				
M2 5.8.7.1	a) If a temperature blank is not available, are other temperature measurement procedures used?				
M2 5.8.7.1	b) Does the laboratory refer to the COC for the matrix definition? In the case where the matrix is not identified on the COC, does the laboratory contact the customer prior to proceeding?				
M2 5.8.7.1	c) Is Chemical preservation checked at the time of sample receipt for all samples, unless it is not technically acceptable to check preservation upon receipt (e.g., VOA samples)?				
M2 5.8.7.1	c) If any of the following conditions exist, is the chemical preservation rechecked in the laboratory? i) continued preservation of the sample is in question (e.g., the sample may not be compatible with the preservation); or ii) deterioration of the preservation is suspected.				
M2 5.8.7.1	d) Does the laboratory have procedures in place that ensure that the appropriate laboratory personnel are notified when samples are received with a quick turn-around time request, short hold times, or a short amount of hold time is remaining?				
M2 5.8.7.1	e) Does the laboratory develop and maintain procedures for sample receiving and login that minimizes changes in thermal preservation?				
M2 5.8.7.1	f) Does the laboratory document if thermal preservation is not maintained in accordance with the laboratory's procedure during sample receiving and login?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.7.1	f) Is client notified in writing if thermal preservation is not maintained? Note: This requirement is for environmental samples and does not apply to industrial hygiene samples (unless the IH method requires thermal preservation).				
M2 5.8.7.1	g) Are subcontract laboratories performing analytical services (i.e., testing, data review, data processing, project management, IT support, etc.) for DOE approved in writing by the appropriate DOE or subcontractor client prior to the commencement of work?				
M2 5.8.7.2	If the sample does not meet the sample receipt acceptance criteria listed in this Standard, does the laboratory either: a) retain correspondence and/or records of conversations concerning the final disposition of rejected samples? Or b) fully document any decision to proceed with the analysis of samples not meeting acceptance criteria? i) The condition of these samples are noted on the chain of custody or transmittal form and laboratory receipt documents. ii) The analysis data is appropriately qualified on the final report.				
M2 5.8.7.3	Does the laboratory utilize a permanent chronological record such as a logbook or electronic database to document receipt of all sample containers?				
M2 5.8.7.3	a) Does the sample receipt log record the following:				
M2 5.8.7.3	i. client/project name?				
M2 5.8.7.3	ii. date and time of laboratory receipt?				
M2 5.8.7.3	iii. unique laboratory ID code (see Section 5.12.1.b)i.)?				
M2 5.8.7.3	iv. signature or initials of the person making the entries?				
M2 5.8.7.3	b) During the login process, is the following information unequivocally linked to the log record or included as a part of the log? If such information is recorded/documented elsewhere, are the records part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.7.3	NOTE: The placement of the laboratory ID number on the sample container is not considered a permanent record.				
M2 5.8.7.3	i. Is the field ID code, which identifies each sample, shall be linked to the laboratory ID code in the sample receipt log?				
M2 5.8.7.3	ii. Is the date and time of sample collection shall be linked to the sample and to the date and time of receipt in the laboratory?				
M2 5.8.7.3	iii. Is the requested analyses (including applicable approved method numbers) linked to the laboratory ID code?				
M2 5.8.7.3	iv. Are the comments resulting from inspection for sample rejection linked to the laboratory ID code?				
M2 5.8.7.4	Are all documentation, such as memos, chain of custody, or transmittal forms that are transmitted to the laboratory by the sample transmitter, retained?				
M2 5.8.7.5	Is a complete chain of custody record form, if utilized, maintained?				
M2 5.8.8	**Additional Requirements – Legal Chain of Custody Protocols:**				
M2 5.8.8	Are legal Chain of Custody (COC) procedures used for evidentiary or legal purposes. If a client specifies that a sample is to be used for evidentiary purposes, then does the laboratory have a written SOP for how that laboratory will carry out legal chain of custody?				
M2 5.8.8	When the legal COC protocols are not provided by a state or federal program and legal custody is required to be maintained for a given project, are the following protocols incorporated?				
M2 5.8.8	**a) Basic Requirements:**				
M2 5.8.8	a) Do the legal COC protocol records establish an intact, continuous record of the physical possession, storage and disposal of used sample containers, collected samples, sample aliquots, and sample extracts or digestates, collectively referred to below as “samples”? Note: For ease of discussion, the above-mentioned items shall be referred to as samples.				
M2 5.8.8	a) Do the COC records account for all time periods associated with the samples?				
M2 5.8.8	i. Is the sample in someone's custody if:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.8	a) it is in one's actual physical possession?				
M2 5.8.8	b) it is in one's view, after being in one's physical possession?				
M2 5.8.8	c) it has been in one's physical possession and then locked or sealed so that no one can tamper with it?				
M2 5.8.8	d) it is kept in a secure area, restricted to authorized personnel only?				
M2 5.8.8	ii. Do the COC records identify all individuals who physically handled individual samples?				
M2 5.8.8	**b) Required Information in Custody Records:**				
M2 5.8.8	Are tracking records maintained until final disposition or return of samples to the customer?				
M2 5.8.8	b) Do tracking records include, by direct entry or linkage to other records:				
M2 5.8.8	i. Time of day and calendar date of each transfer or handling?				
M2 5.8.8	ii. Signatures of all personnel who physically handled the samples?				
M2 5.8.8	ii. Parent organization and physical address?				
M2 5.8.8	iii. All information necessary to produce unequivocal, accurate reports that record the laboratory activities associated with sample receipt, preparation, analysis, and reporting?				
M2 5.8.8	iv) Common carrier records?				
M2 5.8.9	**Additional Requirements – Sample Storage and Disposal:**				
M2 5.8.9	a) Are Samples stored according to the conditions specified by preservation protocols?				
M2 5.8.9	i. Are samples that require thermal preservation stored under refrigeration that is +/- 2°C of the specified preservation temperature unless regulatory or method specific criteria exist? For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable?				
M2 5.8.9	ii. Are samples stored away from all standards, reagents, and food?				
M2 5.8.9	ii. Are samples stored in such a manner to prevent cross contamination?				
M2 5.8.9	b) Are sample fractions, extracts, leachates and other sample preparation products stored according to Section 5.8.9 a) or according to specifications in the method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.9	c) Does the laboratory have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products?				
M2 5.8.9	i. Does disposal of the physical sample occur only with the concurrence of the customer who submitted the sample if those samples are disposed of prior to any project specified time limit? Note: Samples that are completely consumed during analysis shall be recorded as such for their final disposition.				
M2 5.8.9	ii. Are all conditions of disposal and all records and correspondence concerning the final disposition of the physical sample recorded and retained?				
M2 5.8.9	iii. Do records indicate - the date of disposal? - the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to customer)? - the name of the individual who performed the task?				
M2 5.8.9	d) Is the access to all evidentiary samples and subsamples controlled and recorded for all samples associated with legal chain of custody?				
M2 5.8.9	i. Is a clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside designated as a custody room?				
M2 5.8.9	ii. Where possible, are the distribution of samples to the analyst performing the analysis must be made by the custodian(s)?				
M2 5.8.9	iii. Is the laboratory area maintain as a secured area, restricted to authorized personnel only?				
M2 5.8.9	iv. Once the sample analyses are completed, are the unused portion of the sample, together with all identifying labels, must be returned to the custodian?				
M2 5.8.9	iv. Is the returned sample retained in the custody room until permission to dispose of the sample is received by the custodian or other authority?				
M2 5.8.9	e) Are transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for legal COC for all samples associated with legal chain of custody?				
M2 5.9	**Quality Assurance for Environmental Testing**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.1) Does the laboratory have a procedure for monitoring the validity of results?				
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.1) Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results?				
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.1) Is the monitoring planned and reviewed?				
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.1) Does the monitoring include, where appropriate, but not limited to:				
M2 5.9.1 Grey Box 34	a) use of reference material or quality control materials? b) use of alternative instrumentation that has been calibrated to provide traceable results? c) functional check(s) of measuring and testing equipment? d) use of check or working standards with control charts, where applicable? e) intermediate checks on measuring equipment? f) replicate tests or calibrations using the same or different methods? g) retesting or recalibration of retained items? h) correlation of results for different characteristics of an item? i) review of reported results? j) intralaboratory comparisons? k) testing of blind sample(s)?				
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.2) Does the laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate?				
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.2) Is the monitoring planned and reviewed?				
M2 5.9.1 Grey Box 34	(ISO/IEC 17025:2017 7.7.2) Does the monitoring include, but not be limited to, either or both of the following?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.9.1 Grey Box 34	a) participation in proficiency testing? Note: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.				
M2 5.9.1 Grey Box 34	b) participation in interlaboratory comparisons other than proficiency testing?				
M2 5.9.1	Does the laboratory have quality control procedures for monitoring the validity of tests and calibrations undertaken.				
M2 5.9.1	Are the data resulting from quality control procedures recorded in such a way that trends are detectable and, where practicable, are statistical techniques applied to the reviewing of the results?				
M2 5.9.1	Is the quality control monitoring planned and reviewed? Monitoring may include, but not be limited to, the following: a) regular use of certified reference materials and/or internal quality control using secondary reference materials; b) participation in interlaboratory comparison or proficiency-testing programs; c) replicate tests or calibrations using the same or different methods; d) retesting or recalibration of retained items; e) correlation of results for different characteristics of an item. Note: The selected methods should be appropriate for the type and volume of the work undertaken.				
M2 5.9.1	Are QC samples processed in the same manner as field samples?				
M2 5.9.1	Are QC samples analyzed and reported with their associated field samples?				
M2 5.9.2	Is quality control data analyzed and, where it is found outside pre-defined criteria, planned action taken to correct the problem and to prevent incorrect results from being reported?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.9.3	These general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., asbestos, chemical, microbiological, radiological, toxicity) and are further described in Technical Modules. The standards for any given test type shall assure that the applicable principles are addressed:				
M2 5.9.3	a) Does the laboratories have detailed written protocols in place to monitor the following quality controls:				
M2 5.9.3	i. positive and negative controls (see technical modules), chemical or microbiological as applicable to the test type, to monitor tests such as blanks, matrix spikes, reference toxicants?				
M2 5.9.3	ii. tests to define the variability and/or repeatability of the laboratory results such as replicates?				
M2 5.9.3	iii. measures to assure the accuracy of the method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures?				
M2 5.9.3	iv. measures to evaluate method capability, such as limit of detection and limit of quantitation or range of applicability such as linearity?				
M2 5.9.3	v. selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses?				
M2 5.9.3	vi. selection and use of reagents and standards of appropriate quality?				
M2 5.9.3	vii. measures to assure the selectivity of the test for its intended purpose?				
M2 5.9.3	viii. measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method such as temperature, humidity, light or specific instrument conditions?				
M2 5.9.3	b) Are all quality control measures assessed and evaluated on an on-going basis and quality control acceptance criteria used?				
M2 5.9.3	c) Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?				
M2 5.9.3	Are quality control protocols specified by the laboratory's SOP followed (see 4.2.8.5)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.9.3	Does the laboratory ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals?				
M2 5.9.3	When it is not apparent which is more stringent, are the QC in the mandated method or regulations is to be followed?				
M2 5.10	**Reporting the Results**				
M2 5.10	Note: All references to Calibration Certificates in ISO/IEC 17025:2005 are not applicable to environmental testing.				
M2 5.10	Are the results of each test, or series of environmental tests carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the environmental test methods?				
M2 5.10.1	**General**				
M2 5.10.1 Grey Box 35	(ISO/IEC 17025:2017 7.8.1.1) Are the results reviewed and authorized prior to release?				
M2 5.10.1 Grey Box 35	(ISO/IEC 17025:2017 7.8.1.2) Are the results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling)?				
M2 5.10.1 Grey Box 35	(ISO/IEC 17025:2017 7.8.1.2) Does the report include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used?				
M2 5.10.1 Grey Box 35	(ISO/IEC 17025:2017 7.8.1.2) Are all issued reports retained as technical records?				
M2 5.10.1	Does the report include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used? (This information is normally that required by 5.10.2 and 5.10.3 or 5.10.4.)				
M2 5.10.1	In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the customer, are the results reported in a simplified way?				
M2 5.10.1	Is any information listed in.5.10.2 to 5.10.4 which is not reported to the customer readily available in the laboratory which carried out the tests and/or calibrations?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.1	Note1: Test reports and calibration certificates are sometimes called test certificates and calibration reports respectively.				
M2 5.10.1	Note2: The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.				
M2 5.10.1	Note: The requirements of Appendix A in this standard shall be used for reporting results for DoD/DOE unless client specified reporting requirements are invoked.				
M2 5.10.1	Does the laboratory have a written procedure for communicating with the customer for the purpose of establishing project-specific data reporting requirements including: 1) conventions for reporting results below the LOQ 2) specification for the use of data qualifiers				
M2 5.10.1	Is the basis for the use of all data qualifiers adequately explained in the test report?				
M2 5.10.2	**Test Reports and Calibration Certificates**				
M2 5.10.2	Does each test report or calibration certificate include at least the following information, unless the laboratory has valid reasons for not doing so?				
M2 5.10.2	a) a title (e.g. "Test Report" or "Calibration Certificate")?				
M2 5.10.2	b) name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory?				
M2 5.10.2	b) name of a contact person and their phone number included in the laboratory information?				
M2 5.10.2	c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate?				
M2 5.10.2	d) the name and address of the customer?				
M2 5.10.2 Grey Box 36	(ISO/IEC 17025:2017 7.8.2.1.e) the name and contact information of the customer?				
M2 5.10.2	e) identification of the method used?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.2	f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?				
M2 5.10.2	g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration?				
M2 5.10.2	h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results?				
M2 5.10.2	i) the test or calibration results with, where appropriate, the units of measurement?				
M2 5.10.2	j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate?				
M2 5.10.2	k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated?				
M2 5.10.2	Note1: Hard copies of test reports and calibration certificates should also include the page number and total number of pages.				
M2 5.10.2	Note2: It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.				
M2 5.10.2	l) Any failures identified?				
M2 5.10.2 Grey Box 36	(ISO/IEC 17025:2017 7.8.2.1.l) a statement to the effect that the results relate only to the items tested, calibrated or sampled?				
M2 5.10.2	m) For Whole Effluent Toxicity (WET), identification of the statistical method used to provide data?				
M2 5.10.2	n) The date of issuance?				
M2 5.10.2	o) For solid samples, a statement of whether the results are based on a dry weight or wet weight basis?				
M2 5.10.2 Grey Box 36	(ISO/IEC 17025:2017 7.8.2.2) Is the laboratory responsible for all the information provided in the report, except when information is provided by the customer?				
M2 5.10.2 Grey Box 36	(ISO/IEC 17025:2017 7.8.2.2) Is data provided by a customer clearly identified?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.2 Grey Box 36	(ISO/IEC 17025:2017 7.8.2.2) Is a disclaimer put on the report when the information is supplied by the customer and can affect the validity of results?				
M2 5.10.2 Grey Box 36	(ISO/IEC 17025:2017 7.8.2.2) Where the laboratory has not been responsible for the sampling stage (e.g., the sample has been provided by the customer), does the laboratory state in the report that the results apply to the sample as received?				
M2 5.10.3	**Test Reports**				
M2 5.10.3 Grey Box 39	(ISO/IEC 17025:2017 7.8.6.1) When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule?				
M2 5.10.3 Grey Box 39	(ISO/IEC 17025:2017 7.8.6.1) Note: Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.				
M2 5.10.3 Grey Box 39	(ISO/IEC 17025:2017 7.8.6.2) Does the laboratory report on the statement of conformity, such that the statement clearly identifies:				
M2 5.10.3 Grey Box 39	a) to which results the statement of conformity applies?				
M2 5.10.3 Grey Box 39	b) which specification, standards or parts thereof are met or not met?				
M2 5.10.3 Grey Box 39	c) the decision rule applied (unless it is inherent in the requested specification or standard)?				
M2 5.10.3 Grey Box 39	Note: For further information, see ISO/IEC Guide 98-4.				
M2 5.10.3	Where it is necessary for the interpretation of the test results, does the test report also include the following:				
M2 5.10.3.1	a) Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions?				
M2 5.10.3.1	b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.3.1	c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit?				
M2 5.10.3.1 Grey Box 37	(ISO/IEC 17025:2017 7.8.3.1.c) where applicable, the measurement uncertainty presented in the same unit as that of the measured value and/or in a term relative to the measured value (e.g., percent) when: - it is relevant to the validity or application of the test results; - a customer's instructions so requires, or; - the measurement uncertainty affects conformity to a specification limit?				
M2 5.10.3.1	d) where appropriate and needed, opinions and interpretations (see 5.10.5)?				
M2 5.10.3.1	e) additional information which may be required by specific methods, customers or groups of customers?				
M2 5.10.3.1 Grey Box 37	(ISO/IEC 17025:2017 7.8.3.1.e) additional information that may be required by specific methods, authorities, customers or groups of customers?				
M2 5.10.3.1	f) information on any non-standard conditions that may have affected the quality of the results, including the use and definitions of data qualifiers, any manual integrations?				
M2 5.10.3.1	g) where management system requirements are met, a statement of compliance/noncompliance with requirements and/or specifications, including identification of test results derived from any sample that did not meet sample acceptance requirements such as improper container, holding time, or temperature?				
M2 5.10.3.1.1	In the absence of project-specific requirements, are the minimum standard data qualifiers listed below used by the laboratory:				
M2 5.10.3.1.1	U - Analyte was not detected and is reported as less than the LOD or as defined by the client. The LOD has been adjusted for any dilution or concentration of the sample?				
M2 5.10.3.1.1	J - The reported result is an estimated value (e.g., matrix interference was observed or the analyte was detected at a concentration outside the calibration range)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.3.1.1	B - Blank contamination. The recorded result is associated with a contaminated blank?				
M2 5.10.3.1.1	N - Non-target analyte. The analyte is a tentatively identified compound using mass spectrometry or any non-customer requested compounds that are tentatively identified?				
M2 5.10.3.1.1	Q - One or more quality control criteria failed (e.g., LCS recovery, surrogate spike recovery or CCV)?				
M2 5.10.3.1.1	If the laboratory uses additional data qualifiers, or different letters or symbols to denote the qualifiers listed above, are they appropriately defined and their use consistent with project-specific requirements (e.g., this document, the contract, and project-planning documents)?				
M2 5.10.3.1.1	Note: These data qualifiers are for laboratory use only. Data usability must be determined by the project team.				
M2 5.10.3.2	In addition to the requirements listed in 5.10.2 and 5.10.3.1, do test reports containing the results of sampling include the following, where necessary for the interpretation of test results:				
M2 5.10.3.2	a) the date of sampling?				
M2 5.10.3.2	b) unambiguous identification of the substance, material or product sampled? (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate)?				
M2 5.10.3.2	c) the location of sampling, including any diagrams, sketches or photographs?				
M2 5.10.3.2	d) a reference to the sampling plan and procedures used?				
M2 5.10.3.2 Grey Box 39	(ISO/IEC 17025:2017 7.8.5.d) a reference to the sampling plan and sampling method?				
M2 5.10.3.2	e) details of any environmental conditions during sampling that may affect the interpretation of the test results?				
M2 5.10.3.2	f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned?				
M2 5.10.3.2 Grey Box 39	(ISO/IEC 17025:2017 7.8.5.f) information required to evaluate measurement uncertainty for subsequent testing or calibration?				
M2 5.10.4	**Calibration Certificates**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.4	Calibration Certificates (ISO/IEC 17025:2005(E), Clause 5.10.4) does not apply to environmental testing activities.				
M2 5.10.5	**Opinions and interpretations**				
M2 5.10.5	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made?				
M2 5.10.5	Are opinions and interpretations clearly marked as such in a test report?				
M2 5.10.5	Note1: Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.				
M2 5.10.5	Note2: Opinions and interpretations included in a test report may comprise, but not be limited to, the following: - an opinion on the statement of compliance/noncompliance of the results with requirements; - fulfilment of contractual requirements; - recommendations on how to use the results; - guidance to be used for improvements.				
M2 5.10.5	Note3: In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.				
M2 5.10.5	When included, are opinions and interpretations contained in the case narrative?				
M2 5.10.5 Grey Box 40	(ISO/IEC 17025:2017 7.8.7.1) When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement?				
M2 5.10.5 Grey Box 40	(ISO/IEC 17025:2017 7.8.7.1) Does the laboratory document the basis upon which the opinions and interpretations have been made?				
M2 5.10.5 Grey Box 40	(ISO/IEC 17025:2017 7.8.7.1) Note: It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred in ISO/IEC 17025:2017 section 7.8.6.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.5 Grey Box 40	(ISO/IEC 17025:2017 7.8.7.2) Are the opinions and interpretations expressed in reports based on results obtained from the tested or calibrated item and clearly identified as such?				
M2 5.10.5 Grey Box 40	(ISO/IEC 17025:2017 7.8.7.3) When opinions and interpretations are directly communicated by dialogue with the customer, is a record of the dialogue retained?				
M2 5.10.6	**Testing and calibration results obtained from subcontractors**				
M2 5.10.6	When the test report contains results of tests performed by subcontractors, are these results clearly identified?				
M2 5.10.6	Does the subcontractor report the results either in writing or electronically?				
M2 5.10.6	When a calibration has been subcontracted, does the laboratory performing the work issue the calibration certificate to the contracting laboratory?				
M2 5.10.6	Does the laboratory make a copy of the subcontractor's report available to the customer when requested by the customer?				
M2 5.10.6 Grey Box 41	(ISO/IEC 17025:2017 7.8.2.1.p) Do reports include clear identification when results are form external providers?				
M2 5.10.7	**Electronic transmission of results**				
M2 5.10.7	In the case of transmission of environmental test results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this standard met (see also 5.4.7)?				
M2 5.10.8	**Format of reports and certificates**				
M2 5.10.8	Is the format of the report designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse?				
M2 5.10.8	Note1: Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.				
M2 5.10.8	Note2: The headings should be standardized as far as possible.				
M2 5.10.9	**Amendments to test reports and calibration certificates**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.9 Grey Box 42	(ISO/IEC 17025:2017 7.8.8.1) When an issued report needs to be changed, amended or re-issued, is any change of information clearly identified and, where appropriate, the reason for the change included in the report?				
M2 5.10.9	Are material amendments to a test report or calibration certificate after issue made only in the form of a further document, or data transfer, which includes the statement: “Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]”, or an equivalent form of wording?				
M2 5.10.9	Do such amendments meet all the requirements of this standard?				
M2 5.10.9	When it is necessary to issue a complete new test report or calibration certificate, is this uniquely identified contain a reference to the original that it replaces?				
M2 5.10.10	**Exceptions**				
M2 5.10.10	Some regulatory reporting requirements or formats such as monthly operating reports may not require all items listed, in those cases does the laboratory provide all the required information to their client for use in preparing such regulatory reports?				
M2 5.10.10	If the laboratory operates solely to provide data for compliance purposes (in-house or captive laboratories) is all applicable information specified in Section 5.10 readily available for review by the accreditation body? Note: Formal reports detailing the information are not required if: a) the in-house laboratory is itself responsible for preparing the regulatory reports; or b) the laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management shall ensure that the appropriate report items are in the report to the regulatory authority, if such information is required; or c) see Section 5.10.1, paragraph 3.				
M2 5.10.11	**Additional Requirements**				
M2 5.10.11	a) Is the time of sample preparation and/or analysis if the required holding time for either activity less than or equal to seventy-two (72) hours.?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.11	a) Are the date and time of sample collection, preparation, and analysis required to be included as part of the laboratory report, regardless of the length of holding time?				
M2 5.10.11	a) If the time of the sample collection is not provided, does the laboratory assume the most conservative time of day?				
M2 5.10.11	a) For the purpose of batch processing, are the start and stop dates and times of the batch preparation recorded?				
M2 5.10.11	b) Are results reported on a basis other than as received (e. g., dry weight)?				
M2 5.10.11	c) Are any non-accredited tests clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables?				
M2 5.10.11	d) Is there clear identification of numerical results with values outside the calibration range?				
M2 5.10.11	e) Is there qualification of numerical results with values outside the calibration range?				
M2 6.0	**HAZARDOUS AND RADIOACTIVE MATERIALS MANAGEMENT AND HEALTH AND SAFETY PRACTICES (DOE Only)**				
M2 6.0	Does the laboratory comply with all applicable federal and state regulations governing laboratory operations by developing, training and implementing Standard Operating plans/procedures (SOPs)?				
M2 6.1	**Radioactive Materials Management Plan (DOE Only)**				
M2 6.1	The plan will include, but not be limited to the following subject requirements detailed in sections 6.1.1 to 6.1.6:				
M2 6.1.1	**Radioactive Materials Management (DOE Only)**				
M2 6.1.1	For laboratories accepting, receiving, and handling radioactive samples, or potential radioactive samples, has the laboratory developed and implemented a radioactive materials management plan or radiation safety plan?				
M2 6.1.1	Does the plan, however named, comply, identify, and address all applicable site specific related federal and state regulations governing radioactive materials control and radiological protection?				
M2 6.1.1.2	Does laboratory review, at least annually, the radiation protection program content and implementation?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.1.1.2	Are records of audits, reviews, and inspections for the last five years maintained and readily available for review?				
M2 6.1.1.3	Has the laboratory developed and implemented an effective program of radiological controls and procedures for radioactive material handling, emergency actions, and use of instrumentation?				
M2 6.1.1.4	Are airborne releases of radioactivity to the environment monitored, evaluated, and controlled?				
M2 6.1.1.4	Are the records maintained for five years and be readily available for review.				
M2 6.1.2	**Radioactive Materials License Requirements (DOE Only)**				
M2 6.1.2.1	Is there a description of how the laboratory will address, implement, and manage the requirements of their site specific radioactive materials license?				
M2 6.1.2.1	Does the laboratory operate within the parameters of their license?				
M2 6.1.2.1	Does the license authorize possession of isotopes, quantity, physical form, and use of radioactive material sufficient for the laboratory's scope of work in support of DOE sites?				
M2 6.1.3	**Radiation Safety Personnel (DOE Only)**				
M2 6.1.3.1	Is the Radiation Safety Officer (RSO) listed in the Radioactive Materials License available to monitor the radioactive materials and control programs and provide rapid response to any radiological emergencies?				
M2 6.1.3.1	Does the laboratory have an alternate or backup RSO with the necessary training and experience to perform the duties of the RSO in the event that the RSO is not available?				
M2 6.1.3.2	Is initial and refresher training of the RSO and the alternate RSO identified and completed on an established frequency?				
M2 6.1.4	**Radiation Safety Training (DOE Only)**				
M2 6.1.4.1	Training may consist of General Employee Orientation, Radiation Safety Training, Contractor Training and/or special briefings as established for the exposure potential as determined by the RSO.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.1.4.2	Are all individuals entering any portion of a restricted area instructed in the potential health effects associated with exposure to radioactive materials or radiation, precautions/procedures to minimize exposure, and the purpose and functions of protective devices employed?				
M2 6.1.5	**Radiation Survey Plan and Equipment (DOE Only)**				
M2 6.1.5.1	Has a survey and monitoring program been developed and implemented to assess the magnitude and extent of radiation levels, concentrations or quantities of radioactive material, and the extent of potential radiological hazards?				
M2 6.1.5.2	Is radiological survey equipment calibrated according to the manufacturer's recommendation or per more frequent procedures as documented by the laboratory?				
M2 6.1.5.2	Prior to performing radiological surveys, is the radiological survey instrumentation checked for operational performance using a radiological source, a battery check, and a measurement of the nominal background is measured?				
M2 6.1.5.2	Are all performance checks documented and readily available for review?				
M2 6.1.5.2	Is calibrated backup survey equipment available?				
M2 6.1.5.2	Is calibration by an approved supplier or licensed calibration company and accredited to ISO 17025:2005 and ANSI/NCSL Z540-1-1994?				
M2 6.1.5.3	Are instrument and equipment calibration records showing the results of daily calibration checks and daily checks of the operability of radiological monitoring instruments maintained and retained for five years?				
M2 6.1.6	**Radiation Material Receipt and Control (DOE Only)**				
M2 6.1.6	Does the Laboratory ensure:				
M2 6.1.6.1	Personnel dealing with radioactive waste management and materials are trained in general awareness, security and safety?				
M2 6.1.6.2	Active use of a radioactive materials inventory program developed and implemented which is capable of tracking standards, tracers and all radiological samples and radioactive waste?				
M2 6.1.6.2	Is the radioactive material inventory updated according to the schedule established by the laboratory Radioactive Material License?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.1.6.2	If no schedule is established by the license, then has the laboratory updated the inventory within seven days of receipt of radioactive materials?				
M2 6.1.6.3	Radiological surveys of sample shipping containers are conducted as soon as possible from the time of receipt by the laboratory?				
M2 6.1.6.3	Shipping containers from radiological areas are surveyed on all external surfaces?				
M2 6.1.6.4	A radiological control program that addresses analytical radiological control has been implemented by the laboratory?				
M2 6.1.6.5	Low level and high-level samples will be identified, segregated, and processed in order to prevent sample cross-contamination?				
M2 6.1.6.6	At sample receiving, samples from potentially radioactive sites are screened to ensure that: • Customer identification of radioactivity (or lack of radioactivity) is correct? • The sample is properly categorized (per the laboratory's definition of radioactivity) for sample handling in the laboratory? • Data input is obtained for the radioactive materials license tracking system in the absence of customer supplied information? • the shipping container does not exhibit loose contamination or unacceptable external radiation readings?				
M2 6.1.6.7	Prior to performing radiological surveys, the radiological survey instrumentation is checked for operational performance using a radiological source, a battery check, is performed, and the nominal background is measured?				
M2 6.1.6.7	Are all performance checks documented and readily available for review?				
M2 6.1.6.7	Instrument and equipment calibration records showing the results of daily calibration checks and daily checks of the operability of radiological monitoring instruments are maintained and retained for five years?				
M2 6.1.6.7	Records are readily available for review?				
M2 6.1.6.8	Licensed material is secure from unauthorized access or removal?				
M2 6.2	**Waste Management Plan (DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.2	The plan includes, but not be limited to the following subject requirements detailed in the sections listed below:				
M2 6.2.1	**Waste Management Plan Requirements**				
M2 6.2.1	Has the laboratory developed and implemented a waste management plan identifying how they will comply with all federal and state regulations governing waste management and disposal?				
M2 6.2.1	Does the plan:				
M2 6.2.1.1	Identify all waste streams generated by the laboratory including universal wastes such as batteries, thermostats, etc?				
M2 6.2.1.2	Identify the process for management and disposal of the various waste streams?				
M2 6.2.1.3	Track the disposition of waste samples by Sample Delivery Group (SDG)?				
M2 6.2.1.4	Demonstrate compliance through administrative programs to demonstrate compliance for managing effluent discharges as required by regulatory agencies and applicable DOE Orders?				
M2 6.2.1.5	Provide training procedures, required frequency, and management of training records in the areas of waste management, shipping, waste handling, and radioactive materials control?				
M2 6.2.1.6	Communicate radioactive volumetric and surface release policies?				
M2 6.2.1.7	Detail permits and licenses to handle hazardous and radioactive waste?				
M2 6.2.1.8	Give policy or direction on how to conduct waste brokering and TSDF evaluation to ensure proper disposition of waste? This includes waste packaging, control and tracking, labeling, classification identification, and preparing/forwarding manifests.				
M2 6.2.1.9	Tracking of individual sample container from receipt to final disposition?				
M2 6.2.1.10	Address waste minimization and pollution prevention program requirements or plans which include substitution (when permitted), segregation, and recycling?				
M2 6.2.1.11	Identify how radioactive and mixed wastes shall be segregated from non-radioactive waste?				
M2 6.2.1.12	Develop and implement a radioactive materials inventory program capable of tracking radioactive waste?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.2.1.12	Update the radioactive material inventory according to the schedule established by the laboratory RML?				
M2 6.2.1.12	If no schedule is established by the license, does the laboratory update the inventory within seven days of receipt of radioactive materials?				
M2 6.2.2	**Waste Disposal (DOE Only)**				
M2 6.2.2	In managing waste disposition resulting from the receipt, analysis, and shipping of DOE samples, has the laboratories developed and implemented policies and practices to identify the following:				
M2 6.2.2.1	Waste brokering and TSDF evaluation based upon the results of a site visit to the waste facility or a desktop review that includes information from audits of the facilities conducted by state or federal agencies. The evaluation shall include liability coverage, financial stability, any Notices of Violations (NOVs) from the last three years, relevant permits and licenses to accept the waste, and other relevant information.				
M2 6.2.2.2	Waste shipments shall only be transferred to qualified facility/person specifically licensed to receive the waste.				
M2 6.2.2.3	TSDF reviews of waste brokering and TSDF evaluations shall be performed every three years, unless there are changes in the facility operations that require the reviews to be conducted on a more frequent basis (e.g., NOVs, change of ownership, notices of fines, and penalties).				
M2 6.2.2.3	The laboratory shall develop criteria for the evaluation of waste brokers and TSDFs.				
M2 6.2.2.3	Documentation of the evaluations and a list of the facilities that are approved shall be maintained for at least 5 years and records made readily available.				
M2 6.2.2.3	Reference to the Environmental Protection Agency (EPA) public domain Enforcement and History Online (ECHO) and “ENVIROFACTS” websites for information on TSDFs.				
M2 6.2.2.3	Note: DOECAP TSDF audits can be used in place of onsite visit requirements provided all other requirements not included in these audits are addressed (i.e. financial stability, liability insurance, etc.).				
M2 6.2.2.4	Certificate(s) of disposal or destruction shall be obtained for all samples sent to a TSDF, retained for five years, and made readily available.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.2.2.5	The laboratory shall remove or deface all sample container labels prior to container disposal such that they are rendered illegible.				
M2 6.2.2.6	Analytical process waste shall be segregated and removed to a designated storage area to minimize the potential for cross-contamination.				
M2 6.2.2.7	Laboratory analysis for derived waste characterization shall be repeated at a frequency adequate to account for all known variation in the waste streams.				
M2 6.2.2.8	Samples that are consumed during analysis must be included in the sample accountability tracking.				
M2 6.2.2.9	The laboratory shall have provisions for the disposition of excess samples. Unless directed otherwise by contract, the laboratory shall receive written permission from the DOE client prior to disposition of any excess samples.				
M2 6.2.2.10	Management of excess samples whether they are bulked, special samples, or drain disposed.				
M2 6.2.2.11	The laboratory must address how they will manage the requirements for the pre-treatment requirements if disposal includes a Publicly Owned Treatment Works (POTW) or wastewater treatment system. The program must address how the laboratory will be able to demonstrate compliance with these requirements.				
M2 6.2.2.12	Records of waste disposal, destruction, and characterization, including analytical test results and process knowledge determinations, shall be kept for at least five years. Records shall be readily available for review.				
M2 6.2.2.13	Laboratories shall accumulate no more than 55 gallons of hazardous and mixed waste or no more than one quart of acutely hazardous waste at, or near, any point of generation. The labelling of these waste containers are to be properly marked with the words ‘‘Hazardous Waste’. The label must indicate the applicable hazard (accepted labels include completed Department of Transportation (DOT) shipping label, National Fire Protection Association (NFPA) label, or RCRA waste characterization code).				
M2 6.2.2.14	Radioactive and mixed wastes generated during laboratory sample processing shall be labeled as Radioactive.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.2.2.15	Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility or sample returned to client), and the name of the individual who performed the task.				
M2 6.2.3	**Waste Storage Areas (DOE Only)**				
M2 6.2.3.1	Does the laboratory identify their affiliation and requirements as to their RCRA status as a very small, small, or large quantity generator and will identify the locations, storage limitations, and container sizes for each accumulation and storage area identified? Laboratories must reference the requirements per the applicable CFR.				
M2 6.2.3.2	Are hazardous waste storage containers:				
M2 6.2.3.2	- Labeled with the words “Hazardous Waste”?				
M2 6.2.3.2	- Labeled with the start date upon which each period of accumulation begins?				
M2 6.2.3.2	- Clearly marked with the accumulation start date and visible for inspection?				
M2 6.2.3.3	Are waste storage areas, and containers of waste monitored weekly by an operator or someone knowledgeable in waste operations specific to this facility?				
M2 6.2.3.4	Do the user(s) or operator(s) of the satellite accumulation areas understand container/waste compatibility and have been trained with respect to container selection, waste identification, documentation, and management?				
M2 6.2.3.5	Is ignitable and reactive waste stored at least 50 feet from the property line?				
M2 6.2.3.6	Is incompatible waste not stored near other containers or separated by a dike, berm, wall, or other device?				
M2 6.2.3.7	Does the waste storage area provide secondary containment of sufficient capacity for the waste expected to be stored in the areas?				
M2 6.2.3.8	Are accumulation containers:				
M2 6.2.3.8	- In good condition?				
M2 6.2.3.8	- Compatible with the waste?				
M2 6.2.3.8	- Kept closed at all times when not in immediate use?				
M2 6.2.4	**Toxic Substances Control Act (TSCA) Material (DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.2.4.1	Has the laboratory developed and implemented a plan or program stating how laboratory operations will comply with all federal regulations governing TSCA materials control and protection?				
M2 6.2.4.2	Does the laboratory segregate all radioactive TSCA materials from all other analytical samples and associated derived wastes?				
M2 6.2.4.3	Does the laboratory have a procedure for return to the customer of radioactive TSCA materials for which there is no commercial treatment or disposal options?				
M2 6.2.4.4	Is TSCA Polychlorinated biphenyl (PCB) waste stored for less than one year from the date the material was first placed in storage?				
M2 6.2.4.5	Are TSCA PCB waste containers labeled with the accumulation start date?				
M2 6.2.4.6	Does the TSCA one-year waste storage area shall the storage facility requirements for PCB waste (floor curbing, above 100 year flood plain, no floor drains, etc.)?				
M2 6.2.4.7	Are wastes from samples containing PCBs at greater than 50 ppm segregated from other laboratory wastes as TSCA regulated waste? Note: This does not apply to the extracted sample residual, BUT it does apply to the extract and other laboratory process wastes.				
M2 6.2.4.8	Is laboratory-generated TSCA PCB wastes stored in a Temporary Storage Area more than 30 days from the time of generation without being placed in an area that meets one year storage facility requirements?				
M2 6.2.4.9	Are TSCA PCB waste containers and sample storage areas marked with the required TSCA PCB labeling?				
M2 6.3	**Chemical Hygiene Plan (CHP) (DOE Only)**				
M2 6.3.1	Has a CHP been developed and implemented in the laboratory and is readily available to all employees?				
M2 6.3.1	Have SOPs relating to safety and health considerations been developed and implemented?				
M2 6.3.2	Has the laboratory written a contingency plan and ensured a copy is available at the facility?				
M2 6.3.3	Are following information included in the plan and posted next to the phone in the vicinity of the accumulation area?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.3.3	- Name and number of the emergency coordinator;				
M2 6.3.3	- Location of fire extinguishers and spill control material; and				
M2 6.3.3	- Fire department number or a direct alarm.				
M2 6.3.4	Is required equipment available at the accumulation/storage area?				
M2 6.3.4	Equipment includes, but is not limited to:				
M2 6.3.4	- Internal communication or alarm system?				
M2 6.3.4	- Telephone or hand-held two-way radio?				
M2 6.3.4	- Portable fire extinguishers/fire control equipment?				
M2 6.3.4	- Spill control equipment, and water at adequate volume and pressure (e.g., 15 minutes of continuous pressure)?				
M2 6.3.5	Is an emergency eye washlocated within the immediate work area, unobstructed, and readily available to all personnel?				
M2 6.3.5	Are location requirements and ease of access, frequency for testing, refilling or restocking as needed, and an emergency shower addressed in the plan?				
M2 6.3.5	Are all tests and inspections clearly marked by a tag on each device?				
M2 6.3.5	Are records maintained by the personnel responsible for the implementation of the chemical hygiene plan?				
M2 6.3.6	Has the employer shall provided, mounted, located, identified, and inspected portable fire extinguishers so that they are readily available to all employees without subjecting the employees to possible injury?				
M2 6.3.6	Are the location requirements and the frequency for inspection established in the Chemical Hygiene Plan, or equivalent plan?.				
M2 6.3.6	Are all tests and inspections clearly marked by a tag on each device?				
M2 6.3.6	Are records maintained by the personnel responsible for the implementation of the chemical hygiene plan?				
M2 6.3.6	Are records readily available for review?				
M2 6.3.7	Does the employer have a spill control policy developed?				
M2 6.3.7	Are all personnel provided documented training on the use and location of each spill kit?				
M2 6.3.8	Is the facility equipped with an alarm system that is capable of being detected and recognized by the employee in case of emergency?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.3.9	Are initial and periodic exposure monitoring for hazardous chemicals conducted?				
M2 6.3.9	Are exposure limits identified or referenced and actions taken should an exceedance occur?				
M2 6.3.10	Are Safety Data Sheetson file for all hazardous chemical substances maintained by the laboratory and readily accessible to all employees?				
M2 6.3.11	Are measures in place to ensure the performance and maintenance of ventilation hoods and protective equipment? This will include frequency and tested flow rates for each hood.				
M2 6.3.11	Does the laboratory have a procedure and records to verify contamination control on a semiannual basis such as a smoke test or flow meter measurements?				
M2 6.3.11	Is there documentation on the process for ventilation hood contamination control?				
M2 6.3.12	Do laboratory analytical employees have readily available records for training associated on:				
M2 6.3.12	- Contents of the employer's CHP?				
M2 6.3.12	- Physical and health hazards of chemicals in the work area?				
M2 6.3.12	- Methods and observations used to detect the presence or release of a hazardous substance (e.g., monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous substances being released, etc)?				
M2 6.3.13	If respirators are used during sample or waste handling/processing, does the laboratory have an appropriate written respiratory protection program; including: - SOPs governing the fit-testing of personnel using respirators, selection and use of respirators; and an annual evaluation to ensure effectiveness?				
M2 6.3.14	Is chemical hazard labeling on chemical containers in accordance with the laboratory's approved CHP?				
M2 6.3.15	Is a laboratory safety inspection program developed and implemented that includes routine inspections of laboratory areas for health and safety related concerns?				
M2 6.3.16	Are annual safety requirements identified for training and briefings that will be required of all visitors and maintenance personnel?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.3.16	Do auditors receive a safety orientation prior to entering the laboratory?				
M2 6.3.16	Are all training and briefingsdocumented and recorde available?				
M2 6.3.17	Does the laboratory have a Hazardous Waste Operator and Emergency Response (HAZWOPER) trained person on staff?				
M2 6.3.17	Are backup personnel with appropriate training for the Emergency Response (HAZWOPER) trained personnel required?				
M2 6.3.18	Has the laboratory developed an emergency response plan to include re-entry procedures once the laboratory is safe to return?				
M2 6.3.19	Does the Laboratory require clear posting of signs on doors, work stations, and/or safety devices to indicate use of: - Safety glasses required - Laboratory coats or protective clothing - Appropriate footwear; - Safety showers; - Eyewash stations; - Other safety and first aid equipment; - Exits; and - Areas where food and beverage consumption and storage are permitted?				
M2 6.3.20	Are areas containing biological hazards appropriately posted?				
M2 6.3.21	Are all hazardous or toxic chemical cabinets appropriately labeled with the following: - Identity of the hazardous chemical(s); - Appropriate hazard warnings; and - Name and address of the chemical manufacturer, importer, or other responsible party?				
M2 6.3.22	Are all exits properly identified and unobstructed?				
M2 6.3.23	Are locations and procedures for personal protective equipment (PPE), (to include laboratory coats, safety glasses, shoes, etc.) established?				
M2 6.3.23	Doe the procedures identify when, what, and where PPE is required and allowed?				
M2 6.4	**Sample Receiving (DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 6.4.1	Does the laboratory have a documented system for uniquely identifying the items (samples) to be tested?				
M2 6.4.2	Does the laboratory have SOPs in place to address the following: - Containers are opened in a manner to prevent worker exposure - Checking sample preservation (pH); - Proper containers; - Preserving samples when required; - Documenting and notifying clients of shipping or sample anomalies; - Checking holding times and notifying laboratory personnel of short holding times; - Use of fume hoods for opening samples and shipping containers; - Chain of Custody (COC) is not broken during times when laboratory staff are not present; - Access to all samples and subsamples is controlled and documented; - COC forms remain with the samples during transport or shipment; and - Record the chronology of sample entry into the laboratory including, but not limited to, time, date, customer, sample identification numbers, signature or initials of person making the entry?				
M2 6.4.3	Are materials submitted to the laboratory for industrial hygiene or asbestos analyses opened in an established manner to prevent worker exposure and sample receiving practices developed and implemented for the receipt of beryllium, beryllium oxide, and asbestos materials?				
M2 6.4.4	Do sample receipt personnel document anomalies encountered in the sample receiving process?				
M2 6.4.5	Is a sample receiving logbook or equivalent system used to record the chronology of sample entry into the laboratory including, but not limited to, time, date, customer, sample identification numbers, signature or initials of person making the entry?				
M2 6.4.6	When the laboratory receives samples, is there an internal COC procedure in place?				
M2 6.4.6	Is an internal custody maintained until final disposition or return of the sample to the client?				
M3	**VOLUME 1, MODULE 3**				
M3	**Quality Systems for Asbestos Testing**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.4	**Method Selection**				
M3 1.4	When it is necessary to use methods not covered by reference methods, are these methods subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the environmental test?				
M3 1.4	If no QC exists in the method, the laboratory does the laboratory adhere to the requirements outlined in a similar method?				
M3 1.4	Are developed methods validated appropriately before use?				
M3 1.5	**Method Validation**				
M3 1.5	Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use?				
M3 1.5	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
M3 1.5	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
M3 1.5	Does the laboratory participate in a suitable PT program?				
M3 1.6	**Demonstration of Capability (DOC)**				
M3 1.6.1	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (per Section 1.6.2)?				
M3 1.6.1	Does the laboratory perform ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples)? Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				
M3 1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
M3 1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
M3 1.6.2	**Initial DOC**				
M3 1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
M3 1.6.2	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
M3 1.6.2.1	a) analyst(s) involved in preparation and/or analysis? b) matrix? c) analyte(s), class of analyte(s), or measured parameter(s)? d) identification of method(s) performed? e) identification of laboratory-specific SOP used for analysis, including revision number? f) date(s) of analysis? g) summary of analyses, including information outlined in Section 1.6.2.2.c?				
M3 1.6.2.2	For asbestos: If the method or regulation does not specify a DOC, does the laboratory use the procedure stated below and document that the other approaches to initial DOC are adequate? (1.6.2.2.e.i is not allowed for DoD/DOE)				
M3 1.6.2.2	a) The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four aliquots.				
M3 1.6.2.2	b) At least four (4) aliquots shall be prepared and analyzed according to the method either concurrently or over a period of days.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.6.2.2	c) Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the population sample (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory shall assess performance against established and documented criteria.				
M3 1.6.2.2	d) Compare the information from (c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not meet the acceptance criteria, the performance is unacceptable for that parameter.				
M3 1.6.2.2	e) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to i) or ii) below.				
M3 1.6.2.2	i. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.				
M3 1.6.2.2	ii. Beginning with c) above, repeat the test for all parameters that failed to meet criteria.				
M3 1.6.2.2	f) Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with b).				
M3 1.6.3	**Ongoing DOC**				
M3 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC?				
M3 1.6.3.1	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this standard?				
M3 1.6.3.1	Does the laboratory document that other approaches to ongoing DOC are adequate, if applicable?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.6.3.1	For asbestos: Does the laboratory use one of the following for ongoing DOC: a) acceptable performance of a blind sample (single blind to the analyst); Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the test? b) another initial DOC? c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing laboratory control samples (LCS) for each method for each analyst each year? d) a documented process of analyst review using quality control (QC) samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary? e) if a) through d) are not technically feasible, then analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) shall be performed?				
M3 1.7	**Technical Requirements**				
M3 1.7.1	**Calibration:**				
M3 1.7.1	If NIST standard reference materials (SRM) specified below are unavailable, does the laboratory substitute an equivalent reference material with a certificate of analysis?				
M3 1.7.1.1	**Transmission Electron Microscopy (TEM)**				
M3 1.7.1.1.1	**Water and Wastewater:**				
M3 1.7.1.1.1	DoD/DOE Clarification: Frequencies shall be increased following non-routine maintenance or unacceptable calibration performance.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1.1.1	Are all calibrations list below (unless otherwise noted) performed under the same analytical conditions used for routine asbestos analysis? Note: Frequencies stated below may be reduced to "before next use" if no samples are analyzed after the last calibration period has expired. Likewise, frequencies may have to be increased following non-routine maintenance or unacceptable calibration performance.				
M3 1.7.1.1.1	Are all calibrations list below recorded in a notebook and include date and analyst's signature?				
M3 1.7.1.1.1	**a) Magnification Calibration**				
M3 1.7.1.1.1	a) Is magnification calibration done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting, generally 10,000 and 20,000x?				
M3 1.7.1.1.1	a) Is a logbook maintained with the dates of the calibration recorded?				
M3 1.7.1.1.1	a) Is a logbook or electronic record maintained with the: - calibrated magnification? - date of calibration? - analyst's signature or initials recorded?				
M3 1.7.1.1.1	a) Are Calibrations performed monthly to establish the stability of magnification?				
M3 1.7.1.1.1	a) Is Calibration data displayed on control charts that show trends over time?				
M3 1.7.1.1.1	**b) Camera Constant**				
M3 1.7.1.1.1	b) Is the camera length of the TEM in the Selected Area Electron Diffraction (SAED) mode calibrated before SAED patterns of unknown samples are observed?				
M3 1.7.1.1.1	b) Is the diffraction specimen at the eucentric position for this calibration?				
M3 1.7.1.1.1	b) Does the calibration allow accurate (<10% variation) measurement of layer-line spacing on the medium used for routine measurement? (i.e., the phosphor screen or camera film)				
M3 1.7.1.1.1	b) Does the calibration allow accurate (<5% variation) measurement of zone axis SAED patterns on permanent media? (e.g., film)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1.1.1	b) Are Calibrations performed monthly to establish the stability of the camera constant?				
M3 1.7.1.1.1	b) Where non-asbestiform minerals may be expected (e.g., winchite, richterite, industrial talc, vermiculite, etc.):				
M3 1.7.1.1.1	• is an internal camera constant standard such as gold, deposited and measured on each sample to facilitate accurate indexing of zone axis SAED patterns? DoD/DOE Clarification: A gold standard grid shall be used to obtain the characteristic diffraction rings from which the camera constant can be calculated.				
M3 1.7.1.1.1	• is layer line analysis alone not used?				
M3 1.7.1.1.1	b) Is Calibration data displayed on control charts that show trends over time?				
M3 1.7.1.1.1	**c) Spot Size**				
M3 1.7.1.1.1	c) Is the diameter of the smallest beam spot at crossover less than 250 nm as calibrated quarterly?				
M3 1.7.1.1.1	c) Is Calibration data displayed on control charts that show trends over time?				
M3 1.7.1.1.1	**d) Beam Dose**				
M3 1.7.1.1.1	d) Is the beam dose calibrated so that beam damage to chrysotile is minimized?				
M3 1.7.1.1.1	d) Is the electron diffraction pattern from a single fibril >1 µm in length from a NIST SRM chrysotile sample stable in the electron beam dose for at least 15 seconds?				
M3 1.7.1.1.1	**e) Energy Dispersive X-Ray Analysis (EDXA) System**				
M3 1.7.1.1.1	i. Is the x-ray energy vs. channel number for the EDXA system calibrated to within 20 eV for at least two peaks between 0.7 keV and 10 keV?				
M3 1.7.1.1.1	i. Is one peak from the low end (0.7 keV to 2 keV) and the other peak from the high end (7 keV to 10 keV) of this range?				
M3 1.7.1.1.1	i. Is the calibration of the x-ray energy checked prior to each analysis of samples and recalibrated if out of the specified range?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1.1.1	ii. Is the ability of the system to resolve the Na Kα line from the Cu L line confirmed quarterly by obtaining a spectrum from the NIST SRM 1866 crocidolite sample on a copper grid?				
M3 1.7.1.1.1	iii. Are the k-factors for elements found in asbestos (Na, Mg, Al, Si, Ca, and Fe) relative to Si calibrated semiannually, or anytime the detector geometry may be altered?				
M3 1.7.1.1.1	iii. Is NIST SRM 2063a used for Mg, Si, Ca, Fe, and k-factors for Na and Al obtained from suitable materials such as albite, kaersutite, or NIST SRM 99a?				
M3 1.7.1.1.1	iii. Are the k-factors determined to a precision (2s) within 10% relative to the mean value obtained for Mg, Al, Si, Ca, and Fe, and within 20% relative to the mean value obtained for Na.				
M3 1.7.1.1.1	iii. Is the k-factor relative to Si for Na between 1.0 and 4.0, for Mg and Fe between 1.0 and 2.0, and for Al and Ca between 1.0 and 1.75?				
M3 1.7.1.1.1	iii. Is the k-factor for Mg relative to Fe 1.5 or less?				
M3 1.7.1.1.1	iii) Is Calibration data displayed on control charts that show trends over time?				
M3 1.7.1.1.1	iv. Is the detector resolution checked quarterly to ensure a full-width half maximum (FWHM) resolution of <175 eV at Mn Kα (5.90 keV)?				
M3 1.7.1.1.1	iv.) Is Calibration data displayed on control charts that show trends over time?				
M3 1.7.1.1.1	v. Are the portions of a grid in a specimen holder for which abnormal x-ray spectra are generated under routine asbestos analysis conditions determined? Are these areas avoided in asbestos analysis?				
M3 1.7.1.1.1	vi. Is the sensitivity of the detector for collecting x-rays from small volumes documented quarterly by collecting resolvable Mg and Si peaks from a unit fibril of NIST SRM 1866 chrysotile?				
M3 1.7.1.1.1	**f) Low Temperature Asher**				
M3 1.7.1.1.1	f) Is the low temperature asher calibrated quarterly by determining a calibration curve for the weight vs. ashing time of collapsed mixed-celluloseester (MCE) filters?				
M3 1.7.1.1.1	f) Is Calibration data displayed on control charts that show trends over time?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1.1.1	**g) Grid Openings**				
M3 1.7.1.1.1	g) Is the magnification of the grid opening measurement system calibrated using an appropriate standard at a frequency of 20 openings/20 grids/lot of 1000 or 1 opening/sample?				
M3 1.7.1.1.1	g) Is the variation in the calibration measurements (2s) is <5% of the mean calibration value?				
M3 1.7.1.1.2	**Air:**				
M3 1.7.1.1.2	Are all calibrations performed in accordance with Section 1.7.1.1.1, with the exception of magnification?				
M3 1.7.1.1.2	Is Magnification calibration done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting, generally 15,000 to 20,000x?				
M3 1.7.1.1.2	Is a logbook maintained with the dates of the calibration recorded?				
M3 1.7.1.1.2	Are calibrations performed monthly to establish the stability of magnification?				
M3 1.7.1.1.3	**Bulk Samples:**				
M3 1.7.1.1.3	Are all calibrations performed in accordance with Section 1.7.1.1.1?				
M3 1.7.1.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.1.2.1	At least once daily, does the analyst use the telescope ocular (or Bertrand lens, for some microscopes) supplied by the manufacturer to ensure that the phase rings (annular diaphragm and phase-shifting elements) are concentric?				
M3 1.7.1.2.2	Is the phase-shift detection limit of the microscope checked monthly or after modification or relocation using an HSE/NPL phase-contrast test slide for each analyst/microscope combination?				
M3 1.7.1.2.2	Is the phase-shift detection limit of the microscope checked daily and after modification?				
M3 1.7.1.2.2	Does the procedure assure that the minimum detectable fiber diameter (<ca. 0.25µm) for this microscope is achieved?				
M3 1.7.1.2.3	Prior to ordering the Walton-Beckett graticule, is a calibration, in accordance with NIOSH 7400, Issue 2, 15 August 1994, Appendix A, performed to obtain a counting area 100 µm in diameter at the image plane?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1.2.3	Is the diameter, dc (mm), of the circular counting area and the disc diameter specified when ordering the graticule?				
M3 1.7.1.2.3	Is the field diameter (D) verified (or checked), to a tolerance of 100 µm ± 2 µm, with a stage micrometer upon receipt of the graticule from the manufacturer?				
M3 1.7.1.2.3	When changes (zoom adjustment, disassembly, replacement, etc.) occur in the eyepiece-objective reticle combination, is the field diameter re-measured (or recalibrated) to determine field area (mm2)?				
M3 1.7.1.2.3	Is a recalibration of the field diameter required when there is a change in interpupillary distance (i.e., change in analyst)?				
M3 1.7.1.2.3	Is the acceptable range for field area 0.00754 mm2 to 0.00817 mm2?				
M3 1.7.1.2.3	Is the actual field area documented and used?				
M3 1.7.1.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.1.3.1	**Microscope Alignment**				
M3 1.7.1.3.1	Is the PLM aligned before use to accurately measure the required optical properties?				
M3 1.7.1.3.1	a) Are both stereoscope and PLM aligned and checked for function and optimized for correct operation before every use by every analyst?				
M3 1.7.1.3.1	b) Are all alignments and function checks documented in the proper log book or electronic record?				
M3 1.7.1.3.2	**Refractive Index Liquids**				
M3 1.7.1.3.2	Are series of nD = 1.49 through 1.72 in intervals less than or equal to 0.005?				
M3 1.7.1.3.2	Are the Refractive index liquids for dispersion staining, high-dispersion series 1.550, 1.605, 1.680?				
M3 1.7.1.3.2	Is the accurate measurement of the refractive index (RI) of a substance required the use of calibrated refractive index liquids?				
M3 1.7.1.3.2	Are the Refractive index liquids calibrated at first use and semiannually, or next use, whichever is less frequent, to an accuracy of 0.004, with a temperature accuracy of 2°C using a refractometer or RI glass beads?				
M3 1.7.2	**Quality Control**				
M3 1.7.2.1	**Negative Controls**				
M3 1.7.2.1.1	**Transmission Electron Microscopy (TEM)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.2.1.1	**a) Water and Wastewater:**				
M3 1.7.2.1.1	i. Are blank determinations made prior to sample collection?				
M3 1.7.2.1.1	i. When using polyethylene bottles, is one (1) bottle from each batch, or a minimum of one (1) from each twenty-four (24) tested for background level?				
M3 1.7.2.1.1	i. When using glass bottles, are four (4) bottles from each twenty-four (24) tested?				
M3 1.7.2.1.1	i. Is an acceptable bottle blank level defined as < 0.01 Million Fibers per Liter (MFL) > 10 µm?				
M3 1.7.2.1.1	ii. Is a process blank sample consisting of fiber-free water run before the first field sample?				
M3 1.7.2.1.1	ii. Is the quantity of water > 10 mL for a 25-mm diameter filter and > 50 mL for a 47-mm diameter filter?				
M3 1.7.2.1.1	**b) Air:**				
M3 1.7.2.1.1	i. Is a blank filter prepared with each set of samples?				
M3 1.7.2.1.1	i. Is a blank filter left uncovered during preparation of the sample set and is a wedge from that exposed blank filter prepared alongside wedges from the sample filters?				
M3 1.7.2.1.1	i. At minimum, is a blank filter analyzed for each twenty (20) samples analyzed?				
M3 1.7.2.1.1	ii. Is the maximum contamination on a single blank filter no more than 53 structures/mm2?				
M3 1.7.2.1.1	ii. Is the Maximum average contamination for all blank filters no more than 18 structures/mm2?				
M3 1.7.2.1.1	**c) Bulk Samples:**				
M3 1.7.2.1.1	i. Are Contamination checks using asbestos-free material, such as the glass fiber blank in SRM 1866, performed at a frequency of one for every twenty (20) samples analyzed?				
M3 1.7.2.1.1	i. Does the detection of asbestos at a concentration exceeding 0.1% require an investigation to detect and remove the source of the asbestos contamination?				
M3 1.7.2.1.1	ii. Does the laboratory maintain a list of non-asbestos fibers that can be confused with asbestos?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.2.1.1	ii. Does the list include crystallographic and/or chemical properties that disqualify each fiber being identified as asbestos?				
M3 1.7.2.1.1	iii. Does the laboratory have a set of reference asbestos materials, from which a set of reference diffraction and x-ray spectra may be developed?				
M3 1.7.2.1.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.2.1.2	Are at least two field blanks (or 10% of the total samples, whichever is greater) submitted for analysis with each set of samples?				
M3 1.7.2.1.2	Are field blanks handled in a manner representative of actual handling of associated samples in the set with a single exception for air which is not drawn through the blank sample?				
M3 1.7.2.1.2	Is a blank cassette opened for approximately thirty (30) seconds at the same time other cassettes are opened just prior to analysis?				
M3 1.7.2.1.2	Are results from field blank samples used in the calculation to determine final airborne fiber concentration?				
M3 1.7.2.1.2	Is the identity of blank filters unknown to the counter until all counts have been completed?				
M3 1.7.2.1.2	If a field blank yields greater than seven (7) fibers per one hundred (100) graticule fields, does the laboratory report possible contamination of the samples?				
M3 1.7.2.1.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.2.1.3	**a) Friable Materials:**				
M3 1.7.2.1.3	a) Is at least one (1) blank slide prepared daily or with every fifty (50) samples analyzed, whichever is less?				
M3 1.7.2.1.3	a) Is it prepared by mounting a sub-sample of an isotropic verified non-asbestos-containing material (non-ACM) (e.g., fiberglass in SRM 1866) in a drop of immersion oils normally used on a clean slide, rubbing preparation tools (forceps, dissecting needles, etc.) in the mount and placing a clean coverslip on the drop?				
M3 1.7.2.1.3	a) Is the entire area under the coverslip scanned to detect any asbestos contamination?				
M3 1.7.2.1.3	a) Is a similar check made after every twenty (20) uses of each piece of homogenization equipment?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.2.1.3	a) Is an isotropic verified non-ACM homogenized in the clean equipment, a slide prepared with the material and the slide scanned for asbestos contamination? (This can be substituted for the blank slide)				
M3 1.7.2.1.3	**b) Non-Friable Materials:**				
M3 1.7.2.1.3	b) Is at least one (1) non-ACM non-friable material prepared and analyzed with every twenty (20) samples analyzed?				
M3 1.7.2.1.3	b) Does the non-ACM through the full preparation and analysis regimen for the type of analysis being performed?				
M3 1.7.3	**Test Variability/Reproducibility**				
M3 1.7.3.1	**Transmission Electron Microscopy (TEM)**				
M3 1.7.3.1	Are Quality assurance analyses performed regularly covering all time periods, instruments, tasks, and personnel?				
M3 1.7.3.1	Are the selection of samples random and samples of special interest included in the selection of samples for quality assurance analyses?				
M3 1.7.3.1	When possible, are the checks on personnel performance executed without their prior knowledge?				
M3 1.7.3.1	Are a disproportionate number of analyses not being performed prior to internal or external audits?				
M3 1.7.3.1	Note: It is recommended that a laboratory initially be at 100% quality control (all samples re-analyzed). The proportion of quality control samples can later be lowered gradually, as control indicates, to a minimum of 10%.				
M3 1.7.3.1.1	**Water and Wastewater"**				
M3 1.7.3.1.1	Are all analyses performed on relocator grids so that other laboratories can easily repeat analyses on the same grid openings?				
M3 1.7.3.1.1	Are Quality assurance analyses continued to be performed during periods of heavy workloads?				
M3 1.7.3.1.1	Is the total number of QA samples and blanks greater than or equal to 10% of the total sample workload?				
M3 1.7.3.1.1	Is the precision of analyses related to concentration, as gleaned from inter-laboratory PT?				
M3 1.7.3.1.1	Note: Relative standard deviations (RSD) for amphibole asbestos decreased from 50% at 0.8 MFL to 25% at 7 MFL in inter-laboratory PT, while RSD for chrysotile was higher, 50% at 6 MFL.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.3.1.1	**a) Replicate:**				
M3 1.7.3.1.1	a) Is a second, independent analysis performed on the same grids but on different grid openings than used in the original analysis of a sample?				
M3 1.7.3.1.1	a) Are the results within 1.5x of Poisson standard deviation?				
M3 1.7.3.1.1	a) Is it performed at a frequency of one (1) per one hundred (100) samples?				
M3 1.7.3.1.1	**b) Duplicate:**				
M3 1.7.3.1.1	b) Is a second aliquot of sample filtered through a second filter, prepared and analyzed in the same manner as the original preparation of that sample?				
M3 1.7.3.1.1	b) Are the results within 2.0x of Poisson standard deviation?				
M3 1.7.3.1.1	b) Is it performed at a frequency of one (1) per one hundred (100) samples?				
M3 1.7.3.1.1	**c) Verified Analyses:**				
M3 1.7.3.1.1	c) Is a second, independent analysis performed on the same grids and grid openings used in the original analysis of a sample?				
M3 1.7.3.1.1	c) Are the two sets of results compared according to Turner and Steel (NISTIR 5351)?				
M3 1.7.3.1.1	c) Is it performed at a frequency of one (1) per twenty (20) samples?				
M3 1.7.3.1.1	c) Do the Qualified analysts maintain an average of: - ≥ 80% true positives - ≤ 20% false negatives - ≤ 10% false positives?				
M3 1.7.3.1.2	**Air:**				
M3 1.7.3.1.2	a) Are all analyses performed on relocator grids so that other laboratories can easily repeat analyses on the same grid openings?				
M3 1.7.3.1.2	b) Does the laboratory and TEM analysts obtain mean analytical results on NIST SRM 1876b so that trimmed mean values fall within 80% of the lower limit and 110% of the upper limit of the 95% confidence limits as published on the certificate?				
M3 1.7.3.1.2	b) Are the limits derived from the allowable false positives and false negatives (see 1.7.3.1.1.c)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.3.1.2	b) Is SRM 1876b analyzed at a minimum of once per year by each TEM analyst?				
M3 1.7.3.1.2	c) Does the laboratory have documentation demonstrating that TEM analysts correctly classify at least 90% of both bundles and single fibrils of asbestos structures greater than or equal to 1 µm in length in known standard materials traceable to NIST, such as NIST bulk asbestos SRM 1866?				
M3 1.7.3.1.2	d) Are Inter-laboratory analyses performed to detect laboratory bias?				
M3 1.7.3.1.2	d) Does the frequency of inter-laboratory verified analysis correspond to a minimum of one (1) per two hundred (200) grid square analyses for clients?				
M3 1.7.3.1.2	e) If more than one TEM is used for asbestos analysis, are intermicroscope analyses performed to detect instrument bias?				
M3 1.7.3.1.2	i. Replicate:				
M3 1.7.3.1.2	i. Is a second, independent analysis performed in accordance with Section 1.7.3.1.1.a?				
M3 1.7.3.1.2	ii. Duplicate:				
M3 1.7.3.1.2	ii. Is a second wedge from a sample filter prepared and analyzed in the same manner as the original preparation of that sample?				
M3 1.7.3.1.2	ii. Are results within 2.0x of Poisson standard deviation? Is this performed at a frequency of one (1) per one hundred (100) samples?				
M3 1.7.3.1.2	iii. Verified Analyses:				
M3 1.7.3.1.2	iii. Is a second, independent analysis performed on the same grids and grid openings (see 1.7.3.1.1.c?]				
M3 1.7.3.1.3	**Bulk Samples** (and Polarized Light Microscopy (PLM) (see 1.7.3.3))				
M3 1.7.3.1.3	Are at least 30% of a laboratory's QC analyses performed on samples containing from 1% to 10% asbestos? Note: Bulk samples with low (< 10%) asbestos content are the most problematic.				
M3 1.7.3.1.3	**a) Intra-Analyst Precision:**				
M3 1.7.3.1.3	a) Is at least one (1) out of fifty (50) samples reanalyzed by the same analyst?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.3.1.3	a) For single analyst laboratories, is at least one (1) out of every ten (10) samples re-analyzed by the same analyst?				
M3 1.7.3.1.3	**b) Inter-Analyst Precision:**				
M3 1.7.3.1.3	b) Is at least one (1) out of fifteen (15) samples reanalyzed by another analyst? Note: Inter-analyst results will require additional reanalysis, possibly including another analyst, to resolve discrepancies when classification (ACM vs. non-ACM) errors occur, when asbestos identification errors occur, or when inter-analyst precision is found to be unacceptable.				
M3 1.7.3.1.3	**c) Inter-Laboratory Precision:**				
M3 1.7.3.1.3	c) Does the laboratory participate in round robin testing with at least one (1) other laboratory?				
M3 1.7.3.1.3	c) Are samples sent to this other laboratory at least four (4) times per year?				
M3 1.7.3.1.3	c) Are the samples previously analyzed as QC samples?				
M3 1.7.3.1.3	c) Are the results of the analyses assessed in accordance with QC requirements?				
M3 1.7.3.1.3	c) Do the QC requirements address misclassifications (false positives, false negatives) and misidentification of asbestos types?				
M3 1.7.3.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.3.2	**a) Inter-Laboratory Precision:**				
M3 1.7.3.2	a) Does each laboratory analyzing air samples for compliance determination implement an inter-laboratory quality assurance program that includes participation of at least two (2) other independent laboratories?				
M3 1.7.3.2	a) Does each laboratory participate in round robin testing at least once every six months with at least all the other laboratories in its inter-laboratory quality assurance group?				
M3 1.7.3.2	a) Does each laboratory submit slides typical of its own workload for use in the program?				
M3 1.7.3.2	a) Are the round robin results analyzed using appropriate statistical methodology?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.3.2	a) Are results of the round robin QA program posted in each laboratory to keep the microscopists informed?				
M3 1.7.3.2	**b) Intra- and Inter-Analyst Precision:**				
M3 1.7.3.2	b) Does each analyst select and count a prepared slide from a "reference slide library" on each day on which air counts are performed? It is recommended that the labels on the reference slides be periodically changed so that the analysts do not become familiar with the samples.				
M3 1.7.3.2	b) Are reference slides prepared using well-behaved samples taken from the laboratory workload?				
M3 1.7.3.2	b) Are fiber densities cover the entire range routinely analyzed by the laboratory?				
M3 1.7.3.2	b) Are prepared slides counted by all analysts to establish an original standard deviation and corresponding limits of acceptability?				
M3 1.7.3.2	b) Are results from the daily reference sample analysis compared to the statistically derived acceptance limits using a control chart or a database?				
M3 1.7.3.2	b) Are Intra- and inter-analyst precision estimated from blind recounts on reference samples?				
M3 1.7.3.2	b) Is the Inter-analyst precision posted in each laboratory to keep the microscopists informed?				
M3 1.7.3.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.3.3	Refer to Section 1.7.3.1.3				
M3 1.7.4	**Other Quality Control Measures**				
M3 1.7.4.1	**Transmission Electron Microscopy (TEM)**				
M3 1.7.4.1	**a) Water and Wastewater:**				
M3 1.7.4.1	i. Are filter preparations made from all six (6) asbestos types from NIST SRMs 1866 and 1867?				
M3 1.7.4.1	i. Do the filter preparations have concentrations between one (1) and twenty (20) structures (>10µm) per 0.01 mm2?				
M3 1.7.4.1	i. Is one of filter preparations analyzed independently at a frequency of one (1) per one hundred (100) samples analyzed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.4.1	i. Are results evaluated as verified asbestos analysis in accordance with S. Turner and E.B. Steel, NISTIR 5351, Airborne Asbestos Method: Standard Test Method for Verified Analysis of Asbestos by Transmission Electron Microscopy – Version 2.0, 1994?				
M3 1.7.4.1	ii. Is NIST SRM 1876b analyzed annually by each analyst?				
M3 1.7.4.1	ii. Are results evaluated in accordance with limits published for that SRM?				
M3 1.7.4.1	**b) Air:**				
M3 1.7.4.1	i. Are filter preparations made from all six (6) asbestos types in accordance with Section 1.7.4.1.a)i?				
M3 1.7.4.1	ii. Is NIST SRM 1876b analyzed annually?				
M3 1.7.4.1	**c) Bulk Samples:**				
M3 1.7.4.1	i. Are all analysts able to correctly identify the six (6) regulated asbestos types (chrysotile, amosite, crocidolite, anthophyllite, actinolite, and tremolite)? Note: Standards for the six (6) asbestos types listed are available from NIST (SRMs 1866 and 1867).				
M3 1.7.4.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.4.2	a) Test for Non-Random Fiber Distribution:				
M3 1.7.4.2	a) Are blind recounts by the same analyst performed on 10% of the filters counted?				
M3 1.7.4.2	a) Does a person other than the counter re-label slides before the second count?				
M3 1.7.4.2	a) Is a test for type II error performed to determine whether a pair of counts by the same analyst on the same slide shall be rejected due to non-random fiber distribution?				
M3 1.7.4.2	a) If a pair of counts is rejected by this test, are the remaining samples in the set recounted and the new counts tested against first counts?				
M3 1.7.4.2	a) Are all rejected paired counts discarded?				
M3 1.7.4.2	b) It is not be necessary to use this statistic on blank recounts.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.4.2	c) Does the laboratory participate in a national sample testing scheme such as the Proficiency Analytical Testing (PAT) program or the Asbestos Analysts Registry (AAR) program, both sponsored by the American Industrial Hygiene Association (AIHA)?				
M3 1.7.4.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.4.3	**a) Friable Materials:**				
M3 1.7.4.3	a) Because accuracy cannot be determined by re-analysis of routine field samples, is at least one (1) out of one hundred (100) samples are a standard or reference sample that has been routinely resubmitted to determine analyst's precision and accuracy? Note: A set of Friable Material samples can be accumulated from PT samples with predetermined weight compositions or from standards generated with weighed quantities of asbestos and other bulk materials.				
M3 1.7.4.3	a) Do at least half of the reference samples submitted for this QC contain between 1 and 10% asbestos?				
M3 1.7.4.3	**b) Non-Friable Materials:**				
M3 1.7.4.3	b) Is at least one (1) out of one hundred (100) samples verified quantitative standard that has routinely been resubmitted to determine analyst precision and accuracy?				
M3 1.7.5	**Analytical Sensitivity**				
M3 1.7.5.1	**Transmission Electron Microscopy (TEM)**				
M3 1.7.5.1.1	**Water and Wastewater**				
M3 1.7.5.1.1	Is an analytical sensitivity of 200,000 fibers per liter (0.2 MFL) required for each sample analyzed?				
M3 1.7.5.1.1	Is analytical sensitivity defined as the waterborne concentration represented by the finding of one asbestos structure in the total area of filter examined? Note: The value will depend on the fraction of the filter sampled and the dilution factor (if applicable).				
M3 1.7.5.1.2	**Air:**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.5.1.2	Is an analytical sensitivity of 0.005 structures/cm2 required for each sample analyzed?				
M3 1.7.5.1.2	Is analytical sensitivity defined as the airborne concentration represented by the finding of one asbestos structure in the total area of filter examined? Note: The value will depend on the effective surface area of the filter, the filter area analyzed, and the volume of air sampled.				
M3 1.7.5.1.3	**Bulk Samples:**				
M3 1.7.5.1.3	Is the range dependent on the type of bulk material being analyzed?				
M3 1.7.5.1.3	Is the sensitivity as low as 0.0001%?				
M3 1.7.5.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.5.2	Is the normal quantitative working range of the method 0.04 to 0.5 fiber/ cm2 for a 1000 L air sample?				
M3 1.7.5.2	Is an ideal counting range on the filter 100 to 1300 fibers/mm2?				
M3 1.7.5.2	Is the limit of detection (LOD) estimated to be 5.5 fibers per 100 fields or 7 fibers/mm2?				
M3 1.7.5.2	Is the LOD in fiber/cc <0.01 fiber/cm2 for atmospheres free of interferences? Note: The LOD in fiber/cc will depend on sample volume and quantity of interfering dust.				
M3 1.7.5.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.5.3	Does the laboratory utilize a method that provides a limit of detection that is appropriate and relevant for the intended use of the data?				
M3 1.7.5.3	Is the Limit of detection determined by the protocol in the method or applicable regulation?				
M3 1.7.6	**Quality of Standards and Reagents**				
M3 1.7.6.1	**Transmission Electron Microscopy (TEM)** (and Polarized Light Microscopy (PLM) (see 1.7.6.3))				
M3 1.7.6.1	a) Has the quality control program established and maintained provisions for asbestos standards?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.6.1	b) Are reference standards that are used in an asbestos laboratory obtained from NIST, EPA, or suppliers who participate in supplying NIST standards or NIST traceable asbestos? Are any reference standards purchased outside the United States traceable back to each country's national standards laboratory?				
M3 1.7.6.1	b) Do the commercial suppliers of reference standards conform to ANSI N42.22 to assure the quality of their products?				
M3 1.7.6.1	c) Are reference standards accompanied with a certificate of calibration whose content is as described in ANSI N42.22-1995, Section 8, Certificates?				
M3 1.7.6.1	d) Are all reagents used analytical reagent grade or better?				
M3 1.7.6.1	e) Does the laboratory have mineral fibers or data from mineral fibers that will allow differentiating asbestos from at least the following "look-alikes": fibrous talc, sepiolite, wollastonite, attapulgite (palygorskite), halloysite, vermiculite scrolls, antigorite, lizardite, pyroxenes, hornblende, richterite, winchite, or any other asbestiform minerals that are suspected as being present in the sample?				
M3 1.7.6.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.6.2	Are routine workload samples that have been statistically validated and national PT samples such as Proficiency Analytical Testing (PAT) and Asbestos Analysts Registry (AAR) samples available from the American Industrial Hygiene Association (AIHA) utilized as reference samples (refer to Section D.6.2.2 b) to standardize the optical system and analyst? Note: Standards of known concentration have not been developed for this testing method.				
M3 1.7.6.2	Do all other (non-standards) testing reagents and devices (HSE/NPL test slide and Walton-Beckett Graticule) conform to the specifications of the method (refer to National Institute for Occupational Safety and Health (NIOSH) 7400, Issue 2, 15 August 1994)?				
M3 1.7.6.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.6.3	Refer to Section 1.7.6.1				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.7	**Data Acceptance/Rejection Criteria**				
M3 1.7.7.1	**Transmission Electron Microscopy (TEM)**				
M3 1.7.7.1.1	**Water and Wastewater:**				
M3 1.7.7.1.1	a) Is the concentration of asbestos in a given sample shall be calculated in accordance with EPA/600/R-94/134, Method 100.2, Section 12.1?				
M3 1.7.7.1.1	**b) Measurement Uncertainties:**				
M3 1.7.7.1.1	b) Does the laboratory calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample?				
M3 1.7.7.1.2	**Air:**				
M3 1.7.7.1.2	a) Is the concentration of asbestos in a given sample shall be calculated in accordance with the method utilized?				
M3 1.7.7.1.2	**Measurement Uncertainties:**				
M3 1.7.7.1.2	b) Does the laboratory calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample?				
M3 1.7.7.1.3	**Bulk Samples**				
M3 1.7.7.1.3	a) Is the concentration of asbestos in a given sample shall be calculated in accordance with the method utilized? (e.g., EPA/600/R-93/116, July 1993)				
M3 1.7.7.1.3	**b) Measurement Uncertainties:**				
M3 1.7.7.1.3	b) Are PT for floor tiles analyzed by TEM following careful gravimetric reduction has revealed an inter-laboratory standard deviation of approximately 20% for residues containing 70% or more asbestos?				
M3 1.7.7.1.3	b) Do standard deviations range from 20% to 60% for residues with lower asbestos content?				
M3 1.7.7.2	**Phase Contrast Microscopy (PCM)**				
M3 1.7.7.2.1	Is the airborne fiber concentration in a given sample calculated in accordance with NIOSH 7400, Issue 2, 15 August 1994, Sections 20 and 21?				
M3 1.7.7.2.2	**b) Measurement Uncertainties:**				
M3 1.7.7.2.2	Does the laboratory calculate and report the intra laboratory and inter-laboratory relative standard deviation with each set of results (NIOSH 7400, Issue 2, 15 August 1994)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.7.2.3	Are fiber counts above 1300 fibers/mm2 and fiber counts from samples with >50% of the filter area covered with particulate reported as “uncountable” or “probably biased”?				
M3 1.7.7.2.3	Are fiber counts outside the 100-1300 fibers/mm2 range reported as having “greater than optimal variability” and as being “probably biased”?				
M3 1.7.7.3	**Polarized Light Microscopy (PLM)**				
M3 1.7.7.3.1	Is the concentration of asbestos in a given sample calculated in accordance with the method utilized? (e.g., EPA/600/R-93/116, July 1993)				
M3 1.7.7.3.2	**b) Measurement Uncertainties:**				
M3 1.7.7.3.2	Are precision and accuracy determined by the individual laboratory for the percent range involved?				
M3 1.7.7.3.2	If point counting and/or visual estimates are used, is a table of reasonable expanded errors generated for different concentrations of asbestos?				
M3 1.7.8	**Constant and Consistent Test Conditions Sample and Sampling Requirements**				
M3 1.7.8.1	Are samples transported to the laboratory as soon as possible after collection? Note: No preservatives are required during sampling.				
M3 1.7.8.1	Is the date and time of sampling noted on submittal forms?				
M3 1.7.8.1	Are the names of the collectors with their signatures and the site included on the chain-of-custody forms?				
M3 1.7.8.2	Has the laboratory establish and adhere to written procedures to minimize the possibility of cross contamination between samples?				
M4	**Volume 1 Module 4**				
M4	**Quality Systems for Chemical Testing**				
M4 1.4	**Method Selection**				
M4 1.4	When it is necessary to use methods not covered by reference methods, are these methods subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the environmental test?				
M4 1.4	If no QC exists in the method, the laboratory does the laboratory adhere to the requirements outlined in a similar method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.4	Are developed methods validated appropriately before use?				
M4 1.5	**Method Validation**				
M4 1.5.1	a) Does the laboratory validate reference methods via the procedures specified in Sections 1.5.2 and 1.5.3?				
M4 1.5.1	b) Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use?				
M4 1.5.1	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
M4 1.5.1	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
M4 1.5.1	In the absence of other specifications, are the minimum requirements for method validation are given in Sections 1.5.2, 1.5.3 and 1.5.4?				
M4 1.5.1	c) Is the laboratory evaluating modified reference methods and non-standard methods (including laboratory developed methods) using QC procedures and acceptance criteria that are consistent with those of similar standard methods or technologies?				
M4 1.5.1	c) Does the evaluation include the following:				
M4 1.5.1	i. Scope?				
M4 1.5.1	ii. calibration/calibration verification?				
M4 1.5.1	iii. Interferences/Contamination?				
M4 1.5.1	iv. Analyte identification?				
M4 1.5.1	v. Analyte quantitation?				
M4 1.5.1	vi. Selectivity?				
M4 1.5.1	vii. Sensitivity?				
M4 1.5.1	viii. Precision?				
M4 1.5.1	ix. Bias?				
M4 1.5.1	d) Is the use of any modified reference method or non-standard methods being approved by DoD/DOE personnel?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.1	e) Are methods validated when substantive modifications are made to reference methods (i.e., stoichiometry, technology, mass tuning acceptance criteria, quantitation ions, compressing digestion or extraction timeframes, reducing reagent or solvent volumes, changing solvents, or compressing instrument runtimes)?				
M4 1.5.1	Note1: DoD/DOE allows method modifications as described in the November 20, 2007 USEPA Memorandum on method flexibility. Note2: Are the methods that are not published in the Standard Methods for the Examination of Water and Wastewater or Multi-Agency Radiological Laboratory Analytical Protocols Manual, or published in recognized entities such as USEPA, USDOE, ASTM, or NIOSH considered non-standard methods?				
M4 1.5.2	**Limit of Detection (LOD) and Limit of Quantitation (LOQ)**				
M4 1.5.2	Does the laboratory have a document procedure used for determining LODs and LOQs				
M4 1.5.2	Does the documentation include the quality system matrix type?				
M4 1.5.2	Is all supporting data retained?				
M4 1.5.2.1	**Limit of Detection (LOD)**				
M4 1.5.2.1	Note: If the laboratory is not reporting a value below the LOQ, a LOD study is not required.				
M4 1.5.2.1	Does the laboratory utilize a method that provides an LOD that is appropriate and relevant for the intended use of the data?				
M4 1.5.2.1	If a mandated method or regulation includes protocols for determining detection limits, are they followed?				
M4 1.5.2.1	Does the laboratory document how LODs were derived from the determinations?				
M4 1.5.2.1	If the protocol for determining the LOD is not specified, does the selection of the procedure reflect instrument limitations and the intended application of the method?				
M4 1.5.2.1	Are all sample-processing and analysis steps of the analytical method included in the determination or validation of the LOD?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.1	a) When required, does the laboratory determine or verify the LOD for the method for each target analyte of concern in the quality system matrices?				
M4 1.5.2.1	b) Is the validity of the LOD verified by detection (a value above zero) of the analyte(s) in a QC sample in each quality system matrix?				
M4 1.5.2.1	b) Does the QC sample contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests?				
M4 1.5.2.1	b) Is the verification performed on every instrument that is to be used for analysis of samples and reporting of data?				
M4 1.5.2.1	b) Is the validity of the LOD verified as part of the LOD determination process?				
M4 1.5.2.1	b) Is the verification done prior to the use of the LOD for the sample analysis?				
M4 1.5.2.1	b) Does the laboratory establish a detection limit (DL) using accepted, published methodologies from recognized entities such as USEPA, USDOE, ASTM, or NIOSH for each suite of analyte-matrix-method, including surrogates?				
M4 1.5.2.1	b) Is the DL used to determine the LOD for each analyte and matrix as well as for all preparatory and cleanup methods routinely used on samples?				
M4 1.5.2.1	c) Does the laboratory have readily available, if require, an LOD study for any component which spiking solutions or quality control sample are available? Note: An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature.				
M4 1.5.2.1	d) Is the LOD initially determined for the compounds of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or is the LOD performed in the quality system matrix of interest?				
M4 1.5.2.1	e) Is the LOD performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis?				
M4 1.5.2.1	f) Is the LOD, if required, verified annually for each quality system matrix, technology, and analyte.?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.1	f) Does each preparation method listed on the scope of accreditation have quarterly LOD verifications? Note: Not all possible combinations of preparation and cleanup techniques have the required to have LOD/LOQ verifications.				
M4 1.5.2.1	f) If LOD verifications are not performed on all combinations, does the laboratory base the LOD verifications on the worst case basis (preparation method with all applicable cleanup steps)?				
M4 1.5.2.1	f) After each DL determination, does the laboratory establish the LOD by spiking a quality system matrix at a concentration of at least two (2) times but no greater than four (4) times the DL (i.e., 2x DL ≤ LOD Spike ≤ 4x DL)?				
M4 1.5.2.1	f) Does the spike concentration establish the LOD and the concentration at which the LOD is verified?				
M4 1.5.2.1	f) Is the LOD specific to each suite of analyze, matrix, and method (including sample preparation)?				
M4 1.5.2.1	f) Are the following requirements applied to the initial LOD establishment and to the LOD verifications?				
M4 1.5.2.1	i. Is the apparent signal to noise (S/N) ratio at the LOD at least three (3)?				
M4 1.5.2.1	i. Do the results meet all method requirements for analyte identification (e.g., ion abundance, second column confirmation, or pattern recognition)?				
M4 1.5.2.1	i. For data systems that do not provide a measure of noise, is the signal produced by the verification sample a result that is at least three (3) standard deviations greater than the mean MB concentration? Note: This is initially estimated based on a minimum of four MB analyses and later established with a minimum of twenty (20) MB results.				
M4 1.5.2.1	ii. If the LOD verification fails, does the laboratory repeat the DL determination and LOD verification or perform and pass two (2) consecutive LOD verifications at a higher spike concentration and set the LOD at the higher concentration?				
M4 1.5.2.1	iii. Does the laboratory maintain documentation for all DL determinations and LOD verifications?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.1	iv. Are the DL and LOD reported for all analyte-matrix-methods suites, unless it is not applicable to the test or specifically excluded by project requirements?				
M4 1.5.2.1	g) In situations where methods are setup and used on an infrequent basis, does the laboratory choose to perform LOD verifications on a one per batch basis, prior to sample analysis?				
M4 1.5.2.1	g) Are all verification data in compliance, reported, and available for review?				
M4 1.5.2.2	**Limit of Quantitation (LOQ)**				
M4 1.5.2.2	a) Are all sample-processing and analysis steps of the analytical method included in the determination of the LOQ?				
M4 1.5.2.2	b) The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not available or otherwise inappropriate (e.g., pH)				
M4 1.5.2.2	c) Is the validity of the LOQ verified by successful analysis of a QC sample containing the analytes of concern in each quality system matrix at 1 to 2 times the claimed LOQ. Note: A successful analysis is one where the recovery of each analyte is within the laboratory established method acceptance criteria or client data quality objectives for accuracy.				
M4 1.5.2.2	c) Does the laboratory procedure for establishing the LOQ empirically demonstrate precision and bias at the LOQ for each suite of analyte-matrix-method, including surrogates?				
M4 1.5.2.2	c) Do the LOQ and associated precision and bias meet client requirements and are they reported?				
M4 1.5.2.2	c) If the method is modified, are precision and bias at the new LOQ demonstrated and reported?				
M4 1.5.2.2	c) Is the LOQ set within the calibration range, including the lowest calibration level?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.2	Note1: Precision and bias at the limit of quantitation (LOQ) can be demonstrated by analyzing multiple LOQ-verification samples over multiple days. A minimum of 4 samples should be analyzed to establish the initial precision and bias. If specific methods recommend a greater number of LOQ-verification replicates, then more replicates should be initially analyzed (e.g., SW846 6010D and 6020B recommend 7 replicates). If multiple instruments are used for analysis, then LOQ verifications should be performed on each instrument and all of the results should be used for calculation of precision and bias. The precision and bias should be updated at least annually using any additional LOQ verification sample results. LOQ verification samples should meet laboratory-established or Method acceptance criteria.				
M4 1.5.2.2	Note2: Precision should be determined by calculating the standard deviation for each set of analyte-matrix-method results. The standard deviation (precision) should be reported as a percent of the spiked value. Bias should be determined by calculating the difference of the average result from the spiked value. The bias should also be reported as a percentage of the spiked value. Bias will be negative, positive, or zero.				
M4 1.5.2.2	Note3: When reporting precision and bias, a table for each analyte-matrix-method should present the LOQ concentration, and the associated precision and bias at that concentration. The table should also identify how precision and bias were calculated, the spike concentration if different from the LOQ, and how many data points (results) were used in the calculation. This table (or a similar presentation of precision and bias) must be provided to the client during project planning, and on request. Precision and bias information should also be provided in laboratory data packages.				
M4 1.5.2.2	d) When an LOD is determined or verified by the laboratory, is the LOQ above the LOD?				
M4 1.5.2.2	e) Is the LOQ verified annually for each quality system matrix, technology, and analyte? Note: The annual LOQ verification is not required if the LOD was determined or verified annually on that instrument.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.2	e) Is the LOQ verified quarterly? Note1: Not all possible combinations of preparation and cleanup techniques are required to have LOQ verifications. Note2: If LOQ verifications are not performed on all combinations, the laboratory must base the LOQ verifications on the worst case basis (preparation method with all applicable cleanup steps).				
M4 1.5.2.2	e) In situations where methods are setup and used on an infrequent basis, does the laboratory choose to perform LOQ verifications on a one per batch basis in lieu of quarterly verification, prior to sample analysis?				
M4 1.5.3	**Evaluation of Precision and Bias**				
M4 1.5.3	**a) Reference Methods:**				
M4 1.5.3	a) Does the laboratory evaluate the precision and bias of a reference method for each analyte of concern for each quality system matrix according to Section 1.6 or alternate documented procedure when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available?				
M4 1.5.3	**b) Non-Reference Methods:**				
M4 1.5.3	b) For laboratory-developed methods or non-reference methods that were not in use by the laboratory before July 2003, does the laboratory have a documented procedure to evaluate precision and bias?				
M4 1.5.3	b) Does the laboratory compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory?				
M4 1.5.3	b) Are precision and bias measurements used evaluate the method across the analytical calibration range of the method?				
M4 1.5.3	b) Does the laboratory also evaluate precision and bias in the relevant quality system matrices and process the samples through the entire measurement system for each analyte of interest?				
M4 1.5.4	**Evaluation of Selectivity**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.4	Does the laboratory evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors?				
M4 1.6	**Demonstration of Capability (DOC)**				
M4 1.6.1	Prior to acceptance and institution of any method for which data will be reported, a satisfactory initial DOC is required (see Section 1.6.2)?				
M4 1.6.1	Is ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) required?				
M4 1.6.1	In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the ongoing DOC shall be acceptable as an initial DOC.				
M4 1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
M4 1.6.1	For the initial DOC, are appropriate records as discussed in Section 1.6.2 completed?				
M4 1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
M4 1.6.1	Are all demonstrations documented?				
M4 1.6.1	Is all data applicable to the demonstration retained and readily available by the laboratory?				
M4 1.6.2	**Initial DOC**				
M4 1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
M4 1.6.2	a) Does the laboratory have a documented procedure for performing the initial DOC for methods used?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.6.2	b) Do changes in any condition that could potentially affect the precision and bias, sensitivity, or selectivity of the output (e.g., a change in the detector, column type, matrix, method revision, or other components of the sample analytical system) result in a new initial DOC?				
M4 1.6.2.1	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
M4 1.6.2.1	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee: a) analyst(s) involved in preparation and/or analysis? b) matrix? c) analyte(s), class of analyte(s), or measured parameter(s)? d) identification of method(s) performed? e) identification of laboratory-specific SOP used for analysis, including revision number? f) date(s) of analysis? g) summary of analyses, including information outlined in Section 1.6.2.2.c?				
M4 1.6.2.2	If the method or regulation does not specify a DOC, does the laboratory use the procedure stated below (a-d) and document that other approaches to initial DOC are adequate?				
M4 1.6.2.2	a) The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four (4) aliquots at the concentration specified, or if unspecified, to a concentration of one (1) to four (4) times the limit of quantitation.				
M4 1.6.2.2	b) At least four (4) aliquots shall be prepared and analyzed according to the method(s) either concurrently or over a period of days.				
M4 1.6.2.2	c) Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory shall assess performance against established and documented criteria.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.6.2.2	d) Compare the information from (c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not meet the acceptance criteria, the performance is unacceptable for that parameter.				
M4 1.6.2.2	e) When one or more of the tested parameters fail at least one of the acceptance criteria, does the analyst proceed according to i) or ii) below? i. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above. ii. Beginning with c) above, repeat the test for all parameters that failed to meet criteria.				
M4 1.6.2.2	f) Repeated failure, however, confirms a general problem with the measurement system. If this occurs, does the laboratory locate and correct the source of the problem and repeat the test for all compounds of interest beginning with b)?				
M4 1.6.2.2	g) When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited method, is an initial demonstration performed for that analyte?				
M4 1.6.2.2	Does the laboratory document that other approaches to ongoing DOC are adequate, if applicable?				
M4 1.6.3	**Ongoing DOC**				
M4 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC?				
M4 1.6.3.1	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this standard?				
M4 1.6.3.1	Does the laboratory document other adequate approaches for performing an initial DOC, if applicable?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.6.3.2	Does the laboratory use one of the following for ongoing DOC? a) acceptable performance of a blind sample (single blind to the analyst); Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the test. b) another initial DOC; c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing laboratory control samples (LCS) for each method for each analyst each year; d) a documented process of analyst review using quality control (QC) samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary; or e) if a) through d) are not technically feasible, then analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) shall be performed.				
M4 1.7	**Technical Requirements**				
M4 1.7.1	**Initial Calibration**				
M4 1.7.1.1	**Instrument Calibration**				
M4 1.7.1.1	If more stringent standards or requirements are included in a mandated method or by regulation, does the laboratory demonstrate that such requirements are met?				
M4 1.7.1.1	If it is not apparent which Standard is more stringent, are the requirements of the regulation or mandated method followed?				
M4 1.7.1.1	Are the following essential elements of initial instrument calibration performed?				
M4 1.7.1.1	a) Are the details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics included or referenced in the method SOP?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.1	a) When initial instrument calibration procedures are referenced in the method, is the referenced material retained by the laboratory and be available for review?				
M4 1.7.1.1	b) Are sufficient raw data records retained to permit reconstruction of the initial instrument calibration (e.g., calibration date, method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration)?				
M4 1.7.1.1	c) Are sample results quantitated from the initial instrument calibration and not quantitated from any CCV verification unless otherwise required by regulation, method, or program?				
M4 1.7.1.1	d) Are all initial instrument calibrations verified with a standard obtained from a second manufacturer or from a different lot.				
M4 1.7.1.1	d) Is traceability to a national standard, when commercially available?				
M4 1.7.1.1	d) Are all initial instrument calibrations verified with a standard obtained from a second manufacturer prior to analyzing any samples? Note: The use of a standard from a second lot obtained from the same manufacturer (independently prepared from different source materials) is acceptable for use as a second source standard.				
M4 1.7.1.1	d) Is the concentration of the second source standard at or near the midpoint of the calibration range?				
M4 1.7.1.1	d) Are the acceptance criteria for the initial calibration verification at least as stringent as those for the continuing calibration verification?				
M4 1.7.1.1	e) Is the criteria for the acceptance of an initial instrument calibration established (e.g., correlation coefficient or relative percent difference)?				
M4 1.7.1.1	e) Is the criteria used appropriate to the calibration technique employed?				
M4 1.7.1.1	f) Is the lowest calibration standard at or below the LOQ?				
M4 1.7.1.1	f) Is any data reported below the LOQ considered to have an increased quantitative uncertainty and is it reported using defined qualifiers or explained in the narrative?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.1	g) Is the highest calibration standard at or above the highest concentration for which quantitative data are to be reported?				
M4 1.7.1.1	g) Is any data reported above the calibration range considered to have an increased quantitative uncertainty and reported using defined qualifiers or explained in the narrative?				
M4 1.7.1.1	g) Do the LOQ and the highest calibration standard of a multi-level calibration curve establish the calibration range?				
M4 1.7.1.1	g) For metals analysis with a single-point calibration, do the LOQ and the calibration standard establish the calibration range, which lie within the linear dynamic range (LDR)?				
M4 1.7.1.1	g) When sample responses exceed the calibration range, does the laboratory dilute and reanalyze the sample (when sufficient sample volume and holding time permit) to bring results within the calibration range?				
M4 1.7.1.1	g) For metals analysis, if the laboratory reports a sample result with a response above the calibration range, does the laboratory analyze a passing (within 10% of the true value) high level check standard that exceeds the sample concentration but is within the LDR. Note: The high level check standard needs to be analyzed in the same manner as the sample and within the same calibration.				
M4 1.7.1.1	g) Are the results outside the calibration range reported as estimated values and qualified using appropriate data qualifiers that are explained in the case narrative?				
M4 1.7.1.1	h) Does the following occur for instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard?				
M4 1.7.1.1	i. Prior to the analysis of samples, is the zero point and single point calibration standard analyzed and is the linear range of the instrument established by analyzing a series of standards, one of which is at or below the LOQ? Note: Sample results within the established linear range will not require data qualifiers.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.1	ii. Is a zero point and single point calibration standard analyzed with each analytical batch?				
M4 1.7.1.1	iii. Is a standard corresponding to the LOQ analyzed with each analytical batch and does it meet the established acceptance criteria?				
M4 1.7.1.1	iv. Is the linearity verified at a frequency established by the method and/or the manufacturer?				
M4 1.7.1.1	i) if the initial instrument calibration results are outside established acceptance criteria, are corrective actions performed and all associated samples re-analyzed?				
M4 1.7.1.1	i) If the re-analysis of the samples is not possible, is the data associated with an unacceptable initial instrument calibration reported with appropriate data qualifiers?				
M4 1.7.1.1	j) If a reference or mandated method does not specify the number of calibration standards, is the minimum number of points for establishing the initial instrument calibration three?				
M4 1.7.1.1	j) Does the initial calibration range consist of a minimum of five (5) calibration points for organic analytes and three (3) calibration points for inorganic analytes and Industrial Hygiene samples? Note: Exception = metals by ICP-AES or ICP-MS with a single point calibration or otherwise stated in the method.				
M4 1.7.1.1	j) Are all reported analytes and surrogates (if applicable) included in the initial calibration?				
M4 1.7.1.1	j) Are the reported results for all analytes and surrogates quantified using a multipoint calibration curve? Note: Exception = metals by ICP-AES or ICP-MS with a single point calibration or otherwise stated in the method.				
M4 1.7.1.1	j) Is the exclusion of calibration points without documented scientifically valid technical justification not permitted?				
M4 1.7.2	**Continuing Calibration (CCV)**				
M4 1.7.2	When an initial instrument calibration is not performed on the day of analysis, is the validity of the initial calibration verified prior to sample analyses by a CCV verification with each analytical batch?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2	Are the following items essential elements of CCV verification?				
M4 1.7.2	a) Are the details of the CCV procedure, calculations and associated statistics included or referenced in the method SOP?				
M4 1.7.2	b) Is the calibration verified for each compound, element, or other discrete chemical species, except for multi-component analytes such as aroclors, chlordane, total petroleum hydrocarbons, or toxaphene, where a representative chemical, related substance or mixture can be used?				
M4 1.7.2	c) Are instrument calibration verifications performed:				
M4 1.7.2	i. at the beginning and end of each analytical batch. If an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch; ii. if the time period for calibration or the most recent calibration verification has expired; or iii. for analytical systems that contain a calibration verification requirement.				
M4 1.7.2	iv. at a concentration greater than the low calibration standard and less than or equal to the midpoint of the calibration range?				
M4 1.7.2	d) Are sufficient raw data records retained to permit reconstruction of the CCV verification (e.g., method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations)?				
M4 1.7.2	d) Do CCV records explicitly connect the continuing verification data to the initial instrument calibration?				
M4 1.7.2	d) Are all CCVs analyzed evaluated and reported?				
M4 1.7.2	d) If a CCV fails, is reanalysis or corrective actions taken?				
M4 1.7.2	e) Are criteria for the acceptance of a CCV established?				
M4 1.7.2	e) If the CCV fails and analysis of a second consecutive (immediate) CCV fails to produce results within acceptance criteria, are corrective actions performed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2	e) Does laboratory demonstrate acceptable performance after corrective action with two consecutive CCVs, or a new initial instrument calibration is performed?				
M4 1.7.2	e) Does laboratory not permit sample analyses until the analytical system is calibrated or calibration verified.				
M4 1.7.2	e) If samples are analyzed using a system on which the calibration has not yet been verified are the results flagged?				
M4 1.7.2	e) are samples affected by an unacceptable CCV re-analyzed after a new calibration curve has been established, evaluated and accepted, unless the following special conditions occur?				
M4 1.7.2	i. when the acceptance criteria for the CCV are exceeded high (i.e., high bias) and there are associated samples that are non-detects. or ii. when the acceptance criteria for the CCV are exceeded low (i.e., low bias), and there are associated sample results that exceed a maximum regulatory limit/decision level.				
M4 1.7.2	e) If a CCV fails, does the laboratory immediately analyze two (2) additional consecutive CCVs. Note1: Immediately is defined as starting a consecutive pair within one (1) hour; no samples can be run between the failed CCV and the two (2) additional CCVs. Note2: This approach allows for analytes to be reported without reanalysis of samples, while ignoring spurious failures.				
M4 1.7.2	e) Do corrective actions that change the dynamics of the system (e.g., clip column, clean injection port, run blanks) require that all samples since the last acceptable CCV be reanalyzed?				
M4 1.7.2	i. Do both of these CCVs meet acceptance criteria in order for the samples to be reported without reanalysis?				
M4 1.7.2	ii. If either of these two (2) CCVs fail, are the associated samples not reported and required to be reanalyzed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2	iii. If the laboratory cannot immediately analyze two (2) CCVs, then is corrective action performed and the CCV and all associated samples since the last successful CCV repeated?				
M4 1.7.2	iv. Does recalibration occur if the above scenario fails and all affected samples since the last acceptable CCV reanalyzed.?				
M4 1.7.2	v. Is the flagging of data for a failed CCV only appropriate when the affected samples cannot be reanalyzed?				
M4 1.7.2	v. Does the laboratory notify the client prior to reporting data associated with a failed CCV?				
M4 1.7.3	**Quality Control (QC)**				
M4 1.7.3	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken as specified in this section?				
M4 1.7.3	Do all method QC parameters and samples follow Appendix B requirements, as appropriate? Note: Appendix B requirements are considered the minimum technology based requirements regardless of method version.				
M4 1.7.3.1	**Negative Control – Method Performance: Method Blank (MB)**				
M4 1.7.3.1	Note: Method blanks are not applicable for certain analyses, such as pH, Conductivity, Flash Point and Temperature.				
M4 1.7.3.1	a) Is the MB used to assess the samples in the preparation batch for possible contamination during the preparation and processing steps?				
M4 1.7.3.1	a) Is the MB processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure?				
M4 1.7.3.1	a) Are procedures in place to determine if a MB is contaminated?				
M4 1.7.3.1	a) Are any affected samples associated with a contaminated MB reprocessed for analysis or are the results reported with appropriate data qualifying codes?				
M4 1.7.3.1	b) Is the MB analyzed at a minimum of one (1) per preparation batch?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.1	b) In those instances for which no separate preparation method is used (for example, volatiles in water), is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty (20) environmental samples, not including MBs, LCS, MSs and MSDs?				
M4 1.7.3.1	c) Does the MB consist of a quality system matrix that is similar to the associated samples and is known to be free of the analytes of interest?				
M4 1.7.3.2	**Positive Control – Method Performance: Laboratory Control Sample (LCS)**				
M4 1.7.3.2	Is the LCS used to evaluate the performance of the total analytical system, including all preparation and analysis steps?				
M4 1.7.3.2.1	Are results of the LCS compared to established criteria and, if found to be outside of these criteria, the analytical system is considered to be “out of control”?				
M4 1.7.3.2.1	Are any affected samples associated with an out of control LCS reprocessed for re-analysis or the results reported with appropriate data qualifying codes?				
M4 1.7.3.2.2	Is the LCS analyzed at a minimum of one (1) per preparation batch? Note: Exceptions would be for those analytes for which no spiking solutions are available, such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity.				
M4 1.7.3.2.2	In those instances for which no separate preparation method is used (for example, volatiles in water), is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty (20) environmental samples, not including MBs, LCS, MSs and MSDs?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.2.3	Is the LCS quality system matrix, known to be free of analytes of interest and spiked with known concentrations of analytes? Note1: Alternatively, the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). Note2: The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.				
M4 1.7.3.2.3	Are all analyte concentrations within the calibration range of the methods..				
M4 1.7.3.2.3	Is the following used in choosing components for the spike mixtures:				
M4 1.7.3.2.3	Are the components spiked as specified by the mandated method or regulation or as requested by the client?				
M4 1.7.3.2.3	In the absence of specified spiking components, does the laboratory spike per the following?				
M4 1.7.3.2.3	a) For those components that interfere with an accurate assessment, such as spiking simultaneously with technical chlordane, toxaphene and PCBs, is a spike chosen that represents the chemistries and elution patterns of the components to be reported?				
M4 1.7.3.2.3	b) For those methods that have extremely long lists of analytes, is a representative number chosen and the analytes selected representative of all analytes reported?				
M4 1.7.3.2.3	b) Is the following criteria used for determining the minimum number of analytes to be spiked?				
M4 1.7.3.2.3	i. For methods that include one (1) to ten (10) targets, spike all components? ii. For methods that include eleven (11) to twenty (20) targets, spike at least ten (10) or 80%, whichever is greater? iii. For methods with more than twenty (20) targets, spike at least sixteen (16) components?				
M4 1.7.3.2.3	b) Does the laboratory insure that all targeted components are included in the spike mixture over a two (2) year period?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.2.3	b) Are all reported analytes spiked in the LCS (with the exception of Aroclor analysis, which is spiked per the method). Note: This may require the preparation of multiple LCSs to avoid interferences?				
M4 1.7.3.2.3	b) Is the concentration of the spiked compounds at or below the midpoint of the calibration if project specific concentrations are not specified?				
M4 1.7.3.2.3	c) Has the laboratory established LCS in-house limits that:				
M4 1.7.3.2.3	i. Are statistically-derived based on in-house historical data, using scientifically valid and documented procedures?				
M4 1.7.3.2.3	ii. Meet the limits specified by the project or as stated in the method, if available?				
M4 1.7.3.2.3	iii. updated on at least an annual basis or as stated in the method, whichever is more frequent, and re-established after major changes in the analytical process (e.g., new instrumentation)?				
M4 1.7.3.2.3	iv. Are based on at least thirty (30) data points generated under the same analytical process?				
M4 1.7.3.2.3	v. Do not exclude failed LCS recovery data and statistical outliers from the calculation, unless there is a scientifically valid and documented reason (e.g., incorrectly made standard, instrument malfunction)?				
M4 1.7.3.2.3	vi. Control Limits are not greater than ± 3 times the standard deviation of the mean LCS recovery?				
M4 1.7.3.2.3	vii. The LCS consists of a quality system matrix that is similar to the associated samples?				
M4 1.7.3.2.3	d) Are control charts or data analysis software maintained and used to detect trends and prevent out-of-control conditions?				
M4 1.7.3.2.3	d) Are the control limits monitored on an on-going basis (at least quarterly) for shifts in mean recovery, changes in standard deviation, and development of trends?				
M4 1.7.3.2.3	d) Does the laboratory choose representative compounds for control charts for the purpose of trend analysis?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.2.3	e) Does the QA Officer or designee review control charts at a specified frequency for out-of-control conditions and initiate appropriate corrective actions? Note: Data analysis software may also be used for the statistical evaluation of data for trends and biases.				
M4 1.7.3.2.3	f) Does the laboratory use its in-house statistically established LCS control limits for the purpose of trend analysis and use in-house control limits as a component in estimating measurement uncertainty?				
M4 1.7.3.2.3	g) In the absence of client specified LCS reporting criteria, does the LCS control limits outlined in the Appendix C tables used when reporting data?				
M4 1.7.3.2.3	g) Has the laboratory developed processes or procedures to incorporate these limits?				
M4 1.7.3.2.3	h) Are the LCS limits specified in the Appendix C tables used for batch control unless project specific criteria exist?				
M4 1.7.3.2.3	h) Are sporadic Marginal Exceedances allowed for those analytes outside the 3 standard deviation control limits but still within 4 standard deviations?				
M4 1.7.3.2.3	h) Are Marginal Exceedances not allowed for those analytes determined by a project to be target analytes (i.e. “risk drivers”) without project specific approval?				
M4 1.7.3.2.3	i) For analytes that are not listed in the Appendix C control limits tables, does the laboratory use their in-house control limits for batch control and data reporting?				
M4 1.7.3.2.3	j) Does the laboratory develop in-house control limits for all analytes on their scope of accreditation?				
M4 1.7.3.2.3	j) Are the in-house control limits used for trend analysis, and batch control for those analytes not listed in the Appendix C LCS tables?				
M4 1.7.3.3	**Sample Specific Controls**				
M4 1.7.3.3	Does the laboratory have a documented procedure for determining the effect of the sample matrix on method performance?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.3	Does the procedure relate the analyses of quality system matrix specific QC samples and designed as data quality indicators for a specific sample using the designated method? Note: Examples of matrix-specific QC include: Matrix Spike (MS), Matrix Spike Duplicate (MSD), sample duplicates, and surrogate spikes.				
M4 1.7.3.3	Are these controls not used alone to judge laboratory performance?				
M4 1.7.3.3	Does the laboratory have procedures in place for - tracking - managing - handling matrix-specific QC criteria, including - spiking appropriate components at appropriate concentrations - calculating recoveries and relative percent difference - evaluating and reporting results based on performance of the QC samples?				
M4 1.7.3.3	Are the results of all MS/MSDs evaluated using the same acceptance criteria used for the Appendix C LCS limits or project limits, if specified?				
M4 1.7.3.3	If the specific analyte(s) are not available in the Appendix C tables, does the laboratory use their LCS in-house limits as a means of evaluating MS/MSDs?				
M4 1.7.3.3.1	**Matrix Spike (MS); Matrix Spike Duplicates (MSDs)**				
M4 1.7.3.3.1	a) Do the matrix-specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method and not used to determine the validity of the entire batch?				
M4 1.7.3.3.1	b) Is the frequency of the analysis of MSs as specified by the method or determined as part of the contract review process.				
M4 1.7.3.3.1	b) Does each preparation batch of samples contain an associated MS and MSD (or matrix duplicate (MD)) using the same matrix collected for the specific project?				
M4 1.7.3.3.1	b) Are the requirements for MS/MSD not applicable to all methods (e.g., certain radiochemical samples, air-testing samples, classic chemistry, and industrial hygiene samples)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.3.1	b) If adequate sample material is not available, is the lack of MS/MSDs (or MD) noted in the case narrative, and is a LCSD used to determine precision?				
M4 1.7.3.3.1	c) Are the components spiked as specified by the mandated method.				
M4 1.7.3.3.1	c) Are any permit specified analytes, as specified by regulation or client requested analytes, included?				
M4 1.7.3.3.1	c) If there are no specified components, does laboratory spike per the following?				
M4 1.7.3.3.1	c) For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, are spikes chosen that represents the chemistries and elution patterns of the components to be reported?				
M4 1.7.3.3.1	c) For those methods that have extremely long lists of analytes, is a representative number chosen using the following criteria for choosing the number of analytes to be spiked?				
M4 1.7.3.3.1	c) Is the following criteria used for determining the minimum number of analytes to be spiked?				
M4 1.7.3.3.1	i. For methods that include one (1) to ten (10) targets, spike all components. ii. For methods that include eleven (11) to twenty (20) targets, spike at least ten (10) or 80%, whichever is greater. iii. For methods with more than twenty (20) targets, spike at least sixteen (16) components.				
M4 1.7.3.3.1	c) Does the laboratory insure that all targeted components are included in the spike mixture over a two (2) year period?				
M4 1.7.3.3.1	c) Is the MS and MSD spiked with all reported analytes (with the exception of Aroclor analysis, which is spiked per the method)?				
M4 1.7.3.3.1	**Matrix Duplicates**				
M4 1.7.3.3.2	a) Are matrix duplicates defined as replicate aliquots of the same sample taken through the entire analytical procedure?				
M4 1.7.3.3.2	b) Is the frequency of the analysis of matrix duplicates as specified by the method or determined as part of the contract review process?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.3.2	c) Are matrix duplicates performed on replicate aliquots of actual samples? Note: The composition is usually not known.				
M4 1.7.3.3.3	**Surrogate Spikes**				
M4 1.7.3.3.3	a) When required, are surrogates chosen to reflect the chemistries of the targeted components of the method and are they added prior to sample preparation/extraction?				
M4 1.7.3.3.3	b) Except where the matrix precludes its use or when not commercially available, are surrogate compounds added to all samples, standards, and blanks for all appropriate methods?				
M4 1.7.3.3.3	c) Are surrogate compounds chosen to represent the various chemistries of the target analytes in the method?				
M4 1.7.3.3.3	c) Are surrogate specified by the mandated method used, and are they chosen for their being unlikely to occur as an environmental contaminant? Note: Often this is accomplished by using deuterated analogs of select compounds.				
M4 1.7.3.3.3	d) Are surrogate spike results compared with the Appendix C LCS limits or acceptance criteria specified by the client?				
M4 1.7.3.3.3	d) If these criteria are not available, does the laboratory compare the results with its in-house statistically established LCS criteria?				
M4 1.7.3.4	**Data Reduction**				
M4 1.7.3.4	Are the procedures for data reduction, such as use of linear regression, documented?				
M4 1.7.3.5	**Reagent Quality, Water Quality and Checks**				
M4 1.7.3.5	a) In methods where the purity of reagents is not specified, is analytical reagent grade used?				
M4 1.7.3.5	a) Are reagents of lesser purity than those specified by the method not used?				
M4 1.7.3.5	a) Is the documentation of purity available?				
M4 1.7.3.5	b) Is the quality of water sources monitored and documented and does it meet method specified requirements?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.5	c) Does the laboratory verify the concentration of titrants in accordance with written laboratory procedures?				
M4 1.7.3.5	d) Are the quality (e.g., purity) specifications for all standards and reagents (including water) documented or referenced in SOPs?				
M4 1.7.3.6	**Selectivity**				
M4 1.7.3.6	Does the laboratory document selectivity by following the checks established within the method?				
M4 1.7.3.6	a) Is tentative identification of an analyte occurring when a peak from a sample extract falls within the daily retention time window?				
M4 1.7.3.6	a) Is confirmation necessary when the results are D2339 and composition of samples is not well characterized?				
M4 1.7.3.6	a) Are confirmation techniques including further analysis using a second column with dissimilar stationary phase, GC/MS (full scan or SIM) or HPLC/MS (if concentration permits), GC or HPLC with two different types of detectors, or by other recognized confirmation techniques? Note: HPLC UV-Diode Array detectors not considered confirmation for a UV detector				
M4 1.7.3.6	b) When reporting data for methods that require analyte confirmation using a secondary column or detector, are project-specific reporting requirements followed?				
M4 1.7.3.6	b) If project specific requirements have not been specified, are the reporting requirements in the method?				
M4 1.7.3.6	b) If the method does not include reporting requirements, does the report have the results from the primary column or detector? Note: Unless there is a scientifically valid and documented reason for not doing so and is concurred with by the client.				
M4 1.7.3.6	c) Is the client notified of any results that are unconfirmed (e.g., confirmation was not performed or confirmation was obscured by interference)?				
M4 1.7.3.6	c) Are the unconfirmed results identified in the test report, using appropriate data qualifier flags, and explained in the case narrative?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.6	c) Is the analyte presence indicated only if both original and confirmation signals are positive or if confirmation signal cannot be discerned from interference?				
M4 1.7.4	**Data Acceptance/Rejection Criteria**				
M4 1.7.4.1	**Negative Control – Method Performance: Method Blank (MB)**				
M4 1.7.4.1	Is the source of contamination investigated and measures taken to minimize or eliminate the problem? Note: Each MB shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch				
M4 1.7.4.1	a) Are affected samples reprocessed or data appropriately qualified if any of the following exist?				
M4 1.7.4.1	a) the concentration of a targeted analyte in the blank is at or above the reporting limit as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.				
M4 1.7.4.1	a) Is the MB considered to be contaminated if:				
M4 1.7.4.1	i. The concentration of any target analyte (chemical of concern) in the blank exceeds 1/2 the LOQ D2602 is greater than 1/10th the amount measured in any associated sample, or 1/0th the regulatory limit, whichever is greater?				
M4 1.7.4.1	ii. the concentration of any common laboratory contaminant in the blank exceeds the LOQ?				
M4 1.7.4.1	b) If a MB is contaminated as described above, then does the laboratory reprocess affected samples in a subsequent preparation batch?				
M4 1.7.4.1	b) If insufficient sample volume remains for reprocessing, are the results reported with appropriate data qualifiers?				
M4 1.7.4.1	b) the blank contamination otherwise affects the sample results as per the method requirements or the individual project data quality objectives.				
M4 1.7.4.1	c) if a blank is determined to be contaminated, the cause is investigated and measures are taken to minimize or eliminate the problem. Samples associated with a contaminated blank re evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes)				
M4 1.7.4.1	c) In all cases ise the corrective action documented?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.4.2	**Positive Control – Method Performance: Laboratory Control Sample (LCS)**				
M4 1.7.4.2	a) Are the results of the individual batch LCS calculated in %REC or other appropriate statistical technique that allows comparison to established acceptance criteria?				
M4 1.7.4.2	a) Does the laboratory document the calculation?				
M4 1.7.4.2	a) Is the individual LCS compared to the acceptance criteria as published in the mandated method?				
M4 1.7.4.2	a) Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria?				
M4 1.7.4.2	a) Are samples analyzed along with an LCS determined to be “out of control” considered suspect and reprocessed, re-analyzed or the data reported with appropriate data qualifying codes?				
M4 1.7.4.2	a) Is data associated with an unacceptable LCS useable (with data qualifying codes) under the following special conditions?				
M4 1.7.4.2	i. when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non-detects,. or ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), and there are associated sample results that exceed a maximum regulatory limit/decision level.				
M4 1.7.4.2	**b) Allowable Marginal Exceedances (MEs):**				
M4 1.7.4.2	Note: If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. A ME is defined as being beyond the LCS control limit (three standard deviations), but within the ME limits.				
M4 1.7.4.2	b) Are Upper and lower ME limits established to determine when corrective action is necessary?				
M4 1.7.4.2	b) Are the ME limits between three (3) and four (4) standard deviations around the mean?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.4.2	b) Is the number of allowable MEs based on the number of analytes in the LCS?				
M4 1.7.4.2	b) If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, does the LCS fail and corrective action implemented?				
M4 1.7.4.2	b) Does the laboratory's ME approach only apply to methods with long lists of analytes does not apply to target analyte lists with fewer than eleven analytes)?				
M4 1.7.4.2	b) Is number of allowable MEs as follows?				
M4 1.7.4.2	# of Analytes in LCS # allowed as ME >90 5 71-90 4 51-70 3 31-50 2 11-30 1 <11 0				
M4 1.7.4.2	b) If the same analyte exceeds the LCS control limit consecutively, it is considered an indication of a systemic problem and the source of the error investigated and corrective action taken?				
M4 1.7.4.2	b) Does the laboratory have a written procedure to monitor the application of ME allowance to the LCS?				
M4 1.7.4.2	c) Was project-specific approval given when there were sporadic MEs for target analytes?				
M4 1.7.4.2	d) Is corrective action and reanalysis of the LCS performed when the same analyte exceeds the LCS control limit two (2) out of three (3) consecutive LCS measurements (indicative of non-random behavior)?				
M4 1.7.4.2	Guidance: The target analytes are considered those few analytes that are critical for the success of a project (such as risk drivers) where sporadic MEs cannot be allowed.				
M4 1.7.4.2	Guidance: Laboratories should consult with clients whenever long lists of analytes are requested for analysis to determine if MEs will not be allowed.				
M4 1.7.4.3	**Sample Specific Controls**				
M4 1.7.4.3	**a) Matrix Spike (MS); Matrix Spike Duplicates (MSDs)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.4.3	a) Did laboratory document the calculation for %R, RPD or other statistical treatments used for MS/MSD calculations?				
M4 1.7.4.3	a) Does the laboratory compare the results to the acceptance criteria as published in the mandated method?				
M4 1.7.4.3	a) Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
M4 1.7.4.3	a) For matrix spike results outside established criteria, is corrective action documented or the data for that sample reported with appropriate data qualifying codes?				
M4 1.7.4.3	**b) Matrix Duplicates**				
M4 1.7.4.3	b) Did the laboratory document the calculation for RPD or other statistical treatments used for Matrix Duplicate calculations?				
M4 1.7.4.3	b) Does the laboratory compare the results to the acceptance criteria as published in the mandated method?				
M4 1.7.4.3	b) Where there are no established criteria, did the laboratory determine internal criteria and document the method used to establish the limits?				
M4 1.7.4.3	b) Does the laboratory perform corrective action for matrix duplicates results outside established criteria or report the results with appropriate data qualifying codes?				
M4 1.7.4.3	**c) Surrogate Spikes**				
M4 1.7.4.3	c) Are the results of the surrogate spikes compared to acceptance criteria as published in the mandated method?				
M4 1.7.4.3	c) If there are no established criteria, does the laboratory establish internal criteria and document the method used to establish the limits?				
M4 1.7.4.3	c) When surrogates are outside the acceptance criteria, does the laboratory evaluate for the effect indicated for the individual sample results?				
M4 1.7.4.3	c) Are the appropriate corrective actions guided by the data quality objectives or other site-specific requirements?				
M4 1.7.4.3	c) Are results reported from analyses with surrogate recoveries outside the acceptance criteria include appropriate data qualifiers?				
M4 1.7.5	**Sample Handling**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.5	a) Are samples that require thermal preservation considered acceptable if the arrival temperature is either within 2°C of the required temperature or within the method specified range? Note: Samples with a specified temperature of 4°C are acceptable at temperatures from just above 0°C to 6°C.				
M4 1.7.5	a) The following thermal preservation requirements exceptions are acceptable.				
M4 1.7.5	i. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.5.a. In these cases, the samples shall be considered acceptable if the samples were received on ice. ii. If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required. iii. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection.				
M4 1.7.5	b) Does the laboratory implement procedures for checking chemical preservation of samples, such as pH or chlorine, prior to or during sample preparation or analysis, with the exception of VOCs, which may be checked after analysis?				
M5	**Volume 1 Module 5**				
M5	**Quality Systems for Microbiological Testing**				
M5 1.4	**Method Selection**				
M5 1.4	When it is necessary to use methods not covered by reference methods, Are these methods are subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the environmental test?				
M5 1.4	If no QC exists in the method, the laboratory does the laboratory adhere to the requirements outlined in a similar method?				
M5 1.5	**Method Validation**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.5	Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use?				
M5 1.5	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
M5 1.5	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
M5 1.5	Does the laboratory maintain documentation of the validation procedure for as long as the method is in use and for at least five (5) years past the date of last use?				
M5 1.5	Does the laboratory participate in a suitable program of PT?				
M5 1.5	Are the results of the PT analyses used to evaluate the ability of the laboratory to produce acceptable data?				
M5 1.5	If no reference method exists, or if the data quality objectives are different from the refence method, does the laboratory demonstrate that the methods meet the quality objectives for the intended use with the following assessment?				
M5 1.5.1	**Accuracy:** Does the laboratory use at least one (1) known pure reference culture at the anticipated environmental conditions, and compare the method results to that of a reference method?				
M5 1.5.1	**Precision:** Does the laboratory perform at least ten (10) replicate analyses with both the proposed and reference method, using the target microorganisms of choice to show that the methods are not statistically different?				
M5 1.5.3	**Selectivity (sensitivity):** Does the laboratory verify all responses in at least ten (10) samples using mixed cultures that include the target organism(s), and at varying concentrations (microbial identification testing or equivalent processes may be used) and calculate the number of false positive and false negative results?				
M5 1.6	**Demonstration of Capability (DOC)**				
M5 1.6.1	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (see 1.6.2)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.6.1	Is ongoing DOC (see 1.6.3), as per the quality control requirements (see 1.7.3) required thereafter?				
M5 1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required, if applicable? Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				
M5 1.6.1	Are appropriate records as discussed in Section 1.6.2 completed for IDOCs?				
M5 1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
M5 1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
M5 1.6.2	**Initial DOC**				
M5 1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
M5 1.6.2.1	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
M5 1.6.2.1	a) analyst(s) involved in preparation and/or analysis?				
M5 1.6.2.1	b) matrix?				
M5 1.6.2.1	c) Organism(s)?				
M5 1.6.2.1	d) identification of method(s) performed?				
M5 1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number?				
M5 1.6.2.1	f) date(s) of analysis?				
M5 1.6.2.1	g) summary of analyses, including information outlined in section 1.6.2.2.c?				
M5 1.6.2.2	If the method or regulation does not specify a DOC, does the laboratory use the procedure stated in 1.6.2.2 a-g?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.6.2.2	Does the laboratory document that other approaches to initial DOC are adequate, if applicable?				
M5 1.6.3	**Ongoing DOC**				
M5 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC?				
M5 1.6.3.1	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this standard?				
M5 1.6.3.1	Does the laboratory document that other approaches to ongoing DOC are adequate?				
M5 1.6.3.2	Is ongoing DOC demonstrated by including one of the following or by performing another initial DOC?				
M5 1.6.3.2	a) Does ongoing demonstration include the analysis of one sample or clean matrix that is fortified with a known quantity of the target organism, with results meeting the laboratory acceptance criteria for accuracy and, where applicable to the testing technique, also meeting the observational details expected for the presumptive, confirmed and completed phases defined in the method?				
M5 1.6.3.2	b) Does ongoing demonstration include the analysis of one sample in duplicate for each target organism and test, with results meeting the laboratory acceptance criterion for precision?				
M5 1.6.3.2	c) Does ongoing demonstration include acceptable results for one-single-blind proficiency test sample for target organisms in each field of accreditation?				
M5 1.6.3.2	d) Does ongoing demonstration include performance of an alternate adequate procedure for the field of accreditation, the procedure and acceptance criteria being documented in the laboratory's quality system?				
M5 1.6.3.2	e) Does ongoing demonstration include a documented process of analyst review using QC samples? Are QC samples reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
M5 1.6.3.2	f) If a) through e) are not technically feasible, then does the laboratory perform analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7	**Technical Requirements**				
M5 1.7.1	**Calibration**				
M5 1.7.1	a) Does the laboratory have documented procedures for calibration, verification, and quality control of support equipment including conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments?				
M5 1.7.1	a) Do these procedures refer to applicable reference methods?				
M5 1.7.1	b) For instruments that are continuous monitors, such as in-line specific conductance meters:				
M5 1.7.1	i. Does the laboratory document acceptable calibration verification at least once a month?				
M5 1.7.1	ii. Are the initial calibrations being performed in a continuing calibration that is unacceptable, or is the instrument being returned to service after having been taken off line?				
M5 1.7.2	**Continuing Calibration**				
M5 1.7.2	Note: Reserved for specific procedures				
M5 1.7.3	**Quality Control**				
M5 1.7.3.1	**Sterility Checks and Method Blanks (MBs)**				
M5 1.7.3.1	**a) Method Blanks**				
M5 1.7.3.1	a) Does the laboratory demonstrate the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure?				
M5 1.7.3.1	**i. For filtration technique:**				
M5 1.7.3.1	- Does the laboratory conduct method blanks per the analytical method?				
M5 1.7.3.1	- At a minimum, does the filtration series include a beginning and ending blank?				
M5 1.7.3.1	- Does the filtration series include single or multiple filtration units, which have been sterilized prior to beginning the series?				
M5 1.7.3.1	**ii. For filtration series:**				
M5 1.7.3.1	- Is it considered ended when more than thirty (30) minutes have elapsed between successive filtrations?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.1	- Are filter funnels rinsed with three (3) 20-30 ml portions of sterile rinse water after each sample filtration?				
M5 1.7.3.1	- Are the laboratories inserting a MB after every ten (10) samples or sanitize filtration units by UV light after each sample filtration?				
M5 1.7.3.1	**iii. For pour plate techniques:**				
M5 1.7.3.1	- Are MBs of the medium being made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory?				
M5 1.7.3.1	**b. Sterility Checks**				
M5 1.7.3.1	i. Is the sterility check being analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory?				
M5 1.7.3.1	i. Is this done prior to first use of the medium?				
M5 1.7.3.1	ii. For **pre-sterilized single use funnels**, is a sterility check performed on one funnel per lot?				
M5 1.7.3.1	ii. For **laboratory-sterilized funnels**, is a sterility check performed on one funnel per sterilization batch?				
M5 1.7.3.1	iii. Are sterility checks on sample containers performed on at least one (1) container for each lot of purchased, pre-sterilized containers?				
M5 1.7.3.1	iii. For containers prepared and sterilized in the laboratory, is a sterility check performed on one (1) container per sterilized batch with nonselective growth media?				
M5 1.7.3.1	iii. If a contracted laboratory is performing the sterility checks (if the laboratory does not have the requisite equipment to perform them), is all correspondence and results from a contracted laboratory retained for a period of five (5) years after the completion of the test(s)?				
M5 1.7.3.1	iv. Is the sterility check performed on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water with nonselective growth media?				
M5 1.7.3.1	v. Is at least one (1) filter from each new lot of membrane filters checked for sterility with nonselective growth media?				
M5 1.7.3.2	**Test Variability/Reproducibility**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.2	For methods that specify colony counts such as membrane filter or plated media, are duplicate counts performed monthly on one positive sample, for each month that the test is performed?				
M5 1.7.3.2	If the laboratory has two or more analysts:				
M5 1.7.3.2	• Does each analyst count typical colonies on the same plate?				
M5 1.7.3.2	• Are counts required to be within 10% difference to be acceptable?				
M5 1.7.3.2	If the laboratory only has one microbiology analysts:				
M5 1.7.3.2	• Is the same plate counted twice by the analyst with no more than 5% difference between the counts?				
M5 1.7.3.3	**Sample Specific Controls (where applicable)**				
M5 1.7.3.3	a) Are the matrix spikes performed per method requirement?				
M5 1.7.3.3	b) Is the sample matrix duplicates performed per method requirements?				
M5 1.7.3.4	**Data Reduction**				
M5 1.7.3.4	Are the calculations, data reduction and statistical interpretations specified by each method identified and followed?				
M5 1.7.3.5	**Quality of Standards, Reagents and Media**				
M5 1.7.3.5	Does the laboratory ensure that the quality of the reagents and media used is appropriate for the test concerned?				
M5 1.7.3.5	**a) Media:**				
M5 1.7.3.5	a) Is culture media prepared from commercial dehydrated powders and/or purchased ready-to-use?				
M5 1.7.3.5	**i. Laboratory-prepared media:**				
M5 1.7.3.5	1) Is the media prepared by the laboratory from basic ingredients tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition) prior to first use?				
M5 1.7.3.5	2) Is the media used within the holding time limits specified in the accredited method?				
M5 1.7.3.5	3) Is the detailed testing criteria information defined in the laboratory's methods, SOPs, or similar documentation?				
M5 1.7.3.5	**ii. Ready-to-use media**				
M5 1.7.3.5	1) Is the ready-to-use media used within the manufacturer's expiration date?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.5	1) If the manufacturer's expiration date from the manufacturer is greater than the holding time limits specified in the accredited method, does the laboratory request, and have available documentation from the manufacturer demonstrating media quality for the extended time period?				
M5 1.7.3.5	2) Is any ready-to-use media used past the expiration date verified for usability by running quality control checks comparing the media with freshly prepared media or by testing recovery with known densities of culture controls?				
M5 1.7.3.5	b) Are reagents and commercial dehydrated powders used within the shelf life of the product and documented as per TNI Volume 1, Module 2 Quality Systems General Requirements?				
M5 1.7.3.5	**c) Reagent Water:**				
M5 1.7.3.5	i. Is the quality of the reagent water used in the laboratory, such as distilled water, deionized water or reverse-osmosis produced water monitored for bactericidal and inhibitory substances?				
M5 1.7.3.5	i. Is the reagent water used in the preparation of media, solutions and buffers?				
M5 1.7.3.5	ii. Is the quality of the water monitored monthly (when in use) when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month for: - chlorine residual? - specific conductance? - total organic carbon? - ammonia/organic nitrogen? - heterotrophic bacteria plate count?				
M5 1.7.3.5	iii. Is the analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) performed annually? Note: Exception to performing the Bacteriological Water Quality Test may be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.5	iv. Do the results of the above analyses meet the specifications of the required method and records of analyses maintained for five (5) years?				
M5 1.7.3.5	v. Is reagent water purchased from an outside source and used for the preparations of media, solutions and buffers and does it meet the criteria specified in items ii) and iii) above? Does the laboratory have documented records of this information?				
M5 1.7.3.5	v. Is the purchased reagent water that has been in use for longer than the testing intervals specified in items i) through iv) or in the accredited method either be re-tested or discarded?				
M5 1.7.3.5	d) Does the documentation for media prepared in the laboratory include: - date of preparation? - preparer's initials? - type? - manufacturer? - lot number? - final pH? - expiration date? - the amount of reagents used?				
M5 1.7.3.6	**Selectivity**				
M5 1.7.3.6	a) Have all growth and recovery media been checked to assure that the target organism(s) respond in an acceptable and predictable manner?				
M5 1.7.3.6	b) To assure that the analysis results are accurate, is target organism identity verified as specified in the method (e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test or by the use of a completed test such as brilliant green (BG) or E. coli (EC) broth)?				
M5 1.7.3.6	c) In order to ensure identity and traceability, are reference cultures used for positive and negative controls obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body?				
M5 1.7.3.6	c) Are microorganisms single use preparations or cultures maintained for their intended use by documented procedures that demonstrate the continued purity and viability of the organism?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.6	i. Are the reference cultures revived (if freeze-dried) or transferred from slants and subcultures once to provide reference stocks?				
M5 1.7.3.6	i. Are the reference stocks s preserved by a technique that maintains the characteristics of the strains?				
M5 1.7.3.6	i. Are the reference stocks used to prepare working stocks for routine work?				
M5 1.7.3.6	i. If reference stocks have been thawed, are they not refrozen and re-used?				
M5 1.7.3.6	ii. Have the working stocks not been sequentially cultured more than five (5) times and not sub-cultured to replace reference stocks?				
M5 1.7.3.6	**d) Culture Controls:**				
M5 1.7.3.6	**i. Negative Culture Controls**				
M5 1.7.3.6	1) Do negative culture controls demonstrate that the medium does not support the growth of non-target organisms or does not exhibit the typical positive reaction of the target organism(s)?				
M5 1.7.3.6	2) Does each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory analyzed with one or more known negative culture controls (i.e. non-target organisms), as appropriate to the method?				
M5 1.7.3.6	2) Is this done prior to first use of the medium?				
M5 1.7.3.6	**ii. Positive Culture Controls**				
M5 1.7.3.6	1) Do the positive culture controls demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism(s)?				
M5 1.7.3.6	2) Do each pre-prepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory tested with at least one pure culture of a known positive reaction?				
M5 1.7.3.6	2) Is this done prior to first use of the medium?				
M5 1.7.3.7	**Constant and Consistent Test Conditions**				
M5 1.7.3.7	**a) Laboratory Facilities:**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	a) Are the floors and work surfaces non-absorbent and easy to clean and disinfect?				
M5 1.7.3.7	a) Are the work surfaces adequately sealed?				
M5 1.7.3.7	a) Are the laboratories providing sufficient storage space, and cleaned and free from dust accumulation?				
M5 1.7.3.7	a) Are plants, food, and drinks prohibited from the laboratory work area?				
M5 1.7.3.7	**b) Laboratory Equipment:**				
M5 1.7.3.7	**i. Temperature Measuring Devices:**				
M5 1.7.3.7	i. Are the temperature-measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment at the appropriate quality to meet specification(s) in the method?				
M5 1.7.3.7	i. Is the graduation of the temperature measuring devices appropriate for the required accuracy of measurement and verified to national or international standards for temperature?				
M5 1.7.3.7	i. Is the verification performed at least annually? (See TNI Volume1, Module 2, Section 5.5.13.1).				
M5 1.7.3.7	**ii. Autoclaves:**				
M5 1.7.3.7	ii. Is the performance of each autoclave initially evaluated by establishing its functional properties and performance? Note: For example heat distribution characteristics with respect to typical uses.				
M5 1.7.3.7	ii. Are the autoclaves meeting specified temperature tolerances?				
M5 1.7.3.7	ii. Are there any pressure cookers used for sterilization of growth media?				
M5 1.7.3.7	ii. Is the demonstration of sterilization temperature provided by use of a continuous temperature-recording device or used of a maximum registering thermometer with every cycle?				
M5 1.7.3.7	ii. At least once during each month that the autoclave is used, are appropriate biological indicator used to determine effective sterilization?				
M5 1.7.3.7	ii. Is the selected biological indicator effective at the sterilization temperature and time needed to sterilize lactose-based media?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	ii. Is the temperature sensitive tape used with the contents of each autoclave ran to indicate that the autoclave contents have been processed?				
M5 1.7.3.7	ii. Are the records of autoclave operations maintained for every cycle?				
M5 1.7.3.7	ii. Do the records include: - date? - contents? - maximum temperature reached? - pressure? - time in sterilization mode? - total run time (may be recorded as time in and time out)? - analyst's initials?				
M5 1.7.3.7	ii. Is the autoclave maintenance, either internally or by service contract, performed annually, and include a pressure check and verification of temperature device? Note: When it has been determined that the autoclave has no leaks, pressure checks can be documented using the formula PV = nRT.				
M5 1.7.3.7	ii. Are the records of the maintenance maintained in equipment logs?				
M5 1.7.3.7	ii. Is the autoclave mechanical timing device checked quarterly against a stopwatch and the actual time elapsed documented?				
M5 1.7.3.7	**iii. Volumetric Equipment:**				
M5 1.7.3.7	iii. Is the volumetric equipment verified as follows?				
M5 1.7.3.7	1) Does the equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes verified for accuracy quarterly?				
M5 1.7.3.7	2) Does the equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) verified once per lot prior to first use? Note: verification can be volumetric or gravimetric.				
M5 1.7.3.7	3) Is the volume of the disposable volumetric equipment such as sample bottles, and disposable pipettes checked once per lot?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	iv. UV Instruments:				
M5 1.7.3.7	iv. Are the UV instruments, used for sanitization, tested quarterly for effectiveness with an appropriate UV light meter, by plate count agar spread plates or other methods providing equivalent results such as uvcide strips?				
M5 1.7.3.7	iv. Are bulbs replaced if output that is less than 70% of original for light tests or if the count reduction is less than 99% for a plate containing 200 to 300 organisms?				
M5 1.7.3.7	**v. Incubators, Water Baths, Ovens:**				
M5 1.7.3.7	1) Is the uniformity of temperature distribution in incubators and water baths established?				
M5 1.7.3.7	1) Is the temperature of incubators and water baths documented twice daily, at least four hours apart, on each day of use?				
M5 1.7.3.7	2) Are the ovens used for sterilization checked for sterilization effectiveness monthly with appropriate biological indicators?				
M5 1.7.3.7	2) Do records include the following for each cycle? - date - cycle time - temperature - contents - analyst's initials?				
M5 1.7.3.7	**vi. Labware (Glassware and Plasticware):**				
M5 1.7.3.7	1) Does the laboratory have a documented procedure for washing labware, if applicable?				
M5 1.7.3.7	1) Are detergents designed for laboratory use used?				
M5 1.7.3.7	2) Is the glassware made of borosilicate or other non-corrosive material, free of chips and cracks, and have readable measurement marks?				
M5 1.7.3.7	3) Is labware that is washed and reused tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test (IRT): - annually - each time the lab changes the lot of detergent or washing procedures?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	4) Is the washed labware tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with suitable pH indicator such as bromothymol blue?				
M5 1.7.3.7	4) Does the laboratory maintain records of the tests?				
M5 1.7.4	**Data Acceptance/Rejection Criteria**				
M5 1.7.4	Note: Methods criteria and evaluation methods shall be used				
M5 1.7.5	**Sample Handling**				
M5 1.7.5	a) Does the laboratory check the arrival temperature of a representative sample container to verify it meets the method or mandated temperature requirement?				
M5 1.7.5	a) The following thermal preservation requirements exceptions are acceptable.				
M5 1.7.5	i. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.5.a. In these cases, the samples shall be considered acceptable if the samples were received on ice. ii. If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required. iii. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection.				
M5 1.7.5	b) Is the absence of chlorine residual checked for Microbiological samples from: - known chlorinated sources (such as wastewater effluent)? - unknown sources where chlorine usage is suspected (such a new client or a new source)? - all potable water sources (including source water)?				
M5 1.7.5	b) When the laboratory receives samples from potable water sources (including source water) that have a demonstrated history of acceptable preservation, do they check a sample from each source at a frequency of once per month if:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.5	i) the laboratory can show that the received sample containers are from their laboratory; ii) sufficient sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples; iii) one container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15 mg/l chlorine as appropriate and the check is documented; iv) chlorine residual is checked in the field and actual concentration is documented with sample submission?				
M6	**Volume 1 Module 6**				
M6	**Quality Systems for Radiochemical Testing**				
M6 1.4	**Method Selection**				
M6 1.4	When it is necessary to use methods not covered by reference methods, are these methods subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the environmental test?				
M6 1.4	If no QC exists in the method, the laboratory does the laboratory adhere to the requirements outlined in a similar method?				
M6 1.5	**Method Validation**				
M6 1.5.1	Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use?				
M6 1.5.1	Is the validation as extensive as necessary to meet the needs of the given application or field of application?				
M6 1.5.1	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
M6 1.5.2	**Detectable Activity**				
M6 1.5.2	Are all procedures used documented?				
M6 1.5.2	Does the documentation include the quality system matrix type?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2	Is all supporting data retained?				
M6 1.5.2.1	**Minimum Detectable Activity (MDA)**				
M6 1.5.2.1	Does the laboratory utilize a method that provides an MDA that is appropriate and relevant for the intended use of the data?				
M6 1.5.2.1	Are MDAs determined by the protocol in the mandated method?				
M6 1.5.2.1	If the protocol for determining the MDA is not specified, does the selection of the procedure reflect instrument limitations and the intended application of the method?				
M6 1.5.2.1	a) Did the laboratory determine the MDA for the method for each target analyte of concern in the quality system sample matrices?				
M6 1.5.2.1	a) Are all sample-processing steps of the analytical method included in the determination of the MDA?				
M6 1.5.2.1	b) Was the MDA initially determined for the analytes of interest in each method in a quality system matrix in which there are no target analytes and no interferences at levels that would impact the results?				
M6 1.5.2.1	c) Was the MDA determined each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the analytical detection capability?				
M6 1.5.2.1	d) The MDA is an estimate of the smallest true activity (or activity concentration) of analyte in a sample that ensures a 95% probability of detection, given a detection criterion that ensures only a 5% probability of detection in analyte-free samples.				
M6 1.5.2.1	e) Does the laboratory's SOPs incorporate equations to calculate the decision level and the minimum detectable concentration (or activity) that are documented and consistent with the mandated method or regulation?				
M6 1.5.2.1.1	**a) Minimum Detectable Activity (MDA) (DoD/DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2.1.1	a) Is the MDA is the smallest amount of an analyte in a sample that will be detected with a probability b of non-detection (Type II error), while accepting a probability a of erroneously deciding that a positive (non-zero) quantity of analyte is present in an appropriate blank sample (Type I error)? Note1: Confidence levels may be dictated by the project. Note2: For the purposes of this module and the equations below, the a and b probabilities are assumed to be 0.05. Note3: MARLAP utilizes the Minimum Detectable Concentration (MDC) term instead of MDA.				
M6 1.5.2.1.1	**b) MDA Factors and Conditions (DoD/DOE Only)**				
M6 1.5.2.1.1	b) Are MDAs determined based on factors and conditions such as instrument settings and matrix type, which influence the measurement? The MDA is used to evaluate the capability of a method relative to the required detection reporting limit (RL). Sample size, count duration, tracer chemical recovery, detector background, blank standard deviation, and detector efficiency shall be optimized to result in sample MDAs less than or equal to the RLs. If RLs are not achieved, then the cause shall be addressed comprehensively in the case narrative?				
M6 1.5.2.1.1	b) Is the MDA used to evaluate the capability of a method relative to the required detection reporting limit (RL)?				
M6 1.5.2.1.1	b) Are sample size, count duration, tracer chemical recovery, detector background, blank standard deviation, and detector efficiency optimized to result in sample MDAs less than or equal to the RLs				
M6 1.5.2.1.1	b) If RLs are not achieved, is the cause addressed comprehensively in the case narrative?				
M6 1.5.2.1.1	**c) MDA Calculation (DoD/DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2.1.1	c) Is the basic MDA calculation based on the concepts developed by L. A. Currie from his paper "Limits for Qualitative Detection and Quantitative Determination," Analytical Chemistry, March, 1968, Vol. 40, or from the MARLAP Manual Chapter 20? Note: See 1.5.2.1.1 c) i. and ii. for general equations derived from the work of L. A. Currie that can be used to calculate the MDA.				
M6 1.5.2.1.1	**d) MDA Optimization (DoD/DOE Only)**				
M6 1.5.2.1.1	d) Does the laboratory optimize analysis parameters in order to achieve analyte MDAs less than or equal to the required detection threshold?				
M6 1.5.2.1.1	d) Does the laboratory handle samples with elevated activities according to the following requirements:				
M6 1.5.2.1.1	i. Is the appropriate aliquot size determined based on the activity level in the sample?				
M6 1.5.2.1.1	i. Is the aliquant large enough to generate data, which meet the following criteria:				
M6 1.5.2.1.1	a) measurement uncertainty not be greater than 10% (1 sigma) of the sample activity?				
M6 1.5.2.1.1	b) MDA for the analysis at a maximum of 10% of the sample activity?				
M6 1.5.2.1.1	e) Are sample-specific MDAs routinely calculated and reported as standard practice? Note: If MDAs are reported as a nominal detection capability of the measurement process, that shall be clearly stated in the data package.				
M6 1.5.2.1.1	f) The definition of the MDA presupposes that an appropriate detection threshold (i.e., the decision level) has already been defined. The a probabilities assumed for the decision level shall also be used for the calculation of the MDA?				
M6 1.5.2.1.2	**a) Decision Level (DL) (DoD/DOE Only)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2.1.2	a) Is the analyte detection the minimum measured value (e.g., of the instrument signal or the analyte concentration) required to give confidence that a positive (nonzero) amount of analyte is present in the material analyzed? Note: The DL is sometimes called the critical level (Lc) or critical value (MARLAP). It is the quantity of analyte at or above which an a posteriori decision is made that a positive quantity of the analyte is present. Confidence levels may be dictated by the project. For this document, the probability of a Type I error (probability of erroneously reporting a detectable nuclide in an appropriate blank or sample) is assumed to be set at 0.05.				
M6 1.5.2.1.2	**b) DL Factors and Conditions (DoD/DOE Only)**				
M6 1.5.2.1.2	b) Are DLs determined a posteriori based on sample-specific sample size, count duration, tracer chemical recovery, detector background, blank standard deviation, and detector efficiency?				
M6 1.5.2.1.2	**c) DL Calculation (DoD/DOE Only)**				
M6 1.5.2.1.2	c) Is the DL calculation based on concepts developed by L.A. Currie "Limits for Qualitative Detection and Quantitative Determination, Analytical Chemistry, March 1968, Vol. 40, or MARLAP Chapter 20. The following general equation below can be used to calculate the DL. Note1: The DL can either be based on the Combined Standard Uncertainty (CSU) of the blank (preparation or method) or the standard deviation determined from a set of appropriate blanks. Note2: See 1.5.2.1.2 c) i. and ii. for general equations derived from the work of L. A. Currie that can be used to calculate the DL.				
M6 1.5.2.2	**Required Detection Limit for Drinking Water**				
M6 1.5.2.2	If the laboratory analyzes drinking-water samples for Safe Drinking Water Act (SDWA) compliance monitoring do they use methods whose detection limits meet the requirements of 40 CFR 141?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2.2	Do they meet the SDWA detection limit as defined in 40 CFR 141.25(c) as equal to the analyte concentration which can be counted with a precision of plus or minus 100% at the 95% confidence level (1.96σ where σ is the standard deviation of the net counting rate of the sample)? (The SDWA detection limit equivalent to the concentration at which the relative standard deviation of the measurement due to counting statistics is 1/1.96.)				
M6 1.5.3	**Evaluation of Precision and Bias**				
M6 1.5.3	**a) Reference Methods**				
M6 1.5.3	a) Has the laboratory evaluated the precision and bias of a reference method for each analyte of concern for each quality system matrix according to Section 1.6 or alternate documented procedure if the analyte cannot be spiked into the sample matrix and QC samples are not commercially available?				
M6 1.5.3	**b) Non-Reference Methods**				
M6 1.5.3	b) For laboratory-developed methods or non-reference methods that were not in use by the laboratory before July 2003, did the laboratory have a documented procedure to evaluate precision and bias?				
M6 1.5.3	b) Did the laboratory also compare results of the precision and bias measurements with criteria established by the client, given in the reference method, or established by the laboratory?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.3	c) Did the laboratory evaluate precision and bias in the relevant quality system matrices and process the samples through the entire measurement system for each analyte of interest? Note: d) An example of a systematic approach to evaluate precision and bias could be the following: Analyze QC samples in triplicate containing the analytes of concern at or near the MDA, at a level near ten (10) times the MDA, and at a mid-range concentration. Process these samples on different days as three (3) sets of samples through the entire measurement system for each analyte of interest. Each day one QC sample at each concentration is analyzed. A separate MB shall be subjected to the analytical method along with the QC samples on each of the three (3) days. For each analyte, calculate the mean recovery for each day, for each level over days, and for all nine (9) samples. Calculate the relative standard deviation for each of the separate means obtained.				
M6 1.5.4	**Measurement Uncertainty**				
M6 1.5.4	Does all radiochemical measurements provide the uncertainty of each quantitative measurement result?				
M6 1.5.4	Are the results of the precision evaluation in Section 1.5.3 compared to the uncertainty estimates as a check on the validity of the uncertainty evaluation procedures?				
M6 1.5.4	It the experimentally observed precision at each testing level not statistically greater than the maximum combined standard uncertainty of the measurement results at that level, although it may be somewhat less.				
M6 1.5.4	**Measurement Uncertainty**				
M6 1.5.4	Is the combined standard uncertainty, when used, the uncertainty of a measured value expressed as an estimated standard deviation?				
M6 1.5.4	Is it calculated by combining the standard uncertainties of the input estimates?				
M6 1.5.4	Are each result reported with the associated measurement uncertainty as a combined standard uncertainty?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.4	Is the SOP for determining the measurement uncertainty consistent with mandated method and regulation?				
M6 1.5.4	**Combined Standard Uncertainty (CSU) (DoD/DOE Only)**				
M6 1.5.4	Are all measurement uncertainties propagated and reported with each result?				
M6 1.5.4	Is the formula for calculating the Combined Standard Uncertainty (CSU) of a result documented in the appropriate SOP?				
M6 1.5.4	Does the CSU include both systematic and random error?				
M6 1.5.4	Is the CSU always 1 sigma?				
M6 1.5.4	Are results reported at the 95% confidence level, which is 1.96-sigma (often abbreviated as 2-sigma)?				
M6 1.5.4	Is the uncertainty of a count estimated as the square root of counts except when there are zero (0) counts? Note1: In the case of zero (0) counts, the uncertainty of the count is assumed to be the square root of one count.) Note2: For counting methodologies where very low counts are possible, the MARLAP 19.57 equation may be used with acceptance by the client.				
M6 1.5.4	Do Systematic Errors include the following:				
M6 1.5.4	a) The errors from all measurement devices, such as, but not limited to pipettes and balances?				
M6 1.5.4	b) The uncertainty of known values of tracer solutions, calibration uncertainties, etc.?				
M6 1.5.4	Do Random Errors include the total random counting error associated with each sample and appropriately propagated when more than one variable is used to determine the result?				
M6 1.5.5	**Evaluation of Selectivity**				
M6 1.5.5	Does the laboratory evaluate selectivity, if applicable, by following the checks established within the method?				
M6 1.6.1	**Demonstration of Capability (DOC)**				
M6 1.6.1	**General**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.6.1	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (per Section 1.6.2)?				
M6 1.6.1	Does the laboratory perform ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples)? Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				
M6 1.6.1	Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there has been no significant changes in instrument type, personnel or method, the ongoing DOC acceptable as an initial DOC.				
M6 1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
M6 1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
M6 1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
M6 1.6.2	**Initial DOC**				
M6 1.6.2	Is an initial DOC made prior to using any method, and at any time that there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
M6 1.6.2	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	

M6 1.6.2.1	a) analyst(s) involved in preparation and/or analysis;
	b) matrix;
	c) analyte(s), class of analyte(s), or measured parameter(s);
	d) identification of method(s) performed;
	e) identification of laboratory-specific SOP used for analysis, including revision number;
	f) date(s) of analysis; and
	g) summary of analyses, including information outlined in Section 1.6.2.2.c.				

M6 1.6.2.2	If the method or regulation does not specify an initial DOC, has the laboratory used the following procedure or document that other approaches to initial DOC are adequate?				
M6 1.6.2.2	a) ensured that analyte(s) are diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) and are sufficient to prepare four (4) aliquots at a laboratory specified concentration?				
M6 1.6.2.2	a) ensured that where gamma-ray spectrometry is used to identify and quantify more than one analyte that the laboratory control sample contain gamma-emitting radionuclides that represent the low (e.g., 241Am), medium (e.g., 137Cs) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra? (As indicated by these examples, the nuclides need not exactly bracket the calibrated energy range or the range over which nuclides are identified and quantified?				
M6 1.6.2.2	b) ensured that at least four (4) aliquots are prepared and analyzed according to the method either concurrently or over a period of days?				
M6 1.6.2.2	c) ensured all results are used to calculate the mean recovery in the appropriate reporting units and the standard deviations of the population sample (in the same units) for each parameter of interest?				
M6 1.6.2.2	c) ensured to assess performance against established and documented criteria, when it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.6.2.2	d) ensured to compare the information from (c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not meet the acceptance criteria, the performance is unacceptable for that parameter?				
M6 1.6.2.2	e) ensured that when one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to i) or ii) below?				
M6 1.6.2.2	i. located and corrected the source of the problem and repeat the test for all parameters of interest beginning with b) above? ii. Beginning with b) above, repeated the test for all parameters that failed to meet criteria?				
M6 1.6.2.2	f) If repeated failure occurs (confirming a general problem with the measurement system), the laboratory locates and corrects the source of the problem and repeats the test for all compounds of interest beginning with b)?				
M6 1.6.2.2	g) ensured that when an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited method, an initial DOC is performed for that analyte. Note: When analytes are added to gamma-ray spectrometry and quantified this is not required.				
M6 1.6.3	**Ongoing DOC**				
M6 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC?				
M6 1.6.3.1	Does the analyst(s) demonstrate ongoing capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this standard?				
M6 1.6.3.1	If other approaches to on-going DOC are utilized has the laboratory documented its adequacy?				
M6 1.6.3.2	Does the on-going demonstration include one of the following:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.6.3.2	a) acceptable performance of a blind sample (single blind to the analyst); Note: Successful analysis of a blind performance sample on a similar method using the same technology?				
M6 1.6.3.2	b) another initial DOC?				
M6 1.6.3.2	c) at least four (4) consecutive laboratory control samples with acceptable levels of precision; The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis; The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCS for each method for each analyst each year?				
M6 1.6.3.2	d) document a process of analyst review using QC samples; Note: QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
M6 1.6.3.2	e) analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) if a) through d) are not technically feasible?				
M6 1.7	**Technical Requirements**				
M6 1.7.1	**Instrument Calibration**				
M6 1.7.1	**a) Initial Calibration**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	Note: Given that radiation detection efficiency is essentially independent of sample activity at all but high activity levels (where dead time becomes significant), the requirements for calibration ranges of standards, of data reporting in calibration range, and the number of calibration standards are not applicable to radiochemical method calibrations except for mass attenuation in gas-proportional counting and sample quench in liquid scintillation counting. Nuclear counting instruments are subject to calibration prior to initial use, when the instrument is placed back into service after major repairs and the instrument's response has changed as determined by a performance check, when the instrument's response exceeds predetermined acceptance criteria for the instrument quality control. Instruments may also be recalibrated on a regular frequency even in the absence of these conditions.				
M6 1.7.1	a) Does the laboratory have a laboratory method SOP for the frequency of calibration if not specified in the method?				
M6 1.7.1	a) Is a specific frequency (e.g., annually) or calibrations based on observations from the associated control or tolerance chart, specified in the laboratory method SOP?				
M6 1.7.1	a) Are instrument calibrations performed with reference standards (see 1.7.2.5.c) that have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples?				
M6 1.7.1	a) Are following essential items included in the calibration procedure:				
M6 1.7.1	i. The details of the initial instrument calibration procedures including calculations, acceptance criteria and associated statistics are included or referenced in the method SOP?				
M6 1.7.1	i. When initial instrument calibration procedures are referenced in the method, then the referenced material re retained by the laboratory and available for review?				
M6 1.7.1	ii. Are sufficient raw data records retained to permit reconstruction of the ICV (e.g., calibration date, method, instrument, analysis date, each analyte name, analyst's initials or signature; activity and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to activity or concentration)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	iii. Sample results are quantitated from the ICV and may not be quantitated from any CCV verification unless otherwise required by regulation, method, or program				
M6 1.7.1	iv. ICVs verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots?				
M6 1.7.1	iv. Traceability is to a national standard, when commercially available?				
M6 1.7.1	v. Criteria for the acceptance of an ICV established (e.g., correlation coefficient or relative percent difference) appropriate to the calibration technique employed?				
M6 1.7.1	vi. Corrective action and evidence of reanalysis of samples for when instrument calibration results are outside the established acceptance criteria? If re- analysis of the samples is not possible, is data associated with an unacceptable ICV reported with appropriate data qualifiers?				
M6 1.7.1	vii. If a reference or mandated method does not specify the number of calibration standards, a written procedure for determining the number of points for establishing the ICV?				
M6 1.7.1	viii. Detection efficiency is determined with sources traceable to NIST or accepted international standards, or with sources prepared from NIST/international traceable standards?				
M6 1.7.1	viii. When sources used for determinations for detection efficiency are not prepared from NIST/international traceable standards, they are “working reference materials” defined as follows: a reference material with one or more properties sufficiently well established to be used for calibration or assessment of a measurement method. Note: Working reference materials may be prepared by the laboratory for their own use. (See ASTM C1128).				
M6 1.7.1	ix. For alpha spectrometry, is a material balance check performed on each source to clearly demonstrate accountability of all activity by mass balance?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	ix. Is the balance check performed on the fraction remaining from the neodymium fluoride precipitation or the electrodeposition plus all rinses from an adequate cleaning of any vessel used in the process?				
M6 1.7.1	ix. Is the estimated error in preparing the source propagated into the error of the efficiency determination?				
M6 1.7.1	**b) Instrument Calibration Verification (Performance Checks)**				
M6 1.7.1	b) Are performance checks performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly, the detector response has not significantly changed, and therefore the instrument calibration has not changed?				
M6 1.7.1	When results for instrument performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance chart or other QC parameters), is the cause of the problem investigated?				
M6 1.7.1	If a performance check fails, does the laboratory immediately analyze two additional consecutive performance checks? Note1: immediately is defined as starting a consecutive pair within one hour; no samples can be run between the failed performance check and the two additional performance checks. Note2: This approach allows for spurious failures of analytes to be reported without reanalysis of samples. Both of these performance checks must meet acceptance criteria in order for the samples to be reported without reanalysis				
M6 1.7.1	If either of the two performance checks fail, or if the laboratory cannot/does not immediately analyze two performance checks, does the laboratory perform corrective action(s) and repeat the performance check and all associated samples since the last successful performance check?				
M6 1.7.1	Do any corrective actions that change the dynamics of the system require that all samples since the last acceptable performance check be reanalyzed?				
M6 1.7.1	If the problem is not corrected and indicates an intrinsic change in instrument response, is the instrument recalibrated and all affected samples since the last acceptable performance check reanalyzed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	b) Is the same check source used in the preparation of the tolerance chart or control chart at the time of calibration used in the calibration verification of the instrument (performance checks)?				
M6 1.7.1	b) Are the check sources providing adequate counting statistics for a relatively short count time?				
M6 1.7.1	b) Is the source sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel?				
M6 1.7.1	i. For gamma-ray spectroscopy systems, are performance checks for detection efficiency, energy calibration, and peak resolution performed on a day-of-use basis?				
M6 1.7.1	i. For systems using sample changers and/or long count times that run more than a day, is the energy calibration checked before each analytical batch?				
M6 1.7.1	ii. For alpha-particle spectroscopy systems, are the performance check for energy calibration performed on a weekly basis and the performance check for detection efficiency performed on at least a monthly basis?				
M6 1.7.1	ii. Is detector response (counting efficiency) determinations performed when the check source count is outside the acceptable limits of the control chart (reference ANSI N42.23, Annex A5)?				
M6 1.7.1	iii. For gas-proportional and liquid scintillation counters, is the performance check for detection efficiency performed on a day-of-use basis? Note: For batches of samples that uninterruptedly count for more than a day, is a performance check may be performed instead at the beginning and end of the batch as long as this time interval is no greater than one week.				
M6 1.7.1	iv. For scintillation counters is the calibration verification for detection efficiency performed on a day-of-use basis?				
M6 1.7.1	iv. For radon scintillation detectors, is efficiency verified at least monthly, when the system is in use?				
M6 1.7.1	**c) Background Measurement**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	c) Are the background measurements made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required measurement quality objectives? Note: This background measurement is not the short-term check for contamination that is addressed in 1.7.1 d.				
M6 1.7.1	c) Are these values subtracted from the total measured activity in the determination of the sample activity?				
M6 1.7.1	i. For **gamma-ray spectroscopy** systems, are background measurements performed on at least a monthly basis?				
M6 1.7.1	ii. For **alpha-particle spectroscopy** systems, are background measurements performed on at least a monthly basis?				
M6 1.7.1	iii. For **gas-proportional counters**, are background measurements performed on at least a weekly basis?				
M6 1.7.1	iv. For **scintillation counters**, are background measurements performed each day of use?				
M6 1.7.1	v. Are Background Subtraction Count (BSC) measurements conducted after calibration and monthly thereafter and monitored for trends to ensure that a laboratory maintains its capability to meet required project objectives?				
M6 1.7.1	vi. If applicable, are successive long background measurements evaluated in lieu of shorter background check measurement?				
M6 1.7.1	vii. Is the duration of the background check measurement of sufficient duration (i.e., at least as long as the sample count time) to quantify contamination that may impact routine sample measurements? Note: Low levels of contamination not detected in a shorter background counting time may bias the results of sample analyses.				
M6 1.7.1	viii. If applicable, is the background check frequency extended to accommodate long sample count times?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	ix. If the background check is conducted less frequently than daily, are any associated sample results not be released for use until a (bracketing) background check is measured and has met all acceptance criteria? Note: An Instrument Contamination Check (ICC) for alpha spectroscopy can be a shorter measurement that can be performed on a weekly basis, in which case reporting sample results is not contingent on bracketing ICC checks.				
M6 1.7.1	x. Is a background check collected before and after any counting chamber changes are made (i.e., cleaning, liner replacement, or instrument modification)?				
M6 1.7.2	**Quality Control for Radiochemistry**				
M6 1.7.2	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken as specified in this Section?				
M6 1.7.2	Was this monitoring planned and reviewed?				
M6 1.7.2	Are the failures of any QC sample analysis and the corrective actions taken noted in the laboratory report for the associated samples?				
M6 1.7.2	**QC Sample Preparation (DoD/DOE Only)**				
M6 1.7.2	Are all samples and QC samples in each prep batch prepared concurrently and in the same manner?				
M6 1.7.2	**QC Sample Counting (DoD/DOE Only)**				
M6 1.7.2	Are all QC samples counted and analyzed in the same manner as the samples in the prep batch, in the same time frame, and using the same instrument calibration parameters, instrument analysis algorithms, etc.?				
M6 1.7.2	Do all method QC samples follow Appendix B requirement?				
M6 1.7.2	Note: The “same time frame” implies that where multiple detectors are used and are sufficient to count the entire batch at the same time, with the same count time duration. If the number of detectors is not sufficient to count the entire batch at the same time, then samples shall be counted consecutively on the available detector(s).				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2	Note: The "same instrument calibration parameters, instrument analysis algorithms, etc." implies that these parameters for a given instrument shall not be changed for the samples in that batch, counting shall be at the same time, with the same count time duration. It is understood that for multiple detectors, the parameters may not be identical.				
M6 1.7.2.1	**Negative Control – Method Performance: Method Blank (MB)**				
M6 1.7.2.1	a) Is the MB used to assess the preparation batch for possible contamination during the preparation and processing steps or for other low-level bias?				
M6 1.7.2.1	a) Is the MB processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure?				
M6 1.7.2.1	a) Are procedures in place to determine if a MB result is significantly different from zero?				
M6 1.7.2.1	a) Are any affected samples associated with a failed MB reprocessed for analysis or the results reported with appropriate data-qualifying codes?				
M6 1.7.2.1	b) Is the MB analyzed at a minimum of one (1) per preparation batch, with a maximum of twenty (20) field samples, for all radiochemical methods except gross alpha/beta in solid matrices and gamma-ray spectrometry?				
M6 1.7.2.1	c) Does the MB consist of a quality system matrix that is similar to the associated samples and is known to be as free of the analytes of interest as possible?				
M6 1.7.2.1	c) Does the laboratory prevent subtraction of the MB result from the sample results in the associated preparation or analytical batch unless permitted by method or program? Note: This requirement does not preclude corrections for background radiation (e.g., instrument background, analyte in the tracer or carrier, reagent impurities, peak overlap, etc.) to all analyzed samples, both program/project submitted and internal quality control samples. However, these corrections shall not depend on the result of the method blank analysis, whose purpose is to check for uncorrected contamination or other low-level bias.				
M6 1.7.2.1	c) Is the MB sample prepared with aliquot size similar to that of the routine samples for analysis?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.1	d) Are batch blanks counted for a sufficient time to meet the required detection limit, except in the case where the achieved MDA is calculated from the standard deviation of a blank population?				
M6 1.7.2.1	d) In this case where the achieved MDA is calculated from the standard deviation of a blank population, are the batch blanks counted for the same count time as the samples?				
M6 1.7.2.1	e) Is the batch blank matrix the same as the samples, as can be reasonably achieved, and shall be documented in the case narrative?				
M6 1.7.2.1	**f) Blank Acceptance Criteria (DoD/DOE Only)**				
M6 1.7.2.1	i. Is a MB prepared and analyzed per preparatory batch?				
M6 1.7.2.1	ii. Is the blank acceptance criteria: |ZBlank |≤ 3 (MARLAP 18.4.1) or a MB in-house control limits of ±3 σ of the mean?				
M6 1.7.2.1	iii. Is the Batch Blank MDA less than the Reporting Limit?				
M6 1.7.2.1	f) If the above criteria has not been met, has the laboratory taken corrective actions (e.g., recount, interferent cleanup, as appropriate), unless all sample results are greater than five times the blank activity?				
M6 1.7.2.1	f) If the criteria is still not met are the samples reanalyzed?				
M6 1.7.2.1	g) For batch blank matrices has the laboratory used the following for all radiochemistry analyses:				
M6 1.7.2.1	i. Distilled or deionized water, analyte free, as demonstrated in method blanks?				
M6 1.7.2.1	ii. Characterized solid material representative of the sample matrix?				
M6 1.7.2.1	iii. Filters, physically and chemically identical filter media, analyte free (if supplied to the laboratory by customer)?				
M6 1.7.2.2	**Positive Control – Method Performance: Laboratory Control Sample (LCS)**				
M6 1.7.2.2	a) Is the LCS used to evaluate the performance of the total analytical system, including all preparation and analysis steps?				
M6 1.7.2.2	a) Are the results of the LCS are compared to established criteria and, if found to be outside of these criteria may indicate that the analytical system is “out of control?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.2	a) Are any affected samples associated with an out-of-control LCS reprocessed for reanalysis or the results reported with appropriate data qualifying codes?				
M6 1.7.2.2	b) Is the LCS analyzed at a minimum of one per preparation batch? Note: Exceptions would be for those analytes for which no spiking solutions are available.				
M6 1.7.2.2	c) Is the LCS a quality system matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes? Note: The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.				
M6 1.7.2.2	d) Alternatively, does the LCS consist of a medium containing known and verified concentrations of analytes or as Certified Reference Material (CRM)?				
M6 1.7.2.2	d) Are the components to be spiked as specified by the mandated method or regulation or as requested by the client?				
M6 1.7.2.2	e) Is the activity of the LCS: (1) at least ten (10) times the MDA (2) at a level comparable to that of routine samples when such information is available if the sample activities are expected to exceed ten times the MDA?				
M6 1.7.2.2	f) Are the laboratory standards used to prepare the laboratory control sample from a source independent of the laboratory standards used for instrument calibration?				
M6 1.7.2.2	f) Do they meet the requirements for reference standards (see 1.7.5.2.c)?				
M6 1.7.2.2	g) Where a radiochemical method, other than gamma-ray spectroscopy, has more than one reportable analyte isotope (e.g. plutonium, 238Pu and 239Pu, using alpha-particle spectrometry), only one of the analyte isotopes need be included in the laboratory control sample at the indicated activity level. Note: Where more than one analyte is detectable, has each been assessed against the specified acceptance criteria?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.2	h) Where gamma-ray spectrometry is used to identify and quantify more than one analyte, does the laboratory control sample shall contain gamma-emitting radionuclides that represent the low (e.g., 241Am), medium (e.g., 137Cs) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra? Note: As indicated by these examples, the nuclides need not exactly bracket the calibrated energy range or the range over which nuclides are identified and quantified.				
M6 1.7.2.2	i) Are the laboratory control samples prepared with similar aliquot size to that of the routine samples for analyses?				
M6 1.7.2.2	j) Is the LCS counted for a sufficient time to quantify the activity level of the LCS?				
M6 1.7.2.2	k) Is the LCS matrix the same as the samples, or as close as can be reasonably achieved?				
M6 1.7.2.2	k) Is the matrix documented in the case narrative?				
M6 1.7.2.2	**l) LCS Acceptance Criteria (DoD/DOE Only)**				
M6 1.7.2.2	l) Has the laboratory met the LCS Acceptance Criteria as listed below:				
M6 1.7.2.2	l) $\|Z_{LCS}\| \leq 3$ (MARLAP 18.4.3) or use in-house control limits of LCS ± 3 σ of the mean?				
M6 1.7.2.2	l) In-house control limits do not fall more than 25% from the known LCS value?				
M6 1.7.2.2	**m) LCS Selection and Level (DoD/DOE Only)**				
M6 1.7.2.2	m) Does the LCS contain at least one analyte reported for samples by that analytical method (separation chemistry and decay mechanism) and should be at least five times, but not greater than 20 times, the RL with the following exceptions?				
M6 1.7.2.2	i. Note: Some programs may require, following TNI, at least 10 times the MDA and at a level compatible with routine samples.				
M6 1.7.2.2	ii. For RLs of low activity, the analyte shall be at a level where the random counting error does not exceed 10% in the counting time required to attain the RL.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.2	iii. Analytes for gamma spectroscopy need not be the same as the sample analyte but should fall in the approximate energy region of the spectrum (i.e., low, mid-range, and high energy) of the reported analytes.				
M6 1.7.2.2	iv. For gross alpha and/or gross beta analysis, the analytes in the LCS shall be the same analytes used for the calibration curve.				
M6 1.7.2.2	v. If a laboratory standard containing the reported analyte is not available, an LCS analyte having similar separation chemistry, energy and decay mechanisms shall be used unless otherwise agreed to by the client.				
M6 1.7.2.2	n) Is the LCS traceable to the NIST or accepted international standard, or a working reference material as described in 1.7.1 a) viii)? Note: It may be used repeatedly for different analytical batches as long as it is appropriate for the matrix and geometry of the batch.				
M6 1.7.2.3	**Sample-Specific Controls**				
M6 1.7.2.3	Does the laboratory document procedures for determining the effect of the sample matrix on method performance?				
M6 1.7.2.3	Do these procedures relate to the analyses of quality system matrix specific QC samples and are designed as data quality indicators for a specific sample using the designated method? Note: Examples of matrix-specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); and replicates.				
M6 1.7.2.3	Does the laboratory have procedures in place for: - tracking? - managing? - handling matrix-specific QC criteria? including - spiking appropriate components at appropriate concentrations - calculating recoveries and relative percent difference? - evaluating and reporting results based on performance of the QC samples?				
M6 1.7.2.3	**a) Matrix Spike (MS)**				
M6 1.7.2.3	i. Are the results of the matrix spike analysis one of the quality control measures used to assess the batch?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	ii. Does the laboratory determine the frequency of the analysis of matrix spikes as specified by the method or as part of the contract review process?				
M6 1.7.2.3	iii. Are the components to be spiked as specified by the mandated method, including permit specified analytes, as specified by regulation or client requested analytes?				
M6 1.7.2.3	iv. Is the lack of sufficient sample aliquot size to perform a matrix spike noted in the laboratory report?				
M6 1.7.2.3	v. Is the activity of the matrix spike analytes(s) be greater than five times the MDA?				
M6 1.7.2.3	vi. Do laboratory standards used to prepare the matrix spike come from a source independent of the laboratory standards used for instrument calibration and meet the requirements for reference standards (see 1.7.2.5.c).?				
M6 1.7.2.3	vii. Is the matrix spike prepared by adding a known activity of target analyte after sub-sampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.)?				
M6 1.7.2.3	vii. Where a radiochemical method, other than gamma-ray spectroscopy, has more than one reportable analyte isotope (e.g. plutonium, 238Pu and 239Pu, using alpha-particle spectrometry), only one of the analyte isotopes need be included in the matrix spike sample at the indicated activity level. Note: Where more than one analyte is detectable, is each assessed against the specified acceptance criteria?				
M6 1.7.2.3	viii. Are matrix spikes added as early in the sample preparation steps as practicable?				
M6 1.7.2.3	ix. Matrix spikes are not required for radiochemical analyses if an isotopic tracer or chemical carrier is used in the analysis to determine chemical recovery (yield) for the chemical separation and sample mounting procedures. Matrix spikes are not required for gross alpha, gross beta, gamma, or non-aqueous tritium analysis.				
M6 1.7.2.3	x. Are matrix spikes not ran on a separate sample aliquot using the same analyte as that being analyzed whenever possible?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	**xi. MS Acceptance Criteria (DoD/DOE Only)**				
M6 1.7.2.3	Are MS recoveries evaluated using the following criteria:				
M6 1.7.2.3	If the activity of the sample is less than 5 times the spiking level, matrix spike recoveries are within the control limits of 60 - 140%, or as specified by the client?.				
M6 1.7.2.3	If the activity of the sample is greater than 5 times the spiking level, |ZMS | ≤ 3 shall be used (MARLAP 18.4.3)?				
M6 1.7.2.3	**xii. MS Selection and Level (DoD/DOE Only)**				
M6 1.7.2.3	xii) Is the MS added at a concentration of at least five, but not greater than 20 times the RL? Note: For samples having known significant activity of the targeted radionuclides, more than 20 times the RL may be added to minimize the effect of the sample activity on determination of spike recoveries.) Some programs may require, following TNI, at least 5 times the MDA.				
M6 1.7.2.3	**xiii. MS Counting (DoD/DOE Only)**				
M6 1.7.2.3	xiii) Is the MS counted for a sufficient time to quantify the activity level of the spiking?				
M6 1.7.2.3	xiii) Where the original (unspiked) sample contains significantly elevated activity, is the matrix spike counted for a duration equal to that of the associated original sample?				
M6 1.7.2.3	**b) Replicates / Matrix Spike Duplicates (MSDs) / Laboratory Control Sample Duplicates (LCSDs)**				
M6 1.7.2.3	i. Are replicates defined as replicate aliquots of the same sample taken through the entire analytical procedure.				
M6 1.7.2.3	i. Do the results from this analysis indicate the precision of the results for the specific sample using the selected method. Note: Replicates provide the most useful measure of precision when target analytes are found in the sample chosen for replication.				
M6 1.7.2.3	ii. Is the frequency of the analysis of matrix replicates and duplicates as specified by the method or determined as part of the contract review process?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	iii. Are replicates performed on replicate aliquots of actual samples?				
M6 1.7.2.3	iv. Note: For low-level samples (less than approximately three times the MDA) the laboratory may analyze a laboratory control samples duplicate or a replicate matrix spike (matrix spike and a matrix spike duplicate) to determine reproducibility within a preparation batch in place of a sample replicate. In addition based on project or program requirements, the laboratory may analyze a laboratory control sample duplicate or a matrix spike duplicate in place of a sample replicate.				
M6 1.7.2.3	v. Is the purpose of the Duplicate sample analysis is to assess laboratory precision by providing information on the laboratory's reproducibility and the homogeneity of the sample?				
M6 1.7.2.3	vi. Is the Duplicate activity not be averaged with the corresponding sample activity when reporting results?				
M6 1.7.2.3	vii. Are samples identified as Field Blanks not be used for Duplicate sample analysis?				
M6 1.7.2.3	viii. Is at least one Duplicate sample prepared and analyzed with every Analytical Batch of samples?				
M6 1.7.2.3	ix. Is the Duplicate counted for the same duration to meet the required detection limit?				
M6 1.7.2.3	x. When the sample does not contain significantly elevated activity, are QC samples counted for a duration equal to that of the associated original sample?				
M6 1.7.2.3	**xi. Replicates / MSDs / LCSDs Evaluation Criteria (DoD/DOE Only)**				
M6 1.7.2.3	xi. Does the laboratory evaluate duplicates using the following three possible criteria:				
M6 1.7.2.3	a) |ZDup | ≤ 3 (MARLAP 18.4.1) if using MARLAP?				
M6 1.7.2.3	b) the Duplicate Error Ratio (DER) between the sample and the Duplicate is < 3?				
M6 1.7.2.3	c) the relative percent difference (RPD) is < 25%?				
M6 1.7.2.3	Is the Duplicate acceptable when the MARLAP, DER or the RPD criteria pass?				
M6 1.7.2.3	When duplicates do not meet the above requirements due to difficulty in subsampling, is it described in the case narrative?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	**c) Tracer**				
M6 1.7.2.3	c) For those methods that employ a tracer for yield determination, does each sample result have an associated tracer yield calculated and reported?				
M6 1.7.2.3	c) Is the tracer added to the sample after subsampling, if required, but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method?				
M6 1.7.2.3	c) Is the tracer yield assessed against specific acceptance criteria specified in the laboratory method SOP?				
M6 1.7.2.3	c) When the specified tracer yield acceptance criteria are not met, are the specified corrective action and contingencies followed by the laboratory?				
M6 1.7.2.3	c) Are the occurrence of a failed tracer yield and the actions taken noted in the laboratory report to the client?				
M6 1.7.2.3	c) When tracers are used, is each sample (including any batch associated QC samples) also spiked with the same materials and individual sample yields determined?				
M6 1.7.2.3	c) Is the tracer added to the sample at the very beginning of the sample preparation?				
M6 1.7.2.3	c) For solid samples, is the tracer added after grinding, sieving, etc., but prior to any muffling or dissolution of the sample?				
M6 1.7.2.3	**i. Requirements for indirect yield measurements (DoD/DOE Only)**				
M6 1.7.2.3	Note: e.g., radiometric results are corrected for chemical yield using 'indirect' yield measurement techniques such as a second radiometric measurement of added tracer.)				
M6 1.7.2.3	i. Does the chemical yield for each sample determined using an indirect yield measurement method that falls within the range 30% - 110% or as specified by the client?				
M6 1.7.2.3	i. Is the technique used for the indirect yield measurement sufficient to maintain relative uncertainties associated with the yield correction below 10% at the 2-sigma level?				
M6 1.7.2.3	ii. Sample results with yields below 30% are quantitative and considered acceptable if:				
M6 1.7.2.3	a) The relative uncertainty associated with the yield correction is less than 10% (2-sigma)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	b) Spectral resolution requirements are met and there are no indications of spectral interferences?				
M6 1.7.2.3	c) Detection limit requirements are met?				
M6 1.7.2.3	**iii. Reporting yield measurement uncertainties (DoD/DOE Only)**				
M6 1.7.2.3	iii. Is the uncertainty associated with chemical yield corrections incorporated into the CSU of the associated sample results?				
M6 1.7.2.3	**iv. Tracer yield requirements for isotope direct yield methods (usually alpha spectroscopy) (DoD/DOE Only)**				
M6 1.7.2.3	iv. Does the chemical yield for isotope dilution methods fall within the range 30% - 110% or as specified by the client?				
M6 1.7.2.3	iv. Is the tracer activity and sample count duration adequate to achieve relative uncertainties for the tracer measurement of less than 10% at the 2-sigma level?				
M6 1.7.2.3	**d) Carrier**				
M6 1.7.2.3	d) For those methods that utilize a carrier for yield determination, does each sample have an associated carrier yield calculated and reported?				
M6 1.7.2.3	d) Is the carrier added to the sample after subsampling, if required, but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method?				
M6 1.7.2.3	d) Is the carrier yield for each sample one of the quality control measures to be used to assess the associated sample result acceptance?				
M6 1.7.2.3	d) Is the carrier yield assessed against the specific acceptance criteria specified in the laboratory method SOP?				
M6 1.7.2.3	d) When the specified carrier yield acceptance criteria are not met, are the specified corrective action and contingencies followed by the laboratory?				
M6 1.7.2.3	d) Has the occurrence of a failed carrier yield and the actions taken noted in the laboratory report to the client?				
M6 1.7.2.3	d) Does the laboratory ensure that each sample (including any batch associated QC samples) is also spiked with the same materials and individual sample yields determined?				
M6 1.7.2.3	d) Is the carrier added to the sample at the very beginning of the sample preparation?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	d) For solid samples, is the carrier added after grinding, sieving, etc., but prior to any muffling or dissolution of the sample?				
M6 1.7.2.3	**i. Requirements for indirect yield measurements (DoD/DOE Only)**				
M6 1.7.2.3	i. Does the chemical yield for each sample determined using an indirect yield measurement method that falls within the range 30% - 110% or as specified by the client?				
M6 1.7.2.3	i. Is the technique used for the indirect yield measurement sufficient to maintain relative uncertainties associated with the yield correction below 10% at the 2-sigma level?				
M6 1.7.2.3	ii) Sample results with yields below 30% are quantitative and considered acceptable if:				
M6 1.7.2.3	a) The relative uncertainty associated with the yield correction is less than 10% (2-sigma)?				
M6 1.7.2.3	b) Resolution requirements are met, and there are no indications of spectral interferences?				
M6 1.7.2.3	c) Detection limit requirements are met?				
M6 1.7.2.3	**iii. Reporting yield measurement uncertainties (DoD/DOE Only)**				
M6 1.7.2.3	iii. Rare the uncertainties associated with chemical yield corrections incorporated into the CSU of the associated sample results?				
M6 1.7.2.4	**Data Reduction**				
M6 1.7.2.4	a) Are the procedures for data reduction, such as use of linear regression documented?				
M6 1.7.2.4	**b) Measurement Uncertainties:**				
M6 1.7.2.4	b) Is each result reported with its measurement uncertainty?				
M6 1.7.2.4	b) At a minimum does the report:				
M6 1.7.2.4	i. indicate whether the uncertainty is the combined standard uncertainty (“one sigma”) or an expanded uncertainty?				
M6 1.7.2.4	ii. for expanded uncertainties, indicate the coverage factor (k) and optionally the approximate level of confidence?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.4	c) Are the procedures for determining the measurement uncertainty documented consistent with the ISO Guide 98: 1995, Guide to the Expression of Uncertainty in Measurement (GUM) and with the recommendations of Chapter 19 of the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP) Volume I (EPA 402-B-04- 001A), Volume II (EPA 402-B-04-001B), Volume III (EPA 402-B-04-001C), July 2004?				
M6 1.7.2.4	**d) Negative Numbers (DoD/DOE Only)**				
M6 1.7.2.4	d) Are negative activities reported as such:				
M6 1.7.2.4	d) If the sum of the activity and the measurement uncertainty at ± 3 sigma is a negative number, is the cause investigated and evaluated to determine if it is systematic or random error?				
M6 1.7.2.4	d) If the cause is systematic, has it been corrected?				
M6 1.7.2.4	d) If the cause is random, was it documented in the case narrative?				
M6 1.7.2.4	d) Has the laboratory investigated such problems and provided documentation of the resolution in the case narrative when recurrent problems with significant negative results occur (suggest that the background subtraction and/or blank subtraction, if applicable, are in error or that the estimate of error is low)?				
M6 1.7.2.5	**Reagent Quality, Water Quality, and Checks**				
M6 1.7.2.5	a) In methods where the purity of reagents is not specified, are reagents analytical reagent grade or better?				
M6 1.7.2.5	a) Does the laboratory prevent from using reagents of lesser purity than those specified by the method?				
M6 1.7.2.5	a) Are the labels on the container checked to verify that the purity of the reagents meets the requirements of the particular method?				
M6 1.7.2.5	a) Is such information made available?				
M6 1.7.2.5	b) Are the quality of water sources monitored and documented and meet method specified requirements?				
M6 1.7.2.5	c) Does the quality control program establish and maintain provisions for radionuclide standards?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.5	i. Are reference standards that are used in a radiochemical laboratory obtained from NIST or suppliers who participate in supplying NIST standards or NIST traceable radionuclides?				
M6 1.7.2.5	i. Are reference standards purchased outside the United States traceable back to each country's national standards laboratory?				
M6 1.7.2.5	i. Do commercial suppliers of reference standards shall conform to ANSI N42.22 to assure the quality of their products?				
M6 1.7.2.5	ii. Are reference standards accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates?				
M6 1.7.2.5	iii. Has the laboratory should consulted with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value?				
M6 1.7.2.5	iii. Does laboratory use only the decay-corrected certified value?				
M6 1.7.2.5	iii. Does the laboratory have a written procedure for handling, storing, and establishing expiration dates for reference standards?				
M6 1.7.2.5	d) Does the laboratory ensure that water purity is at least distilled or deionized water?				
M6 1.7.2.5	e) Are standards verified prior to initial use?				
M6 1.7.2.5	i. Are preparations of standards solutions used for a period of time exceeding one year verified annually, at a minimum, and documented in a logbook?				
M6 1.7.2.5	ii. Are at least three verification measurements of a standard used to determine the mean value and standard deviation of the verification results?				
M6 1.7.2.5	iii. Is the mean value shall be within 5% of the decay corrected certified value?				
M6 1.7.2.5	vi. Is the 2-sigma value used for the 95% confidence interval of the mean not exceed 10% of the mean value of the three verification measurements.				
M6 1.7.2.5	v. Does the laboratory ensure If all criteria is met, that the certified value is used?				
M6 1.7.2.5	f) Are corrections for radioactive decay and/or ingrowth of progeny performed for radionuclide standards?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.6	**Selectivity**				
M6 1.7.2.6	Does the laboratory evaluate selectivity by following the checks established within the method?				
M6 1.7.2.7	**Constant and Consistent Test Conditions**				
M6 1.7.2.7	a) Does the laboratory assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used?				
M6 1.7.2.7	b) Glassware Cleaning- Is glassware cleaned to meet the sensitivity requirements of the method?				
M6 1.7.2.7	b) Does the laboratory ensure that any cleaning and storage procedures that are not specified by the method are documented in laboratory records and SOPs? Note: Some applications may require single-use glassware.				
M6 1.7.2.7	**c) Radiological Control Program:**				
M6 1.7.2.7	Does the laboratory maintain a radiological control program that addresses analytical radiological control?				
M6 1.7.2.7	c) Does the program address the procedures for segregating samples with potentially widely varying levels of radioactivity?				
M6 1.7.2.7	c) Does the radiological control program explicitly define how low-level and high-level samples will be identified, segregated and processed in order to prevent sample cross-contamination?				
M6 1.7.2.7	c) Does the radiological control program include the measures taken to monitor and evaluate background activity or contamination on an ongoing basis?				
M6 1.7.2.7	d) Are background contamination monitoring samples analyzed at a sufficiently low level of detection to confirm that no impacts to client samples have occurred due to cross-contamination?				
M6 1.7.2.7	d) Are samples segregated by activity levels in sample receipt, processing areas, and storage areas?				
M6 1.7.3	**Data Acceptance/Rejection Criteria**				
M6 1.7.3.1	**Negative Control – Method Performance: Method Blank (MB)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.3.1	a) While the goal is to have no statistically significant difference from zero, does the laboratory ensure that each MB is critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch?				
M6 1.7.3.1	a) Is the source of contamination or other bias investigated and are measures taken to minimize or eliminate the problem?				
M6 1.7.3.1	a) Are affected samples reprocessed?				
M6 1.7.3.1	a) Is data appropriately qualified if either:				
M6 1.7.3.1	i. the absolute value of the activity of a targeted analyte in the blank exceeds three times its combined standard uncertainty, AND is greater than 1/10 of the activity measured in any sample?				
M6 1.7.3.1	ii. the MB result otherwise affects the sample results as per the method requirements or the project-specific measurement quality objectives?				
M6 1.7.3.1	b) Does the laboratory ensure that the acceptance criteria for samples associated with a failed MB are calculated in a manner that compensates for sample results based on differing aliquot sizes?				
M6 1.7.3.1	c) When a blank result is determined to be significantly different from zero, is the cause investigated and measures taken to minimize or eliminate the problem?				
M6 1.7.3.1	c) Are samples associated with a failed blank evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes)?				
M6 1.7.3.1	d) Is the occurrence of a failed MB and any associated corrective action noted in the laboratory report to the client?				
M6 1.7.3.2	**Positive Control – Method Performance: Laboratory Control Sample (LCS)**				
M6 1.7.3.2	a) Does the laboratory ensure the results of the individual batch LCS are calculated in %REC or other appropriate statistical technique that allows comparison to established acceptance criteria?				
M6 1.7.3.2	a) Does the laboratory document the calculation?				
M6 1.7.3.2	b) Does the laboratory ensure that individual LCS is compared to the acceptance criteria as published in the mandated method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.3.2	b) Where there is no established criteria, does the laboratory determine internal criteria?				
M6 1.7.3.2	b) Does the laboratory document the method used to establish the limits or utilize client specified assessment criteria?				
M6 1.7.3.2	c) Does the laboratory ensure that an LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch?				
M6 1.7.3.2	c) Are samples analyzed along with an LCS determined to be “out of control” considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes?				
M6 1.7.3.2	d) Is the occurrence of a failed LCS and any associated actions noted in the laboratory report to the client?				
M6 1.7.3.3	**Sample-Specific Controls**				
M6 1.7.3.3	**a) Matrix Spike (MS); Matrix Spike Duplicates (MSD)**				
M6 1.7.3.3	i. Are the results from MS/MSD primarily designed to assess the precision and accuracy of analytical results in a given matrix and expressed as %REC, RPD, or other appropriate statistical technique that allows comparison to established acceptance criteria?				
M6 1.7.3.3	i. Does the laboratory document the calculation for %R, RPD or other statistical treatment used?				
M6 1.7.3.3	ii. Are the results are compared to the acceptance criteria as published in the mandated method?				
M6 1.7.3.3	ii. Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
M6 1.7.3.3	ii. For MS results outside established criteria, is corrective action documented or the data reported with appropriate data qualifying codes?				
M6 1.7.3.3	iii. Is the occurrence of a failed MS and any associated actions noted in the laboratory report to the client?				
M6 1.7.3.3	**b) Replicates**				
M6 1.7.3.3	i. Are the results from replicates primarily designed to assess the precision of analytical results in a given matrix and are expressed as RPD or another statistical treatment (e.g., normalized differences)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.3.3	ii. Does the laboratory document the calculation for relative percent difference or other statistical treatments?				
M6 1.7.3.3	iii. Are the results compared to the acceptance criteria as published in the mandated method?				
M6 1.7.3.3	iii. Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
M6 1.7.3.3	iii. For replicate results outside established criteria, is corrective action documented or the data reported with appropriate data qualifying codes?				
M6 1.7.3.3	iv. Is the occurrence of a failed replicate and any associated actions shall be noted in the laboratory report to the client?				
M6 1.7.4	**Sample Handling**				
M6 1.7.4	a) Are all samples that require thermal preservation considered acceptable if the arrival temperature of a representative sample container is either within 2°C of the required temperature or the method specified range?				
M6 1.7.4	a) For samples with a specified temperature of 4°C, samples with a temperature ranging from just above the freezing temperature of water to 6°C are they considered acceptable?				
M6 1.7.4	i. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.4.a. In these cases, are the samples are considered acceptable if the samples were received on ice?				
M6 1.7.4	ii. If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection. Does the laboratory adhere to the above requirement?				
M6 1.7.4	b) Does the laboratory implement procedures for checking chemical preservation using readily available techniques, such as pH or chlorine, prior to or during sample preparation or analysis?				
M6 1.8	**Method Specific Directions (DoD/DOE Only)**				
M6 1.8.1	**Isotopic Determinations by Alpha Spectrometry (DoD/DOE Only)**				
M6 1.8.1	**a) Tracer:**				
M6 1.8.1	a) Are tracers used for isotope specific analysis by alpha spectrometry?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.1	a) Does Initial sample preparation include treatment to ensure that tracer and analyte will undergo similar reactions during processing?				
M6 1.8.1	a) Are all tracers of the same element or of an element with the same chemistry for the separation?				
M6 1.8.1	a) If a significant contribution is found, is the method for correction site accepted prior to use?				
M6 1.8.1	**b) Background Correction:**				
M6 1.8.1	b) Are the gross counts in each target analyte and tracer ROI corrected for the particular detector's background contribution in those same ROIs?				
M6 1.8.1	**c) Blank Correction:**				
M6 1.8.1	c) Does the laboratory ensure that blank corrections are not performed, except where required by client and fully documented in the case narrative?				
M6 1.8.1	**d) Conditions Requiring Reanalysis:**				
M6 1.8.1	**i. Sample- and Analyte-Specific Conditions:**				
M6 1.8.1	i. Does the laboratory ensure reanalysis, if sufficient sample quantity remains, is completed for the following criteria:				
M6 1.8.1	a) If the tracer recovery for the sample does not fall within 30% - 110%, reanalysis is required, beginning with preparation (but see 1.7.2.3 c) i) through iii))?				
M6 1.8.1	b) If the FWHM for the tracer peak exceeds 100 keV and/or the peak energy does not fall within ± 50 keV of the known peak energy?				
M6 1.8.1	c) If the target analyte and tracer peaks are not resolved because the target analyte activity is significantly larger than the tracer activity, the sample shall be reanalyzed with a smaller aliquot such that resolution of tracer and analyte peaks is accomplished?				
M6 1.8.1	d) If the sample analyte spectrum contains significant interferences with the analyte and/or tracer ROIs?				
M6 1.8.1	**ii. Analytical Batch Conditions:**				
M6 1.8.1	If the tracer chemical recovery for the Batch Blank does not fall within 30% - 110%, is reanalysis required of the entire Analytical Batch, beginning with the preparation, if sufficient sample is available?				
M6 1.8.1	**e) Instrument Calibration:**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.1	e) Does the calibration of each alpha spectrometry detector used to produce data include channel vs. energy calibration, detector response, efficiency determination and background determination for each ROI?				
M6 1.8.1	**f) Alpha Spectrums:**				
M6 1.8.1	f) Are alpha spectrum regions of interest selected with consistency from analyte to analyte?				
M6 1.8.1	**g) Energy Calibration:**				
M6 1.8.1	i. Is energy calibration for each detector performed?				
M6 1.8.1	i. Is the curve fit for Energy (Y-axis) versus Channel (X-axis)?				
M6 1.8.1	i. Is the equation with the slope and Y-intercept for the fit shall be documented?				
M6 1.8.1	ii. Is the slope of the equation <15 keV/channel?				
M6 1.8.1	iii. Is the energy calibration performed using at least three isotopes within the energy range of 3 to 6 MeV?				
M6 1.8.1	iv. Are the final peak energy positions of all observed isotopes within ±40 keV of the expected peak energy?				
M6 1.8.1	**h) Background Requirements:**				
M6 1.8.1	i. Are the background total counts (or counts per unit time) for each target analyte and tracer isotope ROI analyzed on each detector and documented?				
M6 1.8.1	ii. Is the background for each ROI sufficiently low to ensure that required detection limits are met?				
M6 1.8.1	iii. Are the limits of acceptability for each background ROI documented? Are these set such that RLs can be obtained for backgrounds at the limit of acceptability?				
M6 1.8.1	iv. Are background count times equal to or longer than sample count times?				
M6 1.8.1	**i) Detector Response Determination Requirements:**				
M6 1.8.1	i. Is the detector response used to calculate the estimated yields for evaluation of method performance? Note: Typically, when a tracer is used for the analysis, detector response (detector efficiency) is not used directly in calculation of final results.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.1	i. Do the response (efficiency) counts for the ROI background corrected using the same ROI for the background unless the background is less than 0.5% of the total counts in the ROI?				
M6 1.8.1	ii. Is the response (efficiency) determined on at least 3,000 net counts in the ROI (after background correction)?				
M6 1.8.1	iii. Are check source counts to verify detector response (efficiency) determined on at least 2,000 counts?				
M6 1.8.1	iv. Are detector response and detector response error documented?				
M6 1.8.1	v. Are detector response check as determined by the check source and/or pulsar count and the associated error and limits of acceptability for the check source result documented?				
M6 1.8.1	**j) Spectrum Assessment:**				
M6 1.8.1	i. Are ROIs clearly indicated either graphically or in tabular form on alpha printouts.				
M6 1.8.1	i. Are spectra with ROIs saved and made available for review upon request?				
M6 1.8.1	ii. Is the FWHM resolution for each sample and QC sample tracer peak ≤100 keV?				
M6 1.8.1	iii. Is the tracer peak energy for each sample and QC sample within ±50 keV of the expected energy?				
M6 1.8.1	iv. Is each sample and QC sample spectrum assessed for: - correctly chosen ROIs? - acceptable spectral resolution? - acceptable energy calibration? - interferences with the analyte and tracer ROIs?				
M6 1.8.1	v. Are any manual integration or adjustment of ROIs fully discussed in the case narrative?				
M6 1.8.2	**Radon Scintillation (Lucas Cell) (DoD/DOE Only)**				
M6 1.8.2	a) Do SOPs for sample analyses by Lucas Cell incorporate and adhere to ASTM D3454 (current version), Standard Test Method for Radium-226 in Water?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.2	a) Is performance in accordance with the standard unless otherwise defined in this document or as documented by the laboratory and accepted by clients?				
M6 1.8.2	a) Is the reference to the current version of the method?				
M6 1.8.2	a) When references are updated, is an implementation schedule determined by the lab?				
M6 1.8.2	b) Does the laboratory ensure that the operating voltage plateau for the detector does not exceed a slope of 2%/100V?				
M6 1.8.2	c) Are new lucas cells calibrated every month for the first six months of use and then annually after the initial six months of use?				
M6 1.8.2	d) Are background measurements for quantitation in each cell carried out prior to each sample measurement using the same cell/detector combination used for establishing the calibration factors?				
M6 1.8.2	e) Is the bubbler used for radium-226 standardization not used for sample analysis?				
M6 1.8.3	**Liquid Scintillation Counting (DoD/DOE Only)**				
M6 1.8.3	**a) Tritium in Water:**				
M6 1.8.3	a) Are water samples for tritium analysis and all associated QC samples distilled prior to analysis unless specified otherwise by the client?				
M6 1.8.3	a) Does the applicable preparation SOP specify the fraction to be collected?				
M6 1.8.3	a) Is the same fraction collected for samples and all associated QC samples?				
M6 1.8.3	**b) Counting Vial Preparation:**				
M6 1.8.3	b) Are samples counted in vials equivalent to or superior to low potassium glass vials or high density polyethylene vials?				
M6 1.8.3	b) Are samples in polyethylene vials counted within a time period not to exceed the manufacturer's specification for the cocktail used in the analysis?				
M6 1.8.3	b) Does analysis documentation contain sufficient information for this to be verified?				
M6 1.8.3	b) Are vials prepared according to manufacturer's specification for the cocktail?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.3	b) Are the vials "dark adapted" for a minimum of 30 minutes or according to the cocktail manufacturer's specifications before counting?				
M6 1.8.3	b) Are the prepared vials inspected to verify that the sample loaded properly in the cocktail?				
M6 1.8.3	c) Do the Laboratory SOPs for methods using liquid scintillation counting incorporate and adhere to ANSI N42.15-1997 (or latest version), American National Standard Check Sources for and Verification of Liquid Scintillation Systems?				
M6 1.8.3	c) Does the laboratory ensure that performance is in accordance with the standard unless otherwise defined in this document or as documented by the laboratory and accepted by clients?				
M6 1.8.3	c) Does the laboratory ensure that references are for the current version?				
M6 1.8.3	c) When references are updated, has the lab determined an implementation schedule?				
M6 1.8.3	**d) Instrument Background:**				
M6 1.8.3	d) Is the instrument background vial for all tritium matrices prepared with low-tritium or "dead" water unless the laboratory can demonstrate suitably small background or blank effects from other sources of water?				
M6 1.8.3	d) Is the instrument background vial prepared with the same water to cocktail ratio as the samples are prepared?				
M6 1.8.3	d) Is the type of water used to prepare the instrument background vial explicitly noted on the preparation and counting documentation?				
M6 1.8.3	d) Is the instrument background ran with each sample batch?				
M6 1.8.3	d) Unless calculated from a running average of background counts or a background quench curve, is the most recent background count used to calculate sample activities and MDAs?				
M6 1.8.3	Note: This is not a performance check, rather a background subtraction sample in a configuration equivalent to that of associated samples in the batch. It is used to generate the background subtraction data for the batch (using the results associated directly with that batch, results of a rolling mean, or background quench curve).				
M6 1.8.3	d) Is the effect of quench on background evaluated and corrected using a background quench curve if it is significant?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.3	e) For analysis methods using quench curves to determine individual sample detection efficiency or background, are the quench curves shall be generated at a frequency defined by the laboratory?				
M6 1.8.3	f) If the calibration method is constant quench, is the detection efficiency checked at least weekly when in use or with each counting batch?				
M6 1.8.3	**g) Sample-Specific Conditions:**				
M6 1.8.3	g) Are following conditions that require reanalysis for a particular sample and analyte, beginning with the preparation or recounting, as appropriate:				
M6 1.8.3	i. If the constant quench method of calibration is used, does the quench of each sample analyzed fall within +/-5% relative to the average efficiency at that quench level?				
M6 1.8.3	i. If this condition is not met, is the sample reanalyzed beginning with vial preparation?				
M6 1.8.3	ii. If the sample quench does not fall within the range of the quench curve, are the samples reanalyzed such that the sample quench is in the range of a quench curve?				
M6 1.8.3	**h) Spectrum Assessment:**				
M6 1.8.3	h) For analytes requiring separations other than distillation:				
M6 1.8.3	i. IS sample spectra retained (electronic or hardcopy) for each sample and QC sample including identification of ROIs?				
M6 1.8.3	ii. Is each sample and QC sample spectrum assessed for correctly chosen ROIs, acceptability of peak shape, and interferences due to non-target analytes or luminescence?				
M6 1.8.4	**Gas Flow Proportional Counting (DoD/DOE Only)**				
M6 1.8.4	**a) Planchets:**				
M6 1.8.4	a) Are planchets thoroughly cleaned before use to ensure that there are no interfering residues or contamination?				
M6 1.8.4	a) Are all planchets prepared not to exceed sample weights in excess of the calibrated ranges of established self-absorption curves?				
M6 1.8.4	a) Are sample weights documented and stable prior to counting?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.4	a) Does the laboratory ensure that planchets exhibiting physical characteristics notably different from the self-absorption standards (e.g., evidence of corrosion) are not counted unless remediation efforts such as additional sample preparation and remounting or flaming prove unsuccessful?				
M6 1.8.4	a) Are any non-routine counting situations documented in the case narrative?				
M6 1.8.4	b) Do SOPs for sample analysis by gas flow proportional counting incorporate and adhere to ANSI N42.25 (current version), Calibration and Usage of Alpha/Beta Proportional Counters?				
M6 1.8.4	b) Is this performed in accordance with the standard unless otherwise defined in this document or as documented by the laboratory and accepted by clients?				
M6 1.8.4	b) Are references for the current version?				
M6 1.8.4	b) When references change, has the laboratory determined an implementation schedule?				
M6 1.8.4	**c) Calibration Sources and Standards:**				
M6 1.8.4	c) Is the standard reference material used to prepare sources for determining detector efficiencies and self-absorption curves traceable to NIST or accepted international standards?				
M6 1.8.4	c) Do the calibration sources provide adequate counting statistics over the period for which the source is to be counted?				
M6 1.8.4	i. Does the laboratory ensure that the source is not so radioactive as to cause pulse pileups or dead time that is significantly different from that to be expected from routine analyses?				
M6 1.8.4	ii. Are the geometry of the calibration sources used for efficiency and self-absorption/crosstalk curves the same as that of the prepared sample and QC sample planchets.				
M6 1.8.4	ii. Is the depth and shape (flat, flanged, ringed, etc.), in addition to the diameter, factors the same for calibration sources as for samples?				
M6 1.8.4	iii. Are the sources used for the determination of self-absorption and cross talk of similar isotope content to that of the analytical samples?				
M6 1.8.4	iii. Is Am-241; Po-210; or Th-230 used for alpha and Cs-137 or Sr-90/Y-90 for beta?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.4	**d) Self-Absorption and Crosstalk Curves:**				
M6 1.8.4	i. Does the laboratory use self-absorption curves for both alpha and beta counting?				
M6 1.8.4	ii. Is a crosstalk curve established for alpha to beta crosstalk versus residue weight?				
M6 1.8.4	iii. IS Beta to alpha crosstalk not significantly affected by planchet residue weight, and generally constant over the applicable weight range? Note: Therefore, this crosstalk correction does not require residue weight consideration.				
M6 1.8.4	iv. Does the data used to generate self-absorption and crosstalk curves consist of at least seven points, well distributed throughout the mass range?				
M6 1.8.4	v. Is each alpha and beta calibration standard counted to an accumulation of at least 10,000 counts minimum for the initial calibration and 5,000 counts minimum for the calibration verification?				
M6 1.8.4	vi. Are new cross-talk curves measured prior to initial use, after loss of control, and upon incorporation of new or changed instrument settings. (MARLAP 18.5.6.1)?				
M6 1.8.4	**e) Check Source Requirements**				
M6 1.8.4	i. Is the alpha and beta response and corresponding crosstalk of each detector used to count analytical samples or QC samples checked daily with separate alpha and beta emitting sources? Note: The only exception to this requirement is when performing analyses with extended count times.				
M6 1.8.4	i. When performing analyses with extended count times, are check source measurements performed between sample sets?				
M6 1.8.4	ii. Following gas bottle changes, are check sources and backgrounds analyzed before samples are counted?				
M6 1.8.4	iii. Is check source data documented and retained?				
M6 1.8.5	**Gamma Spectrometry (DoD/DOE Only)**				
M6 1.8.5	**a) Sample Counting Requirements:**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.5	i. Do SOPs for sample analysis gamma spectrometry incorporate and adhere to ANSI N42.14 (current version), Calibration and Use of Germanium Spectrometers for the Measurement of Gamma Ray Emission Rate of Radionuclides, and/or ANSI N42.12 (current version), Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides?				
M6 1.8.5	i. Is performance in accordance with the standard unless otherwise defined in this document or as documented by the laboratory and accepted by clients?				
M6 1.8.5	i. When references change, has the laboratory determined an implementation schedule?				
M6 1.8.5	ii. Do gamma detector systems consist of any detector suitable for measuring the gamma isotopes of interest in the typical energy range of approximately 0.059 to 2 MeV with the capacity to attain specified RLs and to meet bias and precision? Note: Ge detectors of either intrinsic (pure) germanium or lithium drifted germanium are preferred; however for some specific requirements, another detector type, such as sodium iodide, may be more appropriate.				
M6 1.8.5	iii. Are detectors calibrated for the specific geometry and matrix considerations used in the sample analysis?				
M6 1.8.5	iii. Does the laboratory have the capability to seal soil (or other solid matrix) samples in airtight cans or equivalent in order to allow ingrowth of radon for accurate analysis of Ra-226 or its progeny by gamma spectroscopy when requested?				
M6 1.8.5	iv. Spectral Data Reference:				
M6 1.8.5	iv. Is the identification of the reference used for the half-life, abundance, and peak energy of all nuclides documented?				
M6 1.8.5	iv. Does the laboratory document, review, and provide configuration control for gamma spectrometry libraries?				
M6 1.8.5	iv. Are assumptions made for libraries (i.e., half-lives based on supported/unsupported assumptions, inferential determinations (e.g., Th-234 = U-238 because supported) documented and narrated?				
M6 1.8.5	**b) Efficiency Calibration Requirements:**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.5	i. Has each gamma spectrometry system been efficiently calibrated for the sample geometry and matrix with NIST traceable or accepted international standards or prepared from NIST/international traceable sources?				
M6 1.8.5	**i. Germanium Detectors:**				
M6 1.8.5	i. Is an efficiency calibration approach selected for broad spectrum gamma analysis that covers the energy range of the gamma ray peaks used for nuclide quantification? Note: Refer to ANSI N42.14 for guidance on isotope specific efficiency and efficiency as a function of energy calibrations.				
M6 1.8.5	i. When establishing an efficiency curve as a function of energy, are the efficiency calibration measurements at least six peaks which cover the typical energy range of approximately 0.059 to 2 MeV?				
M6 1.8.5	i. Are at least 10,000 net counts (total counts minus the Compton continuum and ambient background) accumulated in each full-energy gamma-ray peak of interest used for the efficiency equation (ASTM D 3649-98a)?				
M6 1.8.5	i. If the detector is to be used for emissions below the lowest energy of a broad spectrum calibration (e.g. below the 0.059 MeV criteria identified above), is additional demonstration of acceptable calibration performed? Note: Acceptable approaches include: 1) If manufacturer's information indicates that low-energy response below the lowest energy in the calibration standard is expected to be constant, use of the detector below that point requires check sources or LCSs to contain the isotope to be quantified (or other isotope with lower emission energies). Acceptable recovery must be demonstrated for every detector used for that isotope analysis. 2) If low-energy response below the lowest energy calibration standard is not expected to be constant, use of a gamma detector at energies below the lowest calibration point requires that a single-isotope efficiency curve or separate low-energy curve bounding the energy of interest be established for that isotope.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.5	i. In all cases, does the laboratory demonstrate that sample matrix effects (including potential attenuation from sample containers) on low energy emissions have been accounted for?				
M6 1.8.5	**i. Sodium Iodide Detectors:**				
M6 1.8.5	i. Refer to ANSI N42.12.				
M6 1.8.5	i. Are efficiencies determined when there is a change in resolution, geometry, or system configuration (ASTM D 3649-98a).				
M6 1.8.5	ii. When software is used that does not require a physical calibration standard to obtain efficiencies for various matrices and geometries, the laboratory supply detailed information and documentation regarding the selection of parameters used to specify the efficiency calibration and sample models? Note: This type of calibration technique is preferred for matrices such as waste or debris.				
M6 1.8.5	ii. Does sample selected for analysis using this type of calibration have a unique set of model parameters associated with it?				
M6 1.8.5	ii. When such models are used, is the closest model to the actual sample shall be selected?				
M6 1.8.5	ii. Is the model selected for each sample presented in the case narrative and include a discussion of actual and predicted peak ratios for isotopes with multiple gamma energies present in the sample?				
M6 1.8.5	**c) Energy Calibration Requirements:**				
M6 1.8.5	c) Is each gamma spectrometry system energy calibrated with NIST/international traceable standards or prepared from NIST/international traceable sources?				
M6 1.8.5	**c) Germanium Detectors:**				
M6 1.8.5	c) Note: Refer to ANSI N42.14, Section 5.1 for guidance on calibrating gamma-ray energy as a function of channel number at a fixed gain).				
M6 1.8.5	c) Are energy calibration measurements made using at least six peaks which cover the energy range from 0.059 to approximately 2 MeV?				
M6 1.8.5	c) Are additional peaks used deemed appropriate by the laboratory?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.8.5	c) Does the laboratory ensure that at least 10,000 net counts (total counts minus the Compton continuum and ambient background) are accumulated in each full-energy gamma-ray peak of interest (ASTM D 3649-98a)?				
M6 1.8.5	c) Is energy calibration linear and accurate to 0.5 keV?				
M6 1.8.5	**c) Sodium Iodide Detectors:**				
M6 1.8.5	c) Note: Refer to ANSI N42.12, Section 4.3.2.				
M6 1.8.5	**d) Performance Evaluation:**				
M6 1.8.5	**d) Germanium Detectors:**				
M6 1.8.5	Refer to ANSI N42.14, Section 7.				
M6 1.8.5	**d) Sodium Iodide Detectors:**				
M6 1.8.5	Refer to ANSI N42.12, Section 4.3.5.				
M6 1.8.5	**e) Spectrum Assessment:**				
M6 1.8.5	e) Is each sample and QC sample spectrum assessed for acceptability of key peak width and shape, and interference due to superimposed peaks or other sources?				
M6 1.8.5	e) Is any major contributor to the spectrum that is an unidentified peak discussed in the case narrative?				
M7	**Volume 1 Module 7**				
M7	**Quality Systems for Toxicity Testing**				
M7 1.4	**Method Selection**				
M7 1.4	When it is necessary to use methods not covered by reference methods, are these methods subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the environmental test?				
M7 1.5	**Method Validation**				
M7 1.5	Does the laboratory confirm by examination and the objective evidence that the particular requirements for a specific intended use are fulfilled?				
M7 1.5	**Demonstration of Capability (DOC)**				
M7 1.6	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (seen 1.6.2)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.6.1	Does the laboratory perform ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.1.2? Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				
M7 1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
M7 1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
M7 1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
M7 1.6.2	**Initial DOC**				
M7 1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
M7 1.6.2.1	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee?				
M7 1.6.2.1	a) analyst(s) involved in preparation and/or analysis? b) matrix? c) species and endpoint? d) identification of method(s) performed? e) identification of laboratory-specific SOP used for analysis, including revision number? f) date(s) of analysis? g) summary of analyses, including information outlined in Section 1.6.2.2.c?				
M7 1.6.2.1	If the method or regulation does not specify a DOC, does the laboratory use the procedure stated in section 1.6.3?				
M7 1.6.2.2	Does the laboratory document other approaches to initial DOC, and are they adequate?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.6.2.2	Does each analyst meet the quality control requirements as specified in section 1.7.1.2?				
M7 1.6.3	**Ongoing DOC**				
M7 1.6.3	Does the laboratory have a documented procedure describing ongoing DOC?				
M7 1.6.3	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this standard?				
M7 1.6.3	Does the laboratory have a documented procedure describing ongoing DOC?				
M7 1.6.3	Does the ongoing demonstration include performing another initial demonstration of capability as per 1.6.2 or a documented process of analyst review using QC samples can serve as the annual on-going demonstration of capability? Note: This ongoing demonstration may include performing another initial demonstration of capability as per 1.6.2 or a documented process of analyst review using QC samples can serve as the annual on-going demonstration of capability.				
M7 1.6.3	Does the laboratory document that other approaches to on-going demonstration of capability are adequate?				
M7 1.6.3	Are QC samples reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
M7 1.7	**Technical Requirements**				
M7 1.7.1	**Quality Control**				
M7 1.7.1	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken?				
M7 1.7.1	IS the resulting data recorded in such a wat that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results?				
M7 1.7.1	Is the monitoring planned and reviewed?				
M7 1.7.1	Does the monitoring include, but not be limited to, any of the following:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1	a) Is there a regular use of certified reference materials and/or internal quality control using secondary reference materials?				
M7 1.7.1	b) Is the participation in inter-laboratory comparison or proficiency-testing program?				
M7 1.7.1	c) Are the replicate tests using the same or different methods?				
M7 1.7.1	d) Is there retesting of retained samples?				
M7 1.7.1	e) Is there a correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate)?				
M7 1.7.1.1	**Essential Quality Control Procedures**				
M7 1.7.1.1	Do the general quality control principles apply, where applicable, to the testing laboratory?				
M7 1.7.1.1	Is the manner in which they are implemented dependent on the types of tests performed by the laboratory and are further described in this module?				
M7 1.7.1.1	Are the standards for any given test type assured that the applicable principles are addressed?				
M7 1.7.1.1	a) Does the laboratory have detailed written protocols in place to monitor the following quality controls:				
M7 1.7.1.1	i. Does the laboratory have positive and negative controls to monitor tests such as blanks, spikes, reference toxicants?				
M7 1.7.1.1	ii. Does the laboratory have tests to define the variability and/or repeatability of the laboratory results such as replicates?				
M7 1.7.1.1	iii. Does the laboratory have measures to evaluate method capability, such as percent minimum significant difference (PMSD)?				
M7 1.7.1.1	iv. Does the laboratory have a selection of appropriate formulae to reduce raw data to final results such as regression and statistical analyses?				
M7 1.7.1.1	v. Does the laboratory have a selection and use of reagents and standards of appropriate quality?				
M7 1.7.1.1	vi. Does the laboratory have measures to assure the selectivity of the test for its intended purpose?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.1	vii. Does the laboratory have measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method such as temperature, humidity, light or specific equipment conditions?				
M7 1.7.1.1	b) Are all quality control measures assessed and evaluated on an ongoing basis, and quality control acceptance criteria used to determine the usability of the data?				
M7 1.7.1.1	c) Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?				
M7 1.7.1.1	d) Are the quality control protocols specified by the laboratory's method manual followed?				
M7 1.7.1.1	d) Does the laboratory ensure that the essential standards outlined in this document or regulations (whichever are more stringent) are incorporated into their method manuals?				
M7 1.7.1.1	d) When it is not apparent which is more stringent does the laboratory have the QC in the regulations to be followed?				
M7 1.7.1.2	**Positive and Negative Controls**				
M7 1.7.1.2	**a) Positive Control:**				
M7 1.7.1.2	a) Does the laboratory have reference toxicant tests to demonstrate a laboratory's ability to obtain consistent results with the method and evaluate the overall health and sensitivity of test organisms over time?				
M7 1.7.1.2	i. Does the laboratory demonstrate its ability to obtain consistent results with standard reference toxicants (SRT)?				
M7 1.7.1.2	ii. Does ongoing laboratory performance demonstrate by performing routine SRT testing for each method, species and endpoint in accordance with the minimum frequency requirements (seen 1.7.1.2.a)iii))?				
M7 1.7.1.2	iii. Is the frequency of ongoing laboratory reference toxicant testing as follows unless the method specifically requires less frequent SRT tests (e.g., sediment tests)?				
M7 1.7.1.2	iii. For methods conducted at a frequency of monthly or greater, are SRT tests conducted monthly?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.2	iii. For methods and species commonly used in the laboratory, but tested at a frequency of less than monthly, are SRT tests conducted concurrently with the environmental test?				
M7 1.7.1.2	iii. If the test organisms are obtained from an outside source, does the sensitivity of each batch of organisms received from a supplier determined via a concurrent SRT test unless the supplier can provide control chart data for the last five SRT tests using the same SRT and test conditions?				
M7 1.7.1.2	iii. Is the supplied SRT data not older than six (6) months?				
M7 1.7.1.2	iv. If the regulation identifies a reference toxicant or dilution series for a particular test, does the laboratory follow the specified requirements?				
M7 1.7.1.2	iv. Do all reference toxicant tests conducted for a given method and species used in the same reference toxicant, test concentrations, dilution water and data analysis methods?				
M7 1.7.1.2	iv. Is a dilution factor of 0.5x or greater used for both acute and chronic tests?				
M7 1.7.1.2	v. Are the reference toxicant tests conducted following the procedures required in the method?				
M7 1.7.1.2	**b) Negative Controls - Control, Brine Control, Control Sediment, Control Soil or Dilution Water**				
M7 1.7.1.2	i. Are the standards for the use, type and frequency of testing of negative controls specified by the methods and by permit or regulation and followed?				
M7 1.7.1.2	i. Is the negative control included with each test to evaluate test performance and the health and sensitivity of the specific batch of organisms?				
M7 1.7.1.2	ii. Are appropriate additional negative controls included when sample adjustments (for example addition of thiosulfate for dechlorination) or solvent carriers are used in the test?				
M7 1.7.1.3	**Variability and/or Reproducibility**				
M7 1.7.1.3	Is the intra-laboratory precision determined on an ongoing basis through the use of further reference toxicant tests and related control charts as described above?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.4	**Test Sensitivity**				
M7 1.7.1.4	a) Is the PMSD calculated according to the formula specified by the method and reported with the test results?				
M7 1.7.1.4	b) For Point estimates: (LCp, ICp, or ECp), are confidence intervals reported as a measure of the precision around the point estimate value, when the calculation is possible?				
M7 1.7.1.5	**Selection and Use of Reagents and Standards**				
M7 1.7.1.5	a) Is the grade of all reagents used in toxicity tests specified in the method except the reference standard?				
M7 1.7.1.5	a) Are all reference standards prepared from chemicals that are analytical reagent grade or better?				
M7 1.7.1.5	a) Is the preparation of all standards and reference toxicants documented?				
M7 1.7.1.5	b) Are all standards and reagents associated with chemical measurements, such as dissolved oxygen, pH or specific conductance, comply with the Chemistry Module?				
M7 1.7.1.5	c) Is only reagent-grade water collected from distillation or de-ionization units used to prepare reagents?				
M7 1.7.1.6	**Constant and Consistent Test Conditions**				
M7 1.7.1.6	a) If closed refrigerator-sized incubators are used, does the laboratory have culturing and testing of organisms separated to avoid cross-contamination?				
M7 1.7.1.6	b) Does the laboratory have space adequate for the types and numbers of tests performed?				
M7 1.7.1.6	b) Does the building provide adequate cooling, heating and illumination for conducting testing and culturing; hot and cold running water available for cleaning equipment?				
M7 1.7.1.6	c) Is air used for aeration of test solutions, dilution waters and cultures free of oil and fumes?				
M7 1.7.1.6	d) Does the laboratory or a contracted outside expert positively identify test organisms to species on an annual basis?				
M7 1.7.1.6	d) Is the taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) kept on file at the laboratory?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	d) When organisms are obtained from an outside source the supplier provide this same information.				
M7 1.7.1.6	e) Is the equipment used for routine support measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, ammonia and weight calibrated, and/or standardized per manufacturer's instructions?				
M7 1.7.1.6	e) Are all measurements and calibrations documented?				
M7 1.7.1.6	f) Is test temperature maintained as specified for the method?				
M7 1.7.1.6	f) Is the temperature control equipment adequate to maintain the required test temperature(s)?				
M7 1.7.1.6	f) Is the average daily temperature of the test solutions maintained within method specified range?				
M7 1.7.1.6	f) Is the minimum frequency of measurement once per twenty-four (24) hour period?				
M7 1.7.1.6	f) Is the test temperature for continuous-flow toxicity tests recorded and monitored continuously?				
M7 1.7.1.6	f) Does the laboratory use electronic data loggers and is temperature monitored at a frequency sufficient to capture temporal variations of the environmental control system?				
M7 1.7.1.6	g) Does the laboratory have reagent grade water, prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration that meets the method specified requirements?				
M7 1.7.1.6	h) Is the quality of the standard dilution water used for testing or culturing sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance?				
M7 1.7.1.6	h) Does the laboratory have water used for culturing and testing analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock that can be identified?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	i) Is the quality of the food used for testing or culturing sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance?				
M7 1.7.1.6	i) Does the laboratory have written procedures for the evaluation of food acceptance?				
M7 1.7.1.6	j) Does the laboratory have a subset of organisms used in bioaccumulation tests analyzed at the start of the test (baseline) for the target compounds to be measured in the bioaccumulation tests?				
M7 1.7.1.6	k) Are the test chamber sizes and test solution volumes as specified in the method, and are the test chambers used identical?				
M7 1.7.1.6	l) Are test organisms fed the quantity and type food or nutrients specified in the method, and are they fed at the intervals specified in the methods?				
M7 1.7.1.6	m) Are all organisms in a test from the same source and lot, where available, are certified seeds used for soil tests?				
M7 1.7.1.6	n) Are all organisms used in tests, or used as brood stock to produce neonate test organisms (for example cladocerans and larval fish), appear healthy, show no signs of stress or disease and do they exhibit acceptable survival (90% or greater) during the twenty-four (24) hour period immediately preceding use in tests?				
M7 1.7.1.6	o) Are all materials used for test chambers, culture tanks, tubing, etc. and coming in contact with test samples, solutions, control water, sediment or soil or food non-toxic and cleaned as described in the methods?				
M7 1.7.1.6	o) Do materials reduced or added to sample toxicity?				
M7 1.7.1.6	o) Are appropriate materials used for toxicity testing and culturing as described in the methods?				
M7 1.7.1.6	p) Is the light intensity maintained as specified in the methods?				
M7 1.7.1.6	p) Are the measurements made and recorded on a yearly basis?				
M7 1.7.1.6	p) Are photoperiod records maintained as specified in the methods and documented at least quarterly?				
M7 1.7.1.6	p) For algal and plant tests, is the light intensity measured and recorded at the start of each test?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	q) Are the health and culturing conditions of all organisms used for testing documented by the laboratory?				
M7 1.7.1.6	q) Does the documentation include culture conditions (e.g. salinity, hardness, temperature, pH) and observations of any stress, disease or mortality?				
M7 1.7.1.6	q) When organisms are obtained from an outside source, does the laboratory obtain written documentation of these water quality parameters and biological observations for each lot of organism received?				
M7 1.7.1.6	q) Do the observation records adequately address the twenty-four (24) hour time period referenced in item 1.7.1.6 n) above?				
M7 1.7.1.6	q) Does the laboratory record each of these observations and water quality parameters upon the arrival of the organisms at the laboratory?				
M7 1.7.1.6	r) Are the age and the age ranges of the test organisms as specified in the method?				
M7 1.7.1.6	r) Is supporting information, such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) documented?				
M7 1.7.1.6	s) Does the maximum holding time of effluents (elapsed time from sample collection to first use in a test) not exceeding thirty-six (36) hours? Note: samples may be used for renewal up to seventy-two (72) hours after first use except as prescribed by the method and approved by the regulatory agency having authority for program oversight.				
M7 1.7.1.6	t) Do all tests have at least the minimum number of replicates per treatment as prescribed by the method?				
M7 1.7.1.6	u) Does the controlled populations of Ceriodaphnia in chronic effluent or receiving water tests contain no more than 20% males?				
M7 1.7.1.6	v) Is the culturing of C. dubia adequate such that blocking by parentage can be established?				
M7 1.7.1.6	w) Is the dissolved oxygen and pH in aquatic tests within acceptable range at test initiation?				
M7 1.7.1.6	w) Is the minimal aeration provided to the tests if acceptable dissolved oxygen concentrations cannot be otherwise maintained?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	x) Are the test soils or sediments within the geochemical tolerance range of the test organism?				
M7 1.7.1.6	y) Does the laboratory have individual tests conditionally acceptable if temperature, dissolved oxygen, pH and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests (see test conditions and test acceptability criteria specified for each method)?				
M7 1.7.1.6	y) Does the acceptability of the test depend on the experience and professional judgment of the technical director and the permitting authority?				
M7 1.7.2	**Data Acceptance/Rejection Criteria**				
M7 1.7.2.1	**Positive Controls**				
M7 1.7.2.1	Does the laboratory record the control performance and statistical endpoints (such as NOEC or ECp) for each method and species on control charts?				
M7 1.7.2.1	Does the laboratory evaluate precision (i.e. coefficient of variation, CV) for these tests against method specific or laboratory-derived criteria to determine validity of the testing result?				
M7 1.7.2.1	For endpoints that are point estimates (ICp, ECp), are control charts constructed by plotting the cumulative mean and the control limits, which consist of the upper and lower 95% confidence limits (+/- 2 standard deviations)?				
M7 1.7.2.1	For endpoints from hypothesis tests (NOEC, NOAEC) are the values plotted directly, and the control limits consist of one concentration interval above and below the concentration representing the central tendency (i.e. the mode)?				
M7 1.7.2.1	For endpoints that are point estimates does the laboratory have the cumulative mean CV is calculated?				
M7 1.7.2.1	For endpoints from hypothesis tests, is the PMSD calculated?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.2.1	Are these values maintained on control charts? Note: Control chart limits are expected to be exceeded occasionally regardless of how well a laboratory performs. Test results that fall outside of control chart limits at a frequency of 5% or less, or which fall just outside control chart limits (especially in the case of highly proficient laboratories which may develop relatively narrow acceptance limits over time), are not rejected de facto. Such data are evaluated in comparison with control chart characteristics including the width of the acceptance limits and the degree of departure of the value from acceptance limits.				
M7 1.7.2.1	Does the laboratory have acceptance/rejection policies, consistent with the methods, for SRT data which considers source of test organisms, the direction of the deviation, test dilution factor, test sensitivity (for hypothesis test values), testing frequency, out-of-control test frequency, relative width of acceptance limits, inter-test CV, and degree of difference between test results and acceptance limits?				
M7 1.7.2.1	In the case of reference toxicant data which fails to meet control chart acceptance criteria, is the test data examined for defects, corrective action taken and the test repeated if necessary, using a different batch of organisms or the data is qualified?				
M7 1.7.2.1	Is the intra-laboratory precision determined on an ongoing basis through the use of control charts?				
M7 1.7.2.1	Are the control charts plotted as point estimate values, such as EC25 for chronic tests and LC50 for acute tests, or as appropriate hypothesis test values, such as the NOEC or NOAEC, over time within a laboratory?				
M7 1.7.2.2	**Negative Controls**				
M7 1.7.2.2	Does the laboratory have the test acceptability criteria specified in the method achieved for both the reference toxicant and the effluent or environmental sample toxicity test?				
M7 1.7.2.2	Does the laboratory have the criteria calculated and does it meet the method specified requirements for performing toxicity tests?				
M7 1.7.2.3	**Selection of Appropriate Statistical Analysis Methods**				
M7 1.7.2.3	a) Are the methods of data analysis and reporting as specified by language in the regulation, permit, or the method followed as required?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.2.3	b) Is the toxicity data plotted on semi-logarithmic graph paper, relating time, mortality, and effluent concentration to verify computational results?				
M7 1.7.3	**Sample Handling**				
M7 1.7.3	Are all samples chilled to 0-6°C during or immediately after collection except as prescribed by the method and approved by the regulatory agency having authority for program oversight?				
Appendix A	**Appendix A**				
Appendix A	**Reporting Requirements**				
Appendix A	In the absence of client specified reporting criteria, are the reporting requirements outlined below used for hard-copy data reports or electronic versions of hard-copy data (such as pdf)?				
Appendix A	Note: This includes mandatory requirements for all printe+D1180:D1204d data reports, and requirements for data reports requiring third party data review or validation. Optional reporting requirements are those that may be required by a specific project, depending upon their needs.				
Appendix A	Are the following required elements included: 1) cover sheet? 2) table of contents? 3) case narrative? 4) analytical results? 5) sample management records? 6) QC information? Note: Information for third-party review may be required depending on project-specific requirements or the method being used.				
Appendix A	**1.0 Cover Sheet**				
Appendix A	Does the cover sheet shall specify the following information:				
Appendix A	a) title of report (i.e., test report, test certificate)?				
Appendix A	b) name and location of laboratory (to include a point of contact, phone and facsimile numbers, and e-mail address)?				
Appendix A	c) name and location of any subcontractor laboratories and appropriate test method performed (information can also be located in the case narrative as an alternative)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix A	d) unique identification of the report (such as serial number)?				
Appendix A	e) client name and address?				
Appendix A	f) project name and site location?				
Appendix A	g) statement of data authenticity and official signature and title of person authorizing report release, date of issuance?				
Appendix A	h) amendments to previously released reports that clearly identify the serial number for the previous report and state the reason(s) for reissuance of the report?				
Appendix A	i) total number of pages?				
Appendix A	**2.0 Table of Contents**				
Appendix A	Are the laboratory data packages organized in a format that allows for easy identification and retrieval of information? Note: An index or table of contents shall be included for this purpose.				
Appendix A	**3.0 Case Narrative**				
Appendix A	Is a case narrative included in each report? Note: Information need not be repeated if noted elsewhere in the data package.				
Appendix A	Does the case narrative:				
Appendix A	1) Describe any abnormalities, deviations, and failures that may affect the analytical results?				
Appendix A	2) Summarize any issues in the data package that need to be highlighted for the data user to help them assess the usability of the data?				
Appendix A	3) Provide a summary of samples included in the report with the methods employed in order to assist the user in interpretation?				
Appendix A	Does the case narrative provide:				
Appendix A	a) a table(s) summarizing samples received, providing a correlation between field sample numbers and laboratory sample numbers, and identifying which analytical, preparation, and clean-up methods were performed. If multiple laboratories performed analyses, the name and location of each laboratory shall be associated with each sample?				
Appendix A	b) a list of samples that were received but not analyzed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix A	c) date of samples received?				
Appendix A	d) sample preservation and condition at receipt?				
Appendix A	e) a description of extractions or analyses that were performed out of holding times?				
Appendix A	f) a definition of all data qualifiers or flags used?				
Appendix A	g) identification of deviations of any calibration standards or QC sample results from appropriate acceptance limits and a discussion of the associated corrective actions taken by the laboratory?				
Appendix A	h) identification of multiple sample runs with reason(s) identified (e.g., dilutions or multiple cleanups)?				
Appendix A	i) identification of QC samples, client samples, and target analytes for which manual integration was necessary including the justification; and				
Appendix A	j) appropriate notation of any other factors that could affect the sample results? (e.g., air bubbles in volatile organic compounds (VOC) sample vials, excess headspace in soil VOC containers, the presence of multiple phases, sample temperature or pH excursions, and container type or volume).				
Appendix A	**4.0 Analytical Results**				
Appendix A	Do the results for each sample contain the following information at a minimum: Note: Information need not be repeated if noted elsewhere in the data package.				
Appendix A	a) project name and site location?				
Appendix A	b) field sample ID number as written on custody form?				
Appendix A	c) laboratory sample ID number?				
Appendix A	d) preparation batch number(s)?				
Appendix A	e) matrix (soil, water, oil, air, etc.)?				
Appendix A	f) date and time sample collected?				
Appendix A	g) date and time sample prepared?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix A	h) date and time sample analyzed?				
Appendix A	i) method numbers for all preparation, cleanup, and analysis procedures employed?				
Appendix A	j) analyte or parameter with the Chemical Abstracts Service (CAS) Registry Number if available?				
Appendix A	k) sample aliquot analyzed?				
Appendix A	l) final extract volume?				
Appendix A	m) identification of analytes for which manual integration occurred, including the cause and justification?				
Appendix A	n) analytical results with correct number of significant figures?				
Appendix A	o) Detection Limit, Limit of Detection, and Limit of Quantitation associated with sample results and adjusted for sample-specific factors (e.g., aliquot size, dilution/concentration factors, and moisture content)?				
Appendix A	p) any data qualifiers assigned?				
Appendix A	q) concentration units?				
Appendix A	r) dilution factors?				
Appendix A	s) all multiple sample run results shall be reported?				
Appendix A	t) percent moisture or percent solids (all soils are to be reported on a dry weight basis)?				
Appendix A	u) statements of the estimated uncertainty of test results (optional)?				
Appendix A	**5.0 Sample Management Records**				
Appendix A	Do the Sample Management records include the documentation accompanying the samples, such as:				
Appendix A	a) chain of custody records?				
Appendix A	b) shipping documents?				
Appendix A	c) records generated by the laboratory which detail the condition of the samples upon receipt at the laboratory (e.g., sample cooler receipt forms, cooler temperature, and sample pH)?				
Appendix A	d) telephone conversation or e-mail records associated with actions taken or quality issues?				
Appendix A	e) records of sample compositing done by the laboratory?				
Appendix A	**6.0 QC Information**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix A	Does the minimum laboratory internal QC data package include:				
Appendix A	a) MB results?				
Appendix A	b) %RECs for LCS, LCSD, MS, and MSD?				
Appendix A	d) surrogate percent recoveries?				
Appendix A	e) tracer recoveries?				
Appendix A	f) spike concentrations for LCS, MS, surrogates?				
Appendix A	g) QC acceptance criteria for LCS, MS, surrogates?				
Appendix A	h) Post-Digestion Spike (PDS) recoveries?				
Appendix A	i) serial dilutions (SD) %D?				
Appendix A	j) batch numbers (preparation, analysis, and cleanup)?				
Appendix A	**7.0 Data Reports for Third Party Review or Validation**				
Appendix A	Note: The data validation guidelines established in other DoD/DOE guidance or project-specific guidelines may have distinct reporting formats. The appropriate QAPP should be consulted to determine what type (stage) of data package is required.				
Appendix A	Do data validation guidelines define the minimum reporting requirements for each stage (formerly called “level”) of data package as outlined below:				
Appendix A	Are a cover sheet, table of contents, and case narrative including all of the information specified in the previous sections required for all stages of data reports?				
Appendix A	Stage 1: Sample results forms, chain of custody, laboratory receipt checklist?				
Appendix A	Stage 2A: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms?				
Appendix A	Stage 2B: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms, instrument QC forms, instrument and preparation logs?				
Appendix A	Stage 3: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms, instrument QC forms, instrument and preparation logs, instrument quantitation forms (raw data), standards traceability?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix A	Stage 4: Sample results forms, chain of custody, laboratory receipt checklist, sample related method QC forms, instrument QC forms, instrument and preparation logs, instrument quantitation forms (raw data), instrument chromatograms and spectra, standards traceability?				
Appendix A	Is standards traceability included in Stages 3 and 4?				
Appendix B	**Appendix B**				
Appendix B	**Quality Control Requirements**				
Appendix B	Are the QC requirements defined in the following Appendix B tables followed by the laboratory **(see also M4 1.7.3 and M6 1.7.2)**?				
Appendix B	Table B-1. Organic Analysis by Gas Chromatography (GC)				
Appendix B	Table B-2. Organic Analysis by High-Performance Liquid Chromatography (HPLC)				
Appendix B	Table B-3. Nitroaromatics, Nitramines, and Nitrate Esters Analysis by HPLC, LC/MS, or LC/MS/MS (Method 8330B)				
Appendix B	Table B-4. Organic Analysis by Gas Chromatography/Mass Spectrometry (GC/MS)				
Appendix B	Table B-5. Dioxin/Furan Analysis by High-Resolution Gas Chromatography/Low-Resolution Mass Spectrometry (Method 8280)				
Appendix B	Table B-6. Dioxin/Furan Analysis by High-Resolution Gas Chromatography/High-Resolution Mass Spectrometry (Method 8290)				
Appendix B	Table B-7. Inorganic Analysis by Atomic Absorption Spectrophotometry (AA)				
Appendix B	Table B-8. Inorganic Analysis by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP/AES)				
Appendix B	Table B-9. Trace Metals Analysis by Inductively Coupled Plasma/Mass Spectrometry (ICP/MS)				
Appendix B	Table B-10. Inorganic Analysis by Colorimetric Hexavalent Chromium				
Appendix B	Table B-11. Cyanide Analysis				
Appendix B	Table B-12. Common Anions Analysis by Ion Chromatography (IC)				
Appendix B	Table B-13. Perchlorate by Mass Spectrometry Methods				
Appendix B	Table B-14. Chemical Warfare Agents by GC/MS				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix B	Table B-15. Per- and Polyfluoroalkyl Substances (PFAS) Using Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) With Isotope Dilution or Internal Standard Quantification in Matrices Other Than Drinking Water				
Appendix B	Table B-16. Alpha Spectrometry				
Appendix B	Table B-17. Gamma Spectrometry				
Appendix B	Table B-18. Gas Flow Proportional Counting				
Appendix B	Table B-19. Liquid Scintillation Counter Analysis				
Appendix B	Table B-20. Radon Scintillation (Ra-226 by Lucas Cell)				
Appendix B	Table B-21. GC/MS Analysis of Air Samples				
Appendix B	Table B-22. Organic Semi-Volatile Analysis by GC/MS in SIM Mode				
Appendix B	Table B-23. Incremental Sampling Methodology (ISM) Soil Preparation for Large Volume (1 kg or greater) Samples Other Than Exposives				
Appendix B	Table B-24. Per- and Polyfluoroalkyl Substances (PFAS) Analysis by LC/MS/MS (EPA Draft Method 1633)				
Appendix C	**Appendix C**				
Appendix C	**LCS Control Limits and Requirements**				
Appendix C	Does the laboratory use control limits that are within the limits found in Appendix C, unless: - Client Specified? - Method/Matrix/Analyte combination not listed in Appendix C? for the following:				
Appendix C	LCS evaluations. **See also V1M4 1.7.3.2.3 g-j) and Appendix B LCS acceptance criteria**				
Appendix C	MS evaluations. **See also V1M4 1.7.3.3 and Appendix B MS acceptance criteria**				
Appendix C	Surrogate evaluations. **See also V1M4 1.7.3.3 d) and Appendix B Surrogate acceptance criteria**				
Appendix D	**APPENDIX D: Non-Destructive Assay (NDA)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	**Non-Destructive Assay (NDA)**				
Appendix D	**1.0 Quality Assurance**				
Appendix D	**1.1 NDA System Calibration**				
Appendix D	Note: NDA is analysis used to evaluate the properties of a material, component or system without causing damage.				
Appendix D	Has the NDA measurement organization developed and implemented procedures for NDA measurement system calibration methods and processes?				
Appendix D	Does the NDA measurement organization demonstrate the calibration and associated uncertainty is compliant with applicable client and/or end-user requirements initially and throughout the contract period?				
Appendix D	**1.1.1 Initial NDA System Calibration**				
Appendix D	Is the NDA measurement system initial calibration performed to ensure the measurement system response provides valid data of known and documented quality?				
Appendix D	Are calibrations performed using traceable working reference materials (WRMs) obtained from suppliers maintaining a nationally recognized reference base and an accredited measurement program?				
Appendix D	Are the calibration technique, process, and results fully documented?				
Appendix D	For cases where there is an insufficient number and denomination of traceable radioactive material standards to support the initial calibration, did the NDA organization develop alternate calibration strategies based on available resources?				
Appendix D	Are alternate strategies clearly documented and technically justifiable?				
Appendix D	Is the development and establishment of an initial calibration address the following as applicable:				
Appendix D	a) Are SOPs in place to specify steps/activities necessary to develop and determine the initial calibration including, but not limited to, specification of traceable radioactive sources or their alternates, geometrical positioning of sources, traceable source/matrix media configurations, acquisition of NDA system response data, computational methods, analysis of response data to determine a robust calibration, calibration acceptance criteria, calibration applicability and qualifiers, and calibration uncertainty?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	b) Is the initial calibration shall be performed through the use of traceable working reference materials unless exceptions have been stipulated and documented?				
Appendix D	b) For mass calibrations (i.e., calibrations that use a direct measurement of the same isotopes, matrices, and containers that will subsequently be measured in unknown items), do the radioactive material mass and matrix characteristics span and bracket the range of anticipated values for the measurement items?				
Appendix D	b) For calibrations based on instrument response modeling, is sufficient information provided in the method description and calibration regimen to assure that the calibration measurements and model appropriately spans and brackets the anticipated analysis space (e.g., provide mechanisms to account for anticipated geometries, radioactive material mass, chemical composition, and matrix characteristics)?				
Appendix D	b) For enrichment determinations using the enrichment meter technique, does the initial calibration span the range of enrichments in anticipated unknown item measurements?				
Appendix D	c) Is the measurement uncertainty associated with the application of the initial calibration established using a sound and technically defensible technique?				
Appendix D	c) Are the methods for the estimation of total measurement uncertainty (TMU) shall be developed and documented?				
Appendix D	c) Where applicable, does the calibration uncertainty include terms for mass, matrix characteristics and configurations and radioactive material properties?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	c) Do these methods consider, at a minimum, uncertainty components, the calibration uncertainty model (method of uncertainty component propagation), estimates of uncertainty introduced by differences between item characteristics and calibration modeling assumptions? For example, if the model assumes a homogeneous distribution of the isotope of interest, the uncertainty introduced if items are not homogeneous using a worst case distribution as determined through a documented engineering judgment including supporting data must be determined.				
Appendix D	d) Is the NDA measurement method capability related to each initial calibration defined and documented?				
Appendix D	d) As applicable, does this capability include waste matrix types, process equipment types, geometries, configurations, radioactive material types, matrix density range, hydrogenous material range, radioactive material mass range, radioactive material compound, and other parameters affecting instrument response?				
Appendix D	d) Is the intent of defining the capability to delineate those source/matrix configurations where the calibration is applicable and where it is not?				
Appendix D	e) Where surrogate materials are used to simulate waste matrices is their configuration(s) nominally representative of the actual waste item population?				
Appendix D	e) Does the design of surrogate matrix configurations documented?				
Appendix D	e) Are surrogate materials used to produce a given matrix configuration carefully specified, procured and the resultant physical properties and configuration documented?				
Appendix D	f) If NDA method manuals, national standards, or a mandated NDA calibration methods do not specify the number of traceable WRMs to span the mass/activity and radioactive material compound(s) characteristics of the waste/process component, is a minimum number determined and technically justified?				
Appendix D	f) Does the NDA organization document this number and their denominations in a calibration SOP or other applicable document?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	f) Note: This requirement does not necessarily apply to NDA methods that rely on modeling.				
Appendix D	f) Is the method used to assure that the calibration and model appropriately spans and brackets the anticipated analysis space (e.g., provide mechanisms to account for anticipated geometries, radioactive material mass, chemical composition, and matrix characteristics) as per item (b) above technically justified and documented?				
Appendix D	f) The For NDA methods that do not necessarily require calibration with source material similar in nature to the waste or process items (e.g., neutron counting), are those source(s) used still required to be traceable?				
Appendix D	f) However, is the accounting of the efficiency variation because of the composition of the actual radioactive material shall be assessed and corrected for (e.g., Californium (252Cf) fission neutron spectrum counter efficiency versus uranyl fluoride (UO2F2) neutron spectrum efficiency.)				
Appendix D	g) Is the initial calibration process clearly documented including the calibration measurement configurations, data acquisition parameters, acquired data, data reduction methods, resultant calibration factors or expressions, statistical analyses and uncertainties?				
Appendix D	g) Do the records containing information pertinent to the calibration process that are retained include following:				
Appendix D	i. WRM and/or surrogate waste matrix configurations used to acquire instrument response data, calibration determination techniques?				
Appendix D	ii. SOP(s) used?				
Appendix D	iii. data acquisition parameters?				
Appendix D	iv. NDA system identification?				
Appendix D	v. analytical software used?				
Appendix D	vi. traceable standard identifications?				
Appendix D	vii. analytical support equipment information?				
Appendix D	viii. electronic file storage locations?				
Appendix D	g) Are the records sufficient to allow reproduction of the initial calibration?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	h) Is the initial calibration re-established when repairs or changes are made to the measurement system that are likely to affect one or more calibration parameters? Examples that may require repeating the "initial calibration" include, but not are limited to: i) major NDA system repairs or modifications; ii) replacement of vital NDA measurement system components (e.g., collimator, multichannel analyzer (MCA), neutron generator); iii) change in collimator depth and/or aperture not accounted for in a model; and iv) significant software modification and/or changes.				
Appendix D	**1.1.2 Calibration Confirmation**				
Appendix D	Is a confirmation of the initial NDA measurement system calibration performed?				
Appendix D	In this context, does confirmation mean the initial calibration assessed and determined is correct and true by the objective collection of evidence supporting the calibration was properly established?				
Appendix D	a) Is this recommended method used to assemble test item(s) consisting of traceable source/matrix configuration(s) nominally representative of the waste form and/or process components to be characterized?				
Appendix D	a) Are they not the same configurations used to establish the initial calibration?				
Appendix D	a) Do they contain a known and traceable radioactive element/isotope, mass/activity and/or enrichment in a known and representative matrix configuration?				
Appendix D	a) Are the confirmation test item(s) then measured using the initial calibration of the NDA system?				
Appendix D	a) Is the number of differing tests item configurations used to confirm the calibration determined by the NDA organization and documented?				
Appendix D	a) Does the reported "calibration confirmation" measurement result agree with criteria as established by the NDA organization, with the known element/isotope, mass/activity and/or enrichment of the confirmation test item(s)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	a) Does the NDA organization acceptance criterion not exceeding the criteria as presented in Section 1.1.3 unless technically justified and documented?				
Appendix D	b) Are the radioactive sources used for “calibration confirmation” purposes, to the extent practicable, representative of the actual radioactive material compositions and chemical compounds as found in the measurement item inventory of interest?				
Appendix D	c) Are radioactive material standards used for “calibration confirmation” traceable to a nationally recognized reference base (e.g., National Institute of Standards and Technology [NIST] or New Brunswick Laboratory [NBL])?				
Appendix D	c) Are the traceable standards used for “calibration confirmation” related to (from the same feedstock or lineage) those used to perform the initial calibration?				
Appendix D	c) If there is lack of a sufficient variety of traceable standards, is an adequate alternate confirmation strategy is devised?				
Appendix D	d) Is calibration confirmation acceptance assessed through the degree of agreement between the known “calibration confirmation“ test item value and that as per the NDA confirmation measurement result?				
Appendix D	d) Is the NDA organization to determine and document representative “calibration confirmation” source/matrix surrogate configuration(s)?				
Appendix D	d) Does the NDA organization also develop “calibration confirmation” bias and precision acceptance criteria specific to the NDA system and measurement items under consideration?				
Appendix D	Note: Recommended “calibration confirmation” acceptance criteria are delineated in Section 1.1.3.				
Appendix D	e) Are the calibration confirmation results outside NDA organization defined acceptance criteria requiring implementation of corrective action(s) as applicable?				
Appendix D	e) Calibration confirmation results are not to exceed the maximum allowable acceptance criteria of Section 1.1.3 unless the NDA organization has specifically determined and documented greater limits with the requisite technical justification.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	f) For the case where a corrective action was required and subsequently implemented, is the “calibration confirmation” process repeated?				
Appendix D	f) Are the acceptable results obtained and documented before the NDA system is considered operational?				
Appendix D	f) Where a “calibration confirmation” failure was determined to be due to a minor issue (e.g., wrong constant, wrong efficiency file, or an inappropriate test item), does the entire “calibration confirmation” measurement regimen need to be repeated?				
Appendix D	f) Was this acceptable to the laboratory provided it is the true cause of the failure?				
Appendix D	f) Are all corrective actions and their effects, supporting data, results, etc., documented and retained?				
Appendix D	g) In the case where the “calibration confirmation” was acceptable for certain types or categories of radioactive material/waste matrix configurations, but unacceptable for other categories with distinctly different source/matrix properties, is conditional acceptance of the “calibration confirmation” made?				
Appendix D	g) Does the NDA organization, however, clearly identify which categories of source/matrix configurations are approved for NDA measurement and which are not?				
Appendix D	g) Is the technical basis for accepting certain source/matrix categories documented and available for review?				
Appendix D	g) Are recalibration or corrective action efforts implemented and documented for source/matrix categories that do not meet acceptance criteria for “calibration confirmation”?				
Appendix D	h) Is the “calibration confirmation” process performed following an initial calibration or where indications warrant a re-assessment of the initial calibration? (e.g., the source/matrix configuration of measurement items varies relative to the source/matrix configurations used to develop the initial calibration).				
Appendix D	h) Do additional causes for a performing a “calibration confirmation” include:				
Appendix D	i. major NDA system repairs or modifications?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	ii. replacement of NDA measurement system components, e.g., detector, neutron generator or supporting electronic components that have the potential to affect data quality?				
Appendix D	iii. re-calibration?				
Appendix D	iv. significant changes to the NDA system software?				
Appendix D	v. relocation of the system (applies primarily to fixed stationary systems)?				
Appendix D	i) Do the records retained permit reconstruction of any NDA measurement system “calibration confirmation”(e.g., NDA method, measurement system configuration, confirmation date, primary radioactive isotope(s), mass or concentration and response, calibration factor(s), or equations/coefficients used to convert NDA instrument response to mass/concentration)?				
Appendix D	i) Does documentation explicitly connect the “calibration confirmation” data/records to the initial calibration?				
Appendix D	**1.1.3 Calibration Confirmation Acceptance Criteria**				
Appendix D	a) Are bias and precision limits used to determine the acceptability of “calibration confirmation” measurements?				
Appendix D	a) Are the specified limits “upper limits” to be applied to all NDA measurement techniques over all matrix configurations?				
Appendix D	a) Are the recommended “calibration confirmation” limits not specifically tied to end-user requirements, or are nominal performance levels expected of NDA systems?				
Appendix D	a) Is failure to comply with these biases and precision limits as an indicator that more capable measurement techniques need to be developed?				
Appendix D	b) Are NDA measurement system bias and precision determined through the acquisition of replicate measurements using matrix container and/or process component mock-ups combined with traceable WRMs?				
Appendix D	b) Are the source/matrix configurations representative of the actual measurement item population of interest?				
Appendix D	b) Is the number of different source/matrix test configurations and replicate measurements of each determined by the NDA organization and documented?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Is the "calibration confirmation" bias determined in terms of %Bias? (mean measured value - known value)/known value]*100 or %R (mean measured value/known value)*100.				
Appendix D	Is the bias not be outside the limits as per Table D-1 at the 95% confidence level.				
Appendix D	c) Is precision reported as percent relative standard deviation (% RSD)?				
Appendix D	c) Does the %RSD not exceed the value listed in the last row of Table D-1 for twenty replicate measurements of the "calibration confirmation" source/matrix test item(s)? Note: Equivalent %RSD limits for a number of different replicate values are tabulated in Table D-2.				
Appendix D	d) If the NDA service provider developed alternate methods and limits for bias and precision, are the alternate methods and limits technically defensible and clearly documented?				
Appendix D	e) Are failure to comply with the bias and precision requirements for "calibration confirmation" addressed in a corrective action plan (CAP)? Note: The CAP shall include detail on the nature of the failure, its suspected causes, methods to evaluate potential causes, and activities proposed to identify and rectify the deficiency. The CAP results shall be documented and show why the failure occurred and what actions were taken to prevent a re-occurrence. The "calibration confirmation" shall be performed again after the corrective actions in the CAP have been implemented and the results documented.				
Appendix D	**1.1.4 Calibration Verification**				
Appendix D	Does the laboratory's "calibration verification" test item(s) meet the bias acceptance criteria delineated in Section 1.1.3?				
Appendix D	Are "calibration verification" performed at least once every five operational days for each measurement system and calibration in use?				
Appendix D	Is a five day operational period defined as a rolling tally of five days where NDA operations were in effect, not necessarily consecutive?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Is the start point for the five day operational period from the start of approved operations or the first operational day after the previous rolling five day tally was completed?				
Appendix D	Is the five day operational "calibration verification" requirement extended to a maximum of thirty operational days provided the NDA organization demonstrate and technically justify the long term stability of the NDA system per established acceptance criteria?				
Appendix D	Are calibration verification test items typically selected from or assembled from the traceable standards and matrix containers or process component mock-ups used in the "calibration confirmation" process?				
Appendix D	Is the "calibration verification" test item to be submitted to NDA operations in a "blind" manner, where applicable, and processed through the measurement routine as though it was an actual measurement item?				
Appendix D	Are the "calibration verification" tests items selected and/or configured and submitted such that during a 12-month period the operational space of the NDA system initial calibration is spanned?				
Appendix D	Is the "calibration verification" a point check in the calibration realm?				
Appendix D	Do the laboratory's "calibration verification" configurations vary over the operational space?				
Appendix D	Does acceptable performance for a "calibration verification" measurement result in terms of bias, trending measures and so forth determined and documented by the NDA organization?				
Appendix D	Is a CAP for out-of-control "calibration verification" results prepared by the NDA organization?				
Appendix D	Does the CAP include a provision requiring the evaluation of measurement item data potentially affected by the failed "calibration verification" measure?				
Appendix D	Is the "calibration verification" protocol, monitoring, acceptance criteria, action levels, etc., clearly documented and readily available for review?				
Appendix D	Is the calibration verification data control charted and monitored for trends over time?				
Appendix D	Does the NDA organization utilize other methods of "calibration verification" provided they are technically justifiable and documented?				
Appendix D	**1.2 NDA Method Detection Limit**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Is methodology in place to determine NDA measurement system detection limit for those radionuclides specified per the client/end-user requirements?				
Appendix D	Is the methodology re-determined each time there is a significant change in the measurement method or matrix configuration?				
Appendix D	Do instruments performing low-level waste discrimination measurements have a minimum detectable activity (MDA)/lower limit of detection (LLD) sufficient to meet the acceptance criteria?				
Appendix D	Is the methodology for determination of the MDA/LLD documented by the NDA organization?				
Appendix D	Does the LLD level of radioactivity, if present, yield a measured value greater than the critical level (Lc) with a 95% probability, where the Lc is defined as that value which measurements of the background will exceed with 5% probability (the LLD may be defined in a different manner to comply with specific client needs)?				
Appendix D	Because the LLD is a measurement- based parameter, it is not feasible to calculate LLDs for radionuclides that are not determined primarily by measurement, e.g., 99Tc; does NDA organization derive the equivalent of an LLD (i.e., a reporting threshold for a radionuclide(s) when technically justified)?				
Appendix D	Is the value based on decay kinetics, scaling factors, or other scientifically based relationships and must be adequately documented in site records?				
Appendix D	**1.3 Infinite Thickness**				
Appendix D	For a given radioactive material thickness (deposit or buildup), is the thickness reached beyond which there is no increase in counts for an increase in thickness?				
Appendix D	Does the NDA organization have a documented process for identifying infinite thickness when performing measurements?				
Appendix D	**1.4 NDA Measurement Uncertainty**				
Appendix D	Does the NDA organizations have and apply methods and procedures for estimating total measurement uncertainty (TMU) for all reported values?				
Appendix D	Does the NDA organization perform a preliminary identification of uncertainty components and produce measurement uncertainty estimates for the waste population to be characterized prior to generating characterization data for the client/end-user?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Does the estimate of the measurement have uncertainty for the measurement item inventory of interest performed and documented?				
Appendix D	Is the estimate based on knowledge of the measurement method performance and make use of previous experience and validation data from similar measurement apparatus and configurations when available?				
Appendix D	Are the estimated measurement uncertainties evaluated per client and/or end-user needs and requirements?				
Appendix D	Is the method used to calculate TMU for the purpose of demonstrating compliance with client and/or end-user requirements documented and technically justified?				
Appendix D	Does the NDA organization have a method to determine total measurement uncertainty for each NDA system employed including:				
Appendix D	a) Develop a document or plan that delineates the approach to TMU determination, defines measurement uncertainty components, and determines a method for acquiring data/information on components of variance and processing of acquired data and information to arrive at technically defensible TMU for the measurement item population of interest?				
Appendix D	b) Procedure or applicable document that provides specific direction on the acquisition of NDA system measurement data for use in deriving the TMU?				
Appendix D	c) Produce documentation that clearly describes the processing of acquired data, accounting for all significant variables, and the application of methods to determine the TMU?				
Appendix D	d) Clearly define how the TMU is expressed (e.g., 95% confidence level, percent, one sigma, etc.)?				
Appendix D	e) The TMU determination method must be clearly documented? Note: NDA organizations that utilize commercial off-the-shelf data analysis and uncertainty software are still accountable to produce clear documentation of the TMU approach, components of variance, and technique for arriving at the TMU value.				
Appendix D	**1.5 NDA Measurement Traceability**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Are the calibrations of NDA instrumentation and support measurement devices (e.g., weight scale), used for NDA characterization purposes have traceable calibrations established and documented before being put into service?				
Appendix D	Is traceability the ability to relate individual measurement results through an unbroken chain of calibrations to a nationally recognized reference base (e.g., NIST, r NBL, etc.)?				
Appendix D	For NDA measurements, do the traceable materials include radioactive WRMs, certified weights for scale calibrations and thickness measurement methods?				
Appendix D	a) Does the NDA organization have a program and procedures for establishing a traceable calibration as well as QC checking of its NDA instrumentation and support equipment?				
Appendix D	a) Does this program include a system for selecting, procuring, using, and controlling traceable reference standards for NDA measurement instrumentation and support equipment?				
Appendix D	a) For cases where traceable working reference materials are not yet available, does the NDA organization propose alternate methods that are technically defensible and clearly documented?				
Appendix D	b) Do traceable sources used for calibration traceable for all attributes used for the calibration (e.g., a 252Cf source shall be certified in its neutron yield and isotopic composition used to calculated the decay rate, and a mixed nuclide source used to perform an efficiency calibration of a gamma-ray detector shall be certified for the yield of each gamma ray energy used in the calibration and the decay properties of the contributing nuclides)?				
Appendix D	c) Does the NDA organization have a procedure(s) for the specification, procurement and acceptance of WRMs?				
Appendix D	c) Are the WRM certifications acquired and maintained, and traceable to a nationally recognized reference base (e.g., NIST, NBL)?				
Appendix D	d) Does the NDA service provider retain records for all WRMs including the manufacturer/vendor, the manufacturer's Certificate of Traceability, the date of receipt, and a certificate expiration date?				
Appendix D	e) Are traceable standards verified at a minimum of every five years?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	e) Do standards with an expiration date less than five years verified at a period equal to the time expiration time interval?				
Appendix D	e) Is verification of a standard is accomplished through an assessment of its usable attribute to the NDA application?				
Appendix D	e) The any of the following means by which a standard can be deemed verified as acceptable used?				
Appendix D	i. Is the standard sent to a qualified facility maintaining measurement systems traceable to a certified reference material (CRM) for a determination of the standard attribute of interest?				
Appendix D	i. Is the standard simply given an updated attribute value and returned to the NDA organization with a revised or new certificate?				
Appendix D	ii. Are the methods cross-compared the standard with another traceable standard possessing the same attribute in a calibrated and operational measurement system?				
Appendix D	ii. Does an evaluation of the results produce a verification of the standard that is about to or has expired?				
Appendix D	ii. Does the NDA organization determine the acceptable uncertainty in the verified value relative to the NDA characterization process at hand?				
Appendix D	e) Is the verification method used and standard verification acceptability criteria documented?				
Appendix D	e) Are the results of the verification are to be documented and maintained as a QA record?				
Appendix D	f) Do the WRM Certificates of Traceability contain information and data that clearly details traceability to a CRM?				
Appendix D	g) Are checks needed to maintain confidence in the status of WRMs carried out according to defined procedures and schedules?				
Appendix D	h) Does the NDA service provider have procedures for the safe handling, transport, storage and use of WRMs in order to prevent contamination or deterioration and protect their integrity?				
Appendix D	**1.6 NDA Measurement System Software**				
Appendix D	Are software quality assurance (SQA) requirements implemented by NDA organizations that utilize software as part of NDA waste characterization, developed in-house or acquired?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of NDA measurement data, does the NDA organization have documentation or SOPs for software related activities?				
Appendix D	Does this documentation include, but is not limited to, the following as applicable:				
Appendix D	a) For software acquired from a commercial vendor or other third party, evidence of software quality control (QC), is verification and validation (V&V) and other pertinent data acquired and maintained by the NDA organization?				
Appendix D	a) Is software verification the processes of evaluating software to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase (IEEE-STD-610)?				
Appendix D	a) Is software validation the process of evaluating software during or at the end of the development process to determine whether it satisfies specified requirements? (IEEE-STD-610)				
Appendix D	b) For software developed or modified in-house by the NDA organization, is software development planning and QA controls identified in documented plans?				
Appendix D	Are the following activities addressed in such plans/procedures:				
Appendix D	i. Software development and testing?				
Appendix D	ii. Software V&V?				
Appendix D	iii. Software configuration control?				
Appendix D	iv. Software operation and maintenance?				
Appendix D	c) Is computer software developed by the NDA organization documented per applicable software development quality standards?				
Appendix D	c) Do the standards include the following documentation:				
Appendix D	i. Software specification document?				
Appendix D	ii. Software design document?				
Appendix D	iii. Software test plan?				
Appendix D	iv. Software V&V document				
Appendix D	iv. If used are NDA organization developed software and/or modifications to commercial software must be validated?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	iv. Were installation and operability checks performed?				
Appendix D	d) Is software change procedures include requirements for the requesting, testing, quality assurance, approving, and implementation of changes?				
Appendix D	e) Is there data including but not limited to, decay constants, branching ratios, material attenuation values, neutron yields, and master gamma libraries used in the reduction of processing of NDA measurement data to a reportable quantity, whether electronic or hardcopy, placed under a control system so only authorized individuals have access?				
Appendix D	f) Are working data or source files (e.g., nuclear data libraries, master gamma libraries, geometry files, and efficiency files) controlled by the NDA organization to prevent unauthorized access or inadvertent changes and controlled to document changes by authorized users to allow for re-creatability of the data used.				
Appendix D	g) Is commercial software used with the capability of performing user-defined calculations or macros (e.g., spreadsheet), all user-defined components verified before initial use and after changes?				
Appendix D	g) Is documentation of such readily available for review?				
Appendix D	g) Are appropriate protections included to preclude inadvertent changes to user-defined equation or macros?				
Appendix D	g) Do printouts from any spreadsheet include that information used to calculate the result?				
Appendix D	h) Are software version control methods in place to document the software version currently used as well as data reports with the date and time of generation and the software version used to generate the data report?				
Appendix D	h) Is the software included user- defined calculations and/or macros also track revisions to the user-defined customization using version information?				
Appendix D	i) Is there confidentiality of data entry or collection, data storage, data transmission and data processing?				
Appendix D	j) Are computers and automated equipment maintained to ensure proper function and appropriate environmental and operating conditions necessary to maintain the integrity of NDA measurement data and information?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	k) Are procedures to be established and implemented for the maintenance of security of data, including the prevention of unauthorized access to and the unauthorized amendment of, computer records?				
Appendix D	l) Is an inventory of all applicable software used to generate NDA characterization data maintained that identifies the software name, version, classification and exemption status (DOE 0 414.C or latest version), operating environment, and the person and organization responsible for the software?				
Appendix D	m) Does the documentation maintain a historical file of software, software operating procedures, software changes, and software version numbers?				
Appendix D	**1.7 Acceptable Knowledge**				
Appendix D	Do the NDA methods typically directly quantify one or more of the prevalent radionuclides known to be present in the waste and process component items?				
Appendix D	Are the radionuclides and isotopes that quantifiable through the NDA methods used in conjunction with AK derived ratios and scaling factors to quantify the radionuclides not directly quantifiable?				
Appendix D	To use AK to determine such ratios and scaling factors, does the NDA organization technically justify the AK data and its use with NDA measurement information?				
Appendix D	Are the AK ratios or scaling factors to the generation point of the waste, process component, etc.?				
Appendix D	**a) AK Documentation**				
Appendix D	a) Does the use of AK information concerning the radiological composition of a waste type or process component documented either in an AK summary report for that waste type/component or other controlled document?				
Appendix D	a) Should this information be contained in AK package(s) prepared to meet other general waste characterization requirements, it need not be duplicated in other controlled documents that address the radiological properties of the waste stream?				
Appendix D	a) Is all relevant information included in the AK record?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	a) Are all ratios or scaling factors used technically sound and based on known, documented relationships or correlations?				
Appendix D	a) Are uncertainties reported when using ratios and scaling factors used include the uncertainty in the ratio or scaling factor?				
Appendix D	a) The type and quantity of supporting documentation may vary by waste stream but does it compile a written record that includes a summary identifying all sources of information used to delineate the waste stream's isotopic distribution or radionuclide scaling factors?				
Appendix D	a) Is the basis and rationale for the delineation clearly summarized in an AK report and traceable to referenced documents?				
Appendix D	a) Are assumptions made in this rationale identified?				
Appendix D	a) Is following information included as part of the AK written record:				
Appendix D	i) map of the site with the areas and facilities involved in waste generation and process equipment identified?				
Appendix D	ii) facility mission description as related to radionuclide-bearing materials and their management (e.g., routine production, fuel research and development, and experimental processes)?				
Appendix D	iii) description of the specific site locations (such as the area or building) and operations relative to the isotopic composition of the uranium bearing wastes and process components they generated?				
Appendix D	iv) waste identification or categorization schemes used at the facility relevant to the waste material's isotopic distribution (e.g., the use of codes that correlate to a specific isotopic distribution and a description of the isotopic/radionuclide composition of each waste stream)?				
Appendix D	v) information regarding the waste's physical and chemical composition that could affect the isotopic distribution (e.g., processes used to remove ingrown daughters or alter its expected contribution based solely on radioactive decay kinetics)?				
Appendix D	vi) statement of all numerical adjustments applied to derive the material's isotopic distribution (e.g., scaling factors, decay/in-growth corrections and secular equilibrium considerations)?				
Appendix D	a) Is the documentation sufficient to enable independent calculation of the scaling factor or ratio of interest?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	**b) Supplemental AK Information**				
Appendix D	b) Is the supplemental AK information obtained dependent on availability?				
Appendix D	b) Is information collected as appropriate to support contentions regarding the waste's isotopic distribution?				
Appendix D	b) Is this information used to compile the waste's AK written record?				
Appendix D	b) Does supplemental AK documentation that is used include information from the following sources:				
Appendix D	i) safeguards and security, materials control and accountability, and other nuclear materials control systems or programs and the data they generated?				
Appendix D	ii) reports of nuclear safety or criticality, accidents/excursions involving the use of special nuclear material (SNM), or nuclear material?				
Appendix D	iii) waste packaging procedures, waste disposal, building or nuclear material management area logs or inventory records, and site databases that provide information on SNM or nuclear materials?				
Appendix D	iv) test plans, research project reports, or laboratory notebooks that describe the radionuclide content of materials used in experiments?				
Appendix D	v) information from site personnel (e.g., documented interviews)?				
Appendix D	vi) historical analytical data relevant to the isotopic distribution of the waste stream?				
Appendix D	**c) AK Discrepancy Resolution**				
Appendix D	c) If there is any form of discrepancy between AK information related to isotopic ratios or composition, is the NDA organization responsible for having the sources of the discrepancy evaluated to determine information credibility?				
Appendix D	c) Is information not credible or information that is limited in its applicability to the NDA characterization effort will be identified as such, and the reasons for dismissing it will be justified in writing.				
Appendix D	c) Are limitations concerning the information documented in the AK record and summarized in the AK report?				
Appendix D	c) In the event the discrepancy cannot be resolved, did the site perform direct measurements for the impacted population of containers or process items?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	c) If discrepancies "result in a change to the original determinations, is the AK summary updated?				
Appendix D	**1.8 NDA Data Reporting, Review, and Verification**				
Appendix D	**a) NDA Measurement Data Reporting**				
Appendix D	a) Is the NDA organization to document individual NDA measurement item results in a standard report format? For each NDA measurement item (waste container/ process component) is there a separate report?				
Appendix D	a) Do the NDA measurement item reports contain or reference the location of information sufficient to fully describe all input data, NDA measurement configuration information, acquisition parameters, analysis technique, software version, QC data, etc. to allow reconstruction of the reported results?				
Appendix D	Does the NDA reports include the following:				
Appendix D	i. Title and contact information, including:				
Appendix D	a) report title (e.g., "NDA Measurement Item Report")? b) name of NDA organization? c) client contact name for which report is to be delivered and NDA service provider point of contact responsible for ensuring the submittal of the report in the approved manner? d) identification of project name, site, or facility NDA measurement items is associated with?				
Appendix D	ii. Measurement item identification and QC information:				
Appendix D	a). measurement item identification/designator and other identifiers/designations as applicable (e.g., the clients own identifier)? b) date(s) of NDA data acquisition? c) analysis, background, and QC file names? d) measurement item description? e) NDA field worksheet file name, log name, or other identifier? f) gross/net weight, if applicable? g) NDA measurement live time? h) location of NDA measurement system, site name, facility name, building name, and other identifying information?				
Appendix D	iii. Primary radionuclide measurement results:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	a) primary NDA measurement quantitation method (e.g., gamma, neutron)? b) primary radioisotopes and their associated TMUs in appropriate units (e.g., gram, activity, activity concentration, MDA, and % uncertainty)? c) total radionuclide mass, activity, concentration, and associated TMU? d) 235U fissile gram equivalent and associated TMU (gram)? e) other primary quantities such as uranium enrichment weight percent (wt%) and associated wt% TMU?				
Appendix D	iv. NDA acquisition and analysis information:				
Appendix D	a) NDA detector or system identification? b) name of ancillary data and/or information sheets associated with the NDA measurement item. These are often called NDA Field Worksheets and contain information pertinent to the analysis of the acquired data such as container fill height and measurement configuration (e.g., detector to item distance and operator signature/date)? c) identification of real time radiography examination files, if applicable? d) the acquisition software identification and version? e) analysis software identification and version?				
Appendix D	v. Comment/Narrative section:				
Appendix D	a) name or reference to procedures used to acquire the NDA measurement data, analyze the data and acquire supporting data/information used in analysis? b) name or reference to QC procedures utilized in the acquisition and processing of the data? c) identification or reference to WRM and check source(s) used for calibration and/or QC activities? d) identification of or reference to calibration procedures and records and/or location? e) if not specified elsewhere, definition of the quoted uncertainties (i.e., one σ, two σ). When TMU is reported differently on the batch cover sheet of the IMS, the method of expressing TMU shall be specified on the NDA measurement item report sheet or the applicable procedures referenced?				
Appendix D	Does the NDA measurement item report have the analyst signature and date and the independent technical reviewer signature and date?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	**b) NDA Data Review**				
Appendix D	Is all NDA measurement data reviewed and approved by qualified personnel prior to being reported?				
Appendix D	At a minimum, is the data and analysis reviewed by an independent technical reviewer (a second qualified person)?				
Appendix D	Is this reviewer an individual other than the data generator (analyst) who is qualified to have performed the initial work?				
Appendix D	Did the technical reviewer verify, at a minimum, the following information:				
Appendix D	i. NDA measurement system QC results are within established control limits and, if not, the data have been appropriately dispositioned using the nonconformance process?				
Appendix D	i. A complete summary of qualitative and/or quantitative data for all items with data flags or qualifiers?				
Appendix D	ii) “calibration verification” measurements were performed and reviewed as acceptable?				
Appendix D	iii) system data acquisition and reduction were conducted in a technically correct manner in accordance with current methods (verification of procedure and revision)?				
Appendix D	iv) calculations performed outside of software that is in the software QA program have been reviewed by a valid calculation program, a periodic spot check of verified calculation programs (not required with every report) and/or 100 percent check of all hand calculations?				
Appendix D	v) proper constants such as half-lives, branching ratios, attenuation values, neutron yields, gamma libraries were used?				
Appendix D	vi) data were reported in the proper units and correct number of significant figures?				
Appendix D	vii) values that are not verifiable to within rounding or significant difference discrepancies must be rectified prior to completion of independent technical review?				
Appendix D	viii) the data have been reviewed for transcription errors?				
Appendix D	ix) calibrations have been documented?				
Appendix D	x) Standards used are traceable to nationally recognized certificates?				
Appendix D	**c) NDA Data Verification**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	i. Are batch data reports prepared for each measurement batch on standard form (hard copy or electronic equivalent)?				
Appendix D	i. Do batch data reports at a minimum include the following:				
Appendix D	a) NDA organization name, NDA measurement system identification, batch number, NDA measurement item identifications included in the batch, date and signature release by authorized personnel?				
Appendix D	b) Table of contents?				
Appendix D	c) QC data, backgrounds, replicate data, and control charts, etc., for the relevant batch time period?				
Appendix D	d) Does data verification per the NDA service provider QA Plan, and as per applicable procedures?				
Appendix D	ii. Are batch reports reviewed and approved by qualified personnel before being submitted?				
Appendix D	ii. Are only appropriately trained and qualified personnel allowed to perform data verification/review?				
Appendix D	ii. Do verification reviews shall ensure:				
Appendix D	a) The QC documentation for the batch report is complete and includes as applicable a list of containers in the set or batch and applicable set or batch QC results?				
Appendix D	b) Data were collected as described in the planning documents and are complete and correct. Are all batch data reports approved by the project manager or designee?				
Appendix D	b) The project manager verify at a minimum the following information:				
Appendix D	i. Data generation-level verification performed by a second qualified person and appropriate signature release?				
Appendix D	ii. Batch review checklists complete?				
Appendix D	iii. Batch reports are complete and data are properly reported (e.g., data are reported in the correct units and with the correct number of significant figures), and Data comply with program objectives?				
Appendix D	iv. Data comply with program objectives?				
Appendix D	Do results of the review require that qualifiers be placed on the use of the data?				
Appendix D	Are verification methods planned and documented?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Does the documentation include the acceptance criteria used to determine if the data are valid?				
Appendix D	For noncompliant data, are corrective action procedures implemented?				
Appendix D	**1.9 NDA Measurement Performance Evaluation**				
Appendix D	Do elements of the performance evaluation process include:				
Appendix D	a) Do NDA organization demonstrate successful participation in applicable PE program(s)?				
Appendix D	a) Does the NDA organization shall demonstrate continued proficiency throughout its' the term of operation?				
Appendix D	b) Are unacceptable NDA results for PE test sample(s), as determined per PE program criteria, require the NDA organization to implement corrective action procedures and submit a corrective action plan to the PE program or applicable oversight agency?				
Appendix D	b) Are the results of the corrective action plan documented and available for review?				
Appendix D	c) Is documentation of successful capability demonstration such as a Certification Statement or letter of concurrence from the qualifying agency acquired and retained by the NDA organization?				
Appendix D	c) Are all associated supporting data necessary to reproduce the PE measurement results as contained in the Certification Statement or equivalent document retained by the NDA organization?				
Appendix D	d) Once the initial capability demonstration is successfully completed, is continuing demonstration of method performance accomplished through the periodic "calibration verification" measurements as well as all applicable QC requirements?				
Appendix D	**2.0 NDA Quality Control**				
Appendix D	Is the purpose of a measurement control program to test and ensure the stability of the measurement process and to gain additional information on measurement uncertainties where practicable?				
Appendix D	Does the measurement control program provide for the administration, evaluation, and control of measurement processes?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	Is the design of the measurement control program is to ensure the NDA measurement process provides data of sufficient quality (i.e., the measurement system is in control per defined criteria)?				
Appendix D	Does the NDA organization then make and document qualifying statements about the suitability and validity of measurement data as generated for the client and/or end-user?				
Appendix D	Are QC measurements to be performed in conjunction with and related to a batch of NDA measurement items?				
Appendix D	Is the replicate QC measure performed once per batch?				
Appendix D	Do performance checks bracket the NDA measurements which comprise the batch?				
Appendix D	Do out of control performance checks for a given NDA instrument cause the batch data to be considered suspect?				
Appendix D	Are corrective actions in place to evaluate the measurement item results for the affected batch?				
Appendix D	**2.1 QC Procedures**				
Appendix D	Are the NDA organization procedures implementing applicable QCs for monitoring the validity of NDA measurements and the analytical results?				
Appendix D	Does the NDA QA program specify qualitative and quantitative acceptance criteria for the QC checks? D				
Appendix D	Do the NDA QC measures and acquired information/data documented or logged in such a way that trends are detectable?				
Appendix D	Are statistical techniques applied to the evaluation of acquired QC data and action levels specified?				
Appendix D	Are procedures also in place to implement the corrective action process when QC criteria are not satisfied? Is the QC program periodically reviewed?				
Appendix D	Does the NDA service provider address the following:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	a) Is development of a QC plan with clearly defined roles and responsibilities? Do the QC program assure objectivity and independence of action? Is the person assigned responsibility for the QC program knowledgeable of the measurement system being controlled, statistical QC, and the process being monitored? Is the organization providing sufficient separation of functions to avoid any conflict of interest?				
Appendix D	b) Is acquisition and maintenance of suitable WRMs and check sources to monitor measurement system performance during NDA characterization operations? Are records concerning specification and acquisition of standards and sources, including an assessment of their uncertainties and procurement documented and retained?				
Appendix D	c) Do QC checks include a means to evaluate the variability and/or repeatability of NDA measurement results?				
Appendix D	d) Are determination of measurement parameters and acceptance criteria necessary to ensure the accuracy of the NDA method using daily performance checks and analysis of performance check data (e.g., control charts, trending analysis, and replicate measurements)?				
Appendix D	e) Are QC protocols as specified in the NDA organization method manual and/or procedure(s) followed?				
Appendix D	f) Are QC measurement parameter action levels established and documented?				
Appendix D	g) Are written procedures developed and documented to address out-of-control conditions and the subsequent re-qualification of the instrument?				
Appendix D	**2.2 NDA QC Requirements**				
Appendix D	Do QC requirements a minimum include the following:				
Appendix D	a) Background Measurements must be performed and recorded for neutron and gamma systems for each system in use at least once per day and twice for each batch?				
Appendix D	a) The once per day Background Measurement can serve as the beginning or ending background measurement required for the batch?				
Appendix D	a) The two Background Measurements for each batch shall bracket the start and end of the batch- one at the beginning of the batch and one at the end of the batch- unless technical justification to do otherwise is developed and documented.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	a) The count time for neutron and gamma background checks shall be at least as long as the measurement count time unless otherwise specified and documented by an appropriately qualified individual.				
Appendix D	a) The background measurement shall be evaluated before daily NDA measurements commence.				
Appendix D	a) Depending on environmental conditions, the background frequency may need to be increased to ensure data quality.				
Appendix D	a) Increases in the frequency of background measurements shall be determined and documented by an appropriately qualified individual				
Appendix D	Note: Enrichment measurement systems that employ an infinite-thickness analysis technique do not require a background performance check).				
Appendix D	a) The recorded background data is to be monitored using control charts or tolerance charts to ensure the background environment is within statistical control.				
Appendix D	a) Contributions to background because of radiation from nearby radiation producing equipment, standards, or wastes must be controlled to the extent practicable or more frequent background checks must be performed.				
Appendix D	b) Instrument Performance Measurement checks must be acquired for each NDA measurement system in use at least once per day and twice for each data batch.				
Appendix D	b) For each performance check, two measurements shall be used to bracket the batch- one before and one after the batch measurements are completed.				
Appendix D	b) Performance checks include detection efficiency checks; matrix correction checks; and for spectrometric instruments, energy calibration and energy resolution checks.				
Appendix D	b) The NDA organization is to establish acceptable performance check ranges or limits as applicable.				
Appendix D	b) Does an out of control energy calibration check cause measurement item results to be suspect since the last successful energy calibration check?				
Appendix D	b) Energy calibration checks can be performed at a greater frequency than once per day.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	b) Performance checks, as applicable, shall also be acquired on support equipment.				
Appendix D	b) The recorded performance measurement checks are to be monitored using control charts or tolerance charts to ensure the instrument performance is within statistical control.				
Appendix D	c) Replicate Measurements are used to determine the repeatability of a measurement system that represents the intrinsic instrument variability.				
Appendix D	c) Repeatability variance is a short-term variance usually dominated by counting statistics.				
Appendix D	c) The Replicate Measurement is acquired by randomly selecting one measurement item that has been processed through the NDA system for the batch.				
Appendix D	c) This measurement item is then to be re-measured using the same NDA system, software, and acquisition/reduction parameters.				
Appendix D	c) Data analysis is to be performed independently for the two measurements.				
Appendix D	c) The second measurement of the item is to be performed any time before the start of the next data set or batch.				
Appendix D	c) This repeat measurement is then the replicate for that batch.				
Appendix D	c) A minimum of one Replicate Measurement is required for each batch.				
Appendix D	c) For a randomly selected Replicate Measurement item that corresponds to a measurement below the lower limit of quantitation (LLQ), the 95% uncertainty ranges of the pair of measurements must overlap.				
Appendix D	c) When two replicates are utilized to assess repeatability, the data should be evaluated using the Relative Percent Difference (RPD).				
Appendix D	c) An acceptable RPD shall be less than or equal to 25% or other criteria specifically requested by the client.				
Appendix D	c) A control chart of the RPD shall be maintained for trending analysis.				
Appendix D	c) Procedures shall be established for the collection, processing, and periodic evaluation of replicate data.				
Appendix D	c) Alternate methods for determining repeatability and assessing its acceptability may be implemented by the NDA organization provided they are technically justifiable, documented, and available for review.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
Appendix D	c) The replicate data is to be monitored using control charts or tolerance charts to ensure the instrument reproducibility is within statistical control.				
Appendix D	d) Check sources used for QC checks should be traceable, long-lived, and provide adequate counting statistics for a relatively short count time.				
Appendix D	d) If the check source is not traceable, it should be correlated with a traceable source or well-known, characterized, and documented.				
Appendix D	e) All performance data shall be monitored on an as-recorded basis and over time using control charts and trending techniques.				
Appendix D	e) Most monitoring techniques assume that measurement data are distributed normally and that observations are independent.				
Appendix D	e) The assumption of normality should be assessed prior to implementation of a control regimen.				
Appendix D	e) The NDA organization is responsible for determining acceptance criteria for as-recorded and long term data trending.				
Appendix D	e) Recommended control chart limits and actions levels are contained in Table D-3.				
Appendix D	e) Corrective action plans or procedures shall be in place to manage out-of-control results and the associated measurement item data.				
Appendix D	**3.0 QC Action Levels and Response**				
Appendix D	Are quality control measurements performed on a periodic basis as prescribed above and evaluated relative to established acceptance criteria?				
Appendix D	Are quality control measurements also be reviewed and evaluated over time to determine continued acceptability of the assay system and to monitor trends?				
Appendix D	If daily quality control checks yield results that are outside the acceptable range(s), is the required responses in Table -3 followed?				
Appendix D	Are all control limits and associated actions documented and maintained? Refer to Table D-3 Range of Applicability?				
Appendix E	See checklist in Appendix E of QSM DoD/DOE QSM.				
SOP-3	**SOP-3 Accreditation Symbol Procedure**				
SOP-3	**For applicant laboratories:**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
SOP-3	Does the applicant laboratory use the PJLA Logo? Note: Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval.				
SOP-3	**For Accredited Laboratories:**				
SOP-3	Is the laboratory utilizing the correct symbol?				
SOP-3	Does the laboratory reference its accreditation number within close proximity of the accreditation symbol?				
SOP-3	If the laboratory uses the actual accreditation symbol and issues an endorsed or accredited report, are they specifying the following on their report in lieu of the actual symbol:				
SOP-3	• accreditation number?				
SOP-3	• program (i.e. medical testing)?				
SOP-3	• the standard (i.e. ISO/IEC 17025:2005 and DoD ELAP)?				
SOP-3	• a reference to PJLA as the accrediting body?				
SOP-3	Is the symbol reproduced in a size that is clearly distinguishable?				
SOP-3	Is the symbol reproduced in a single-color (black or a single color belonging to the house-style of the accredited lab)?				
SOP-3	Is the symbol identifiable?				
SOP-3	Is the accredited laboratory properly stating their accreditation status? “Accredited to ISO/IEC 17025:2005” or utilizing the ILAC criteria listed in the SOP-3 Procedure. (ILAC guidance not mandatory)?				
SOP-3	Does the laboratory have a documented procedure outlining requirements listed in PJLA SOP-3?				
SOP-3	If the ILAC Mark is utilized, does the lab have approval by PJLA HQ (LF-133 or sublicense agreement should on file)?				
SOP-3	Note: PJLA should be notified immediately when a violation of the ILAC MRA occurs.				
SOP-3	Is the laboratory properly using the symbol on:				
SOP-3	Promotional material and business stationary?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
SOP-3	Test certificate or labels?				
SOP-3	Website?				
SOP-3	Technical literature?				
SOP-3	Business reports?				
SOP-3	Quotations or proposals for work (symbols may only be listed for accredited laboratories)?				
SOP-3	Was the proper accreditation symbols used and in accordance to the laboratory accredited scope?				
SOP-3	Is the accredited laboratory appropriately using the symbol by **not** placing the symbol on:				
SOP-3	Legal documents?				
SOP-3	Test or Calibrations Reports or Certificates for work that is not covered by the scope of accreditation?				
SOP-3	Documents that list sites not accredited?				
SOP-3	Tested or Calibrated Products, except calibration labels (May be misleading that PJLA has accredited the product)?				
SOP-3	If the accredited laboratory included the results of subcontracted tests or calibrations on reports or certificates can they demonstrate that they have done the following:				
SOP-3	a) obtained approval from the subcontracted laboratory?				
SOP-3	b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate?				
SOP-3	c) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate?				
PL-1	**PL-1 PT Requirements**				
PL-1	**For Applicant Laboratories:**				
PL-1	Is there objective evidence for PT activity for each item to be included within proposed scope of accreditation?				
PL-1	Are the results meaningful (i.e. demonstrating the laboratory's competence in performing specified tests or calibrations)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
PL-1	**For Accredited Laboratories:**				
PL-1	Is there a documented PT plan or schedule?				
PL-1	Has the PT plan or schedule been approved by PJLA?				
PL-1	Has the laboratory completed at least one proficiency test each year?				
PL-1	For any unfavorable results gathered during PT, was appropriate corrective action taken?				
PL-2	**PL-2 Measurement Traceability Policy**				
PL-2	Does the laboratory have documented policies and procedures regarding measurement traceability and reference this traceability on test reports?				
PL-2	Does the laboratory have documented procedures detailing the verification, transport and storage of reference standards?				
PL-2	Has the laboratory employed the services of an external calibration provider(s) that are accredited to ISO/IEC 17025:2005 for the calibration(s) performed?				
PL-2	If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI?				
PL-2	Is this documented on an LF-123?				
PL-2	Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed?				
PL-3	**PL-3 Policy on Measurement Uncertainty**				
PL-3	**For Applicant Laboratories:**				
PL-3	Has the laboratory applied its documented procedure for measurement uncertainties consistent with ISO/IEC 17025:2005 (5.4.6.2, 5.4.6.3) and PJLA PL-3?				
PL-3	Note: (Well recognized test methods or calibration procedures that specify limits to the values of major sources of uncertainties will meet this requirement)				
PL-3	**For Accredited Laboratories:**				
PL-3	Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty budget?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
PL-3	Does the laboratory include a metrological statement or reference estimated uncertainties on calibration/test reports?				
PL-3	Does the laboratory's documented procedure for estimating uncertainty include a definition of the method used to determine significance of each potential uncertainty contributor?				
PL-3	Does the laboratory's documented procedure for estimating uncertainty include a definition of the method used to account for uncertainty when making a statement of compliance?				