TNI VERSION 2016 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 4.0	**Requirements for Accreditation**				
M1 4.1	**General Requirements**				
M1 4.1.1	TNI publishes lists of FoPTs on the TNI website for which PT studies are required, called TNI FoPT Tables. These FoPT tables may be updated, as needed, by publishing revised FoPT tables on the TNI website.				
M1 4.1.2	Does the laboratory participate in PT studies for each field of accreditation where corresponding FoPTs exist in the TNI FoPT tables and for which the laboratory seeks to obtain or maintain accreditation?				
M1 4.1.3	Does the laboratory obtain scheduled PT studies or supplemental studies for the individual fields of proficiency testing from a PT Provider accredited to Volume 3 of this Standard by a TNI approved PTPA?				
M1 4.1.4	Does the laboratory analyze unique, single-blind, single-concentration PT samples, when required as stated in the TNI FoPT tables described in Section 4.1.1, to determine compliance for each field of accreditation for which the laboratory seeks to obtain or maintain accreditation?				
M1 4.1.4	Note: PT results are required by Federal Regulations, 40 CFR 141, per test method, rather than technology, for potable water PTs.				
M1 4.1.5	Does the laboratory ensure, prior to the closing date of a study, that laboratory personnel, including corporate personnel, shall not:				
M1 4.1.5	a) send a PT study, or a portion of a PT study, in which it is participating, to another laboratory for the analysis of a field of accreditation for which it seeks accreditation or is accredited;				
M1 4.1.5	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 of that laboratory;				
M1 4.1.5	c) communicate with any individual at another laboratory, including other laboratories under common ownership, concerning the analysis of the PT sample;				
M1 4.1.5	d) attempt to obtain the assigned value of any portion of the PT study from the PT Provider?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 4.1.6	Participation in any of the above activities listed in 4.1.5 is cause for revocation of accreditation.				
M1 4.1.7	When a regulatory program has additional PT requirements for FoPTs not covered by this Standard, does the laboratory follow those requirements?				
M1 4.2	**Sample Handling, Preparation, and Analysis Requirements**				
M1 4.2.1	Does the laboratory handle and prepare the PT study samples in accordance with the instructions provided by the PT Provider?				
M1 4.2.2	Does the laboratory analyze PT samples in accordance with the laboratory's routine standard operating procedures (SOPs) using the same quality control (QC), acceptance criteria and staff as used for the analysis of routine environmental samples?				
M1 4.2.3	Does the laboratory evaluate the analytical result for each chemistry and radiochemistry field of accreditation to the PTRL as established by the TNI FoPT Tables?				
M1 4.2.4	For chemistry analyses, if the laboratory's Limit of Quantitation (LOQ) is below the PTRL, they may evaluate results to their normal LOQ.				
M1 4.2.5	For chemistry PT results where the concentrations are below the calibration range established by the initial calibration curve, does the laboratory use the following acceptable actions:				
M1 4.2.5	a) the laboratory may re-scale its initial calibration curve to bracket the concentration of the PT sample result; or b) the laboratory may report the results, as measured with the initial calibration curve, without qualification to the PT Provider, provided the laboratory adheres to the requirements of Section 4.3.7?				
M1 4.3	**Reporting Requirements**				
M1 4.3.1	Does the laboratory report PT study results to the PT Provider on or before the closing date of the study using the reporting format offered by the PT Provider?				
M1 4.3.2	Does the laboratory, on or before the closing date of the study, direct the PT Provider to report the PT study performance results directly to the AB(s) designated by the laboratory?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 4.3.2	For initial accreditation(s), does the laboratory direct the PT Provider to provide all relevant PT study results to the AB to support their accreditation application?				
M1 4.3.3	Does the laboratory report results in such a way that there is a specific match between the analytical result for the FoPT and the corresponding Field of Accreditation for which the PT sample was analyzed?				
M1 4.3.4	Except for drinking water analytes referenced in 40 CFR 141, a laboratory may choose to analyze and report a single method to represent a technology in a single PT study for a particular analyte. If the laboratory analyzes and reports PT studies by "technology," the score obtained for the reported method will be applied to all methods in that technology for which the laboratory seeks to obtain or maintain accreditation in that matrix.				
M1 4.3.4	Note: If a laboratory reports PT results for multiple methods using the same analytical technology, an evaluation of "not acceptable" for one method will be applied to all methods reported with that technology.				
M1 4.3.5	Does the laboratory report chemistry PT study results to the PTRL as established by the TNI FoPT tables, or if the laboratory LOQ is below the PTRL, the laboratory may report results down to their normal LOQ, and as specified in Section 4.2.4?				
M1 4.3.6	Does the laboratory report radiochemistry results as measured, including zero, negative, and positive results, and shall not be censored or reported as "less than" values?				
M1 4.3.6	Does the laboratory report all radiochemistry PT study results in association with the measurement uncertainty, as appropriate to the program?				
M1 4.3.7	Does the laboratory evaluate and report each chemistry FoPT result to the PT Provider as follows:				
M1 4.3.7	a) If the analytical result is a numeric value above or equal to the PTRL, the laboratory shall report the value. If the PTRL is less than the laboratory's LOQ, the laboratory shall report the result without the qualification of result required in Volume 1, Module 4 of this Standard?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 4.3.7	b) If the analytical result is a numeric value below the PTRL, the laboratory shall report one of the following: i. <PTRL or, ii. the obtained analytical result, if the result is between the LOQ and the PTRL, or, iii. <LOQ, if the analytical result is below the LOQ and the PTRL?				
M1 4.3.7	c) If the analytical result is a "non-detect", the laboratory shall report one of the following: i. <PTRL, or ii. <LOQ?				
M1 4.3.7	Note: In the case where the laboratory LOQ is greater than the PTRL: If the laboratory chooses to report a value of <LOQ and the analyte is present above the PTRL, the result will be scored as "Not Acceptable" by the PT Provider.				
M1 4.3.8	Does the laboratory no adjust the PTRL value for sample amount used or percent moisture?				
M1 4.4	**Record Retention**				
M1 4.4.1	Does the laboratory retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for PT samples for a minimum of five (5) years?				
M1 4.4.1	Does the laboratory make these records available for review upon request by the Primary AB?				
M1 5.0	**PT Study Frequency Requirements for Accreditation**				
M1 5.1	**Initial Accreditation**				
M1 5.1.1	Chemical Testing, Radiochemical Testing, Asbestos, and Microbiology				
M1 5.1.1	a) Has the laboratory achieved a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts for each field of accreditation specified in Section 4.1.1 for which the laboratory seeks accreditation?				
M1 5.1.1	Note: If the laboratory has two (2) consecutive acceptable PT scores, a third study is not needed.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 5.1.1	b) Were the two (2) PT studies identified in Section 5.1.1 a) performed no more than eighteen (18) months prior to obtaining initial accreditation from an AB?				
M1 5.1.1	c) Is the opening date of the second study at least seven (7) calendar days after the closing date of the first study?				
M1 5.1.1	d) Is closing date of the most recent successful PT study for an FoPT no more than six (6) months prior to the application for initial accreditation?				
M1 5.1.1	d) Does the laboratory continue to participate in PT studies at least semi-annually (no more than seven (7) months apart between consecutive attempts) from that point on?				
M1 5.1.2	For Whole Effluent Toxicity (WET) testing, does the laboratory demonstrate to the Primary AB that it has received an acceptable evaluation for at least one (1) PT study to obtain initial accreditation?				
M1 5.1.2	Is the study closing date of the most recent successful PT study no more than twelve (12) months prior to obtaining initial accreditation from an AB?				
M1 5.1.2	Will the laboratory continue to participate in PT studies annually from that point on?				
M1 5.1.2	Note: "Acceptable" PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to provide the PT Provider with a release of results to the AB before the close of the study, failure to report results to the PT Provider before the closing date, failure to handle PT study samples in the same manner as routine environmental samples, etc., may be cause for an unsuccessful evaluation by an AB.				
M1 5.2	**Continued Accreditation**				
M1 5.2.1	Chemical Testing, Radiochemical Testing, Asbestos, and Microbiology				
M1 5.2.1.1	Does the laboratory maintain a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts for each field of accreditation specified in Section 4.1.1 for which the laboratory holds accreditation?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 5.2.1.1	Failure to do so may result in suspension of the affected field of accreditation. The laboratory's accreditation for a field of accreditation may be revoked for failure of three (3) consecutive PT studies, either by failure to participate in the required PT study or due to failure to obtain acceptable results.				
M1 5.2.1.2	Does the laboratory analyze and report a PT study at least twice per year for each accreditation FoPT for which it seeks to maintain accreditation, in accordance with the following criteria:				
M1 5.2.1.2	a) The closing dates of subsequent PT study samples for a particular accreditation FoPT no more than seven (7) months apart?				
M1 5.2.1.2	b) The opening date of PT study samples for a particular field of accreditation at least seven (7) calendar days after the closing date of a PT study for the same field of accreditation?				
M1 5.2.1.2	c) A laboratory that analyzes and reports PT study results with an opening date of subsequent PT studies for the same field of accreditation that are closer than seven (7) days from the closing date of the previous PT study are invalid for the purposes of compliance with this Standard and are not counted toward the laboratory's PT history of the most recent three (3) attempts.				
M1 5.2.2	For WET testing: To maintain accreditation, does the laboratory participate in one (1) WET PT study per calendar year for each accreditation FoPT that correspond to the fields of accreditation for which the laboratory is accredited?				
M1 5.2.2	a) This requirement can be met by annual participation in the Environmental Protection Agency (EPA) Discharge Monitoring Report-Quality Assurance (DMRQA) studies for WET, or				
M1 5.2.2	b) If the laboratory is not participating in an EPA DMRQA study for WET, are the closing dates of subsequent PT study samples for WET testing PT studies no more than fourteen (14) months apart?				
M1 5.2.3	A laboratory that fails to analyze and report PT studies for a particular field of accreditation with the frequency specified in Sections 5.2.1 or 5.2.2 for which it seeks to maintain accreditation is charged with a failed PT study.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 5.2.3	Note1: A laboratory may withdraw from a PT study, but withdrawal from a PT study does not exempt the laboratory from analyzing and reporting a PT study as specified in Sections 5.2.1 and 5.2.2.				
M1 5.2.3	Note2: "Acceptable" PT study scores from a PT Provider do not automatically result in a successful evaluation of a PT study by an AB. For example, failure to report an analytical method or reporting of an incorrect method, failure to provide the PT Provider with a release of results to the AB before the close of the study, failure to report results to the PT Provider before the closing date, failure to handle PT study samples in the same manner as routine environmental samples, etc., may be cause for an unsuccessful evaluation by an AB.				
M1 6.0	**Requirements for Corrective Action**				
M1 6.1	When the laboratory fails to successfully analyze a PT study for a particular FOA does the laboratory determine the root cause of the failure and take corrective action?				
M1 6.2	Does the laboratory document the root cause investigation and subsequent corrective action?				
M1 6.2	Note: The requirements for corrective action are described in Volume 1, Module 2 of this Standard.				
M1 6.3	Does the laboratory provide the root cause investigation and corrective action documentation to the Primary AB within thirty (30) calendar days of a request from the AB?				
M1 6.4	Failure to submit documentation of the root cause investigation or corrective action records, or both, to the AB within thirty (30) calendar days of the request from the Primary AB is due cause for suspension of accreditation for a particular FOA.				
M1 6.5	6.5 Does documentation for WET corrective actions include:				
M1 6.5	a) a copy of the raw data used for the study;				
M1 6.5	b) a copy of the current Standard Reference Toxicant (SRT) control chart relevant to the PT study?				
M1 7.0	**Requirements for Complaint Resolution**				
M1 7.1	The laboratory shall submit questions about PT samples or performance evaluations made by the PT Provider to the PT Provider.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M1 7.1	If the PT Provider is not able or is unwilling to resolve the question to the satisfaction of the laboratory, the laboratory shall refer those questions to the PT Provider's PTPA.				
M1 7.2	The laboratory shall submit questions to its AB in regards to the AB's PT evaluation, if necessary.				
M1 8.0	**Requirements for Reinstatement of Accreditation after Suspension or Revocation**				
M1 8.1	When seeking to have its accreditation reinstated for an FoPT after suspension, does the laboratory meet the requirements for continued accreditation as described in Section 5.2 of this module?				
M1 8.2	When seeking to have its accreditation reinstated for an FoPT after revocation, does the laboratory meet the requirements for initial accreditation as described in Section 5.1 of this module?				
M1 8.3	When seeking to have its accreditation reinstated for an FoPT after suspension due to not supplying a requested corrective action report, does the laboratory meet the requirements for continued accreditation as described in Section 5.2 of this module?				
M2	**Volume 1 Module 2**				
M2	**Quality Systems General Requirements**				
M2 1.0	**Introduction, Scope, and Applicability**				
M2 1.1	**Introduction**				
M2 1.1	Does the laboratory have a quality system?				
M2 1.1	Does the laboratory's quality system provide the framework for planning, implementing, assessing, and improving work performed by an organization so as to provide the client with data of known and documented quality, sufficient to evaluate the usability of the data to the clients needs?				
M2 1.1	Is the quality system documented in the laboratory's quality manual and related quality documentation, and referenced in the quality manual?				
M2 1.1	Does the laboratory seeking accreditation under this Standard ensure that the laboratory is implementing their quality system and that all Quality Control (QC) procedures specified in this module are being followed?				
M2 1.1	Are all items identified in this document available for an on-site assessment?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.0	**Management Requirements**				
M2 4.1	**Organization**				
M2 4.1.1	Is the laboratory or the organization of which it is part an entity that can be held legally responsible?				
M2 4.1.2	Does of the laboratory carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition?				
M2 4.1.3	Does the management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities?				
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 of the laboratory 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	Does the laboratory:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.5	a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also Section 5.2);				
M2 4.1.5	b) 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) 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) 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) 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) 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) provide adequate supervision of testing and 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) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.5	i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;				
M2 4.1.5	j) appoint deputies for key managerial personnel (see Note);				
M2 4.1.5	Note: Individuals may have more than one function and it may be impractical to appoint deputies for every function.				
M2 4.1.5	k) ensure that its 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 within the laboratory and that communication takes place regarding the effectiveness of the management system?				
M2 4.1.7	Additional Requirements for Laboratories				
M2 4.1.7.1	Where staffing is limited, the technical manager and the quality manager may be the same person.				
M2 4.1.7.1	Does the laboratory's quality manager and/or his/her designee(s):				
M2 4.1.7.1	a) serve as the focal point for QA/QC and be responsible for the oversight and/or review of QC data;				
M2 4.1.7.1	b) have functions independent from laboratory operations for which they have QA oversight;				
M2 4.1.7.1	c) be able 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; and				
M2 4.1.7.1	h) monitor corrective actions?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.1.7.2	Does the laboratory's technical manager(s), however named, and/or his/her designee(s):				
M2 4.1.7.2	a) be 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) be 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 QC and QA, and				
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 be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include:				
M2 4.1.7.2	i. the extent to which operating hours of the laboratories to be directed overlap,				
M2 4.1.7.2	ii. adequacy of supervision in each laboratory, and				
M2 4.1.7.2	iii. the availability of environmental laboratory services in the area served.				
M2 4.1.7.2	e) if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and				
M2 4.1.7.2	f) meet qualification requirements as specified in Section 5.2.6.1?				
M2 4.2	**Management (ISO/IEC 17025:2005, Clause 4.2)**				
M2 4.2.1	Does the laboratory establish, implement and maintain a management system appropriate to the scope of its activities?				
M2 4.2.1	Does the laboratory document its policies, systems, programmes, 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 system's documentation communicated to, understood by, available to, and implemented by the appropriate personnel?				
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	Are the overall objectives established, and reviewed during management review?				
M2 4.2.2	Is the quality policy statement issued under the authority of top management?				
M2 4.2.2	Does the quality policy 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 testing and calibration 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; and				
M2 4.2.2	e) the laboratory management's commitment to comply with this International Standard and to 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 provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?				
M2 4.2.4	Does top management communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements?				
M2 4.2.5	Does the quality manual include or make reference to the supporting procedures including technical procedures?				
M2 4.2.5	Does the quality manual outline the structure of the documentation used in the management system?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.6	Are the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, defined in the quality manual?				
M2 4.2.7	Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?				
M2 4.2.8	Additional Management System Requirements				
M2 4.2.8.1	Does the laboratory establish and maintain a documented data integrity system?				
M2 4.2.8.1	Does the data integrity system include the following four (4) required elements? 1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) periodic in-depth data monitoring, and 4) data integrity procedure documentation.				
M2 4.2.8.1	Are data integrity procedures signed and dated by top management?				
M2 4.2.8.1	The requirements for data integrity investigation are listed in Section 4.16.				
M2 4.2.8.1	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 laboratory management provide a procedure for confidential reporting of data integrity issues in their laboratory? A primary element of the procedure is to 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) In instances of ethical concern, does the procedure include a process whereby laboratory management is to be informed of the need for any further detailed investigation?				
M2 4.2.8.2	Is the quality manager responsible for maintaining the currency of the quality manual?				
M2 4.2.8.3	Does the quality manual contain:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 that 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;				
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, which shall include quality system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and				
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, proficiency testing programs, use of reference materials and internal QC 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;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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;				
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	q) procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training; and				
M2 4.2.8.4	r) policy addressing the use of unique electronic signatures, where applicable?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.2.8.5	a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents..				
M2 4.2.8.5	a) Do these documents have adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result?				
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) Documents that contain sufficient information to perform the tests, do not need to be supplemented or rewritten as internal procedures if the documents are 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 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?				

Section Reference	Question	Compliant? Yes	No	NA	Comments
M2 4.2.8.5	f) Does each method include or reference the following topics where applicable: i. identification of the method; ii. applicable matrix or matrices; iii. limits of detection and quantitation; iv. scope and application, including analytes to be analyzed; v. summary of the method; vi. definitions; vii. interferences; viii. safety; ix. equipment and supplies; x. reagents and standards; xi. sample collection, preservation, shipment and storage; xii. quality control; xiii. calibration and standardization; xiv. procedure; xv. data analysis and calculations; xvi. method performance; xvii. pollution prevention; xviii. data assessment and acceptance criteria for QC measures; xix. corrective actions for out-of-control data; xx. contingencies for handling out-of-control or unacceptable data; xxi. waste management; xxii. references; and xxiii. any tables, diagrams, flowcharts and validation data?				
M2 4.3	**Document Control (ISO/IEC 17025:2005, Clause 4.3)**				
M2 4.3.1	General				
M2 4.3.1	Does the laboratory establish and maintain 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	Are all documents issued to personnel in the laboratory as part of the management system reviewed and approved for use by authorized personnel prior to issue?				
M2 4.3.2.1	Is a master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system established and readily available to preclude the use of invalid and/or obsolete documents?				
M2 4.3.2.2	Do the 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 preservation purposes are suitably marked?				
M2 4.3.2.3	Are management system documents generated by the laboratory uniquely identified?				
M2 4.3.2.3	Does such identification include the date of issue and/or revision identification, page numbering, and the total number of pages or a mark to signify the end of the document, and 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.3.3.1	Does the designated personnel have access to pertinent background information upon which to base their review and approval?				
M2 4.3.3.2	Where practicable, is the 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 the procedures and authorities for such amendments defined?				
M2 4.3.3.3	Are amendments 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 (ISO/IEC 17025:2005, Clause 4.4)**				
M2 4.4.1	Does the laboratory establish and maintain procedures for the review of requests, tenders and contracts?				
M2 4.4.1	Does 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 customers' 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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 proficiency testing and/or the running of trial test or calibration programmes 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, including any significant changes, maintained?				
M2 4.4.2	Are records also be 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?				
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 customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.				
M2 4.4.3	Does the review also cover any work that is subcontracted by the laboratory?				
M2 4.4.4	Is the customer informed of any deviation from the contract?				
M2 4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated and any amendments communicated to all affected personnel?				
M2 4.5	**Subcontracting of Environmental Tests (ISO/IEC 17025:2005, Clause 4.5)**				
M2 4.5.1	When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), is this work placed with a competent subcontractor?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.5.1	A competent subcontractor is one that, for example, complies with this International 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	Is the laboratory responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used?				
M2 4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question?				
M2 4.5.5	When a laboratory subcontracts work, is this 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	Does the laboratory performing the subcontracted work indicated in the final report?				
M2 4.5.5	Does the laboratory make a copy of the subcontractor’s report available to the client when requested?				
M2 4.6	**Purchasing Services and Supplies (ISO/IEC 17025:2005, 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 4.6.2	Does the laboratory ensure that purchased supplies and reagents and consumable materials that affect the quality of 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	Do these services and supplies used comply with specified requirements?				
M2 4.6.2	Are records of actions taken to check compliance shall be maintained?				
M2 4.6.3	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.6.3	Are these purchasing documents reviewed and approved for technical content prior to release?				
M2 4.6.3	Note: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.				
M2 4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and maintain records of these evaluations and list those approved?				
M2 4.7	**Service to the Client (ISO/IEC 17025:2005, Clause 4.7)**				
M2 4.7.1	Is the laboratory willing to cooperate with customers or their representatives in clarifying 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?				
M2 4.7.1	Note1: Such cooperation may include:				
M2 4.7.1	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 (ISO/IEC 17025:2005, Clause 4.8)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.8	Does the laboratory have a policy and procedure for the resolution of complaints received from customers or other parties?				
M2 4.8	Are records maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11)?				
M2 4.9	**Control of Nonconforming Environmental Testing Work (ISO/IEC 17025:2005, Clause 4.9)**				
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 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) correction is 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?				
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 4.11 promptly followed?				
M2 4.10	**Improvement (ISO/IEC 17025:2005, Clause 4.10)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.10	Does the laboratory continually improve 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 (ISO/IEC 17025:2005, Clause 4.11)**				
M2 4.11.1	General				
M2 4.11.1	Has the laboratory established a policy and a procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified?				
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 to prevent recurrence?				
M2 4.11.3	Are corrective actions 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				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?				
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 have documented procedure(s) to address Sections 4.11.1 and 4.11.3 through 4.11.5?				
M2 4.11.6	Does the laboratory have documented procedure(s) to address Sections 4.11.1 and 4.11.3 through 4.11.5?				
M2 4.11.6	Do these procedure(s) also include:				
M2 4.11.6	a) which individual(s) or positions are responsible for assessing each QC data type; and				
M2 4.11.6	b) which individual(s) or positions are responsible for initiating and/or recommending corrective actions?				
M2 4.11.7	Cause analysis described in Section 4.11.2 applies to failures that indicate a systematic error.				
M2 4.12	**Preventive Action (ISO/IEC 17025:2005, Clause 4.12)**				
M2 4.12.1	Are needed improvements and potential sources of nonconformities, either technical or concerning the management system, identified?				
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 4.12.2	Do procedures for preventive actions include the initiation of such actions and the application of controls to ensure that they are effective?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 (ISO/IEC 17025:2005, Clause 4.13)**				
M2 4.13.1	General				
M2 4.13.1.1	Has the laboratory established and maintained procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records?				
M2 4.13.1.1	Do quality record 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 legible and stored and 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 retention times of records established?				
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 4.13.2.1	Does the laboratory retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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.				
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 and identifiable to the specific task?				
M2 4.13.2.3	When mistakes occur in records, is each mistake shall be 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 records stored electronically, 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 this 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 stored only on electronic media supported by the hardware and software necessary for their retrieval?				
M2 4.13.3	e) Is access to archived information documented with an access log?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.3	f) Is all information necessary for the historical reconstruction of data maintained by the laboratory?				
M2 4.13.3	i. all raw data, whether hard copy or electronic, for calibrations, samples and QC 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 is required 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 or operator 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. QC 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 QC requirements;				
M2 4.13.3	xvii. proficiency test results;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.13.3	xviii. records of demonstration of capability for each analyst; and				
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) Is all generated data, except those that are generated by automated data collection systems, recorded legibly in permanent ink?				
M2 4.13.3	i. Does an individual making corrections to records date and initial 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	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) In addition, are appropriate regulatory and state legal requirements concerning laboratory records followed?				
M2 4.14	**Internal Audits (ISO/IEC 17025:2005, Clause 4.14)**				
M2 4.14.1	Does the laboratory periodically, and 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 International Standard?				
M2 4.14.1	Does the internal audit programme address all elements of the management system, including the testing and/or calibration activities?				
M2 4.14.1	It the quality manager responsible to plan and organize audits as required by the schedule and requested by management? Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.				
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 4.14.1	Note: The cycle for internal auditing should normally be completed in one year.				
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, and notify customers in writing if investigations show that the laboratory results may have been affected?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 4.14.3	Are the area of activity audited, the audit findings and corrective actions that arise from them recorded?				
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	Additional Items				
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?				
M2 4.15	**Management Reviews (ISO/IEC 17025:2005, Clause 4.15)**				
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	Does the review take account of:				
M2 4.15.1	- 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 interlaboratory comparisons or proficiency tests; - changes in the volume and type of the work; - customer feedback; - complaints; - recommendations for improvement; - other relevant factors, such as quality control activities, resources, and staff training?				
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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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?				
M2 4.15.2	Does the 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 5.0	**Technical Requirements**				
M2 5.1	**General (ISO/IEC 17025:2005, Clause 5.1)**				
M2 5.1.1	Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:				
M2 5.1.1	- 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	The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations.				
M2 5.1.2	Does the laboratory take account of these factors 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 (ISO/IEC 17025:2005, Clause 5.2)**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.1	Does laboratory management ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates?				
M2 5.2.1	When using staff who are undergoing training, is appropriate supervision provided?				
M2 5.2.1	Are 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.				
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:				
M2 5.2.1	- 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 of the laboratory formulate the 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	Is the training programme 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 management 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?				
M2 5.2.4	Note: Job descriptions can be defined in many ways. As a minimum, the following should be defined:				
M2 5.2.4	— 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 programmes; — managerial duties.				
M2 5.2.5	Does the 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 is confirmed?				
M2 5.2.5	All references to Calibration Certificates in ISO/IEC 17025:2005 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 technical manager meet the applicable requirements given 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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.6.1	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.				
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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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				
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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 orientation and also provided on an annual basis for all current employees?				
M2 5.2.7	Are employees required to understand that any infractions of the laboratory data integrity procedures 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 the data integrity training emphasize 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; and				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.2.7	Do the data integrity procedures 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 5.3	**Accommodation and Environmental Conditions (ISO/IEC 17025:2005, Clause 5.3)**				
M2 5.3.1	Do the laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, facilitate correct performance of the tests and/or calibrations?				
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 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 tests and calibrations 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 the 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 shall be taken to prevent cross-contamination?				
M2 5.3.4	Does the laboratory determine the extent of control based on its particular circumstances?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.3.5	Are measures taken to ensure good housekeeping in the laboratory? Special procedures shall be prepared where necessary.				
M2 5.4	**Environmental Methods and Method Validation**				
M2 5.4	All references to Calibration Laboratories and Calibration Methods in ISO/IEC 17025:2005 in these Clauses are not applicable to environmental testing.				
M2 5.4.1	General (ISO/IEC 17025:2005, Clause 5.4.1)				
M2 5.4.1	Does the laboratory use appropriate methods and procedures for all tests and/or calibrations within its scope?				
M2 5.4.1	Does these include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as 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 shall be made readily available to personnel (see 4.3)?				
M2 5.4.1	Does a deviation 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 (ISO/IEC 17025:2005, Clause 5.4.2)				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used?				
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?				
M2 5.4.2	Are Laboratory-developed methods or methods adopted by the laboratory 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?				
M2 5.4.2	If the standard method changes, is the confirmation 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 (ISO/IEC 17025:2005, Clause 5.4.3)				
M2 5.4.3	Is the introduction of test and calibration methods developed by the laboratory for its own use a planned activity and 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 shall be ensured?				
M2 5.4.4	Non-Standard Methods (ISO/IEC 17025:2005, Clause 5.4.4)				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.4	When it is necessary to use methods not covered by standard methods, are these 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:				
M2 5.4.4	a) appropriate identification; b) scope;080116 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 5.4.4.1	Is the note in 5.4.4 above, which includes a – k, considered during the development of the method?				
M2 5.4.4.2	Does the laboratory ensure that once the method has been developed, a Standard Operating Procedure as outlined in 4.2.8.5 f shall be written?				
M2 5.4.5	Validation of Methods (ISO/IEC 17025:2005, Clause 5.4.5)				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.5.1	Validation is the 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	Does the laboratory 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?				
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 record the results obtained, the procedure used for the validation, and 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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.				
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 5.4.5.4	Are all methods used by the laboratory, whether non-standard or standard (reference) methods validated before use to ensure that the laboratory has the capability of using the method for its intended use?				
M2 5.4.5.4	See Section 1.5. of each of the technical modules (Volume 1, Modules 3 through 7) for specific validation requirements.				
M2 5.4.5.4	Do non-standard methods comply with 5.4.5.1 – 5.4.5.3 above, in addition to specific requirements in Section 1.5 of the technical modules?				
M2 5.4.6	Estimation of Analytical Uncertainty				
M2 5.4.6	Clause 5.4.6 of the ISO/IEC/IEC 17025:2005 concerning calibration testing does not apply. The following requirement replaces the ISO/IEC Clause.				
M2 5.4.6	Does the environmental testing laboratory have a procedure(s) for estimating analytical uncertainty?				
M2 5.4.6	Quality control measurement data may be used to determine analytical uncertainty.				
M2 5.4.6.1	Does the calibration laboratory, or a testing laboratory performing its own calibrations, have and apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations?				
M2 5.4.6.2	Does the testing laboratory have and apply procedures for estimating uncertainty of measurement?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.6.2	In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement.				
M2 5.4.6.2	In these cases does the laboratory at least attempt to identify all the components of uncertainty and make a reasonable estimation, and ensure that the form of reporting of the result does not give a wrong impression of the uncertainty?				
M2 5.4.6.2	Is reasonable estimation based on knowledge of the performance of the method and on the measurement scope and make use of, for example, previous experience and validation data?				
M2 5.4.6.2	Note1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: - the requirements of the test method; - the requirements of the customer; - the existence of narrow limits on which decisions on conformity to a specification are based.				
M2 5.4.6.2	Note2: In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).				
M2 5.4.6.3	When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis?				
M2 5.4.6.3	Note1: Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.				
M2 5.4.6.3	Note2: The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.				
M2 5.4.6.3	Note3: For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see Bibliography).				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.4.7	Control of Data (ISO/IEC 17025:2005, Clause 5.4.7)				
M2 5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner?				
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 and 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 programmes) 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 5.5	**Calibration Requirements (ISO/IEC 17025:2005, Clause 5.5)**				
M2 5.5	ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories.				
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 International Standard are met?				
M2 5.5.2	Is equipment and its software used for testing, calibration and sampling capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.2	Are calibration programmes stablished 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 it 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 and significant to the result shall, when practicable, uniquely identified?				
M2 5.5.5	Are records maintained of each item of equipment and its software significant to the tests and/or calibrations performed?				
M2 5.5.5	Do the records include at least the following:				
M2 5.5.5	a) the identity of the item of equipment and its software; b) the manufacturer's name, type identification, and serial number or other unique identification; c) checks that equipment complies with the specification (see 5.5.2); d) the current location, where appropriate; e) the manufacturer's instructions, if available, or reference to their location; f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; g) the maintenance plan, where appropriate, and maintenance carried out to date; h) any damage, malfunction, modification or repair to the equipment?				
M2 5.5.6	Does the laboratory have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration?				
M2 5.5.6	Note: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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?				
M2 5.5.7	Is it 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	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labelled, 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	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 5.5.13	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				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.13.1	This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices, and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).				
M2 5.5.13.1	a) Are the results of any calibration or verification within the specifications required of the application for which this equipment is used?				
M2 5.5.13.1	a) Does the laboratory define the specifications for acceptability if none exist in method or regulation?				
M2 5.5.13.1	a) If any equipment fails to meet the specifications for acceptability:				
M2 5.5.13.1	i. is the equipment removed from service until repaired; or				
M2 5.5.13.1	ii. does the laboratory maintain records of established correction factors to correct all measurements?				
M2 5.5.13.1	b) Does the laboratory maintain all support equipment in proper working order?				
M2 5.5.13.1	b) Are the records of all repair and maintenance activities, including service calls, kept?				
M2 5.5.13.1	c) On each day the equipment is used, are balances, ovens, refrigerators, freezers, incubators, and water baths checked and documented?				
M2 5.5.13.1	c) Is the acceptability for use or continued use according to the needs of the analysis or application for which the equipment is being used?				
M2 5.5.13.1	d) Are temperature measuring devices calibrated or verified at least annually?				
M2 5.5.13.1	d) Is calibration or verification performed using a recognized National Metrology Institute traceable reference, such as NIST, when available?				
M2 5.5.13.1	i. If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable.				
M2 5.5.13.1	ii. If the temperature measuring device is used over a range of greater than 10°C, then does the verification bracket the range of use?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.5.13.1	e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, does the laboratory verify volumetric measuring devices as follows:				
M2 5.5.13.1	i. glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;				
M2 5.5.13.1	ii. disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;				
M2 5.5.13.1	iii. mechanical devices shall be verified prior to first use and on a quarterly basis; mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device;				
M2 5.5.13.1	iv. all other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use?				
M2 5.5.13.1	f) Is all other support equipment calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable reference when available, bracketing the range of use?				
M2 5.5.13.1	g) Are raw data records retained to document equipment performance?				
M2 5.6	**Measurement Traceability**				
M2 5.6.1	General (ISO/IEC 17025:2005, Clause 5.6.1)				
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?				
M2 5.6.1	Does the laboratory have an established programme and procedure for the calibration of its equipment?				
M2 5.6.1	Note: Such a programme 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 (ISO/IEC 17025:2005, Clause 5.6.2)				
M2 5.6.2.1	Calibration				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.2.1.1	For calibration laboratories, is the programme for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités)?				
M2 5.6.2.1.1	A calibration laboratory establishes 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 units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.				
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?				
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 also 5.10.4.2)?				
M2 5.6.2.1.1	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	Note2: Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.2.1.1	Note3: Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.				
M2 5.6.2.1.1	Note4: The term “identified metrological specification” means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.				
M2 5.6.2.1.1	Note5: When the terms “international standard” or “national standard” are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.				
M2 5.6.2.1.1	Note6: Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.				
M2 5.6.2.1.1	Note7: If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.				
M2 5.6.2.1.1	Note8: The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.				
M2 5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units.				
M2 5.6.2.1.2	In these cases does calibration provide confidence in measurements by establishing traceability to appropriate measurement standards such as: - the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; - 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	Is participation in a suitable programme of interlaboratory comparisons required where possible?				
M2 5.6.2.2	Testing				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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.				
M2 5.6.2.2.1	When this situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?				
M2 5.6.2.2.1	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 5.6.2.2.2	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 (ISO/IEC 17025:2005, Clause 5.6.3)				
M2 5.6.3.1	Reference Standards				
M2 5.6.3.1	Does the laboratory have a programme 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				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.3.3	Are checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials carried out 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				
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, proficiency testing, or independent analysis?				
M2 5.6.4.1	a) Reference Standards				
M2 5.6.4.1	Where commercially available, is this traceability to a national standard of measurement?				
M2 5.6.4.1	a) Reference Standards				
M2 5.6.4.1	Where possible, is traceability to national or international standards of measurement or to national or international standard reference materials?				
M2 5.6.4.1	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	Do documented procedures exist 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	b) For original containers, if an expiration date is provided by the manufacturer or vendor, is it recorded on the container?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.6.4.2	b) If an expiration date is not provided by the manufacturer or vendor, is it 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?				
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	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 not be used after their expiration dates unless their reliability is verified by the laboratory?				
M2 5.7	**Collection of Samples (ISO/IEC 17025:2005, Clause 5.7)**				
M2 5.7.1	Does the laboratory have a sampling plan and procedures 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?				
M2 5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the 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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, are these recorded in detail with the appropriate sampling data and included in all documents containing test and/or calibration results, and 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?				
M2 5.7.3	Does these records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon?				
M2 5.7.3	Additional Requirements				
M2 5.7.3	a) Does documentation include the date and time of sampling?				
M2 5.7.3	b) Are any deviations from sampling procedures documented?				
M2 5.8	**Handling Samples and Test Items (ISO/IEC 17025:2005, Clause 5.8)**				
M2 5.8.1	Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer?				
M2 5.8.2	Does the laboratory have a system for identifying test and/or calibration items?				
M2 5.8.2	Is the 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?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 and record the discussion?				
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?				
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 5.8.5	Additional Requirements – Documentation				
M2 5.8.5	The following are essential 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 sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time?				
M2 5.8.5	a) Does this system include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.5	b) Does this 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 the link that associates 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	Additional Requirements – Sample Acceptance Policy				
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 shall include 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;				
M2 5.8.6	f) procedures to be used when samples show signs of damage, contamination or inadequate preservation; and				
M2 5.8.6	g) qualification of any data that do not meet the above requirements?				
M2 5.8.7	Additional Requirements – Sample Receipt Protocols				
M2 5.8.7.1	Does the laboratory implement procedures for verifying and documenting preservation?				
M2 5.8.7.2	If the sample does not meet the sample receipt acceptance criteria listed in this Standard, does the laboratory either:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.7.2	a) retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or				
M2 5.8.7.2	b) fully document any decision to proceed with the analysis of samples not meeting acceptance criteria?				
M2 5.8.7.2	i. Is the condition of these samples noted on the chain of custody or transmittal form and laboratory receipt documents?				
M2 5.8.7.2	ii. Is the analysis data 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 this 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 5.8.5 a); and				
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?				
M2 5.8.7.3	b) 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?				
M2 5.8.7.3	b) Is the placement of the laboratory ID number on the sample container not considered a permanent record?				
M2 5.8.7.3	i. Is the field ID code, which identifies each sample, 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 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 any comments resulting from inspection for sample rejection linked to the laboratory ID code?				
M2 5.8.7.4	Is 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.8.8	Additional Requirements – Legal Chain of Custody Protocols				
M2 5.8.8	Are legal chain of custody procedures used for evidentiary or legal purposes?				
M2 5.8.8	If a client specifies that a sample is to be used for evidentiary purposes, does the laboratory have a written SOP for how that laboratory will carry out legal chain of custody?				
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?				
M2 5.8.9	i. For samples with a specified storage temperature of 4°C, is storage at a temperature above the freezing point of water to 6°C 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) above or according to specifications in the method?				
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 5.9	**Quality Assurance for Environmental Testing (ISO/IEC 17025:2005, Clause 5.9)**				
M2 5.9.1	Does the laboratory have quality control procedures for monitoring the validity of tests and calibrations undertaken?				
M2 5.9.1	Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results?				
M2 5.9.1	Is this monitoring planned and reviewed and may include, but not be limited to, the following:				
M2 5.9.1	a) regular use of certified reference materials and/or internal quality control using secondary reference materials;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.9.1	b) participation in interlaboratory comparison or proficiency-testing programmes;				
M2 5.9.1	c) replicate tests or calibrations using the same or different methods;				
M2 5.9.1	d) retesting or recalibration of retained items;				
M2 5.9.1	e) correlation of results for different characteristics of an item?				
M2 5.9.1	Note: The selected methods should be appropriate for the type and volume of the work undertaken.				
M2 5.9.2	Is quality control data analyzed and, where they are found to be outside pre-defined criteria, planned action taken to correct the problem and to prevent incorrect results from being reported?				
M2 5.9.3	Essential Quality Control Procedures				
M2 5.9.3	These general QC principles shall apply, where applicable, to all testing laboratories.				
M2 5.9.3	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.				
M2 5.9.3	Do the standards for any given test type assure that the applicable principles are addressed?				
M2 5.9.3	a) Does the laboratory 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;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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; and				
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 QC measures assessed and evaluated on an on-going basis and QC 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 the QC protocols specified by the laboratory's SOP followed (see Section 4.2.8.5 in this Standard)?				
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, is the QC in the mandated method or regulations followed?				
M2 5.10	**Reporting the Results**				
M2 5.10	All references to Calibration Certificates in ISO/IEC 17025:2005 are not applicable to environmental testing.				
M2 5.10.1	General (ISO/IEC 17025:2005, Clause 5.10.1)				
M2 5.10.1	Are the results of each test, calibration, or series of tests or calibrations carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods?				
M2 5.10.1	Are the results reported, usually in a test report or a calibration certificate (see Note 1), and 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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.1	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, results may be 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?				
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 5.10.2	Test Reports and Calibration Certificates (ISO/IEC 17025:2005, Clause 5.10.2)				
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) the 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	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	e) identification of the method used;				
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;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 5.10.3	Test Reports (ISO/IEC 17025:2005, Clause 5.10.3)				
M2 5.10.3.1	In addition to the requirements listed in 5.10.2, do test reports, where necessary for the interpretation of the test results, 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;				
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	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 5.10.3.2	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;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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	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 5.10.4	Calibration Certificates (ISO/IEC 17025:2005, Clause 5.10.4) does not apply to environmental testing activities.				
M2 5.10.4.1	In addition to the requirements listed in 5.10.2, do calibration certificates include the following, where necessary for the interpretation of calibration results:				
M2 5.10.4.1	a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;				
M2 5.10.4.1	b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;				
M2 5.10.4.1	c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1)?				
M2 5.10.4.2	Does the calibration certificate relate only to quantities and the results of functional tests?				
M2 5.10.4.2	If a statement of compliance with a specification is made, dies it identify which clauses of the specification are met or not met?				
M2 5.10.4.2	When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, does the laboratory record those results and maintain them for possible future reference?				
M2 5.10.4.2	When statements of compliance are made, is the uncertainty of measurement taken into account?				
M2 5.10.4.3	When an instrument for calibration has been adjusted or repaired, are the calibration results before and after adjustment or repair, if available, reported?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.4.4	Does the calibration certificate (or calibration label) not contain any recommendation on the calibration interval except where this has been agreed with the customer?				
M2 5.10.4.4	This requirement may be superseded by legal regulations.				
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 5.10.6	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 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 5.10.7	Electronic transmission of results				
M2 5.10.7	In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this International Standard met (see also 5.4.7)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.8	Format of reports and certificates				
M2 5.10.8	Is the format designed to accommodate each type of test or calibration 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				
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 International Standard?				
M2 5.10.9	When it is necessary to issue a complete new test report or calibration certificate, is this uniquely identified and 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 5.10.2 and 5.10.3 above; however, does the laboratory provide all the required information to their client for use in preparing such regulatory reports?				
M2 5.10.10	Does the laboratory operated solely to provide data for compliance purposes (in-house or captive laboratories) have all applicable information specified in Section 5.10 readily available for review by the accreditation body?				
M2 5.10.10	However, formal reports detailing the information are not required if:				
M2 5.10.10	a) the in-house laboratory is itself responsible for preparing the regulatory reports; or				
M2 5.10.10	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				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M2 5.10.10	c) see Section 5.10.1, paragraph 3?				
M2 5.10.11	Are the following additional requirements met?				
M2 5.10.11	a) Time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to seventy-two (72) hours?				
M2 5.10.11	b) Results that are reported on a basis other than as received (e. g., dry weight)?				
M2 5.10.11	c) 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) Clear identification of numerical results with values outside the calibration range?				
M3	**Volume 1 Module 3**				
M3	**Quality Systems for Asbestos Testing**				
M3 1.0	**Asbestos Testing**				
M3 1.2	**Scope**				
M3 1.2	The essential quality control (QC) procedures applicable to asbestos measurements are included in this document.				
M3 1.2	Are additional QC requirements that are specified by method, regulation or project met by the laboratory?				
M3 1.4	**Method Selection**				
M3 1.4	Refer to Volume 1 Module 2, Sections 5.4.2, 5.4.3 and 5.4.4.				
M3 1.4	Does the inclusion of the analyte in the method meet all required calibration requirements of the method and the QC requirements of the method to which the analyte is being added?				
M3 1.4	If no QC exists in the method, does the laboratory adhere to the requirements outlined in a similar reference method (when available)?				
M3 1.4	Is the method that meets these requirements identified in such a way so that there is no confusion that the method has been modified?				
M3 1.4	When it is necessary to use methods not covered by reference methods, are these 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	Has the method developed been validated appropriately before use?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.5	Method Validation				
M3 1.5	Prior to acceptance and institution of any method for which data will be reported, are all methods validated?				
M3 1.5	For both reference and non-standard methods, does the laboratory participate in proficiency testing programs?				
M3 1.5	Are the results of these analyses used to evaluate the ability of the laboratory to produce acceptable data?				
M3 1.5	Do non-standard methods comply with the requirements in Volume 1, Module 2, Section 5.4.5?				
M3 1.6	Demonstration of Capability (DOC)				
M3 1.6.1	General				
M3 1.6.1	a) Does an individual who performs any activity involved with preparation and/or analysis of samples have constant, close supervision as defined in the laboratory's training procedure until a satisfactory initial DOC is completed (see Section 1.6.2)?				
M3 1.6.1	b) Thereafter, is ongoing DOC (Section 1.6.3), as per the QC requirements in Section 1.7.3 (such as laboratory control samples) required?				
M3 1.6.1	c) In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation, and there have been no significant changes in instrument type or method, the on-going DOC shall be acceptable as an initial DOC.				
M3 1.6.1	c) Does the laboratory have records on file to demonstrate when an initial DOC is not required?				
M3 1.6.1	d) Are all demonstrations documented?				
M3 1.6.1	d) Is all data applicable to the demonstration retained and readily available at the laboratory?				
M3 1.6.2	Initial DOC				
M3 1.6.2	Does an individual successfully perform an initial DOC prior to using any method (see 1.6.1.a) above), and at any time there is a change in instrument type or method, or any time that a method has not been performed by the analyst in a twelve (12) month period?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 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:				
M3 1.6.2	a) analyst(s) involved in preparation and/or analysis;				
M3 1.6.2	b) matrix;				
M3 1.6.2	c) analyte(s), class of analyte(s), or measured parameter(s);				
M3 1.6.2	d) identification of method(s) performed;				
M3 1.6.2	e) identification of laboratory-specific SOP used for analysis, including revision number;				
M3 1.6.2	f) date(s) of analysis; and				
M3 1.6.2	g) summary of?				
M3 1.6.2.2	For asbestos, if the method or regulation does not specify a DOC, the following procedure is acceptable.				
M3 1.6.2.2	Does the laboratory document that other approaches to DOC are adequate?				
M3 1.6.2.2	a) Are the analyte(s) 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?				
M3 1.6.2.2	b) Aer at least four (4) aliquots prepared and analyzed according to the method either concurrently or over a period of days?				
M3 1.6.2.2	c) Using all of the results, does the laboratory calculate the mean recovery in the appropriate reporting units and the standard deviations of the population sample (in the same units) for each analyte of interest?				
M3 1.6.2.2	c) When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?				
M3 1.6.2.2	e) When one or more of the tested analytes fail at least one of the acceptance criteria, does the analyst 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 analytes of interest beginning with c) above?				
M3 1.6.2.2	ii. Beginning with c) above, repeat the test for all analytes that failed to meet criteria?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.6.2.2	f) Repeated failure, however, confirms a general problem with the measurement system.				
M3 1.6.2.2	f) 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)?				
M3 1.6.3	On-Going DOC				
M3 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC that includes procedures for how the laboratory will identify data associated with ongoing DOCs?				
M3 1.6.3.1	Does the analyst(s) demonstrate on-going capability by routinely meeting the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
M3 1.6.3.1	If the method has not been performed by the analyst in a twelve (12) month period, is an initial DOC (1.6.2) performed?				
M3 1.6.3.1	Does the laboratory document that other approaches to ongoing DOC are adequate?				
M3 1.6.3.2	For asbestos, is this ongoing DOC one of the following:				
M3 1.6.3.2	a) acceptable performance of a blind sample (single blind to the analyst) or successful analysis of a blind performance sample on a similar method using the same technology (e.g., EPA Methods 100.1 and 100.2);				
M3 1.6.3.2	b) another initial DOC;				
M3 1.6.3.2	c) at least four (4) consecutive laboratory control samples (LCS) 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 LCS or reference sample(s) for each method for each analyst each year;				
M3 1.6.3.2	d) a documented process of analyst review using QC samples. The QC samples can be reviewed to identify patterns for individuals or groups of analysts and to determine if corrective action or retraining is necessary; or				
M3 1.6.3.2	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**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1	Calibration				
M3 1.7.1	Refer to methods referenced in the following Sections for specific equipment requirements.				
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				
M3 1.7.1.1	Refer to methods referenced in the following sections for specific equipment requirements.				
M3 1.7.1.1.1	Water and Wastewater				
M3 1.7.1.1.1	Are all calibrations listed below (unless otherwise noted) performed under the same analytical conditions used for routine asbestos analysis and recorded in a notebook and include date and analyst's signature?				
M3 1.7.1.1.1	Are frequencies stated below reduced to "before next use" if no samples are analyzed after the last calibration period has expired?				
M3 1.7.1.1.1	Likewise, are frequencies increased following non-routine maintenance or unacceptable calibration performance?				
M3 1.7.1.1.1	a) Is Magnification Calibration. 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) 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.1.1.1	b) Does this calibration allow accurate (<10% variation) measurement of layer-line spacings on the medium used for routine measurement, i.e., the phosphor screen or camera film?				
M3 1.7.1.1.1	b) Does this calibration also allow accurate (<5% variation) measurement of zone axis SAED patterns on permanent media (e.g., film)?				
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.), is an internal camera constant standard such as gold, deposited and measured on each sample to facilitate accurate indexing of zone axis SAED patterns?				
M3 1.7.1.1.1	b) In such cases, 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 250nm 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, specifically so that an electron diffraction pattern from a single fibril >1µm in length from a NIST SRM chrysotile sample is stable in the electron beam dose for at least fifteen (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, while k-factors for Na and Al may be 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 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 and 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 mixedcelluloseester (MCE) filters?				
M3 1.7.1.1.1	f) Is calibration data displayed on control charts that show trends over time?				
M3 1.7.1.1.1	g) Grid Openings.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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) <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				
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? This procedure assures that the minimum detectable fiber diameter (<ca. 0.25 µm) for this microscope is achieved.				
M3 1.7.1.2.3	Prior to ordering the Walton-Beckett graticule, is 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?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 recalibration of 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				
M3 1.7.1.3.1	Microscope Alignment.				
M3 1.7.1.3.1	To accurately measure the required optical properties, is a properly aligned polarized light microscope (PLM) utilized?				
M3 1.7.1.3.1	Is the PLM aligned before each use?				
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 refractive index liquids for dispersion staining, high-dispersion series 1.550, 1.605, 1.680?				
M3 1.7.1.3.2	The accurate measurement of the refractive index (RI) of a substance requires the use of calibrated refractive index liquids.				
M3 1.7.1.3.2	Are these 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				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 a wedge from that blank filter prepared alongside wedges from the sample filters?				
M3 1.7.2.1.1	i. At minimum, is the blank filter analyzed for each twenty (20) samples analyzed?				
M3 1.7.2.1.1	ii. Is maximum contamination on a single blank filter no more than 53 structures/mm2?				
M3 1.7.2.1.1	ii. Is 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 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?				
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				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.2.1.2	Are at least two (2) 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 that air shall not be 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				
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 this 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?				
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 mentioned in this Section.)				
M3 1.7.2.1.3	b) Non-Friable Materials.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 this non-ACM go 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				
M3 1.7.3.1	Are quality assurance (QA) analyses performed regularly covering all time periods, instruments, tasks, and personnel?				
M3 1.7.3.1	Is the selection of samples random and samples of special interest may be included in the selection of samples for QA analyses?				
M3 1.7.3.1	When possible, are the checks on personnel performance executed without their prior knowledge?				
M3 1.7.3.1	Is a disproportionate number of analyses not be performed prior to internal or external audits?				
M3 1.7.3.1	It is recommended that a laboratory initially be at 100% QC (all samples re-analyzed). The proportion of QC 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 postponed 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 precision of analyses related to concentration, as gleaned from inter-laboratory proficiency testing?				
M3 1.7.3.1.1	Are relative standard deviations (RSD) for amphibole asbestos decreased from 50% at 0.8 MFL to 25% at 7 MFL in inter-laboratory proficiency testing, while RSD for chrysotile was higher, 50% at 6 MFL?				
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 results within 1.5x of Poisson standard deviation?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.3.1.1	a) Is this 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 results within 2.0x of Poisson standard deviation?				
M3 1.7.3.1.1	b) Is this 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 this performed at a frequency of one (1) per twenty (20) samples?				
M3 1.7.3.1.1	c) Do qualified analysts maintain an average of ≥ 80% true positives, ≤ 20% false negatives, and ≤ 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 these limits derived from the allowable false positives and false negatives given in Section 1.7.3.1.1.c, Verified Analysis, below?				
M3 1.7.3.1.2	b) Is SRM 1876b analyzed a minimum of once per year by each TEM analyst?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 interlaboratory 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, is intermicroscope analyses performed to detect instrument bias?				
M3 1.7.3.1.2	e) If more than one TEM is used for asbestos analysis, is 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?				
M3 1.7.3.1.2	ii. 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 in accordance with Section 1.7.3.1.1.c?				
M3 1.7.3.1.3	Bulk Samples				
M3 1.7.3.1.3	Bulk samples with low (< 10%) asbestos content are the most problematic.				
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?				
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 re-analyzed 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 re-analyzed by another analyst?				
M3 1.7.3.1.3	b) Do inter-analyst results require additional re-analysis, 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 these samples previously analyzed as QC samples?				
M3 1.7.3.1.3	c) Are results of these 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				
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 (6) 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 this program?				
M3 1.7.3.2	a) Is the round robin designed and results analyzed using appropriate statistical methodology?				
M3 1.7.3.2	a) Are results of this QA program posted in each laboratory to keep the microscopists informed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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?				
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) Do fiber densities cover the entire range routinely analyzed by the laboratory?				
M3 1.7.3.2	b) Are these 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) 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) Intra- and inter-analyst precision may be estimated from blind recounts on reference samples.				
M3 1.7.3.2	b) Is inter-analyst precision posted in each laboratory to keep the microscopists informed?				
M3 1.7.3.3	Polarized Light Microscopy				
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				
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 these preparations have concentrations between one (1) and twenty (20) structures (>10µm) per 0.01 mm2?				
M3 1.7.4.1	i. Are one of these preparations analyzed independently at a frequency of one (1) per one hundred (100) samples analyzed?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.4.1	ii. Is NIST SRM 1876b analyzed annually by each analyst? Results shall be evaluated in accordance with limits published for that SRM?				
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	Are all analysts able to correctly identify the six (6) regulated asbestos types (chrysotile, amosite, crocidolite, anthophyllite, actinolite, and tremolite)?				
M3 1.7.4.1	Standards for the six (6) asbestos types listed are available from NIST (SRMs 1866 and 1867).				
M3 1.7.4.2	Phase Contrast Microscopy				
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) 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) Is it not be necessary to use this statistic on blank recounts?				
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				
M3 1.7.4.3	a) Friable Materials.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 a standard or reference sample that has been routinely resubmitted to determine analyst's precision and accuracy?				
M3 1.7.4.3	a) Is a set of these samples accumulated from proficiency testing samples with predetermined weight compositions or from standards generated with weighed quantities of asbestos and other bulk materials?				
M3 1.7.4.3	a) Does 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 a 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				
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?				
M3 1.7.5.1.1	This value will depend on the fraction of the filter sampled and the dilution factor (if applicable).				
M3 1.7.5.1.2	Air				
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 is defined as the airborne concentration represented by the finding of one asbestos structure in the total area of filter examined?				
M3 1.7.5.1.2	This 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	The range is dependent on the type of bulk material being analyzed. The sensitivity may be as low as 0.0001%.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.5.2	Phase Contrast Microscopy				
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	The LOD in fiber/cc will depend on sample volume and quantity of interfering dust but is <0.01 fiber/cm2 for atmospheres free of interferences?				
M3 1.7.5.3	Polarized Light Microscopy				
M3 1.7.5.3	Does the laboratory utilize a method that provides a LOD that is appropriate and relevant for the intended use of the data?				
M3 1.7.5.3	Is the LOD 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				
M3 1.7.6.1	a) Has the QC program established and maintained provisions for asbestos standards?				
M3 1.7.6.1	b) Are reference standards that are used in an asbestos obtained from NIST, EPA, or suppliers who participate in supplying NIST standards or NIST traceable asbestos?				
M3 1.7.6.1	b) 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 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 analytical reagent grade or better?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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				
M3 1.7.6.2	Standards of known concentration have not been developed for this testing method. Routine workload samples that have been statistically validated and national proficiency testing samples such as Proficiency Analytical Testing (PAT) and Asbestos Analysts Registry (AAR) samples available from the American Industrial Hygiene Association (AIHA) may be utilized as reference samples (refer to Section D.6.2.2 b) to standardize the optical system and analyst.				
M3 1.7.6.2	Do all other 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				
M3 1.7.6.3	Refer to Section 1.7.6.1.				
M3 1.7.7	Data Acceptance/Rejection Criteria				
M3 1.7.7.1	Transmission Electron Microscopy				
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 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 calculated in accordance with the method utilized?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M3 1.7.7.1.2	b) 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 calculated in accordance with the method utilized (e.g. EPA 600/M4-82-020(1982))?				
M3 1.7.7.1.3	b) Measurement Uncertainties.				
M3 1.7.7.1.3	b) Proficiency testing 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. Standard deviations range from 20% to 60% for residues with lower asbestos content.				
M3 1.7.7.2	Phase Contrast Microscopy				
M3 1.7.7.2.1	Is 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	Measurement Uncertainties.				
M3 1.7.7.2.2	Does the laboratory calculate and report the intra-laboratory and interlaboratory RSD with each set of results (NIOSH 7400, Issue 2, 15 August 1994)?				
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 other 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				
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/M4-82-020(1982))?				
M3 1.7.7.3.2	Method Uncertainties.				
M3 1.7.7.3.2	Is precision and accuracy determined by the individual laboratory for the percent range involved?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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?				
M3 1.7.8.1	Is 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 1.7.8.1	No preservatives are required during sampling.				
M3 1.7.8.2	Has the laboratory established and adhere to written procedures to minimize the possibility of cross contamination between samples?				
M3 1.7.8.3	Refer to the specific method of analysis for additional requirements.				
M4	**Volume 1 Module 4**				
M4	**Quality Systems for Chemical Testing**				
M4 1.0	**Chemical Testing**				
M4 1.2	**Scope**				
M4 1.2	The essential QC procedures applicable to chemistry measurements are included in this module.				
M4 1.2	Are additional QC requirements that are either specified by method, regulation or project met by laboratory?				
M4 1.4	**Method Selection**				
M4 1.4	Refer to Volume 1, Module 2, Sections 5.4.2, 5.4.3, and 5.4.4.				
M4 1.4	When adding a new analyte to a reference method, does the inclusion of the analyte in the method meet all required calibration requirements and the QC requirements of the method to which the analyte is being added?				
M4 1.4	If no QC exists in the method, does the laboratory adhere to the requirements outlined in a reference method of the same technology (when available)?				
M4 1.4	For example, when adding acetone to EPA Method 624, the calibration and QC requirements shall follow EPA Method 624.				
M4 1.4	Is a method that meets these requirements identified in such a way so that there is no confusion that the analyte list has been modified?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5	**Method Validation**				
M4 1.5.1	**Validation of Methods**				
M4 1.5.1	Prior to acceptance and institution of any method for which data will be reported, are all methods validated?				
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	a) For reference methods, do the procedures outlined in Section 1.6 satisfy the requirements of Section 1.5.3?				
M4 1.5.1	b) For all methods, except reference methods, does the validation comply with Volume 1, Module 2, Sections 5.4.5.1, 5.4.5.2, and 5.4.5.3?				
M4 1.5.1	b) Does this validation include the minimum requirements outlined in Sections 1.5.2, 1.5.3, and 1.5.4 of this module?				
M4 1.5.1	c) For both reference and non-standard methods, does the laboratory participate in proficiency testing programs?				
M4 1.5.1	c) Are the results of these analyses used to evaluate the ability of the laboratory to produce acceptable data?				
M4 1.5.2	**Limit of Detection and Limit of Quantitation (however named)**				
M4 1.5.2	Are procedures used for determining limits of detection and quantitation documented?				
M4 1.5.2	Does documentation include the quality system matrix type?				
M4 1.5.2	Is all supporting data retained?				
M4 1.5.2.1	**Detection Limit (DL)**				
M4 1.5.2.1	If a mandated test method or applicable regulation includes protocols for determining detection limits, are they followed?				
M4 1.5.2.1	Does the laboratory document the procedure used for determining the DL?				
M4 1.5.2.1	If the method or regulation does not contain specific directions for determination of the detection limit, do the following requirements apply?				
M4 1.5.2.1	DL determinations are not required for methods/analytes for which a detection limit is not applicable such as pH, color, odor, temperature, or dissolved oxygen.				
M4 1.5.2.1	DL determinations based on low level spikes are not required for analytes for which no spiking solutions are available.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.1	If results are not reported below the limit of quantitation (LOQ), an initial DL determination is required, but ongoing verification is not.				
M4 1.5.2.1.1	**Initial determination of the DL**				
M4 1.5.2.1.1	Does the laboratory DL procedure, unless following a mandated test method or procedure, at a minimum, incorporate language addressing the following requirements:				
M4 1.5.2.1.1	a) the DL shall reflect current operating conditions;				
M4 1.5.2.1.1	b) the DL determination shall incorporate the entire analytical process;				
M4 1.5.2.1.1	c) the DL determination shall include data from low level spikes and routine method blanks prepared and analyzed over multiple days; at least one low level spike and routine method blank must be analyze on each applicable instrument; a minimum of seven (7) replicates is required for both low level spikes and routine method blanks;				
M4 1.5.2.1.1	d) results from low level spikes used in the DL determination shall meet qualitative identification criteria in the method, and shall be above zero;				
M4 1.5.2.1.1	e) the DL procedure shall include criteria for and evaluation of false positive rates in routine method blanks;				
M4 1.5.2.1.1	Note: One option is to follow the United States Environmental Protection Agency Method Detection Limit (MDL) procedure, effective September 27, 2017?				
M4 1.5.2.1.2	**Ongoing verification of the DL**				
M4 1.5.2.1.2	At a minimum, does ongoing verification of the DL include assessments of spikes at or below the LOQ and of method blanks?				
M4 1.5.2.1.2	Is a minimum of one (1) verification spike and one (1) blank analyzed on each instrument during each quarter in which samples are being analyzed and results are being reported below the LOQ?				
M4 1.5.2.1.2	Is the criteria listed in Section 1.5.2.1.1 met for ongoing verification over the course of a year?				
M4 1.5.2.1.2	If the method is altered in a way other than routine maintenance, and the change can be expected to elevate the detection limit, is a spike at or below the LOQ concentration and a blank prepared and analyzed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.1.2	If the spike at the LOQ concentration gives a result meeting qualitative identification criteria above zero, and the blank gives a result below the DL, then is the DL is verified?				
M4 1.5.2.1.2	If not, is the DL re-determined?				
M4 1.5.2.1.2	In the event that verification fails, does the laboratory perform a new DL study within thirty (30) calendar days?				
M4 1.5.2.1.3	When a new DL is determined, does the laboratory verify that the LOQ value is greater than the DL?				
M4 1.5.2.1.3	If it is not, does the laboratory raise the LOQ value to greater than the DL?				
M4 1.5.2.2	**Limit of Quantitation (LOQ)**				
M4 1.5.2.2	If a mandated test method or applicable regulation includes protocols for determining quantitation limits, are they followed?				
M4 1.5.2.2	Is the procedure used for determining the LOQ documented by the laboratory?				
M4 1.5.2.2	Does the laboratory select an LOQ for each analyte, consistent with the needs of its clients, and greater than the DL?				
M4 1.5.2.2	Is an LOQ is required for each quality system matrix of interest, technology, method, and analyte, except for any component or property for which spiking solutions are not available or a quantitation limit is not appropriate, such as pH, color, odor, temperature, dissolved oxygen, or turbidity?				
M4 1.5.2.2	a) Is each selected LOQ verified through analysis of initial verification samples?				
M4 1.5.2.2	a) Does an initial verification sample consist of a spiked matrix blank at or below the selected LOQ?				
M4 1.5.2.2	b) Are all sample processing and analysis steps performed for routine sample analysis included in the LOQ verification testing?				
M4 1.5.2.2	c) Is the LOQ at or above the lowest corresponding calibration standard concentration with the exception of methods using a single point calibration?				
M4 1.5.2.2	d) Does the laboratory establish acceptance criteria for accuracy for the LOQ verification spikes?				
M4 1.5.2.2.1	**Initial verification of the LOQ**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.2.1	When first establishing an LOQ, or when an LOQ concentration has been selected that is lower than the concentration of performed as follows?				
M4 1.5.2.2.1	a) Is a minimum of seven (7) low level spikes at or below the LOQ concentration processed through all steps of the method?				
M4 1.5.2.2.1	a) Do both preparation and analysis of these low level spikes include at least three (3) batches on three (3) separate days?				
M4 1.5.2.2.1	Note 1: Spiking slightly below the LOQ may help ensure that the results are also suitable for DL determination.				
M4 1.5.2.2.1	Note 2: If low level spikes have been analyzed in order to generate a DL, the results may be used to perform the initial verification of the LOQ.				
M4 1.5.2.2.1	i. If there are multiple instruments that will be assigned the same LOQ, then are these low level spikes distributed across all of the instruments?				
M4 1.5.2.2.1	ii. Are a minimum of two (2) low level spikes prepared and analyzed on different days tested on each instrument?				
M4 1.5.2.2.1	b) If existing data is used is it compliant with the requirements for at least three (3) batches, generated within the last two (2) years and representative of current operations?				
M4 1.5.2.2.1	c) Is the LOQ verified if the following criteria are met?				
M4 1.5.2.2.1	i. Are all results quantitative (above zero and meet the qualitative identification criteria of the method; e.g., recognizable spectra, signal to noise requirements, and presence of qualifier ions)?				
M4 1.5.2.2.1	If a result from an LOQ verification sample is not above zero and/or does not meet the qualitative identification criteria in the method, is the problem corrected and the verification repeated, or the LOQ verification repeated at a higher concentration?				
M4 1.5.2.2.1	ii. Is recovery of each analyte within the laboratory established accuracy acceptance criteria?				
M4 1.5.2.2.1	iii. Is the LOQ greater than the established DL and at or above the spiking concentration?				
M4 1.5.2.2.1	If the LOQ is less than or equal to the DL, is the LOQ raised to greater than the DL?				
M4 1.5.2.2.1	Note: It is not necessary to repeat the LOQ verification at a higher concentration when it is necessary to raise the LOQ to greater than the DL.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.2.1	d) Does the laboratory document the results of the initial LOQ verification as described in Section 1.5.2.4?				
M4 1.5.2.2.2	**Ongoing verification of the LOQ**				
M4 1.5.2.2.2	Does the laboratory prepare and analyze a minimum of one (1) LOQ verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are being analyzed for each quality system matrix, method, and analyte?				
M4 1.5.2.2.2	a) Are results of each LOQ verification sample analysis evaluated at the time of the testing and meet the qualitative identification criteria in the method and laboratory Standard Operating Procedure (SOP) and the quantitated result greater than the DL and meet the laboratory established accuracy criteria as established by Section 1.5.2.2 d)?				
M4 1.5.2.2.2	b) If a continuing LOQ verification test does not meet this requirement, does the laboratory take corrective action and document a technically valid reason for the corrective action?				
M4 1.5.2.2.2	b) Is corrective action one of the following:				
M4 1.5.2.2.2	(i) correcting method or instrument performance and repeating the verification test; (ii) evaluating the laboratory established control limits to ensure they reflect current performance; or (iii) raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study within thirty (30) calendar days of the initial failure?				
M4 1.5.2.2.2	b) Are any samples analyzed in a batch associated with a failing LOQ verification reanalyzed or reported with qualifiers?				
M4 1.5.2.3	**Verification of DL/LOQ**				
M4 1.5.2.3	If no analysis was performed in a given year, the verification of the DL/LOQ is not required, but is a new initial DL/LOQ verification performed prior to analysis of client samples?				
M4 1.5.2.4	**Documentation**				
M4 1.5.2.4	At least once per year, does the laboratory tabulate all results of the ongoing verification sample testing?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.2.4	Is all data representative of the current operations used, if generated within the last two (2) years?				
M4 1.5.2.4	Is a minimum of seven (7) samples required?				
M4 1.5.2.4	a) Does the laboratory record the analytical and preparation methods used, dates of preparation and testing, the batch identifiers, the testing instrument, quality system matrix, technology, analyte, concentration in the spiked sample with units, and the test result (if any) for each LOQ and/or DL verification test?				
M4 1.5.2.4	b) For each analyte, does the laboratory record the percent recovery, the number of results (n), the mean and standard deviation of the percent recovery, and the spiking concentration of the spiked samples with units?				
M4 1.5.2.4	b) Is the data provided to clients upon request?				
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 also 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	Do precision and bias measurements evaluate the method across the analytical calibration range of the method?				
M4 1.5.3	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 1.5.3	Examples of a systematic approach to evaluate precision and bias could be the following:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.5.3	i. Analyze QC samples in triplicate containing the analytes of concern at or near the LOQ, at the upper-range of the calibration (upper 20%), 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 (1) QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three (3) days. (Note that the three (3) samples at the LOQ concentration can demonstrate sensitivity as well.)				
M4 1.5.3	For each analyte, calculate the mean recovery for each day, for each level over each day, and for all nine (9) samples. Calculate the relative standard deviation for each of the separate means obtained. Compare the standard deviations for the different days and the standard deviations for the different concentrations. If the different standard deviations are all statistically insignificant (e.g., F-test), then compare the overall mean and standard deviation with the established criteria from above.				
M4 1.5.3	ii. A validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process.				
M4 1.5.4	**Evaluation of Selectivity**				
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	**General**				
M4 1.6.1	a) Does an individual who performs any activity involved with preparation and/or analysis of samples have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is completed (see Section 1.6.2)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.6.1	b) Thereafter, is ongoing DOC (Section 1.6.3), as per the QC requirements in Section 1.7.2 (such as laboratory control samples), required?				
M4 1.6.1	c) In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation, and there have been no significant changes in instrument type or method, is the ongoing DOC acceptable as an initial DOC?				
M4 1.6.1	c) Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
M4 1.6.1	d) Are all demonstrations documented?				
M4 1.6.1	d) Is all data applicable to the demonstration retained and readily available at the laboratory?				
M4 1.6.2	**Initial DOC**				
M4 1.6.2	Does an individual successfully perform an initial DOC prior to using any method (see Section 1.6.1.a above), and any time there is a change in instrument type, method, or any time that a method has not been performed by the analyst in a twelve (12) month period?				
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	a) analyst(s) involved in preparation and/or analysis;				
M4 1.6.2.1	b) matrix;				
M4 1.6.2.1	c) analyte(s), class of analyte(s);				
M4 1.6.2.1	d) identification of method(s) performed;				
M4 1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number;				
M4 1.6.2.1	f) date(s) of analysis; and				
M4 1.6.2.1	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 an initial DOC, is the following procedure is acceptable? It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.6.2.2	a) Is the analyte(s) 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 LOQ?				
M4 1.6.2.2	b) Are at least four (4) aliquots 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, is the mean recovery calculated in the appropriate reporting units and the standard deviations of the sample (in the same units) for each analyte of interest? W				
M4 1.6.2.2	c) When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?				
M4 1.6.2.2	d) Is the information from (c) above compared 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)?				
M4 1.6.2.2	d) If all analytes meet the acceptance criteria, does the analysis of actual samples may begin?				
M4 1.6.2.2	d) If any one of the analytes does not meet the acceptance criteria, is the performance unacceptable for that analyte?				
M4 1.6.2.2	e) When one or more of the tested analytes fail at least one (1) of the acceptance criteria, does the analyst proceed according to i) or ii) below?				
M4 1.6.2.2	i. Locate and correct the source of the problem and repeat the test for all analytes of interest beginning with b) above?				
M4 1.6.2.2	ii. Beginning with b) above, repeat the test for all analytes 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 analytes of interest beginning with b)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 1.6.3	**Ongoing DOC**				
M4 1.6.3.1	Does laboratory have a documented procedure describing ongoing DOC that includes procedures for how the laboratory will identify data associated with ongoing DOCs?				
M4 1.6.3.1	Does the analyst(s) demonstrate on-going capability by routinely meeting the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
M4 1.6.3.1	If the method not been performed by the analyst in a twelve (12) month period, Is an initial DOC (Section 1.6.2) performed?				
M4 1.6.3.1	Does the laboratory document that other approaches to ongoing DOC are adequate?				
M4 1.6.3.2	**Is this on-going demonstration one of the following:**				
M4 1.6.3.2	a) acceptable performance of a blind sample (single blind to the analyst) or 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);				
M4 1.6.3.2	b) another initial DOC;				
M4 1.6.3.2	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 LCSs or reference sample(s) for each method for each analyst each year;				
M4 1.6.3.2	d) a documented process of reviewing QC samples performed by an analyst or groups of analysts relative to the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard. This review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.6.3.2	e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a pre-defined acceptance criterion (as defined by the laboratory or method) shall be performed?				
M4 1.7	**Technical Requirements**				
M4 1.7.1	**Calibration**				
M4 1.7.1	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	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	**Initial Calibration**				
M4 1.7.1.1	Are samples associated with an acceptable initial calibration?				
M4 1.7.1.1	If the initial calibration is not acceptable, are corrective actions performed and all associated samples re-analyzed?				
M4 1.7.1.1	If reanalysis of the samples is not possible, is data associated with an unacceptable initial calibration only be reported with appropriate data qualifiers?				
M4 1.7.1.1	Are the following items essential elements of initial calibration:				
M4 1.7.1.1	a) the details of the initial calibration procedures including calculations, integrations, acceptance criteria, and associated statistics shall be included or referenced in the method SOP. When initial calibration procedures are referenced in the test method, then the referenced material shall be retained by the laboratory and be available for review;				
M4 1.7.1.1	b) sufficient raw data records shall be retained to permit reconstruction of the initial calibration (e.g., calibration date, method, instrument, analysis date, each analyte name, and 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) the laboratory shall use the most recent initial calibration analyzed prior to the analytical batch, unless otherwise specified by the method;				
M4 1.7.1.1	d) standards used for calibration shall be traceable to a national standard, when commercially available;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.1	e) the laboratory shall have a written procedure addressing removal and replacement of calibration standards. The procedure shall comply with the following requirements:				
M4 1.7.1.1	i If the laboratory removes individual analyte calibration levels, are they from the lowest and/or highest levels of the curve?				
M4 1.7.1.1	i If multiple levels are removed, is removal of interior levels not permitted?				
M4 1.7.1.1	ii. If the laboratory removes an entire single standard calibration level from the interior of the calibration curve, is it when the instrument response demonstrates that the standard was not properly introduced to the instrument, or an incorrect standard was analyzed?				
M4 1.7.1.1	ii. If the laboratory that chooses to remove a calibration standard from the interior of the calibration, does it remove that particular standard calibration level for all analytes?				
M4 1.7.1.1	ii. Does the laboratory not remove calibration points from the interior of the curve to compensate for lack of maintenance or repair to the instrument?				
M4 1.7.1.1	iii. The laboratory shall adjust the LOQ/reporting limit and quantitation range of the calibration based on the concentration of the remaining high and low calibration standards.				
M4 1.7.1.1	iv. Does the laboratory ensure that the remaining initial calibration standards are sufficient to meet the minimum requirements for number of initial calibration points as mandated by this Standard, the method, or regulatory requirements?				
M4 1.7.1.1	v. Does the laboratory replace a calibration standard only provided that:				
M4 1.7.1.1	a. the laboratory analyzes the replacement standard within twenty-four (24) hours of the original calibration standard analysis for that particular calibration level;				
M4 1.7.1.1	b. the laboratory replaces all analytes of the replacement calibration standard if a standard within the interior of the calibration is replaced; and				
M4 1.7.1.1	c. the laboratory limits the replacement of calibration standards to one calibration standard concentration?				
M4 1.7.1.1	vi. Does the laboratory document a technically valid reason for either removal or replacement of any interior calibration point?				

Section Reference	Question	Compliant? Yes	No	NA	Comments
M4 1.7.1.1	f) for regression or average response/calibration factor calibrations, the minimum number of non-zero calibration standards shall be as specified in the table below;				
M4 1.7.1.1	**Type of Cal Curve** **# of Cal Stds**[b] Threshold Testing[a] 1 Avg. Response 4 Linear Fit 5 Quad. Fit 6 [a]The initial one-point calibration shall be at the project-specified threshold level. [b]Fewer calibration standards may be used only if equipment firmware or software cannot accommodate the specified number of standards. Documentation detailing that limitation shall be maintained by the laboratory.				
M4 1.7.1.1	g) the lowest calibration standard shall be at or below the lowest concentration for which quantitative data are to be reported without qualification;				
M4 1.7.1.1	h) the highest calibration standard shall be at or above the highest concentration for which quantitative data are to be reported without qualification;				
M4 1.7.1.1	i) sample results shall be quantitated from the initial calibration and may not be quantitated from any continuing calibration verification unless otherwise required by regulation, method, or program;				
M4 1.7.1.1	j) criteria for the acceptance of an initial calibration shall be established (e.g., correlation coefficient or relative standard deviation);				
M4 1.7.1.1	k) the laboratory shall use and document a measure of relative error in the calibration;				
M4 1.7.1.1	i. for calibrations evaluated using an average response factor, the determination of the relative standard deviation (RSD) is the measure of the relative error;				
M4 1.7.1.1	ii. for calibrations evaluated using correlation coefficient or coefficient of determination, does the laboratory evaluate relative error by either:				
M4 1.7.1.1	a. measurement of the Relative Error (%RE)				
M4 1.7.1.1	Relative error is calculated using the following equation: $((x'_i-x_i)/x_i)*100$ x_i = True value for the calibration standard x'_i = Measured concentration of the calibration standard				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.1	Is this calculation performed for two (2) calibration levels: the standard at or near the mid-point of the initial calibration and the standard at the lowest level?				
M4 1.7.1.1	The Relative Error at both of these levels shall meet the criteria specified in the method.				
M4 1.7.1.1	If no criterion for the lowest calibration level is specified in the method, is the criterion and the procedure for deriving the criterion specified in the laboratory SOP?				
M4 1.7.1.1	or,				
M4 1.7.1.1	b. measurement of the Relative Standard Error (%RSE)				
M4 1.7.1.1	Relative Standard Error is calculated using the following equation: x_i = True value of the calibration level i x'_i = Measured concentration of calibration level i p = Number of terms in the fitting equation (average = 1, linear = 2, quadratic = 3) n = Number of calibration points $\sqrt{\sum_{n}\left[\frac{x'i + xi}{xi}\right]}/$				
M4 1.7.1.1	Does the RSE meet the criterion specified in the method?				
M4 1.7.1.1	If no criterion is specified in the method, is the maximum allowable RSE numerically identical to the requirement for RSD in the method?				
M4 1.7.1.1	If there is no specification for RSE or RSD in the method, is the RSE specified in the laboratory SOP?				
M4 1.7.1.1	l) when test procedures are employed that specify calibration with a single calibration standard and a zero point (blank or zero, however specified by the method), does the following occur:				
M4 1.7.1.1	i. The zero point and single calibration standard within the linear range is analyzed at least daily and used to establish the slope of the calibration?				
M4 1.7.1.1	ii. To verify adequate sensitivity a standard is analyzed at or below the lowest concentration for which quantitative data are to be reported without qualification?				
M4 1.7.1.1	ii. This standard is analyzed prior to sample analysis with each calibration and meets the quantitation limit criteria established by the method?				
M4 1.7.1.1	ii. If no criteria exist does the laboratory specify criteria in the SOP?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.1	m) for analysis of Aroclors which use a linear through origin model (or average response factor) does the laboratory perform an initial multi-point calibration for a subset of Aroclors (e.g., a mixture of 1016/1260) and use a one-point initial calibration to determine the calibration factor and pattern recognition for the remaining Aroclors?				
M4 1.7.1.1	n) Initial Calibration Verification (ICV):				
M4 1.7.1.1	n) Are all initial calibrations verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer?				
M4 1.7.1.1	o) for those methods where reporting non-detected analytes based on successful completion of a sensitivity check is allowed (similar to threshold testing but only for non-detects) do the requirements of this Standard not prohibit the practice?				
M4 1.7.1.1	p) some methods allow data within the linear range of the instrument, but above the daily calibration, to be reported without qualification.				
M4 1.7.1.1	p) For these methods, does the laboratory establish the upper reporting limit through analysis of a series of standards?				
M4 1.7.1.1	p) Is the upper reporting limit equal to the concentration of the highest standard meeting the method limits for accuracy?				
M4 1.7.1.1	p) Does the laboratory establish linearity annually and check it at least quarterly with a standard at the top of the linear working range, or at the frequency defined by the method?				
M4 1.7.1.1	p) Does the laboratory dilute samples with results above the linear calibration range, or qualify the over-range results as estimated values?				
M4 1.7.1.2	**Continuing Calibration Verification (CCV)**				
M4 1.7.1.2	Is the validity of the initial calibration verified prior to sample analyses by a continuing calibration verification with each analytical batch?				
M4 1.7.1.2	Are the following items essential elements of continuing calibration verification?				
M4 1.7.1.2	a) Are the details of the continuing calibration procedure, calculations and associated statistics included or referenced in the method SOP?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.2	b) Are 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 1.7.1.2	c) Is the concentration of the calibration verification standard equal to or less than half the highest level in the calibration?				
M4 1.7.1.2	d) Is instrument continuing calibration verification performed at the beginning and end of each analytical batch, and at the frequency defined in the method except:				
M4 1.7.1.2	i. if an internal standard is used, calibration verification shall be performed at the beginning of each analytical batch, and at the frequency defined in the method;				
M4 1.7.1.2	ii. a second source initial calibration verification that passes the continuing calibration verification criteria may be used in place of a continuing calibration verification standard;				
M4 1.7.1.2	iii. a laboratory control sample (LCS) may be used in place of a continuing calibration verification (CCV) (but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS (using the continuing calibration verification acceptance criteria)?				
M4 1.7.1.2	e) Are sufficient raw data records retained to permit reconstruction of the continuing instrument calibration 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 1.7.1.2	e) Do continuing calibration verification records explicitly connect the continuing calibration verification data to the initial calibration?				
M4 1.7.1.2	f) Is criteria for the acceptance of a continuing instrument calibration verification established?				
M4 1.7.1.2	f) If the continuing instrument calibration verification results obtained are outside the established acceptance criteria, are the following steps taken?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.2	i. if a cause for the calibration verification failure is identified that impacts only the calibration verification sample (e.g. a missed autosampler injection), then is analysis allowed to proceed if a second calibration verification sample is analyzed immediately and the result is within acceptance criteria?				
M4 1.7.1.2	i. Are samples analyzed previously considered valid if bracketed by a passing calibration verification sample (refer to Section 1.7.1.2.d)?				
M4 1.7.1.2	i. Is the cause for the failure of the first calibration verification result documented?				
M4 1.7.1.2	ii. if the cause for the calibration verification failure is not identifiable or has impacted other samples, then is corrective action performed and documented?				
M4 1.7.1.2	ii. Prior to analyzing samples, does the laboratory demonstrate acceptable performance after corrective action with calibration verification or a new initial calibration shall be performed?				
M4 1.7.1.2	ii. Are samples analyzed prior to the calibration verification failure reanalyzed or the results qualified if calibration verification bracketing is required (refer to Section 1.7.1.2.d)?				
M4 1.7.1.2	iii. Is data associated with an unacceptable calibration verification qualified if reported, and not be reported if prohibited by the client, a regulatory program or regulation?				
M4 1.7.1.2	iii. Is data associated with calibration verifications that fail under the following special conditions qualified, but may use a different qualifier?				
M4 1.7.1.2	a. when the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are nondetects, then those non-detects may be reported.				
M4 1.7.1.2	a. Otherwise, are the samples affected by the unacceptable calibration verification re-analyzed after a new calibration curve has been established, evaluated and accepted; or				
M4 1.7.1.2	b. when the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias), are those sample results reported if they exceed a maximum regulatory limit/decision level?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.1.2	b. Otherwise are the samples affected by the unacceptable verification re-analyzed after a new calibration curve has been established, evaluated and accepted?				
M4 1.7.2	**Quality Control (QC)**				
M4 1.7.2	Does the laboratory have QC procedures for monitoring the validity of environmental tests undertaken as specified in this Section?				
M4 1.7.2.1	**Negative Control – Method Performance: Method Blank**				
M4 1.7.2.1	a) Is the method blank used to assess the samples in the preparation batch for possible contamination during the preparation and processing steps?				
M4 1.7.2.1	a) Is the method blank processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure?				
M4 1.7.2.1	a) Are procedures in place to determine if a method blank is contaminated?				
M4 1.7.2.1	a) Are any affected samples associated with a contaminated method blank processed for analysis or the results reported with appropriate data qualifying codes?				
M4 1.7.2.1	b) Is the method blank analyzed at a minimum of one (1) per preparation batch?				
M4 1.7.2.1	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 method blanks, LCS, matrix spikes and matrix duplicates?				
M4 1.7.2.1	c) Does the method blank 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 1.7.2.1	d) Method blanks are not applicable for certain analyses, such as pH, Conductivity, Flash Point, and Temperature.				
M4 1.7.2.2	**Positive Control – Method Performance: Laboratory Control Sample (LCS)**				
M4 1.7.2.2.1	Is the LCS used to evaluate the performance of the total analytical system, including all preparation and analysis steps?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2.2.1	Are results of the LCS compared to established criteria and, if found to be outside of these criteria, indicate that the analytical system is “out of control"?				
M4 1.7.2.2.1	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 1.7.2.2.2	Is the LCS analyzed at a minimum of one (1) per preparation batch?				
M4 1.7.2.2.2	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 1.7.2.2.2	In those instances for which no separate preparation method is used (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 method blanks, LCS, matrix spikes and matrix duplicates?				
M4 1.7.2.2.3	Is the LCS quality system matrix, known to be free of analytes of interest, spiked with known concentrations of analytes?				
M4 1.7.2.2.3	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.				
M4 1.7.2.2.3	Alternatively, does the LCS consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM)?				
M4 1.7.2.2.3	Are all analyte concentrations within the calibration range of the methods?				
M4 1.7.2.2.3	Are the following used in choosing components for the spike mixtures?				
M4 1.7.2.2.3	Are the components spiked as specified by the mandated method or regulation or as requested by the client?				
M4 1.7.2.2.3	In the absence of specified spiking components, does the laboratory spike per the following?				
M4 1.7.2.2.3	a) for those components that interfere with an accurate assessment, such as spiking simultaneously with technical chlordane, toxaphene and PCBs, is the spike chosen that represents the chemistries and elution patterns of the components to be reported; and				
M4 1.7.2.2.3	b) for those methods that have extremely long lists of analytes, a representative number may be chosen.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2.2.3	b) Are analytes selected representative of all analytes reported?				
M4 1.7.2.2.3	Is the following criteria used for determining the minimum number of analytes to be spiked?				
M4 1.7.2.2.3	However, does the laboratory insure that all targeted components are included in the spike mixture over a two (2) year period?				
M4 1.7.2.2.3	i. for methods that include one (1) to ten (10) targets, spike all components;				
M4 1.7.2.2.3	ii. for methods that include eleven (11) to twenty (20) targets, spike at least ten (10) components or 80%, whichever is greater;				
M4 1.7.2.2.3	iii. for methods with more than twenty (20) targets, spike at least sixteen (16) components?				
M4 1.7.2.3	**Sample Specific Controls**				
M4 1.7.2.3	Does the laboratory document procedures for determining the effect of the sample matrix on method performance?				
M4 1.7.2.3	Do these procedures relate to the analyses of quality system matrix specific QC samples and designed as data quality indicators for a specific sample using the designated method?				
M4 1.7.2.3	Are these controls alone not used to judge laboratory performance?				
M4 1.7.2.3	Examples of matrix-specific QC include: Matrix Spike (MS), Matrix Spike Duplicate (MSD), sample duplicates, and surrogate spikes. The laboratory shall have procedures in place for tracking, managing, and handling matrix-specific QC criteria, including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, and evaluating and reporting results based on performance of the QC samples.				
M4 1.7.2.3.1	**Matrix spike; matrix spike duplicates**				
M4 1.7.2.3.1	a) Matrix-specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.				
M4 1.7.2.3.1	b) Is the frequency of the analysis of matrix spikes as specified by the method or determined as part of the contract review process?				
M4 1.7.2.3.1	c) Are the components to be spiked as specified by the mandated method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2.3.1	c) Are any permit-specified analytes, as specified by regulation or client requested analytes, also be included?				
M4 1.7.2.3.1	c) If there are no specified components, does the laboratory spike per the following?				
M4 1.7.2.3.1	i. For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike chosen represents the chemistries and elution patterns of the components to be reported?				
M4 1.7.2.3.1	ii. For those methods that have extremely long lists of analytes, a representative number is chosen using the following criteria for choosing the number of analytes to be spiked?				
M4 1.7.2.3.1	ii. However, does the laboratory insure that all targeted components are included in the spike mixture over a two (2) year period?				
M4 1.7.2.3.1	a. For methods that include one (1) to ten (10) targets, spike all components?				
M4 1.7.2.3.1	b. For methods that include eleven (11) to twenty (20) targets, spike at least ten (10) components or 80%, whichever is greater?				
M4 1.7.2.3.1	c. For methods with more than twenty (20) targets, spike at least sixteen (16) components?				
M4 1.7.2.3.2	**Matrix duplicates**				
M4 1.7.2.3.2	a) Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate may provide a usable measure of sample homogeneity. It may also provide a measure of precision when target analytes are present.				
M4 1.7.2.3.2	b) Are the frequency of the analysis of matrix duplicates specified by the method or determined as part of the contract review process?				
M4 1.7.2.3.2	c) Are matrix duplicates performed on replicate aliquots of actual samples?				
M4 1.7.2.3.2	c) Is the composition is usually not known?				
M4 1.7.2.3.3	**Surrogate spikes**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.2.3.3	a) Are surrogates, when required, chosen to reflect the chemistries of the targeted components of the method and added prior to sample preparation/extraction?				
M4 1.7.2.3.3	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 1.7.2.3.3	c) Are surrogate compounds chosen to represent the various chemistries of the target analytes in the method?				
M4 1.7.2.3.3	c) They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.				
M4 1.7.2.4	**Data Reduction**				
M4 1.7.2.4	Are the procedures for data reduction, such as use of linear regression, documented?				
M4 1.7.2.5	**Reagent Quality, Water Quality, and Checks**				
M4 1.7.2.5	a) In methods where the purity of reagents is not specified, is analytical reagent grade used?				
M4 1.7.2.5	a) Are reagents of lesser purity than those specified by the method not be used?				
M4 1.7.2.5	a) Is documentation of purity available?				
M4 1.7.2.5	b) Is the quality of water sources monitored and documented and meet method specified requirements?				
M4 1.7.2.5	c) Does the laboratory verify the concentration of titrants in accordance with written laboratory procedures?				
M4 1.7.2.6	**Selectivity**				
M4 1.7.2.6	Does the laboratory document selectivity by following the checks established within the method?				
M4 1.7.3	**Data Acceptance/Rejection Criteria**				
M4 1.7.3.1	**Negative Control – Method Performance: Method Blank**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.1	While the goal is to have no detectable contaminants, is each method blank critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch?				
M4 1.7.3.1	Is the source of contamination investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data appropriately qualified if:				
M4 1.7.3.1	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 1.7.3.1	b) the blank contamination otherwise affects the sample results as per the method requirements or the individual project data quality objectives; and				
M4 1.7.3.1	c) a blank is determined to be contaminated?				
M4 1.7.3.1	c) Is the cause investigated and measures taken to minimize or eliminate the problem?				
M4 1.7.3.1	c) Are samples associated with a contaminated blank evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes)?				
M4 1.7.3.1	c) In all cases, is the corrective action documented?				
M4 1.7.3.2	**Negative Control – Method Performance: Method Blank**				
M4 1.7.3.2	a) Are the results of the individual batch LCS calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria?				
M4 1.7.3.2	a) Does the laboratory document the calculation?				
M4 1.7.3.2	Is the individual LCS compared to the acceptance criteria as published in the mandated method?				
M4 1.7.3.2	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 1.7.3.2	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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.2	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?				
M4 1.7.3.2	Does this include any allowable marginal exceedance as described in b) below?				
M4 1.7.3.2	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, then are those non-detects reported with data qualifying codes; or				
M4 1.7.3.2	ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), are those sample results reported if they exceed a maximum regulatory limit/decision level with data qualifying codes?				
M4 1.7.3.2	b) Allowable Marginal Exceedances.				
M4 1.7.3.2	b) 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. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary.				
M4 1.7.3.2	b) Is an ME defined as being beyond the LCS control limit (three (3) standard deviations), but within the ME limits?				
M4 1.7.3.2	b) Are ME limits between three (3) and four (4) standard deviations around the mean?				
M4 1.7.3.2	b) Are the number of allowable marginal exceedances based on the number of analytes in the LCS?				
M4 1.7.3.2	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 is necessary?				
M4 1.7.3.2	b) Is this marginal exceedance approach relevant for methods with long lists of analytes?				
M4 1.7.3.2	b) Does this marginal exceedance not apply to target analyte lists with fewer than eleven analytes?				
M4 1.7.3.2	Is the number of allowable marginal exceedances follows?				

Section Reference	Question	Compliant? Yes	No	NA	Comments
M4 1.7.3.2	**# Analytes in LCS** / **# Allowed as Marginal Exceedances** >90 — 5 71 - 90 — 4 51 - 70 — 3 31 - 50 — 2 11 - 30 — 1 <11 — 0				
M4 1.7.3.2	If the same analyte exceeds the LCS control limit consecutively, it is an indication of a systemic problem.				
M4 1.7.3.2	Is the source of the error located and corrective action taken?				
M4 1.7.3.2	Does the laboratory have a written procedure to monitor the application of marginal exceedance allowance to the LCS?				
M4 1.7.3.3	**Sample Specific Controls**				
M4 1.7.3.3	a) Matrix Spike; Matrix Spike Duplicates				
M4 1.7.3.3	The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R), relative percent difference (RPD), or other appropriate statistical technique that allows comparison to established acceptance criteria.				
M4 1.7.3.3	Does the laboratory document the calculation for %R, RPD or other statistical treatment used?				
M4 1.7.3.3	Are the results compared to the acceptance criteria as published in the mandated method?				
M4 1.7.3.3	Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
M4 1.7.3.3	For matrix spike results outside established criteria, is corrective action documented or the data for that sample reported with appropriate data qualifying codes?				
M4 1.7.3.3	b) Matrix Duplicates				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.3.3	The results from matrix duplicates are primarily designed to assess the homogeneity of the particular sample chosen. If that sample is homogenous it may also describe the precision of analytical results in a given matrix. These may be expressed as RPD or another statistical treatment (e.g., absolute differences).				
M4 1.7.3.3	Does the laboratory document the calculation for RPD or other statistical treatments?				
M4 1.7.3.3	Are results are compared to the acceptance criteria as published in the mandated method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix duplicates results outside established criteria, corrective action shall be documented or the data for that sample reported with appropriate data qualifying codes.				
M4 1.7.3.3	c) Surrogate Spikes				
M4 1.7.3.3	The results compared to the acceptance criteria as published in the mandated method?				
M4 1.7.3.3	Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
M4 1.7.3.3	Are surrogates outside the acceptance criteria evaluated for the effect indicated for the individual sample results?				
M4 1.7.3.3	The appropriate corrective action may be guided by the data quality objectives or other site-specific requirements.				
M4 1.7.3.3	Do results reported from analyses with surrogate recoveries outside the acceptance criteria include appropriate data qualifiers?				
M4 1.7.4	**Sample Handling**				
M4 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?				
M4 1.7.4	a) For samples with a specified temperature of 4°C, are samples with a temperature ranging from just above the freezing temperature of water to 6°C acceptable?				
M4 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.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M4 1.7.4	i. In these cases, are the samples considered acceptable if the samples were received on ice?				
M4 1.7.4	ii. If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required.				
M4 1.7.4	iii. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection.				
M4 1.7.4	b) Does the laboratory implement procedures for checking sample preservation using readily available techniques, such as pH or chlorine, prior to or during sample preparation or analysis?				
M4 1.7.4	b) An exception is allowed for volatile organic analyte analyses; chemical preservation may be checked after analysis.				
M5	**Volume 1 Module 5**				
M5	**Quality Systems for Microbiological Testing**				
M5 1.0	**Microbiological Testing**				
M5 1.2	**Scope**				
M5 1.2	The essential QC procedures applicable to microbiological analysis are included in this module.				
M5 1.2	Are additional QC or program requirements that are either specified by method, regulation or project met by the laboratory?				
M5 1.4	**Method Selection**				
M5 1.4	Refer to Volume 1, Module 2, Sections 5.4.2, 5.4.3, and 5.4.4.				
M5 1.5	**Method Validation**				
M5 1.5	a) For methods other than reference methods, does validation comply with Volume 1, Module 2?				
M5 1.5	a) Does this validation include the minimum requirements outlined in Sections 1.5.1, 1.5.2, and 1.5.3 of this module?				
M5 1.5	b) For both reference and non-standard methods, does the laboratory participate in proficiency testing (PT) programs, where available?				
M5 1.5	c) 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 1.5.1	Accuracy				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.5.1	Does the laboratory use at least one (1) known pure positive reference culture at the anticipated environmental conditions and compare the method results to that of a reference method?				
M5 1.5.2	Precision				
M5 1.5.2	Does the laboratory perform at least ten (10) replicate analyses with both the proposed and reference method, using a sample containing the target microorganisms of choice?				
M5 1.5.2	Do the results show that the precision of the proposed method is statistically equivalent or better than that of the reference method?				
M5 1.5.3	Selectivity (sensitivity)				
M5 1.5.3	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)?				
M5 1.5.3	Does the laboratory calculate the number of false positive and false negative results?				
M5 1.6	**Demonstration of Capability (DOC)**				
M5 1.6.1	General				
M5 1.6.1.1	Does an individual who performs any activity involved with preparation and/or analysis of samples have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is completed (see Section 1.6.2).?				
M5 1.6.1.2	Thereafter, is ongoing DOC (Section 1.6.3) performed and documented at least every twelve (12) months?				
M5 1.6.1.3	In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation and where there have been no significant changes in instrument type or method, is the ongoing DOC acceptable as an initial DOC?				
M5 1.6.1.3	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
M5 1.6.1.4	Are all demonstrations documented?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.6.1.4	Is 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 made 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 Standard Operating procedure (SOP) used for analysis, including revision number;				
M5 1.6.2.1	f) date(s) of analysis; and				
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 an initial DOC, the following procedure is acceptable.				
M5 1.6.2.2	Does the laboratory document that other approaches to initial DOC are adequate?				
M5 1.6.2.2	a) Is the target organism(s) diluted in a volume of sterile, quality system matrix (a sample in which no target organisms or interferences are present at concentrations that will impact the results of a specific method)?				
M5 1.6.2.2	a) When required by method, is the diluent sterile buffered water and/or sterile peptone water unless specified by the manufacturer?				
M5 1.6.2.2	a) Does the laboratory prepare at least four (4) aliquots at the concentration specified, or if unspecified, to the countable range for plate methods or working range for most probable number (MPN) type methods?				
M5 1.6.2.2	b) Are at least four (4) aliquots prepared and analyzed concurrently according to the method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.6.2.2	c) Using all of the results, does the laboratory convert these results to logarithmic values, then calculate the mean recovery and standard deviation of the log converted results in the appropriate reporting units for each organism of interest?				
M5 1.6.2.2	c) When it is not possible to determine mean and standard deviations, such as for presence/absence, does the laboratory assess performance against established and documented criteria?				
M5 1.6.2.2	d) For qualitative tests, is acceptable performance in a blind study, either internally or externally generated, used to meet this Standard, provided that the study consists of a minimum of a blank, a negative culture, and a positive culture for each target organism?				
M5 1.6.2.2	e) Does the laboratory 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 such as relative standard deviation (if there are not established mandatory criteria)?				
M5 1.6.2.2	e) If all parameters meet the acceptance criteria, does the analysis of actual samples may begin?				
M5 1.6.2.2	e) If any one of the parameters does not meet the acceptance criteria, is the performance unacceptable for that parameter?				
M5 1.6.2.2	f) 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?				
M5 1.6.2.2	i. Does the laboratory locate and correct the source of the problem and repeat the initial DOC for all parameters of interest beginning with b) above?				
M5 1.6.2.2	ii. R Does the laboratory repeat the initial DOC for all parameters that failed to meet criteria?				
M5 1.6.2.2	g) Repeated failure, however, confirms a general problem with the measurement system.				
M5 1.6.2.2	g) If this occurs, does the laboratory locate and correct the source of the problem and repeat the test for all organisms of interest beginning with b) above?				
M5 1.6.3	Ongoing DOC				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC that includes how the laboratory will identify data associated with ongoing DOCs?				
M5 1.6.3.1	Does the analyst(s) demonstrate ongoing capability by routinely meeting the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
M5 1.6.3.1	If the method has not been performed by the analyst in a twelve (12) month period, is an initial DOC (Section 1.6.2) performed prior to performing analysis?				
M5 1.6.3.1	Does the laboratory document that other approaches to ongoing DOC are adequate?				
M5 1.6.3.2	Does this ongoing demonstration include one of the following, or by performing another initial DOC?				
M5 1.6.3.2	a) Analysis of one (1) sample of 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) Analysis of one (1) positive sample in duplicate for each target organism and test, with results meeting the laboratory acceptance criterion for precision?				
M5 1.6.3.2	c) Acceptable results for a blind proficiency test sample or sample set, as required by the program, for target organisms in each field of accreditation?				
M5 1.6.3.2	d) 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) A documented process of reviewing QC samples performed by an analyst, or groups of analysts, relative to the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard? This review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.6.3.2	f) If a) through e) are not technically feasible, then is analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) performed?				
M5 1.7	**Technical Requirements**				
M5 1.7.1	Calibration				
M5 1.7.1.1	Does the laboratory have documented procedures for calibration, verification, and QC of support equipment including conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments?				
M5 1.7.1.1	Do these procedures refer to applicable reference methods?				
M5 1.7.1.2	For instruments that are continuous monitors, such as in-line specific conductance meters:				
M5 1.7.1.2	a) does the laboratory document acceptable calibration verification at least once a month?				
M5 1.7.1.2	b) is an initial calibration performed if a continuing calibration is unacceptable, or when the instrument is being returned to service after having been taken off-line?				
M5 1.7.2	**Continuing Calibration**				
M5 1.7.2	Reserved for specific procedures.				
M5 1.7.3	**Quality Control**				
M5 1.7.3.1	Quality and Sterility of Standards, Reagents, Materials, and Media				
M5 1.7.3.1	Does the laboratory demonstrate and document that the quality of the reagents and media used is appropriate for the test concerned including, but not limited to, test conditions and incubation times?				
M5 1.7.3.1	a) Sterility Checks				
M5 1.7.3.1	Are all materials and supplies that are needed to process the sample and are required to be sterile prior to use (whether sterilized in the laboratory or purchased as sterilized) checked by the laboratory once per purchased or prepared lot using non-selective growth media as appropriate?				
M5 1.7.3.1	Are certificates of analysis provided by vendors verified by the laboratory and retained in accordance with V1M2 5.6.4.2.a?				
M5 1.7.3.1	Do these checks include, but are not limited to:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.1	i. Sterility check for each lot of prepared, ready-to-use, media and on each batch of media prepared in the laboratory?				
M5 1.7.3.1	a. For chromo/fluorgenic media:				
M5 1.7.3.1	a. addition of media to sterile deionized water and incubation at the appropriate temperature and time?				
M5 1.7.3.1	b. For all other media, incubate is uninocculated at the appropriate temperature and time?				
M5 1.7.3.1	b. Where media are made as concentrates (e.g., double strength), then the medium is diluted to working strength with sterile deionized water before testing?				
M5 1.7.3.1	ii. Sterility check performed on one (1) funnel per lot of pre-sterilized single use funnels using non-selective growth media?				
M5 1.7.3.1	ii. A sterility check performed on one (1) funnel per batch of laboratory-sterilized funnels, using nonselective growth media?				
M5 1.7.3.1	iii. Sterility check performed on at least one (1) container for each lot of purchased, pre-sterilized sample containers with non-selective growth media?				
M5 1.7.3.1	iii. Sterility check performed on one (1) container/object per sterilization batch sterilized in the laboratory with nonselective growth media?				
M5 1.7.3.1	iv. 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 non-selective growth media?				
M5 1.7.3.1	iv. The concentration of the non-selective growth media is single strength after the addition of dilution water?				
M5 1.7.3.1	v. Sterility check performed on at least one (1) filter from each new lot of membrane filters with nonselective growth media?				
M5 1.7.3.1	b) Media				
M5 1.7.3.1	Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use.				
M5 1.7.3.1	i. Is all media tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition)?				
M5 1.7.3.1	i. Are these tests performed at a minimum with first use?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.1	ii. Does the laboratory use all media within the expiration date or shelf-life provided by the manufacturer?				
M5 1.7.3.1	iii. Does the laboratory use all laboratory-prepared media within the holding time limits specified in the accredited method?				
M5 1.7.3.1	iv. Does the laboratory have detailed testing criteria information defined in the laboratory's methods, SOPs, or similar documentation?				
M5 1.7.3.1	c) Do the laboratory use reagents, media and commercial dehydrated powders within the shelf-life of the product, and maintain documentation as per Volume1, Module2 Quality Systems: General Requirements, Section 5.6.4.2?				
M5 1.7.3.1	d) Reagent Water				
M5 1.7.3.1	i. Does the laboratory monitor the quality of the reagent water used in the laboratory, which will come into contact with test organisms and is used in preparation of media, solutions, and buffers, for bactericidal and inhibitory substances?				
M5 1.7.3.1	i. Is this water distilled water, deionized water, or reverse-osmosis-produced water?				
M5 1.7.3.1	ii. Does the laboratory monitor the quality of the water for disinfectant residual, specific conductance, total organic carbon, and heterotrophic bacteria plate count 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?				
M5 1.7.3.1	ii. Analysis may be performed by another certified laboratory.				
M5 1.7.3.1	iii. Does the laboratory monitor the quality of the water for metals (Cd, Cr, Cu, Ni, Pb, and Zn) and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) annually?				
M5 1.7.3.1	iii. An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that:				
M5 1.7.3.1	iii. Can the laboratory supply documentation to show that their water source meets the criteria, as specified by the method, for High Quality (Type I) or Medium Quality (Type II) reagent water?				
M5 1.7.3.1	iii. Analysis may be performed by another certified laboratory.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.1	iv. Do results of the above analyses meet the specifications of the required method?				
M5 1.7.3.1	iv. Dare records of analyses maintained for five (5) years?				
M5 1.7.3.1	v. Does reagent water purchased from an outside source and used for the preparations of media, solutions and buffers meet the criteria specified in items ii) and iii) above?				
M5 1.7.3.1	v. Does the laboratory have documented records of this information?				
M5 1.7.3.1	vi. Is reagent water that has been opened for longer than the testing intervals specified in items i) through iv), or in the accredited method, either re-tested or discarded?				
M5 1.7.3.1	e) Dilution water, however used, includes buffer water and/or peptone water.				
M5 1.7.3.1	e) Does the laboratory monitor the quality of the dilution water for sterility, pH and volume once per lot or batch whether purchased or lab-prepared?				
M5 1.7.3.1	f) Does documentation for media and reagents prepared in the laboratory include date of preparation, preparer's initials, type, manufacturer, lot number, final pH, expiration date, and the amount of reagents used?				
M5 1.7.3.1	f) Does documentation for media purchased pre-prepared, ready-to use (including reagent water purchased from outside sources) include manufacturer, lot number, type of media received, date of receipt, expiration date of the media, and pH of the media?				
M5 1.7.3.1	f) Are records retained by the laboratory in accordance with Volume 1, Module 2, Section 5.4.6.2?				
M5 1.7.3.2	Method Blanks				
M5 1.7.3.2	Does the laboratory demonstrate that the filtration equipment and filters, sample containers, media, and reagents have not been contaminated through improper handling or preparation, or environmental exposure?				
M5 1.7.3.2	a) For filtration technique, does the laboratory conduct method blanks per the analytical method?				
M5 1.7.3.2	a) At a minimum, does the filtration series include a beginning and ending blank?				
M5 1.7.3.2	a) If the filtration series includes single or multiple filtration units, has it been sterilized prior to beginning the series?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.2	b) Is the filtration series considered ended when more than thirty (30) minutes elapses between successive filtrations?				
M5 1.7.3.2	b) During a filtration series, are filter funnels rinsed with three (3) 20- 30 ml portions of sterile rinse water after each sample filtration?				
M5 1.7.3.2	b) In addition, does the laboratory insert a method blank after every ten (10) samples or sanitize filtration units by UV light (254- nm) after sample filtration?				
M5 1.7.3.2	c) For pour plate technique, are method blanks of the medium made by pouring, at a minimum, one (1) uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory?				
M5 1.7.3.3	Test Variability/Reproducibility				
M5 1.7.3.3	For methods that specify counts (i.e. cfu/100mL or MPN/100mL), such as membrane filter, plated media or other methods which specify a quantitative result, are duplicate counts performed monthly on one (1) positive sample for each month that the test is performed?				
M5 1.7.3.3	If the laboratory has two (2) or more analysts, does each analyst count typical results on the same sample?				
M5 1.7.3.3	Are counts within ten percent (10%) difference to be acceptable?				
M5 1.7.3.3	In a laboratory with only one (1) microbiology analyst, is the same sample counted twice by the analyst, with no more than a five percent (5%) difference between the counts?				
M5 1.7.3.4	Sample Specific Controls (where applicable)				
M5 1.7.3.4	a) Does the laboratory perform matrix spikes per method requirements?				
M5 1.7.3.4	b) Does the laboratory perform sample matrix duplicates per method requirements?				
M5 1.7.3.5	Data Reduction				
M5 1.7.3.5	Are the calculations, data reduction and statistical interpretations specified by each method identified and followed?				
M5 1.7.3.6	Selectivity				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.6	a) Are all growth and recovery media checked to assure that the target organism(s) respond in an acceptable and predictable manner once per lot or batch?				
M5 1.7.3.6	b) To ensure that 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 selective medium such as *Brilliant Green Lactose Bile Broth* (BGLB) or *EC* or *EC + MUG* 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 by single-use preparations or cultures maintained for their intended use done by documented procedures that demonstrate the continued purity and viability of the organism?				
M5 1.7.3.6	i. Reference cultures may be revived (if freeze-dried) or transferred from slants and subcultured once to provide reference stocks.				
M5 1.7.3.6	i. Are the reference stocks preserved by a technique that maintains the characteristics of the strains?				
M5 1.7.3.6	i. Are 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 be refrozen and re-used?				
M5 1.7.3.6	ii. Are working stocks not sequentially cultured more than five (5) times and not sub-cultured to replace reference stocks?				
M5 1.7.3.6	d) Culture Controls (i.e. working cultures)				
M5 1.7.3.6	i. Negative Culture Controls				
M5 1.7.3.6	a. 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	b. Is 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 (1) or more known negative culture controls (i.e. non-target organisms), as appropriate to the method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.6	b. Is this done prior to first use of the medium?				
M5 1.7.3.6	ii. Positive Culture Controls				
M5 1.7.3.6	a. 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	b. Is each pre-prepared, ready-to-use lot of medium (including chromo/fluorogenic reagent) and each batch of medium prepared in the laboratory tested with at least one (1) or more known pure positive culture controls (i.e. target organism) as appropriate to the method and that produce typical results based on the method?				
M5 1.7.3.6	b. 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				
M5 1.7.3.7	Are floors and work surfaces non-absorbent and easy to clean and disinfect?				
M5 1.7.3.7	Are work surfaces adequately sealed?				
M5 1.7.3.7	Does the laboratory provide sufficient storage space, and is it clean and free from dust accumulation?				
M5 1.7.3.7	b) Laboratory Equipment				
M5 1.7.3.7	i. Temperature Measuring Devices				
M5 1.7.3.7	Does the laboratory use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum-resistance thermometers to assess and document equipment temperatures?				
M5 1.7.3.7	Is the temperature measuring devices appropriate quality to meet specification(s) in the method?				
M5 1.7.3.7	Is the graduation and range of the temperature measuring devices appropriate for the required accuracy of the measurement?				
M5 1.7.3.7	Is the temperature measuring devices verified to national or international standards for temperature?				
M5 1.7.3.7	Is verification performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	If this verification is accomplished by a single point, does it represent the method mandated temperature and use conditions?				
M5 1.7.3.7	ii. Sterilization Equipment				
M5 1.7.3.7	Autoclaves				
M5 1.7.3.7	1. Does the laboratory evaluate the performance of each autoclave initially by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses?				
M5 1.7.3.7	1. Do autoclaves meet specified temperature tolerances?				
M5 1.7.3.7	1. Are pressure cookers not used for sterilization of growth media?				
M5 1.7.3.7	2. Does the laboratory demonstrate proper sterilization temperature by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle?				
M5 1.7.3.7	2. Does the laboratory, at least once during each month that the autoclave is used, demonstrate the effective sterilization through the use of appropriate biological indicators?				
M5 1.7.3.7	2. Is the selected biological indicator effective at the sterilization temperature and time needed to sterilize lactose-based media?				
M5 1.7.3.7	2. Does the laboratory use temperature-sensitive tape with the contents of each autoclave run to indicate that the autoclave contents have been processed?				
M5 1.7.3.7	3. Does the laboratory maintain records of autoclave operations for every cycle?				
M5 1.7.3.7	3. Do records include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out), and analyst's initials?				
M5 1.7.3.7	4. Is autoclave maintenance, internally or by service contract, performed annually, and include a pressure check and verification of temperature device?				
M5 1.7.3.7	4. Are records of the maintenance maintained in equipment logs?				
M5 1.7.3.7	4. When it has been determined that the autoclave has no leaks, are pressure checks documented using the formula PV = nRT?				
M5 1.7.3.7	5. Does the laboratory check the autoclave mechanical timing device quarterly against a stopwatch and document the actual time elapsed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	b. Ovens				
M5 1.7.3.7	Does the laboratory check ovens used for sterilization for sterilization effectiveness monthly with appropriate biological indicators?				
M5 1.7.3.7	Does the laboratory maintain records for each cycle that include date, cycle time, temperature, contents, and analyst's initials?				
M5 1.7.3.7	Does the laboratory use temperature sensitive tape with the contents of each run to indicate that the contents have been processed?				
M5 1.7.3.7	iii. Volumetric Equipment				
M5 1.7.3.7	Does the laboratory verify equipment used for measuring volume as follows?				
M5 1.7.3.7	a. Equipment with movable parts, such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes, verified for accuracy quarterly?				
M5 1.7.3.7	b. 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?				
M5 1.7.3.7	c. The volume of the disposable volumetric equipment, such as sample bottles and disposable pipettes, checked once per lot?				
M5 1.7.3.7	d. Verification of volume considered acceptable if the accuracy is within 2.5% of expected volume?				
M5 1.7.3.7	d. This verification can be volumetric as compared to Class A or gravimetric.				
M5 1.7.3.7	iv. UV Instruments				
M5 1.7.3.7	Does the laboratory evaluate UV instruments used for sanitization quarterly for effectiveness with an appropriate UV light meter, by plate count, agar spread plates, or other methods providing equivalent results, such as UV-cide strips?				
M5 1.7.3.7	Does the replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99%for a plate containing 200 to 300 organisms?				
M5 1.7.3.7	v. Incubators, Water Baths				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.3.7	a. Does the laboratory establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service?				
M5 1.7.3.7	a. Does the equilibrium check include time required after test sample addition to re-establish equilibrium conditions under full capacity load appropriate for the intended use?				
M5 1.7.3.7	b. During periods when samples are under test, Does the laboratory have a system in place to monitor and document the temperature of incubators and water baths twice daily, at least four (4) hours apart?				
M5 1.7.3.7	b. Is “Under test” defined as the time period that the sample is in the incubation phase of the method?				
M5 1.7.3.7	b. If data loggers, continuous temperature monitoring devices, or other temperature monitoring equipment are used, are they calibrated in accordance with TNI Volume 1, Module 2, Section 5.5.13.1 for Support Equipment?				
M5 1.7.3.7	b. Are records maintained in accordance with Volume 1, Module 2, Section 4.13: Records Maintenance?				
M5 1.7.3.7	Note: There is no intent to take the temperature of incubation units during periods when there are no samples under test.				
M5 1.7.3.7	vi. Labware (Glassware and Plasticware)				
M5 1.7.3.7	a. Does the laboratory have a documented procedure for washing labware, if applicable?				
M5 1.7.3.7	a. Are detergents designed for laboratory used?				
M5 1.7.3.7	b. Is glassware made of borosilicate or other non-corrosive material, free of chips and cracks, and have readable measurement marks?				
M5 1.7.3.7	c. 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 initially and each time the laboratory changes the detergent formulation or washing procedures?				
M5 1.7.3.7	d. Is washed labware tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one (1) piece of labware with a suitable pH indicator such as bromothymol blue?				
M5 1.7.3.7	d. Are records of tests maintained?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M5 1.7.4	Data Acceptance/Rejection Criteria				
M5 1.7.4	Are methods criteria and evaluation methods used?				
M5 1.7.5	Sample Handling				
M5 1.7.5	Receipt of samples must comply with Volume 1, Module 2, Sections 5.8.6 and 5.8.7, as well as:				
M5 1.7.5.1	Receipt of samples must comply with Volume 1, Module 2, Sections 5.8.6 and 5.8.7, as well as:				
M5 1.7.5.1	Are samples that require thermal preservation considered acceptable if the arrival temperature of a representative sample container meets the method or mandated temperature requirement?				
M5 1.7.5.1	Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of this section or the method or the regulatory requirement.				
M5 1.7.5.1	In these cases, are the samples considered acceptable if the samples are received on ice with evidence that the cooling process has begun?				
M5 1.7.5.1	Note: The intent is for the samples to be preserved immediately and analyzed as soon as possible.				
M5 1.7.5.2	Are microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where disinfectant (e.g. chlorine) usage is suspected (such as a new client or a new source), and all potable water supplies (including source water) checked for absence of disinfectant residual in the laboratory unless all of the following conditions are met?				
M5 1.7.5.2	a. The laboratory can show that the received sample containers are from its laboratory or have been appropriately tested and documented?				
M5 1.7.5.2	b. 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?				
M5 1.7.5.2	c. One (1) 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?				
M5 1.7.5.2	d. Disinfectant residual is checked in the field and actual concentration is documented with sample submission?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6	**Volume 1 Module 6**				
M6	**Quality Systems for Radiochemical Testing**				
M6 1.0	**Radiochemical Testing**				
M6 1.2	**Scope**				
M6 1.2	Essential QA and QC requirements for laboratories undertaking the examination of environmental samples by radiochemical analysis are defined in this Standard.				
M6 1.2	Are additional QA and QC requirements (e.g., Measurement Quality Objectives (MQOs)) as indicated in a method, regulation, or contract, or as established in the laboratory's quality system (if there are no established mandatory criteria), met by laboratories?				
M6 1.3.2	Exclusions and Exceptions				
M6 1.3.2	The elements of this module apply to techniques used for the purpose of measuring or monitoring radioactivity, or techniques used to demonstrate compliance with regulations pertaining to radioactivity.				
M6 1.3.2	Does the laboratory comply with the requirements of Volume 1, Module 4 in cases where technique-specific QA/QC is not defined in Module 6 (e.g., Mass Spectrometry [ICP-MS, TIMS] or Kinetic Phosphorimetry) or by the respective reference method (e.g., calibrations, calibration verifications, determinations of detection statistics, or method-specific QCs)?				
M6 1.3.2	Does the laboratory identify in its Quality System how and when it is complying with the requirements and elements of Volume 1, Module 4 and Module 6, as applicable?				
M6 1.4	**Method Selection**				
M6 1.4	Refer to Volume 1, Module 2, Sections 5.4.2, 5.4.3, and 5.4.4.				
M6 1.5	**Method Validation**				
M6 1.5.1	Validation of Methods				
M6 1.5.1	a) Prior to their acceptance and institution, are methods for which data will be reported validated across the range of physical and chemical parameters (e.g., density, Test Source composition, and analytical configurations) and activities that will be encountered in samples. Where applicable, the activity range shall include zero activity?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.1	b) Does the laboratory validate the method in each quality system matrix for which it is applicable by demonstrating the method's detection capability, precision, bias, Measurement Uncertainty, and selectivity using the procedures specified in Sections 1.5.2 through 1.5.5?				
M6 1.5.1	c) Does the laboratory perform validation for each method for which documented data are not available to demonstrate that the above requirements are met?				
M6 1.5.1	c) For reference methods, published data, if available, may be used to satisfy these requirements.				
M6 1.5.1	d) Does the laboratory record the quality system matrix used in the initial method validation and retain all supporting documentation for the initial study in a readily retrievable format for the lifetime of the method?				
M6 1.5.1	e) For all methods, does the validation comply with Volume 1, Module 2, Sections 5.4.5.1 through 5.4.5.3?				
M6 1.5.1	f) Does the laboratory document the results obtained, the procedure used for the validation, and a statement as to whether the method is suitable for the intended use?				
M6 1.5.1	g) Does the laboratory analyze for all methods, whenever available, externally-produced QC samples from a nationally- or internationally-recognized source (i.e., a national metrology institute, accredited TNI Proficiency Test (PT) Provider, an accredited ISO 17043: 2010 PT Provider, an accredited ISO Guide 34: 2006 reference material provider, or from an ANSI N42.22 compliant PT manufacturer)?				
M6 1.5.1	g) Does the laboratory evaluate the results of these analyses to determine its ability to produce acceptable data?				
M6 1.5.1	Note: The use of non-TNI accredited PT Providers is strictly for method validation purposes, and not for laboratory accreditation.				
M6 1.5.2	Detection Capability				
M6 1.5.2	a) Does the laboratory establish the detection capability for each method/matrix combination?				
M6 1.5.2	a) Detection Capability may refer to the Critical Value, MDA, or SDWA DL (terms defined in Section 1.3.1).				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2	b) Does the laboratory document the procedure used to determine the detection capability?				
M6 1.5.2	c) Does the procedure the laboratory uses to determine the detection capability of a method comply with the specific requirements of Volume 1, Module 6, Sections 1.5.2.1 and 1.5.2.2?				
M6 1.5.2	d) Does method validation documentation include identification of software used for detection capability calculations and the software must conform to the requirements in Volume 1, Module 2, Section 5.4.7.2?				
M6 1.5.2.1	Minimal Detectable Activity (MDA) (see definition in Volume 1, Module 6, Section 1.3.1)				
M6 1.5.2.1	Does the laboratory utilize a method that is capable of providing an MDA that is appropriate and relevant for the intended use of the data (see Volume 1, Module 2, Section 4.4)?				
M6 1.5.2.1	Does the laboratory determine MDAs using the protocol specified in mandated methods?				
M6 1.5.2.1	If no protocol is specified, does the laboratory select a procedure that reflects instrument limitations and the intended application of the method?				
M6 1.5.2.1	a) Unless specified otherwise in the mandated method protocols, does the laboratory include all sample-processing steps of the analytical method in the determination of detection capability?				
M6 1.5.2.1	b) Does the laboratory initially determine the detection capability of each method for the analytes of interest in a quality system matrix free of target analytes and interferences at levels that would impact the results?				
M6 1.5.2.1	c) Does the laboratory determine the detection capability each time there is a change in the test method or when there is a change in instrumentation that affects the analytical detection capability?				
M6 1.5.2.2	Required Detection Limit for Drinking Water Compliance (see definition in Section 1.3.1)				
M6 1.5.2.2	Does the laboratory performing radiochemical testing of drinking-water samples for SDWA compliance monitoring meet the requirements of 40 CFR 141.25(c)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.2.2	Does the laboratory use only approved methods that provide sufficient detection capability to meet the detection limit requirements established in 40 CFR 141.25(c)?				
M6 1.5.2.2	Is the detection capability expressed in terms of the DL as defined in Section 1.3.1 instead of Method Detection Limit (MDL) as defined in 40 CFR Part 136, Appendix B?				
M6 1.5.3	Evaluation of Precision and Bias				
M6 1.5.3	Does the laboratory compare results of precision and bias measurements determined during validation with criteria established by method, regulation, or contract, or as established in the laboratory's quality system (if there are no established mandatory criteria)?				
M6 1.5.3	a) Does the laboratory utilize a method that provides precision and bias data for each of the analytes of interest that is appropriate and relevant for the intended use of the data (see Volume 1, Module 2, Section 4.4)?				
M6 1.5.3	a) Is precision and bias characterized across the range of activities that brackets those applicable in samples, including zero activity?				
M6 1.5.3	b) Does the laboratory process the validation samples through the entire measurement system for each analyte of interest and shall evaluate precision and bias in each relevant quality system matrix?				
M6 1.5.3	c) Does the laboratory determine the precision and bias of a method each time there is a change in the test method that affects the performance of the method or when a change in instrumentation occurs that affects the precision and bias?				
M6 1.5.3	d) Where there are no established criteria, does the laboratory develop acceptance criteria for precision and bias based on one or more of the following?				
M6 1.5.3	i. intended use of the data;				
M6 1.5.3	ii. applicable regulations;				
M6 1.5.3	iii. guidelines in publications such as MARLAP, The Forum on Environmental Measurements Validation and Peer Review of U.S. Environmental Protection Agency Radiochemical Methods of Analysis, and/or The Fitness for Purpose of Analytical Methods, A Laboratory Guide to Method Validation and Related Topics?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.4	Measurement Uncertainty				
M6 1.5.4	a) Are all radiochemical measurement results reported with an estimate of Total Uncertainty expressed either as a standard deviation (i.e., a Standard Uncertainty) or a multiple thereof (i.e., an Expanded Uncertainty)?				
M6 1.5.4	i. Is total Uncertainty documented by the laboratory's quality system consistent with the GUM4, the recommendations in the MARLAP Volume II Chapter 19, or other equivalent approaches?				
M6 1.5.4	ii. For purposes of compliance with the SDWA, or in order to comply with specific requirements established by method, regulation, or contract, or as established by the laboratory's quality system (if there are no established mandatory criteria), laboratories may report the Counting Uncertainty in lieu of the Total Uncertainty as specified in the appropriate method, regulation or contract, and as documented in the laboratory's Quality System.				
M6 1.5.4	b) Does the report clearly specify the type of uncertainty reported?				
M6 1.5.4	b) Does the report:				
M6 1.5.4	i. express the uncertainty in the same unit of measurement as the measurement result unless the report clearly states otherwise;				
M6 1.5.4	ii. indicate whether the uncertainty is a Total Uncertainty or Counting Uncertainty;				
M6 1.5.4	iii. indicate whether the uncertainty is the Standard Uncertainty (i.e., "one-sigma") or an Expanded Uncertainty (e.g., "k-sigma"); and				
M6 1.5.4	iv. for Expanded Uncertainties, indicate the coverage factor (k) or the level of confidence?				
M6 1.5.4	c) 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	i. Is the experimentally-observed standard deviation from the initial precision evaluation at any testing level not be statistically greater than the maximum Standard Uncertainty of the measurement results at that level, although it may be somewhat less?				
M6 1.5.4	i. If the experimentally-observed standard deviation at each testing level statistically exceeds the Standard Uncertainty, then the uncertainty estimate should be re-evaluated.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.5.4	ii. A comparison of the experimentally-observed precision evaluation need not be performed for measurements that are required to be reported only with Counting Uncertainty per Section 1.5.4 a) ii).				
M6 1.5.5	Evaluation of Selectivity				
M6 1.5.5	a) Does the laboratory qualitatively evaluate selectivity, if applicable, by addressing the following sample and matrix characteristics:				
M6 1.5.5	i. the effect of matrix composition on the ability of the method to detect analyte;				
M6 1.5.5	ii. the ability of the method to chemically separate the analyte from the interfering analytes; and				
M6 1.5.5	iii. spectral and instrumental interferences?				
M6 1.5.5	b) The evaluation of selectivity may be accomplished by testing matrix blanks, spiked matrix blanks, worst-case samples, or certified reference materials.				
M6 1.5.5	b) If applicable, is a qualitative selectivity statement included in the SOP?				
M6 1.6	**Demonstration of Capability (DOC)**				
M6 1.6.1	General				
M6 1.6.1	a) Does an individual who prepares and/or analyzes samples have constant, close supervision until a satisfactory initial DOC is completed (see Section 1.6.2)?				
M6 1.6.1	b) Thereafter, is an ongoing DOC (Section 1.6.3) required?				
M6 1.6.1	c) In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation, and there have been no significant changes in instrument type or method, is ongoing DOC acceptable as an initial DOC?				
M6 1.6.1	c) Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
M6 1.6.1	d) Are all demonstrations of capability documented?				
M6 1.6.1	d) Is all data applicable to the demonstrations retained and readily available at the laboratory?				
M6 1.6.2	Initial DOC				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.6.2	IS an initial DOC made 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?				
M6 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:				
M6 1.6.2.1	a) analyst(s) involved in preparation and/or analysis;				
M6 1.6.2.1	b) matrix;				
M6 1.6.2.1	c) analyte(s), class of analyte(s), or measured parameter(s);				
M6 1.6.2.1	d) identification of method(s) performed;				
M6 1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number;				
M6 1.6.2.1	f) date(s) of analysis;				
M6 1.6.2.1	g) summary of analyses, including information outlined in Section 1.6.2.2?				
M6 1.6.2.2	If the method, regulation or contract does not specify an initial DOC, the following procedure is acceptable.				
M6 1.6.2.2	Does the laboratory document that other approaches to initial DOC are adequate?				
M6 1.6.2.2	a) Does the laboratory prepare four (4) Test Samples consistent with Section 1.7.2.3?				
M6 1.6.2.2	a) Does the analyst also prepare four (4) blank samples of clean quality system matrix in which no target analytes or interferences are present at activities that will impact the results of a specific method?				
M6 1.6.2.2	b) Where gamma-ray spectrometry is used to identify and quantify more than one analyte, does the Test 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?				
M6 1.6.2.2	b) 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	c) Are the samples prepared and analyzed according to the method?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.6.2.2	d) Using all of the results, does the laboratory calculate the mean recovery of the spiked samples and the mean of the blank results 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	d) When it is not possible to determine means and standard deviation, does the laboratory assess performance against established and documented criteria?				
M6 1.6.2.2	e) Does the laboratory compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy specified by method, regulation, or contract, or as established by the laboratory's quality system (if there are no established mandatory criteria)?				
M6 1.6.2.2	e) If all parameters meet the acceptance criteria, does the analysis of field samples begin?				
M6 1.6.2.2	f) When one or more of the tested parameters fail at least one of the acceptance criteria, does the laboratory repeat the test for the parameters that exceed acceptance criteria?				
M6 1.6.2.2	f) If test results fall outside acceptance criteria again, this confirms there is a general problem with the method and or measurement system.				
M6 1.6.2.2	f) W If this occurs, does the laboratory locate and correct the source of the problem and repeat the test for all parameters of interest?				
M6 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 DOC performed for that analyte?				
M6 1.6.2.2	g) When analytes are added to gamma-ray spectrometry, 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 that includes procedures for how the laboratory will identify data associated with ongoing DOCs?				
M6 1.6.3.1	Does the analyst(s) demonstrate ongoing capability by routinely meeting the QC requirements specified by the method, regulation, or contract, or as established by this Standard and by the laboratory's quality system (if there are no established mandatory criteria)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.6.3.1	If the method has not been performed by the analyst in a twelve (12) month period, is an initial DOC (Section 1.6.2) performed?				
M6 1.6.3.1	Does the laboratory document that other approaches to ongoing DOC are adequate?				
M6 1.6.3.2	Does the on-going demonstration include one of the following:				
M6 1.6.3.2	a) Acceptable performance of blank(s) and sample(s) that have known, accepted values, single blind to the analyst?				
M6 1.6.3.2	b) Another initial DOC?				
M6 1.6.3.2	c) At least four (4) consecutive spiked samples (e.g., batch laboratory control samples) each with levels of precision and accuracy consistent with those specified in the method scope; and four (4) consecutive blank samples, each with activity consistent method performance specified in the method scope (e.g., generally activity less than Critical Value)?				
M6 1.6.3.2	c) Does the laboratory tabulate or is able to readily retrieve four (4) consecutive passing Laboratory Control Samples (LCS) and four (4) consecutive blank samples for each method for each analyst each year?				
M6 1.6.3.2	c) Does the laboratory specify acceptable limits for precision and accuracy prior to analysis?				
M6 1.6.3.2	d) A documented process of reviewing ongoing QC samples by an analyst or a predefined group of analysts relative to the QC requirements specified by the method, regulation, or contract, or as established by this Standard, or by the laboratory's quality system (if there are no established mandatory criteria)?				
M6 1.6.3.2	d) This review should be used to identify patterns for individuals or groups of analysts and identify the need for corrective action or retraining as necessary; or				
M6 1.6.3.2	e) If a) through d) are not technically feasible, then is analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) performed?				
M6 1.7	**Technical Requirements**				
M6 1.7.1	Instrument Set-up, Calibration, Performance Checks, and Background Measurements				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1	At a minimum, the instrument QC program shall incorporate requirements imposed by the method, regulation, contract, or this Standard. Where imposed regulations are more stringent than this Standard, the imposed regulations take precedence (see Volume I, Module 2, Section 5.9.3.c). If it is not apparent which Standard is more stringent, the laboratory shall follow the requirements of the regulation or the method in that order. Where there are no established mandatory requirements, the laboratory shall incorporate guidelines consistent with MARLAP or other consensus standard organizations.				
M6 1.7.1.1	Initial Set-Up of Instrumentation				
M6 1.7.1.1	a) Does the laboratory maintain the required radiation measurement systems for each method it performs? The laboratory shall set up radiation measurement systems to produce consistent, comparable results across multiple detectors used for a common method. The laboratory shall establish the configuration and operating parameters for each radiation measurement system used consistent with the method requirements.				
M6 1.7.1.1	a) Does the laboratory set up radiation measurement systems to produce consistent, comparable results across multiple detectors used for a common method?				
M6 1.7.1.1	a) Does the laboratory establish the configuration and operating parameters for each radiation measurement system used consistent with the method requirements?				
M6 1.7.1.1	b) Does the laboratory document radiation measurement system configuration and maintainable values for hardware- and software-related operational parameters prior to initial calibration?				
M6 1.7.1.1	b) If a specific method or application requires that system configuration or operational parameters deviate from the manufacturer recommended specifications, does the laboratory identify the modifications and document the rationale for such changes?				
M6 1.7.1.1	c) Does the laboratory periodically verify user-maintainable values for operational parameters to ensure their consistency with values recorded at the time of initial calibration to ensure the continued integrity of system configuration?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.1	c) If system configuration or operating parameters have changed, does the laboratory perform corrective actions to determine and ameliorate any potential impact of the changes?				
M6 1.7.1.2	Initial Calibration				
M6 1.7.1.2	This section specifies the essential elements that define the procedures and documentation for initial calibration of radiation measurement systems.				
M6 1.7.1.2	a) Are radiation measurement systems subject to calibration prior to initial use and any time the following conditions occur:				
M6 1.7.1.2	i. following replacement of a key detector element (e.g., a photomultiplier tube, silicon barrier detector, gas proportional detector chamber, germanium crystal, etc.);				
M6 1.7.1.2	ii. after a repair when subsequent performance checks indicate a change in performance;				
M6 1.7.1.2	iii. after modification of system parameters that affect instrument response;				
M6 1.7.1.2	iv. when instrument performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance control chart or other QC parameters) indicating a change in instrument response since the initial calibration;				
M6 1.7.1.2	v. when indicated by corrective actions;				
M6 1.7.1.2	vi. when calibration is due according to a predetermined frequency?				
M6 1.7.1.2	Does the laboratory document the criteria that initiate (re)calibration in its SOPs?				
M6 1.7.1.2	b) Given that the instrument detection efficiency is linear with respect to count rate at all but the highest activity levels (i.e., where detection system dead time becomes significant), calibration curves with standards of varying activity need not be performed for radiometric techniques.				
M6 1.7.1.2	b) Do some techniques require multiple-point calibration curves to correlate a number of parameters other than activity?				
M6 1.7.1.2	b) For example:				
M6 1.7.1.2	i. channel-energy calibration of alpha or gamma spectrometers;				
M6 1.7.1.2	ii. energy-efficiency calibration of gamma spectrometers;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.2	iii. mass-efficiency (mass-attenuation) calibration of gas-flow proportional or x-ray detectors;				
M6 1.7.1.2	iv. quench-efficiency calibration of liquid scintillation detectors;				
M6 1.7.1.2	v. mass-crosstalk calibration of gas-flow proportional; and				
M6 1.7.1.2	vi. quench-crosstalk calibration of liquid scintillation detectors?				
M6 1.7.1.2	c) Does the laboratory base instrument calibrations on physical measurement of reference standards as defined in Section 1.7.2.6.c?				
M6 1.7.1.2	c) Do these standards have general physical characteristics (i.e., geometry, density, composition, nuclear decay properties, etc.) that match as closely as possible those of the samples to which the calibration will be applied, except as noted in Section 1.7.1.2.d?				
M6 1.7.1.2	d) In some cases, calibration standard characteristics do not exactly match sample characteristics.				
M6 1.7.1.2	d) Does the laboratory use empirical techniques (e.g., gamma transmission) and/or computational techniques (e.g., Monte Carlo or efficiency modeling techniques) to generate corrections that are applied to calibrations performed with reference standards to account for minor differences between the physical characteristics of the calibration standard (i.e., geometry, density, coincidence-summing, etc.) and the samples to which the correction is to be applied, if:				
M6 1.7.1.2	i. the laboratory has performed a documented validation of the correction method or model by physical measurement of reference standards as defined in Section 1.7.2.6.c. The validation shall span the entire range of physical characteristics observed in samples to which the correction shall be applied (i.e., geometry, density, etc.);				
M6 1.7.1.2	ii. the applied correction consistently minimizes measurement bias across the range of physical characteristics; and				
M6 1.7.1.2	iii. the laboratory has estimated and validated the uncertainty associated with the correction (see Section 1.5.4) and included it in the uncertainty reported with each associated sample result?				
M6 1.7.1.2	e) The following items are essential elements of initial instrument calibration:				
M6 1.7.1.2	i. Does the laboratory establish and document, in written procedures and in records, the details of the initial instrument calibration?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.2	i. Do details, at minimum, include:				
M6 1.7.1.2	a. the type of calibrations to be performed;				
M6 1.7.1.2	b. the number of calibration points required;				
M6 1.7.1.2	c. a description of the calibration standards required;				
M6 1.7.1.2	d. the preparation of the calibration standards;				
M6 1.7.1.2	d. the preparation of the calibration standards;				
M6 1.7.1.2	e. the counting of the calibration standards;				
M6 1.7.1.2	f. the maximum permissible uncertainty for calibration measurements (e.g., a maximum relative combined uncertainty of the calibration parameter or a minimum number of counts collected); and				
M6 1.7.1.2	g. all calculations?				
M6 1.7.1.2	ii. Does the laboratory establish criteria, appropriate to the calibration technique, for the acceptance of an initial instrument calibration in written procedures?				
M6 1.7.1.2	iii. If the initial instrument calibration results are outside established acceptance criteria, does the laboratory corrective actions?				
M6 1.7.1.2	iv. Does the laboratory retain sufficient raw data records to permit reconstruction of the initial instrument calibration?				
M6 1.7.1.2	f) Does the laboratory quantitate sample results only from the initial instrument calibrations unless otherwise allowed by regulation, method, or contract?				
M6 1.7.1.3	Calibration Verification				
M6 1.7.1.3	a) Prior to use of an initial calibration for analysis of samples, does the laboratory verify the initial instrument calibration with a reference standard as defined in Section 1.7.2.6.c?				
M6 1.7.1.3	a) Does the laboratory obtain the standard from a source or a lot independent of the reference standard used in the initial calibration, if available?				
M6 1.7.1.3	a) Does the calibration verification take wither of the following two (2) forms:				
M6 1.7.1.3	i. performing a second set of calibration measurements to be compared to the initial calibration;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.3	ii. quantifying a set of prepared standards using the initial calibration?				
M6 1.7.1.3	b) Does the laboratory specify the maximum permissible uncertainty for calibration verification measurements (e.g., the minimum number of counts collected for each measurement) in their SOPs?				
M6 1.7.1.3	c) Does the laboratory specify calibration verification acceptance criteria in their SOPs (e.g., for the relative combined uncertainty of the prepared standard recovery)?				
M6 1.7.1.3	c) If the criteria for the calibration verification is not met, does the laboratory perform corrective action?				
M6 1.7.1.4	Instrument Performance Checks				
M6 1.7.1.4	Instrument performance checks measure and track the stability of key detector response-related parameters over time.				
M6 1.7.1.4	The continuing validity of initial calibrations is established by demonstrating the stability of the detection system from the point of initial calibration to the time of the Test Source measurement.				
M6 1.7.1.4	a) Are the following essential elements of instrument performance checks?				
M6 1.7.1.4	i. The check source used for instrument performance checks need not be a reference standard as defined in Section 1.7.2.6.c?				
M6 1.7.1.4	ii. Does the laboratory use the same check source for ongoing performance checks as the one in the preparation of the tolerance or control chart limits at the point of the initial calibration?				
M6 1.7.1.4	iii. Does the laboratory prepare, handle, seal and/or encapsulate check sources to prevent damage, loss of activity and contamination?				
M6 1.7.1.4	iv. Does the laboratory minimize the uncertainty of the check source count to allow detection of small changes in detector response relative to the acceptance criteria?				
M6 1.7.1.4	iv. Is the count duration and check source activity sufficient to provide adequate counting statistics over the life of the source?				
M6 1.7.1.4	v. Where significant, is the radioactive decay in the check source taken into account when evaluating count-rate sensitive parameters such as efficiency?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.4	vi. Does the laboratory monitor the results of instrument performance checks using control or tolerance charts to ensure that instrument performance does not change significantly relative to the point of the initial calibration?				
M6 1.7.1.4	vii. Does the laboratory procedure specify what corrective actions are to be taken when performance check acceptance criteria are not met?				
M6 1.7.1.4	Note: If a performance check result exceeds established limits, instrument performance may have changed since the initial calibration. The laboratory should verify that the change is not attributable to normal statistical variability of the check measurement prior to taking corrective action.				
M6 1.7.1.4	b) Does the laboratory establish the minimum frequency for performance checks for specified calibration parameters as follows?				
M6 1.7.1.4	i. Gamma-ray spectrometry systems				
M6 1.7.1.4	Detection efficiency, energy calibration, and peak resolution:				
M6 1.7.1.4	a. Semiconductor detectors: At least twice weekly, but not on consecutive days, for a continuously operating detector; day of use for a non-continuously operating detector.				
M6 1.7.1.4	b. Scintillation detectors (e.g., sodium iodide): Day of use.				
M6 1.7.1.4	ii. Alpha-particle spectrometry systems				
M6 1.7.1.4	a. Energy calibration: Weekly.				
M6 1.7.1.4	b. Detection efficiency: Monthly.				
M6 1.7.1.4	iii. Gas-proportional and semiconductor alpha/beta detectors				
M6 1.7.1.4	Alpha and beta efficiency: Day of use.				
M6 1.7.1.4	iv. Liquid scintillation detectors				
M6 1.7.1.4	a. Manufacturer system calibration: At the frequency recommended by the manufacturer.				
M6 1.7.1.4	b. Efficiency with unquenched 3H and 14C standards: Day of use.				
M6 1.7.1.4	v. Solid-state scintillation detectors (e.g., zinc sulfide) used for non-spectrometric measurements				
M6 1.7.1.4	Efficiency: Day of use.				
M6 1.7.1.4	c) Are the following exceptions to minimum frequencies for performance checks allowed?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.4	i. An individual Test Source may be uninterruptedly measured for a time longer than the required interval between performance checks to allow completion of the count of a Test Source as long as instrument performance checks performed at the beginning and end of the measurement period meet all applicable acceptance criteria?				
M6 1.7.1.4	ii. Test Sources may be uninterruptedly measured for a time longer than the required interval between performance checks to allow for completion of a Preparation Batch or RMB (Section 1.3.1) measured on an instrument with an automated sample changer (e.g., a liquid scintillation or gas proportional counter), as long as the period between the checks does not exceed seven (7) calendar days, and checks are done at the beginning and end of the measurement in question and meet all applicable acceptance criteria?				
M6 1.7.1.4	d) If the detection system is powered off between performance checks, is a new performance check performed prior to the next Test Source measurement?				
M6 1.7.1.5	Subtraction Background Measurements				
M6 1.7.1.5	Subtraction background measurements are performed to assess and correct for contributions due to cosmic radiation, naturally-occurring radioactivity, electronic noise, impurities in the detector, shielding, and source mounting material, or other sources that are not affected by the analytical processes.				
M6 1.7.1.5	Are contributions from impurities in the reagents, reference standards, or other sources introduced during the analytical processes assessed with the use of method blanks (Section 1.7.2.2)?				
M6 1.7.1.5	Numerous counting configurations may be used to determine subtraction background, depending on the detector and the method, including: counting an empty detector; counting an empty container or blank Test Source in a detector; or counting a container filled with a surrogate matrix material free of measurable levels of radioactivity.				
M6 1.7.1.5	a) Is the subtraction background specific to each detector and appropriate to the method?				
M6 1.7.1.5	b) Is the subtraction background counting time at least as long as the longest associated sample counting time and ensure a representative determination of the background rate?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.5	c) Is the subtraction background measurement accomplished in one of the following ways:?				
M6 1.7.1.5	i. Paired measurements in which the subtraction background measurement is counted before or after the Test Source measurement or batch of Test Source measurements?				
M6 1.7.1.5	ii. Measurements performed at a fixed frequency, in which Test Sources may be measured between successive background subtraction measurements?				
M6 1.7.1.5	ii. In this case, does the laboratory perform background subtraction measurements at the following minimum frequencies?				
M6 1.7.1.5	a. Gamma-ray spectrometry systems: Monthly.				
M6 1.7.1.5	b. Alpha-particle spectrometry systems: Monthly.				
M6 1.7.1.5	c. Gas-proportional and semiconductor alpha/beta detectors: Quarterly.				
M6 1.7.1.5	d. Liquid scintillation detectors.				
M6 1.7.1.5	• Individual quenched background: Once per Preparation Batch.				
M6 1.7.1.5	• Quenched background curve: According to frequency specified in laboratory procedures.				
M6 1.7.1.5	e. Solid-state scintillation detectors (e.g., zinc sulfide) used for non-spectrometric measurements: Day of use.				
M6 1.7.1.5	Note: The frequency of subtraction background measurements may be increased from the above requirements when there is a low tolerance for unacceptable data due to failure of a subtraction background measurement.				
M6 1.7.1.5	iii. Composite measurements, in which the subtraction background is determined by combining background measurements collected in a manner that results in a representative determination of the background with a combined counting time at least as long as the longest associated Test Source count time?(See also Section 1.7.2.2.f))				
M6 1.7.1.5	d) Does the laboratory have written procedures for performing and evaluating subtraction background measurements?				
M6 1.7.1.5	d) Do these procedures:				
M6 1.7.1.5	i. indicate the frequency and length of subtraction background measurements;				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.5	ii. establish control or tolerance charts and acceptance criteria of subtraction background measurements;				
M6 1.7.1.5	iii. ensure that the subtraction background measurement counts or count rate of a detector or an analytical region of interest is monitored for significant changes that introduce bias significant enough that could compromise the use of these measurements?				
M6 1.7.1.5	e) When the subtraction background has changed since the previous determination such that significant bias is imparted to intervening Test Source measurements, does the laboratory initiate a corrective action?				
M6 1.7.1.5	e) If the bias cannot be resolved, does the laboratory qualify affected results?				
M6 1.7.1.6	Short-Term Background Checks				
M6 1.7.1.6	Short-term background checks, performed between subtraction background measurements, are QC measures used to verify the integrity of subtraction background measurements, check for possible detector contamination, electronics noise and to monitor each detector for trends and deviations from Poisson statistics. These background checks may be shorter in duration, yet more frequent than the subtraction background measurements, and therefore they may not always effectively identify every discrepancy that could compromise Test Source measurements (e.g., lowlevel contamination).				
M6 1.7.1.6	a) Does the laboratory have written procedures for performing and evaluating short-term background checks?				
M6 1.7.1.6	a) Do these procedures:				
M6 1.7.1.6	i. Indicate the frequency and length of checks?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.6	Note: Short-term background checks are performed after a predetermined number of samples, after a hot sample, or at a predetermined frequency. The frequency for the checks should be based on an evaluation of the laboratory instrument system and an acceptable rate for unacceptable data should short-term background check result fails. The frequency of these checks may be decreased if the laboratory is able to document that doing so does not result in an unacceptable rate of lost data. Conversely, the frequency should be increased when there is a high probability of the checks failing or there is a low tolerance for lost data due to failure of short-term background check.				
M6 1.7.1.6	ii. Establish control or tolerance charts and acceptance criteria of short-term background checks?				
M6 1.7.1.6	iii. Ensure that the short-term background counts or count rate of a detector or an analytical region of interest is monitored for significant changes that would indicate background bias significant enough that could compromise Test Source results?				
M6 1.7.1.6	b) Exceptions to minimum frequencies for short-term background checks:				
M6 1.7.1.6	i. Is an individual Test Source uninterruptedly measured for a time longer than the required interval between short-term background checks to allow completion of the count of a Test Source as long as short-term background checks performed at the beginning and end of the measurement period meet all applicable acceptance criteria?				
M6 1.7.1.6	ii. Are Test Sources uninterruptedly measured for a time longer than the required interval between short-term background checks to allow for completion of a Preparation Batch or RMB measured on an instrument with an automated sample changer (e.g., a liquid scintillation or gas proportional counter), as long as the period between the checks does not exceed seven (7) calendar days and the checks are done at the beginning and end of the measurement period and meet all applicable acceptance criteria?				
M6 1.7.1.6	c) When short-term background has changed since the previous determination, such that significant background bias is imparted to intervening Test Source measurements, does the laboratory initiate a corrective action?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.1.6	c) If the bias cannot be resolved, does the laboratory qualify affected results?				
M6 1.7.1.6	d) If subtraction background measurements are performed with sufficient frequency for a given method or detector type, such that they ensure background integrity and are capable of identifying detector contamination, are the subtraction background measurements may be substituted for short-term background checks, in which case the short-term background checks are not required?				
M6 1.7.1.6	e) For liquid scintillation detectors, does the laboratory check short-term unquenched background each day of use?				
M6 1.7.1.7	Contamination Monitoring				
M6 1.7.1.7	The laboratory shall have written procedures that address cases where radiation detectors have been contaminated, as determined by the subtraction background measurements, short-term background checks, or method blanks (Section 1.7.2.3). Detectors may not be brought back into service until corrective actions are completed.				
M6 1.7.2	Quality Control for Radiochemistry				
M6 1.7.2.1	General				
M6 1.7.2.1	a) Does the laboratory follow a documented QC program that monitors and assesses the performance of the laboratory's analytical systems?				
M6 1.7.2.1	a) At a minimum, does the QC program incorporate requirements imposed by regulation, methods and this Standard?				
M6 1.7.2.1	a) Where imposed regulations are more stringent than this Standard, do the imposed regulations take precedence (see Module 2, Section 5.9.3.c)?				
M6 1.7.2.1	a) If it is not apparent which requirement is more stringent, does the laboratory follow the requirements of the regulation or the mandated method?				
M6 1.7.2.1	a) Where there are no established requirements, does the laboratory reference guidelines consistent with MARLAP or other consensus standard organizations in its quality system?				
M6 1.7.2.1	b) Does the laboratory process batch and sample-specific QCs to provide empirical evidence that demonstrates that the analytical system is in control?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.1	b) Results for these controls may be used to assess the data quality of sample results produced by the analytical system.				
M6 1.7.2.1	c) Does the laboratory employ either a sample Preparation Batch or an RMB to determine the grouping of samples and assignment of batch QC?				
M6 1.7.2.1	i. Is a sample Preparation Batch initiated where sample testing is performed that involves physical or chemical processing which affects the outcome of the test?				
M6 1.7.2.1	i. Are samples and associated QC assigned to a Preparation Batch prepared together using the same processes, personnel, and lot(s) of reagents?				
M6 1.7.2.1	ii. Where testing is performed that does not involve physical or chemical processing which affects the outcome of the test (e.g., non-destructive gamma spectrometry, alpha/beta counting of air filters, or swipes on gas proportional detectors), an RMB may be initiated in lieu of a Preparation Batch.				
M6 1.7.2.1	ii. Do the samples and associated QC in the RMB share similar physical and chemical parameters, and analytical configurations (e.g., analytes, geometry, calibration, and background correction)?				
M6 1.7.2.1	iii. Samples may be added to the RMB for fourteen (14) calendar days from the start of the first sample count, or until twenty (20) environmental samples have been counted, whichever occurs first.				
M6 1.7.2.1	iv. The laboratory may combine samples and associated QC within an RMB that share a range of physical and chemical parameters, and analytical configurations (e.g., analytes, geometry, calibration, density) that conform to the ranges of physical and chemical parameters, and analytical configurations demonstrated by method validation studies (see Section 1.5).				
M6 1.7.2.1	iv. Do laboratory procedures document how method validation is performed, and laboratory records shall document any corrections (e.g., for efficiency, density, cascade summing, and background) applied to physical calibrations?				
M6 1.7.2.1	d) Does the laboratory's QC program document the frequency required for QCs?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.1	d) Are minimum QC requirements as specified below?				
M6 1.7.2.1	e) Does the laboratory process all batch QC samples together with and under the same conditions as the associated samples, and use the same processes and procedures for preparation, analysis, data reduction and reporting of results?				
M6 1.7.2.1	Note: Although samples in a Preparation Batch must be prepared together, they need not be analyzed concurrently on a single detection system, rather they may be analyzed on different detection systems as long as the detection systems are calibrated for the technique in question and instrument QCs indicate that the systems are in control.				
M6 1.7.2.1	f) Does the laboratory not systematically or preferentially use specific detectors, equipment or glassware for the analysis of QC samples?				
M6 1.7.2.1	f) If the laboratory segregates detectors, equipment, or glassware to minimize the risk of cross-contamination of samples or equipment, does the criteria for segregation apply equally to batch QC samples and samples?				
M6 1.7.2.1	g) Does the laboratory's QC program document acceptance criteria for batch QC samples, sample-specific QCs, and for the evaluation of long-term trends and the methods used to establish these criteria?				
M6 1.7.2.1	h) Does the laboratory assess the results of the QC samples against acceptance criteria documented in the QC program?				
M6 1.7.2.1	h) Where there are no established criteria in regulations, the method, or contract, does the laboratory develop its acceptance criteria consistent with guidelines in MARLAP or other consensus standards, or other criteria such as statistical control charts developed by the laboratory?				
M6 1.7.2.1	i) Does the laboratory track and trend the results of batch QC samples using statistical or tolerance control charts?				
M6 1.7.2.1	j) Does the laboratory investigate the cause when results do not meet acceptance criteria and take corrective actions to eliminate the source or minimize the magnitude of the problem?				
M6 1.7.2.1	j) Does the laboratory consider samples associated with a failed QC parameter as suspect and shall, wherever possible, reprocess such samples?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.1	j) Where reprocessing is not possible, does the laboratory report results with appropriate data qualifiers?				
M6 1.7.2.1	j) Does the laboratory note the occurrence of a failed QC sample and any associated actions in the laboratory report?				
M6 1.7.2.2	Negative Control – Method Performance: Method Blank (MB)				
M6 1.7.2.2	The MB assesses the process of handling, preparation and analysis for cross-contamination and for low-level analytical bias. For methods with minimal physical treatment or no chemical processing (e.g., drying, grinding and homogenization of solid samples, or preparation of sample Test Sources for swipe or air filter samples for non-destructive gamma spectrometry or alpha-beta counting), the MB assesses sample handling and the analytical process.				
M6 1.7.2.2	a) Does the laboratory analyze a method blank at a minimum of one (1) per Preparation Batch or RMB?				
M6 1.7.2.2	b) Does the MB sample Test Source simulate quality system matrix characteristics that significantly affect results, such as geometry, size, and other factors, as appropriate?				
M6 1.7.2.2	i. Does the laboratory prepare the MB using materials that are free of analytes of interest at levels that will interfere with the evaluation of the results?				
M6 1.7.2.2	i. If an analyte-free matrix is not available, does the laboratory use a surrogate matrix to simulate the quality system matrix?				
M6 1.7.2.2	ii. Is the sample aliquot used for the MB similar to that of routine samples?				
M6 1.7.2.2	ii. If the sample aliquot in a Preparation Batch varies (e.g., due to differences in sample density or restrictions on the activity or mass residue that may be processed), does the laboratory use acceptance criteria that compensate for differing aliquot sizes (e.g., z-score per MARLAP, Vol. III, Chapter 18, Section 18.4.1)?				
M6 1.7.2.2	c) Does the laboratory have procedures in place to determine if a MB result is significantly different from zero or impacts the analytical results? For example:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.2	i. The MB exceeds the pre-established upper or lower bounds for the measurement, where the upper and lower bounds are plus x times the Standard Uncertainty and negative y times the Standard Uncertainty and x and y are the coverage factors for the confidence interval as established by the laboratory's quality system. The upper and lower bounds are not necessarily symmetrical?				
M6 1.7.2.2	ii. When applicable, the sample-specific MDA for the MB is greater than the required MDA?				
M6 1.7.2.2	d) Are corrective actions taken if it is determined that a MB result is significantly different from zero and associated sample results are less than five (5) times the MB activity, or if a MB result may impact the analytical results?				
M6 1.7.2.2	e) Does the laboratory evaluate results of MBs for long term trends, absolute bias, possible contamination, or interferences that may affect sample results?				
M6 1.7.2.2	f) Does the laboratory not subtract the batch MB from sample results in the associated Preparation Batch or RMB?				
M6 1.7.2.2	f) The laboratory may subtract the average historical activity of MB measurements to address a demonstrated bias.				
M6 1.7.2.2	f) Does the laboratory account for the uncertainty of the subtracted value in its estimate of uncertainty for the final result?				
M6 1.7.2.3	Positive Control – Method Performance: Laboratory Control Sample (LCS)				
M6 1.7.2.3	The LCS is used to evaluate the performance of the analytical system, including all preparation and analysis steps. For methods with minimal physical treatment and no chemical processing (e.g., drying, grinding and homogenization of solid samples, or preparation of sample Test Sources for swipe or air filter samples for non-destructive gamma spectrometry or alpha-beta counting), the LCS assesses the analytical process for bias.				
M6 1.7.2.3	a) Does the laboratory analyze a LCS at a minimum of one (1) per Preparation Batch or RMB?				
M6 1.7.2.3	a) For RMBs, a calibration verification standard may be analyzed in lieu of the LCS.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	b) Does the LCS Test Source simulate quality system matrix characteristics that significantly affect results, such as geometry, size or other factors?				
M6 1.7.2.3	i. Is the material used to create the LCS free of analytes of interest at levels that will interfere with the evaluation of the results?				
M6 1.7.2.3	i. If an analyte-free matrix is not available, does the laboratory use a surrogate matrix to simulate the sample matrix?				
M6 1.7.2.3	i. If analyte-free materials are not available for the LCS, are the materials characterized and documented for the analyte(s) of concern and accounted for in the evaluation of the LCS?				
M6 1.7.2.3	ii. Is the aliquot used for the LCS similar to that of routine samples?				
M6 1.7.2.3	ii. If the aliquot in a Preparation Batch varies (e.g., due to restrictions on the activity or mass residue that may be processed), does the laboratory use acceptance criteria for samples that compensate for differing aliquot sizes (e.g., z-score per MARLAP, Vol. III, Chapter 18, Section 18.4.3)?				
M6 1.7.2.3	c) For methods with minimal physical treatment and no chemical processing, does the laboratory prepare the LCS a single time and reuse the standard with subsequent batches of samples?				
M6 1.7.2.3	d) Does the laboratory spike the LCS at a level such that the uncertainty of the analytical result is less than one-third (1/3) of the acceptance criteria?				
M6 1.7.2.3	d) For example, if it is required that the LCS result be within +/- 30% of the known value, the laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than or equal to 10%.				
M6 1.7.2.3	d) When practical, is the LCS spiked at a level comparable to the action level if known; or that of routine samples if the activities are expected to exceed ten (10) times the Decision Level (Critical Value)?				
M6 1.7.2.3	e) When available, does the standard used to prepare the LCS meet the requirements for reference standards provided in Section 1.7.2.6.c?				
M6 1.7.2.3	e) The final prepared LCS need not be traceable to a national standard organization.				
M6 1.7.2.3	e) Does the LCS include all of the radionuclide(s) being determined with the following exceptions?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.3	i. For methods that measure gross activity (e.g., gross alpha, gross beta), is an appropriate surrogate analyte used? This will generally be the radionuclide(s) used to calibrate the detector.				
M6 1.7.2.3	i. For methods that measure gross activity (e.g., gross alpha, gross beta), is an appropriate surrogate analyte used? This will generally be the radionuclide(s) used to calibrate the detector.				
M6 1.7.2.3	ii. For alpha spectrometry measurements, when multiple individual radionuclides with similar chemical characteristics are determined simultaneously with a single measurement and calibration, only one of the analytes/isotopes needs to be included in the LCS at the activity level indicated in Section 1.7.2.3.d)?				
M6 1.7.2.3	iii. Where a non-destructive gamma-ray spectrometry measurement is made using a multipoint energy/efficiency calibration curve which covers the energy range of the analyte(s) of interest:				
M6 1.7.2.3	a. is a radionuclide with similar gamma energies as those of the analyte(s) of interest used (e.g., 133Ba may be used in place of 131I); or				
M6 1.7.2.3	b. does the LCS contain gamma-emitting radionuclides that, at a minimum, represent the low (e.g., 241Am) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra? Commonly a medium energy radionuclide is also included in the LCS (e.g., 137Cs). As indicated by these examples, the nuclides need not exactly bracket the calibration energy range or the range over which radionuclides are identified and quantified.				
M6 1.7.2.3	f) Does the laboratory evaluate results of the batch LCS using a statistical technique such as the percent recovery or z-score that allows comparison to acceptance criteria documented in the laboratory QC program?				
M6 1.7.2.3	g) Where more than one (1) analyte is spiked at a level that meets the LCS requirements (see Section 1.7.2.3.d above), is each assessed against the specified acceptance criteria?				
M6 1.7.2.4	Sample-Specific QC Measures				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.4	Does the laboratory document procedures for determining the effect of the sample matrix on the analytical results?				
M6 1.7.2.4	Do these procedures relate to the analyses of specific QC samples and designed as data quality indicators for a specific sample using the designated method?				
M6 1.7.2.4	Examples of sample-specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD), Matrix Duplicate (MD), Tracers, and Carriers.				
M6 1.7.2.4	Does the laboratory have procedures in place for tracking, managing, and handling sample-specific QC criteria including spiking radionuclides at appropriate activities, calculating recoveries, determining variability (e.g., relative percent difference and/or z-score), and evaluating and reporting results based on the performance of the QC samples?				
M6 1.7.2.4	a) Matrix Spike				
M6 1.7.2.4	i. MS recoveries are an indication of effects of the matrix on sample result accuracy using the selected method. The MS results are employed by the data user to determine if an MS issue has any impact on their related batch samples. MSs are not typically employed for non-destructive methods (e.g., gamma spectrometry or direct counting of samples for alpha or beta radioactivity), or for methods that employ a chemical yield tracer or carrier for each sample.				
M6 1.7.2.4	ii. Is the frequency of the analysis of MSs specified by the method, a regulation or determined as part of the contract review process?				
M6 1.7.2.4	iii. Are the radionuclides spiked as specified by the mandated method, regulation or as determined as part of the contract review process?				
M6 1.7.2.4	iii. At minimum, are they consistent with those specified for the LCS in Sections 1.7.2.3.e and 1.7.2.3.f?				
M6 1.7.2.4	iv. Is the quantity of the aliquot used for MS similar to that of routine samples analyzed in the Preparation Batch?				
M6 1.7.2.4	iv. If the sample size in the Preparation Batch varies (e.g., due to restriction on the activity or mass residue that may be processed), does the laboratory apply appropriate corrections to compensate for differing aliquot sizes when applying the acceptance criteria for the batch?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.4	v. When an MS is required, is the lack of sufficient sample aliquot to perform an MS noted in the laboratory report?				
M6 1.7.2.4	vi. Is the activity of the MS analyte(s) greater than five (5) times the MDA?				
M6 1.7.2.4	vii. Are acceptance criteria for MS recoveries established as specified by the method, regulation or contract?				
M6 1.7.2.4	vii. Where there are no mandatory acceptance criteria established in the method, regulation or contract, does the laboratory develop acceptance criteria based on industry practices and guidelines, or consistent with the guidelines of MARLAP or other consensus standards?				
M6 1.7.2.4	vii. Are these criteria documented or referenced in the laboratory's quality manual?				
M6 1.7.2.4	viii. When available, does the standard used to prepare the MS meet the requirements for reference standard provided in Section 1.7.2.6.c?				
M6 1.7.2.4	viii. The final prepared MS need not be traceable to a national standards organization.				
M6 1.7.2.4	ix. Is the MS prepared by adding a known activity of target analyte prior to performing any processes that affect the analyte of interest (e.g., chemical digestion, dissolution, ashing, separation, etc.)?				
M6 1.7.2.4	b) Matrix Duplicates/Matrix Spike Duplicates/LCS Duplicates				
M6 1.7.2.4	i. A duplicate is defined as a second aliquot of the same sample taken through the entire analytical procedure. The results of this analysis provide indications of the measurement precision of the analyte for the specific sample using the selected method. Duplicate analyses provide a measure of precision when the target analyte is present in the sample chosen for duplication.				
M6 1.7.2.4	ii. Is acceptance criteria for duplicates established as specified by the method, regulation or contract?				
M6 1.7.2.4	ii. Where there are no mandatory acceptance criteria established in the method, regulation or contract, does the laboratory develop acceptance criteria based on industry practices and guidelines, such as control charting developed by the laboratory, or consistent with the guidelines of MARLAP or other consensus standards?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.4	ii. Are these criteria documented or referenced in the laboratory's quality manual?				
M6 1.7.2.4	iii. At a minimum, does the laboratory analyze one (1) MD per Preparation Batch or RMB?				
M6 1.7.2.4	iii. For RMBs, is the MD consist of a second measurement of one sample?				
M6 1.7.2.4	iii. If the batch is counted on more than one (1) detector, is the MD performed on a second detector?				
M6 1.7.2.4	iv. When samples have low-levels of activity (less than approximately three (3) times the MDA) the laboratory, at its discretion, may analyze MS/MSD to determine reproducibility within a Preparation Batch in place of a MD.				
M6 1.7.2.4	v. Based on specific project or program requirements or when there is insufficient sample available, does the laboratory choose to analyze a LCS in duplicate in place of a MD?				
M6 1.7.2.4	v. Does the LCS and its duplicate provide a measure of analytical precision?				
M6 1.7.2.4	v. However, they will not provide information on matrix effects.				
M6 1.7.2.4	c) Chemical Yield Tracers and Carriers				
M6 1.7.2.4	i. For those methods that employ a radioactive Tracer or a stable Carrier as a chemical yield monitor in the analysis, does each sample have an associated chemical yield calculated and reported?				
M6 1.7.2.4	i. Is the chemical yield one of the QC measures to be used to assess the associated sample result acceptance?				
M6 1.7.2.4	ii. Does the selection of a Tracer or Carrier not significantly interfere with the analyte(s) of interest nor cause bias in its measurements?				
M6 1.7.2.4	ii. When such a Tracer or Carrier is unavailable, is the interference or bias caused quantifiable and appropriate correction applied to the sample results?				
M6 1.7.2.4	iii. Is the Tracer or Carrier used to monitor chemical yield added to the sample prior to performing any processes that affect the analyte of interest (e.g., chemical digestion, dissolution, ashing, separation, etc.) unless otherwise specified by the method?				
M6 1.7.2.4	iv. Is the chemical yield assessed against acceptance criteria specified in the method, regulation, contract or laboratory SOP?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.4	iv. Does the laboratory develop its criteria for data acceptance based on guidelines established in the MARLAP or other criteria such as control charting developed by the laboratory?				
M6 1.7.2.4	iv. Does this assessment meet established project or program MQOs (Section 1.3.1)?				
M6 1.7.2.4	v. When the established chemical yield acceptance criteria are not met, is the specified corrective action and contingencies followed?				
M6 1.7.2.4	v. Is the occurrence of a failed chemical yield and the actions taken noted in the laboratory report?				
M6 1.7.2.5	Data Reduction				
M6 1.7.2.5	a) Are the procedures for data reduction documented?				
M6 1.7.2.5	b) Is detection capability (e.g., MDA or Critical Level) calculated as described in Section 1.5.2?				
M6 1.7.2.5	c) Are measurement uncertainties calculated and reported as described in Section 1.5.4?				
M6 1.7.2.6	Reagent Quality, Water Quality, and Checks				
M6 1.7.2.6	a) In methods where the purity of reagents is not specified, are reagents analytical reagent grade or better?				
M6 1.7.2.6	a) Are reagents of lesser purity than those specified by the method not used?				
M6 1.7.2.6	b) Is quality of water sources monitored and documented and meet method specified requirements?				
M6 1.7.2.6	c) Does the QC program establish and maintain provisions for radionuclide standards?				
M6 1.7.2.6	i. Are reference standards obtained from a national metrology institute (NMI), e.g. NIST in the USA or NPL in Great Britain, or from suppliers of NMI reference standards?				
M6 1.7.2.6	i. Alternatively, are reference standards obtained from an ISO Guide 34:2009 accredited reference material provider, or an ANSI N42.22 reference material manufacturer?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.6	ii. Are reference standards accompanied with a certificate of calibration that meets the requirements of either ISO Guide 31:2000, or ANSI N42.22, Section 8, Certificates, and include at least the following information: manufacturer, radionuclides calibrated, identification number, calibration method, activities or emission rates with associated uncertainties and the confidence limits, standard quantity, activity reference time (date or time as appropriate to the half-life of the radionuclide), physical and/or chemical description of the source, and radionuclide impurities?				
M6 1.7.2.6	iii. Are standards prepared or derived from externally-obtained reference materials verified against an independent standard obtained from a second manufacturer prior to use for analysis of samples?				
M6 1.7.2.6	iii. The use of a standard from a second lot obtained from the same manufacturer is acceptable for use as a second source standard.				
M6 1.7.2.6	iii. Are discrepancies between observed and expected values investigated and appropriate measures taken that document the validity of standards prior to use?				
M6 1.7.2.6	iv. Does the laboratory account for radioactive decay/ingrowth whenever decay/ingrowth has occurred between the Activity Reference Date and use that could impact use of the results?				
M6 1.7.2.6	v. Does the laboratory have written procedures for handling, storing, and establishing expiration dates for reference standards?				
M6 1.7.2.6	vi. If there is no known provider of a particular standard (e.g., non-routine radionuclide or non-standard matrix) that is traceable to the International System of Units (SI), the laboratory may have no alternative but to use a standard with less rigorously established traceability.				
M6 1.7.2.6	vi. In this event, does the laboratory obtain from the provider the minimum information described in Section 1.7.2.6.c.ii?				
M6 1.7.2.6	vi. Does the laboratory independently verify the activity of such standards prior to use and document the verification?				
M6 1.7.2.6	vii. If the laboratory's verification indicates a significant deviation from the original information from the provider, is the standard not be used unless the discrepancy can be resolved?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.2.6	vii. If the standard is used for analysis of sample unknowns, is the source and any other known limitations of the standard disclosed in the final report?				
M6 1.7.2.7	Constant and Consistent Test Conditions				
M6 1.7.2.7	a) Does the laboratory assure that test instruments consistently operate within the specifications required of the application for which the equipment is used, according to Section 1.7.1?				
M6 1.7.2.7	b) Is labware cleaned to meet the sensitivity requirements of the method?				
M6 1.7.2.7	b) Are any cleaning and storage procedures that are not specified by the method documented in the laboratory's quality system and records?				
M6 1.7.2.7	b) Note that some applications may require single-use glassware.				
M6 1.7.2.7	c) Does the laboratory maintain a radiological control program that addresses analytical radiological control?				
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 to identify and minimize 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 1.7.3	Data Evaluation and Reporting				
M6 1.7.3.1	Negative Control – Method Performance: Method Blank (MB)				
M6 1.7.3.1	a) Are MB results evaluated for long term trends, absolute bias, possible contamination or interferences that may affect results for samples in the batch?				
M6 1.7.3.1	b) MB acceptance criteria are discussed in Section 1.7.2.2 above.				
M6 1.7.3.1	b) If acceptance limits are not met, are corrective actions taken to investigate the source of contamination or other bias?				
M6 1.7.3.1	b) If sample activity levels are greater than five times the activity found in the MB, lacking other requirements, it is acceptable to report qualified results for the samples associated with the blank. Otherwise, reprocessing and reanalysis of the associated samples shall be required.				
M6 1.7.3.1	b) Otherwise, does the laboratory reprocess and reanalyze the associated samples?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.3.1	c) When sample results associated with a failed MB are reported, is the failure and associated corrective actions, or inability to complete corrective actions, noted in the laboratory report?				
M6 1.7.3.2	Positive Control – Method Performance: Laboratory Control Sample (LCS)				
M6 1.7.3.2	a) LCS recoveries shall be evaluated to assess the performance of the entire analytical system independent of the sample matrix. LCS results shall be calculated in percent recovery or other appropriate statistical measure that allows comparison to established acceptance criteria. The laboratory shall document the calculation.				
M6 1.7.3.2	b) LCS acceptance criteria are discussed in Section 1.7.2.3 above.				
M6 1.7.3.2	b) An LCS that is determined to be within established acceptance limits effectively demonstrates that the analytical system is in control and validates system performance for the samples in the associated batch.				
M6 1.7.3.2	b) Are samples associated with an LCS that fails to meet acceptance limits considered suspect and reprocessed and reanalyzed?				
M6 1.7.3.2	b) A If samples cannot be reprocessed and reanalyzed, is the failure and associated corrective actions or inability to complete corrective actions noted in the laboratory report?				
M6 1.7.3.3	Sample-Specific Controls				
M6 1.7.3.3	a) Matrix Spike, Matrix Duplicates, and Matrix Spike Duplicates				
M6 1.7.3.3	i. MSs and MDs allow evaluation of the effect of matrix on the accuracy and precision of results.				
M6 1.7.3.3	i. Are results from MSs calculated as percent recovery or other appropriate statistical measure that allows comparison to established acceptance criteria?				
M6 1.7.3.3	i. Are results from MD and MSD precision calculated as relative percent difference, zRep (see MARLAP, Vol. III, Chapter 18, Section 18.4.2), or other appropriate statistical measure that allows comparison to established acceptance criteria?				
M6 1.7.3.3	i. Does the laboratory document the calculation of QC results?				
M6 1.7.3.3	ii. Acceptance criteria are discussed in Section 1.7.2.4 above.				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.3.3	ii. For results outside established criteria, is corrective action documented and the data reported with appropriate data qualifying codes?				
M6 1.7.3.3	ii. Are QC results outside acceptance limits noted in the laboratory report?				
M6 1.7.3.3	b) Tracers and Carriers				
M6 1.7.3.3	i. For those methods that employ radioactive Tracers or stable Carriers as chemical yield monitors in each sample, are results expressed as percent yield or other appropriate statistical measure that allows comparison to established acceptance criteria?				
M6 1.7.3.3	ii. For alpha spectrometry, does evaluation of Tracer acceptability include evaluation of chemical yield (e.g., uncertainty, variability) and peak resolution?				
M6 1.7.3.3	iii. Acceptance criteria are discussed in Section 1.7.2.4 above.				
M6 1.7.3.3	iii. Are samples associated with Tracers or Carriers that fail to meet acceptance limits considered suspect, and reprocessed and/or reanalyzed?				
M6 1.7.3.3	iii. If samples cannot be reprocessed and/or reanalyzed, is the failure and associated corrective actions or inability to complete corrective actions noted in the laboratory report?				
M6 1.7.3.4	Evaluation of Sample Results				
M6 1.7.3.4	a) Is instrument raw data from energy spectral analysis evaluated to ensure that the target radionuclides are quantified consistent with laboratory procedures and applicable MQOs, and that target radionuclides in the spectra are evaluated for possible interferences?				
M6 1.7.3.4	b) Are results reviewed for internal consistency, such as the presence of radionuclides consistent with known parent-progeny relationships and expected or likely decay series?				
M6 1.7.3.4	c) Are sample-specific estimates of uncertainty and MDA evaluated to ensure that MQOs have been met?				
M6 1.7.3.4	d) If these objectives have not been met, then are samples reprocessed and/or reanalyzed?				
M6 1.7.3.4	d) If samples cannot be reprocessed and/or reanalyzed, is the failure and associated corrective actions, or inability to complete corrective actions, noted in the laboratory report?				
M6 1.7.3.5	Reporting Results				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M6 1.7.3.5	a) Are reports delivered to the laboratory's client consistent with the requirements of this Standard (Volume 1, Module 2, Section 5.10)?				
M6 1.7.3.5	b) Following evaluation according to Section 1.7.3.4, are results reported directly as obtained, with appropriate units, even if the results are negative?				
M6 1.7.3.5	c) Are results expressed with an appropriate number of significant figures?				
M6 1.7.3.5	d) Are all radiochemical results reported with an estimate of uncertainty, as discussed in Section 1.5.4?				
M6 1.7.3.5	e) Does the laboratory report the Activity Reference Date in association with all radiochemical measurement results?				
M6 1.7.3.5	f) Project- or client-specified reporting requirements can take precedence over the requirements of this Standard.				
M6 1.7.4	Sample Handling				
M6 1.7.4.1	While it may not be possible to physically verify all methods of preservation (e.g., addition of oxidizing or reducing agents), wherever practicable does the laboratory verify that samples have been preserved in compliance with all applicable requirements specified by regulation, method, or contract, or as established in the laboratory's quality system (if there are no established mandatory criteria)?				
M6 1.7.4.2	Does the laboratory document the required timing, methods for performing measurements to verify preservation, the acceptance range, or any other conditions indicating acceptable preservation?				
M6 1.7.4.2	a) Where thermal preservation of samples is required, does the laboratory verify the temperature of samples upon receipt?				
M6 1.7.4.2	b) Where chemical preservation of samples is required, does the laboratory verify that samples have been preserved using readily available techniques such as pH measurement prior to sample preparation or analysis?				
M6 1.7.4.3	If the results of the preservation verification do not satisfy established criteria, does the laboratory initiate corrective actions (i.e., notification of the client, preservation of the sample at the time of discovery), and qualify all impacted test results in the report to the client?				
M7	**Volume 1 Module 7**				
M7	**Quality Systems for Toxicity Testing**				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.0	**Toxicity Testing**				
M7 1.2	**Scope**				
M7 1.2	Are the essential quality control procedures applicable to toxicity measurements are included in this Standard. Additional quality control requirements that are specified by method, regulation or project met by laboratories?				
M7 1.4	**Method Selection**				
M7 1.4	When it is necessary to use testing methods not covered by an approved method, are these subject to agreement with the data user and include a clear specification of the data user's requirements and the purpose of the environmental test?				
M7 1.4	Is the method developed validated appropriately before use?				
M7 1.4	Are the characteristics of validated methods (e.g., the uncertainty of the results, 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 users' needs?				
M7 1.5	**Method Validation**				
M7 1.5	Validation is the confirmation by examination and the objective evidence that the particular requirements for a specific intended use are fulfilled.				
M7 1.6	**Demonstration of Capability (DOC)**				
M7 1.6.1	General				
M7 1.6.1	Prior to acceptance and institution of any method for data reporting, is satisfactory initial DOC required (see Section 1.6.2)?				
M7 1.6.1	Thereafter, is ongoing DOC (Section 1.6.3), as per the quality control (QC) requirements in Section 1.7.1.2 required?				
M7 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 personnel or method, is the ongoing DOC 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.6.1	For the initial DOC, are appropriate records as discussed in Section 1.6.2.1 completed?				
M7 1.6.1	Is an initial DOC completed each time there is a change in personnel, or method?				
M7 1.6.1	In general, this demonstration does not test the performance of the method in real world samples.				
M7 1.6.1	However, before any results are reported, is the initial DOC performed?				
M7 1.6.1	An initial DOC may be completed by a group of analysts and is for situations in which several individuals perform part of a set of activities that would produce a testing result.				
M7 1.6.1	Are all demonstrations documented?				
M7 1.6.1	Is 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 made prior to using any method, and at any time there is a significant change in 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 available for each affected employee:				
M7 1.6.2.1	a) analyst(s) involved in preparation and/or analysis;				
M7 1.6.2.1	b) matrix;				
M7 1.6.2.1	c) species and endpoint(s);				
M7 1.6.2.1	d) identification of method(s) performed;				
M7 1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number;				
M7 1.6.2.1	f) date(s) of analysis;				
M7 1.6.2.1	g) summary of analyses, including information outlined in Section 1.6.2.2?				
M7 1.6.2.2	If the method or regulation does not specify an initial DOC, the following procedure is acceptable.				
M7 1.6.2.2	Does the laboratory document that other approaches to initial DOC are adequate?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.6.2.2	Does each analyst meet the QC 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 QC requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
M7 1.6.3	Does the laboratory document that other approaches to on-going DOC are adequate?				
M7 1.6.3	This on-going 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 DOC.				
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 QC procedures for monitoring the validity of environmental tests undertaken?				
M7 1.7.1	Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results?				
M7 1.7.1	Is this monitoring planned and reviewed and include, but not be limited to, the following:				
M7 1.7.1	a) regular use of certified reference materials and/or internal QC using secondary reference materials;				
M7 1.7.1	b) participation in inter-laboratory comparison or proficiency-testing program;				
M7 1.7.1	c) replicate tests using the same or different methods;				
M7 1.7.1	d) retesting of retained samples; and				
M7 1.7.1	e) correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.1	Essential Quality Control Procedures				
M7 1.7.1.1	Do these general QC principles apply, where applicable, to all testing laboratories?				
M7 1.7.1.1	The manner in which they are implemented is dependent on the types of tests performed by the laboratory and are further described in this module.				
M7 1.7.1.1	Do the standards for any given test type assure 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 QCs?				
M7 1.7.1.1	i. Are positive and negative controls used to monitor tests such as blanks, spikes, reference toxicants?				
M7 1.7.1.1	ii. Do tests define the variability and/or repeatability of the laboratory results such as replicates?				
M7 1.7.1.1	iii. Are there measures evaluate method capability, such as percent minimum significant difference (PMSD)?				
M7 1.7.1.1	iv. Does the selection of appropriate formula reduce raw data to final results such as regression and statistical analyses?				
M7 1.7.1.1	v. Is the selection and use of reagents and standards of appropriate quality?				
M7 1.7.1.1	vi. Are there measures to assure the selectivity of the test for its intended purpose?				
M7 1.7.1.1	vii. Are there 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 QC measures assessed and evaluated on an ongoing basis, and QC 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 QC 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.1	d) When it is not apparent which is more stringent, is the QC in the regulations followed?				
M7 1.7.1.2	Positive and Negative Controls				
M7 1.7.1.2	a) Positive Control. Reference toxicant tests 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. Is ongoing laboratory performance demonstrated by performing routine SRT testing for each method, species and endpoint in accordance with the minimum frequency requirements specified in Section 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	For methods conducted at a frequency of monthly or greater, are SRT tests conducted monthly?				
M7 1.7.1.2	For methods and species commonly used in the laboratory, but which are tested at a frequency of less than monthly, are SRT tests conducted concurrently with the environmental test?				
M7 1.7.1.2	If the test organisms are obtained from an outside source, is 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	Is supplied SRT data not be older than six (6) months?				
M7 1.7.1.2	iv. These standards do not currently specify a particular reference toxicant and dilution series.				
M7 1.7.1.2	iv. However, 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 use 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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 followed?				
M7 1.7.1.2	i. Is a 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 intra-laboratory precision determined on an ongoing basis through the use of further reference toxicant tests and related control charts as described above?				
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) 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 as 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) Do 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				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	a) If closed refrigerator-sized incubators are used, are culturing and testing of organisms separated to avoid cross-contamination?				
M7 1.7.1.6	b) Is laboratory 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?				
M7 1.7.1.6	b) Dis 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) Are the taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) kept on file at the laboratory?				
M7 1.7.1.6	d) When organisms are obtained from an outside source does the supplier provide this same information?				
M7 1.7.1.6	e) Is 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 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) Where electronic data loggers are used, is the temperature monitored at a frequency sufficient to capture temporal variations of the environmental control system?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	g) Does reagent grade water, prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration, meet 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) Is 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, can be identified?				
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) Is 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 test chamber size and test solution volume as specified in the method?				
M7 1.7.1.6	k) Are all test chambers used in a test identical?				
M7 1.7.1.6	l) Are test organisms fed the quantity and type food or nutrients specified in the method?				
M7 1.7.1.6	l) Are they also be 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?				
M7 1.7.1.6	m) Where available, are certified seeds used for soil tests?				
M7 1.7.1.6	n) Do all organisms used in tests, or used as broodstock to produce neonate test organisms (for example cladocerans and larval fish), appear healthy, show no signs of stress or disease and exhibit acceptable survival (90% or greater) during the twenty-four (24) hour period immediately preceding use in tests?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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 not reduce or add to sample toxicity? A				
M7 1.7.1.6	o) Are appropriate materials for use in toxicity testing and culturing described in the methods?				
M7 1.7.1.6	p) Is light intensity maintained as specified in the methods?				
M7 1.7.1.6	p) Are measurements made and recorded on a yearly basis?				
M7 1.7.1.6	p) Is photoperiod 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?				
M7 1.7.1.6	q) Is the health and culturing conditions of all organisms used for testing documented by the testing laboratory?				
M7 1.7.1.6	q) Does such 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 these observations 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 also record each of these observations and water quality parameters upon the arrival of the organisms at the testing laboratory?				
M7 1.7.1.6	r) Are age and the age range 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 exceed thirty-six (36) hours?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.1.6	s) Are samples allowed to 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 control population 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) Are dissolved oxygen and pH in aquatic tests within acceptable range at test initiation?				
M7 1.7.1.6	w) Is minimal aeration provided to tests if acceptable dissolved oxygen concentrations cannot be otherwise maintained?				
M7 1.7.1.6	x) Are test soils or sediments within the geochemical tolerance range of the test organism?				
M7 1.7.1.6	y) Are individual test 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) and the acceptability of the test depends 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 also 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)?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
M7 1.7.2.1	For endpoints from hypothesis tests (NOEC, NOAEC) are the values are plotted directly, and do 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 the cumulative is mean CV calculated?				
M7 1.7.2.1	For endpoints from hypothesis tests, is the PMSD calculated?				
M7 1.7.2.1	Are these values maintained on control charts?				
M7 1.7.2.1	Control chart limits are expected to be exceeded occasionally regardless of how well a laboratory performs. Acceptance limits for point estimates (ICp, ECp) that are based on 95% confidence limits should theoretically be exceeded for one in twenty tests. Depending on the dilution factor and test sensitivity, control charts based on hypothesis test values (NOEC, NOAEC) may be expected to be exceeded on a similar frequency. 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 defacto.				
M7 1.7.2.1	Are such data 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	Has the laboratory developed 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 fail 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 intra-laboratory precision determined on an ongoing basis through the use of control charts?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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	Is 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	Is the criteria calculated and 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 methods of data analysis and reporting as specified by language in the regulation, permit, or the method followed as required?				
M7 1.7.2.3	b) Is 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?				
SOP-3	**SOP-3 Accreditation Symbol Procedure**				
SOP-3	**For applicant laboratories:**				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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?				
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:				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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)?				
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?				

Section Reference	Question	Compliant?			Comments
		Yes	No	NA	
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?				
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?				