THIS CHECKLIST IS ONLY A TOOL, NOT THE REQUIREMENTS OF THE 2009 NELAC STANDARDS! IF THERE IS A DISAGREEMENT BETWEEN THIS CHECKLIST AND THE STANDARDS, ISO/IEC 17025:2005 and DoD QSM 5.1 SHALL PREVAIL.	
THE DoD-QSM REV 5.1 IS USED AS THE STANDARD FOR DoD ELAP REQUIREMENTS.	
Organization Name:	
Address (Mailing):	
Address:	
(Physical Location):	
Telephone:	
Fax:	
E-mail:	
Web Address:	
Assessment Location (If different):	
Assessment Date:	
Assessment Organization:	
Assessors(s):	
(Signatures):	
Receipt acknowledgment by Laboratory:	

Section Reference	Question	Yes	No	NA	Comments
	Volume 1 Module 1				
	Proficiency Testing				
2	**Requirements for Accreditation (DoD Only)**				
2.1	Initial Accreditation Requirements				
2.1.1	Does the laboratory analyze at least two Proficiency Testing (PT) samples for each combination of analyte-matrix-method (e.g., Trichloroethylene (TCE)-water-Method 624, TCE-water-Method 8260, TCE-soil-Method 8260, lead-soil-6010, or lead-soil-6020) that corresponds to their scope of accreditation?				
2.1.1	Note: Laboratories that combine multiple methods into one Standard Operating Procedure (SOP) (e.g., SOP that combines Method 624 volatiles & Method 8260 volatiles) can report those methods with a single PT sample. All other analyte-matrix-method combinations require unique PT samples.				
2.1.2	Are PT samples used for initial accreditation obtained from PT providers that are accredited under (ISO) 17043 (General Requirements for Proficiency Testing) from an (ILAC) approved signatory Accreditation Body?				
2.1.2	Does the laboratory obtain PT samples from the Mixed Analyte Performance Evaluation Program (MAPEP)? Note: MAPEP is required for all laboratories that possess a radioactive materials license for analysis of radiological samples. MAPEP PT samples for analyte suites that do not contain radioactive materials can be accepted by laboratories without a radioactive materials license.				
2.1.3	For PT samples that were not obtained by an ISO 17043 accredited PT provider, does the laboratory have special permission to use the non-ISO 17043 provider from PJLA using for LF-123?				
2.1.4	Does the laboratory submit in writing, to PJLA HQ, when PT samples for an analyte-matrix-method combination cannot be obtained from any PT provider and the analyte-matrix-method combination is required for a scope of accreditation?				
2.1.5	Are the PT samples analyzed by the laboratory for initial DoD ELAP accreditation no more than twelve (12) months old?				

Section Reference	Question	Yes	No	NA	Comments
2.1.5	If 2 or more successive PT samples are performed, is the analysis date between PT samples at least 15 calendar days apart?				
2.1.5	Note: The fifteen (15) calendar day requirement does not apply to the MAPEP program. Laboratories that participate in the MAPEP program shall follow the MAPEP program requirements				
2.1.6	Is the success or failure of the analyte-matrix-method combination determined by the PT provider under the requirements of the governing body or ISO 17043 statistically derived program?				
2.1.7	Are PT samples evaluated in the same was as regular environmental samples?				
2.1.7	Does the laboratory employ the same QC, sequence of analytical steps, and replicates as when analyzing routine analytical samples?				
2.2	**Continuing Accreditation Requirements**				
2.2.1	Has the laboratory successfully analyze at least two PT samples per calendar year for each analyte-matrix-method combination on their scope of accreditation?				
2.2.1	Is each PT sample analyzed approximately six (6) months apart (i.e., any time frame from four (4) to eight (8) months apart is considered acceptable) if two PT samples are analyzed?				
	Note: Failure to meet the semiannual schedule is regarded as a failed study.				
2.2.1	Is the Whole Effluent Toxicity (WET), proficiency testing (PT)study performed at least once per year?				
2.2.2	Is the laboratory rated proficient for the associated field of testing/Method on their accredited scope? **i.e. Does the laboratory maintain a history of at least 2 successful PT rounds out of the most recent 3 attempts?**				
2.2.2	If PT samples are required for corrective action to reestablish history of successful PT rounds, is the analysis dates of successive corrective action PT samples at least fifteen (15) calendar days apart?				
	Note: The fifteen (15) calendar day requirement does not apply to the MAPEP program. Laboratories that participate in the MAPEP program shall follow the MAPEP program requirements.				

Section Reference	Question	Yes	No	NA	Comments
2.2.3	Note: Analyte-matrix-method combinations that do not meet the above criteria must be removed from the DoD ELAP scope of accreditation.				
	Volume 1 Module 2				
	Quality Systems (QS)				
4	**Organization**				
4.1.1	Does the laboratory or the organization of which it is part, an entity that can be held legally responsible?				
4.1.2	Does the laboratory uphold its responsibility to carry out its testing and/or calibration activities in such a way as to meet the requirements of this standard?				
4.1.2	Does the laboratory carry out its testing and/or calibration activities in such a way as to meet the requirements of the customer, the regulatory authorities or organizations providing recognition?				
4.1.3	Does the laboratory management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, and/or in its associated temporary or mobile facilities?				
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 defined in order to identify potential conflicts of interest?				
	Note: 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.				
	Note: 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.				

Section Reference	Question	Yes	No	NA	Comments
4.1.5.	a. Does the laboratory managerial and technical personnel have the authority and resources needed to perform their duties?				
4.1.5.	a. Does the laboratory managerial and technical personnel have the authority and resources needed to identify departures from the management system or from the procedures for performing tests and/or calibrations?				
4.1.5.	a. Does the laboratory managerial and technical personnel have the authority and resources needed to initiate actions to prevent or minimize such departures?				
4.1.5.	a. Does the laboratory managerial and technical personnel have the authority and resources needed to implement, maintain and improve the management system irrespective of other responsibilities?				
4.1.5.	b. Does the laboratory have arrangements to ensure that its management & personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work?				
4.1.5.	c. Does the laboratory have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?				
4.1.5.	d. Does the laboratory avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?				
4.1.5.	e. Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management technical operations and support services?				
4.1.5.	f. Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations?				
4.1.5.	g. Does the laboratory provide adequate supervision of testing and/or calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each environmental test, and with the assessment of the results?				

Section Reference	Question	Yes	No	NA	Comments
4.1.5.	h. Does the laboratory have technical management, which has overall responsibility for the technical operations and the provision of the resources needed, ensure the required quality of laboratory operations?				
4.1.5.	i. Does the laboratory appoint a member of staff as quality manager (however named)?				
4.1.5.	i. Does the quality manager (however named) have defined responsibility and authority for ensuring that the management system is implemented and followed at all times?				
4.1.5.	i. Does the quality manager (however named) have direct access to the highest level of management at which decisions are made on laboratory policy or resources?				
4.1.5.	j. Does the laboratory appoint deputies for key managerial personnel including the technical director(s) and/or quality manager?				
4.1.5.	j) At a minimum, is the following laboratory management staff (however named) considered key managerial personnel: i) Management (e.g., President, Chief Executive Officer, Chief Operating Officer, Laboratory Director)? ii) Technical managers (e.g., Technical Director, Section Supervisors)? iii) Quality managers;? iv) Support systems and administrative managers (e.g., LIMS manager, purchasing manager, project managers)? v) Customer services managers?				
4.1.5.	k. Does the laboratory ensure that personnel are aware of the relevance and importance of their activities and how they contribute to overall management system goals?				
4.1.6	Does top management ensure that communication processes are established and that communication regarding the effectiveness of the management system takes place?				
4.1.7.1.	a. Does the laboratory's quality manager and/or his/her designee(s) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data?				

Section Reference	Question	Yes	No	NA	Comments
4.1.7.1.	b. Does the laboratory's quality a manger and/or his/her designee(s) have functions independent from laboratory operations for which they have quality assurance oversight?				
4.1.7.1.	c. Are the laboratory's quality manager and/or his/her designee(s) able to evaluate data objectively and perform assessments without outside (e.g. Managerial) influence?				
4.1.7.1.	d. Does the laboratory's quality manager and/or his/her designee(s) have documented training and/or experience in QA/QC procedures and the laboratory's quality system?				
4.1.7.1.	e. Does the laboratory's quality manager and/or his/her designee(s) have a general knowledge of the analytical methods for which data review is performed?				
4.1.7.1.	f. Does the laboratory's quality manager and/or his/her designee(s) arrange for or conduct internal audits as per Section 4.14 annually?				
4.1.7.1.	g. Does the laboratory's quality manager and/or his/her designee(s) notify laboratory management of deficiencies in the quality system?				
4.1.7.1.	h. Does the laboratory's quality manager and/or his/her designee(s) monitor corrective actions?				
4.1.7.1.	NOTE: Where staffing is limited, the quality manager may also be the technical manager.				
4.1.7.1.	i. Does the laboratory's quality manager and/or his/her designee(s) implement, maintain, and improve the management system by using available tools such as audit and surveillance results, control charts, proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends?				
4.1.7.2.	a. Is the laboratory's technical manager(s) and/or his/her designee(s) 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?				

Section Reference	Question	Yes	No	NA	Comments
4.1.7.2.	b. Is the laboratory's technical manager(s) and/or his/her designee(s) experienced in the fields of accreditation for which the laboratory is seeking accreditation?				
4.1.7.2.	c. Does the laboratory's technical manager(s) and/or his/her designee(s) have duties that include monitoring standards of performance in quality control and quality assurance and monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data?				
4.1.7.2.	d. If the technical manager is the technical manager of more than one accreditation environmental laboratory, does the technical manager have authorization from the primary AB?				
4.1.7.2.	e. If the technical manager is absent for a period of time exceeding fifteen (15) consecutive calendar days does the laboratory designated another full-time staff member meeting the qualifications of the technical manager(s) to temporarily perform this function?				
4.1.7.2.	e. If the technical manager has been absent for a period of time exceeding thirty-five (35) consecutive calendar days, is the primary accreditation body notified in writing?				
4.1.7.2.	f. Does the technical manager meet the requirements as specified in Section 5.2.6.1 of TNI EL-V1M2-2009?				
4.2	**Management System**				
4.2.1	Has the laboratory established, implemented, & maintained a management system appropriate to the scope of its activates?				
4.2.1	Are copies of all management system documentation provided to DoD ELAP Accreditation Bodies, , or to personnel on behalf of DoD provided for review in English?				
4.2.2	Are the laboratory's quality system policy and objectives defined in a quality manual (however named)?				
4.2.2	Are the overall objectives documented in a quality policy statement, issued under the authority of the chief executive?				

Section Reference	Question	Yes	No	NA	Comments
4.2.2.	a. Does the quality policy include the laboratory management's commitment to good professional practice and to the quality of its environmental testing in servicing its clients? Note: The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing and/or calibration services.				
4.2.2.	b. Does the quality policy include the management's statement of the laboratory's standard of service?				
4.2.2.	c. Does the quality policy include the objectives of the quality system?				
4.2.2.	d. Does the quality policy include a requirement that all personnel concerned with environmental testing activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work?				
4.2.2.	e. Does the quality policy include the laboratory management's commitment to compliance with this Standard?				
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.				
4.2.3	Does top management provided evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?				
4.2.3	a. Does top management define the minimum qualifications, experience, and skills necessary for all positions in the laboratory?				
4.2.3	b. Does top management ensured that all laboratory technical staff have demonstrated capability in the activities for which they are responsible and have it recorded?				

Section Reference	Question	Yes	No	NA	Comments
4.2.3	c. Does top management ensure the training of each member of the technical staff is kept up-to-date (on-going) by ensuring the following: i) Each employee training file must contain a certification that the employee has read, understands, and is using the latest version of the management system records relating to his/her job responsibilities? ii) Recorded training courses or workshops on specific equipment, analytical techniques, or laboratory procedures? iii) Is the Review of analyst work by relevant technical managers on an on-going basis recorded or is there another annual Demonstration of Capability performed by one of the following: a. Acceptable performance of a blind sample (single or double blind to the analyst)? b. At least four consecutive laboratory control samples with acceptable levels of precision and bias. The laboratory must determine the acceptable levels of precision and bias prior to analysis? c. If the above cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst?				
4.2.3	d. Is top management responsible for recording all analytical and operational activities of the laboratory?				
4.2.3	e. Is top management responsible for ensuring adequate supervision of all personnel employed by the laboratory?				
4.2.3	f. Is top management responsible for ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored?				
4.2.3	g. Is top management responsible for ensuring the recording of the quality of all data reported by the laboratory?				
4.2.4	Does top management communicated to the organization the importance of meeting customer, statutory and regulatory requirements?				

Section Reference	Question	Yes	No	NA	Comments
4.2.5	Does the quality manual include or make reference to supporting and technical procedures and does it outline the structure of the documentation used in the management system?				
4.2.6	Does the quality manual define the roles and responsibilities of the technical and quality managers, including the roles which ensure compliance with this standard?				
4.2.7	Does Top Management ensured that the integrity of the management system is maintained when changes are planned and implemented?				
4.2.8.1	Does the laboratory's data integrity system include the following four required elements:				
4.2.8.1	data integrity training?				
4.2.8.1	signed data integrity documentation for all laboratory employees?				
4.2.8.1	in-depth, periodic monitoring of data integrity?				
4.2.8.1	data integrity procedure documentation?				
4.2.8.1	Has the laboratory established and maintained a documented data integrity system?				
4.2.8.1	Are the data integrity procedures signed and dated by top management?				
4.2.8.1	Are the requirements for data integrity investigation as defined inSection 4.16 TNI EL-V1M2-2009 listed?				
4.2.8.1	Does management annually review data integrity procedures and update as needed				
4.2.8.1	a. Does the laboratory have a procedure for confidential reporting of data integrity issues in their laboratory?				
4.2.8.1	a. Does the procedure assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern?				
4.2.8.1	b. Where there is ethical concern, does the procedure include a process whereby laboratory management is to be informed of the need for any further detailed investigation?				
4.2.8.1	c. Does the laboratory have a documented program to detect and deter improper or unethical actions?				

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

Section Reference	Question	Yes	No	NA	Comments
4.2.8.3.	g. the objectives of the quality system and contain or reference the laboratory's policies and procedures?				
4.2.8.3.	h. does the laboratory's official quality policy statement include quality system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard?				
4.2.8.3.	i. a table of contents, and applicable lists of references, glossaries and appendices?				
4.2.8.4	Does the quality manual contain or reference (a thru y):				
4.2.8.4	a) All maintenance, calibration and verification procedures used by the laboratory in conducting tests?				
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?				
4.2.8.4	c) Verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes?				
4.2.8.4	d) Procedures for reporting analytical results?				
4.2.8.4	e) The organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts?				
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?				
4.2.8.4	g) job descriptions of key staff and reference to the job descriptions of other laboratory staff?				
4.2.8.4	h) procedures for achieving traceability of measurements?				
4.2.8.4	i) a list of all methods under which the laboratory performs its accredited testing?				

Section Reference	Question	Yes	No	NA	Comments
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?				
4.2.8.4	k) procedures for handling samples?				
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?				
4.2.8.4	m) policy for permitting departures from documented policies and procedures or from standard specifications?				
4.2.8.4	n) procedures for dealing with complaints?				
4.2.8.4	o) procedures for protecting confidentiality (including national security concerns, and proprietary rights)?				
4.2.8.4	p) procedures for audits and data review?				
4.2.8.4	p) Do the procedures for audits and data reviews specify which records must be included in the review?				
4.2.8.4	p) Do internal data reviews consist of a tiered or sequential system of verification, consisting of at least three tiers, 100% review by the analyst, 100% verification review by a technically qualified supervisor or data review specialist, and a final administrative review?				
4.2.8.4	p) Does the analyst and verification review include at least the following procedures (i thru viii):				
4.2.8.4	p) i) Determination of whether the results meet the laboratory-specific quality control criteria?				
4.2.8.4	p) ii) Checks to determine consistency with project-specific measurement performance criteria MPCs if available?				
4.2.8.4	p) iii) Checks to ensure that the appropriate sample preparatory and analytical SOPs and methods were followed, and that chain-of-custody and holding time requirements were met?				
4.2.8.4	p) iv) Checks to ensure that all calibration and quality control requirements were met?				

Section Reference	Question	Yes	No	NA	Comments
4.2.8.4	p) v) Checks for complete and accurate explanations of anomalous results, corrections, and the use of data qualifiers in the case narrative?				
4.2.8.4	p) Does the final administrative review verify that previous reviews were recorded properly and that the data package is complete?				
4.2.8.4	p) In addition, does the quality manager or designee review a minimum of 10% of all data packages for technical completeness and accuracy on a quarterly basis?				
4.2.8.4	p) Is the quality manager or designee review considered a part of overall data review and does not need to be completed before the data package is issued to the customer?				
4.2.8.4	p) If data quality issues are discovered during the review,is the client notified within 15 business days of the discovery of the issue?				
4.2.8.4	p) If electronic audit trail functions are available, are they in use at all times, and associated data accessible?				
4.2.8.4	p) If the instrument does not have an audit trail, does the laboratory have procedures to record the integrity of the data?				
4.2.8.4	p) Are Initial and annual ethics training conducted as described in Section 5.2.7?				
4.2.8.4	p) Do the analysts record an explanation an dsign off on all manual changes to datat?				
4.2.8.4	Where availabel is the instrument software, all eeltronic tracking and audit functions enabled?				
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?				
4.2.8.4	r) policy addressing the use of unique electronic signatures, where applicable?				
4.2.8.4	s) procedures for procurement of standards?				
4.2.8.4	t) procedures for data management including validation, verification, and purging of electronic data and data systems?				

Section Reference	Question	Yes	No	NA	Comments
4.2.8.4	u) procedures for manual entry of raw data from analytical measurements that are not interfaced to LIMS and the verification and records of the accuracy of manually entered data?				
4.2.8.4	v) procedures for making changes to electronic data (including establishing the requirements for a hardcopy or electronic log to record all changes to electronic data that affect data quality)?				
4.2.8.4	w) procedures for how electronic data are processed, maintained, and reported?				
4.2.8.4	x) procedures for ensuring that data review includes all quality-related steps in the analytical process, including sample preparation, dilution calculations, chromatography evaluation, and spectral interpretations?				
4.2.8.4	x) Does the SOP for data review require that records of the review be maintained and available for external review?				
4.2.8.4	y) Does it include a list of all current certifications and accreditations that the laboratory holds and the scope of certification or accreditation (with expiration date) for each?				
4.2.8.5	a) Does the laboratories maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods?				
4.2.8.5	a) Do these documents include adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result?				
4.2.8.5	Note: for example, documents may be equipment manuals provided by the manufacturer, or internally written documents.				
4.2.8.5	b) Are the relevant SOPs readily accessible to all personnel?				
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?				
4.2.8.5	d) If the documents contain sufficient information to perform the tests, is it supplemented or rewritten as an internal procedures to document any changes, including the use of a selected option?				

Section Reference	Question	Yes	No	NA	Comments
4.2.8.5	d) Does the laboratory's method records include the documents that contain sufficient information to perform the tests without any changes or supplements?				
4.2.8.5	e) Does the laboratory have and maintain an SOP for each accredited analyte or method?				
4.2.8.5	f) Is the SOP copy of a published or referenced method and/or written by the laboratory?				
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?				
4.2.8.5	f) Does each method include or reference the following topics where applicable (I thru xxvi):				
4.2.8.5	f) i. Identification of the method?				
4.2.8.5	f) ii. Applicable matrix or matrices?				
4.2.8.5	f) iii. Limits of detection and quantitation?				
4.2.8.5	f) iv. Scope and application, including parameters to be analyzed?				
4.2.8.5	f) v. Summary of the method?				
4.2.8.5	f) vi. Definitions?				
4.2.8.5	f) vii. Interferences?				
4.2.8.5	f) viii. Safety?				
4.2.8.5	f) ix. Equipment and supplies?				
4.2.8.5	f) x. Reagents and standards?				
4.2.8.5	f) xi. Sample collection, preservation, shipment and storage?				
4.2.8.5	f) xii. Quality control?				
4.2.8.5	f) xiii. Calibration and standardization?				
4.2.8.5	f) xiv. Procedure?				
4.2.8.5	f) xv. Data analysis and calculations?				
4.2.8.5	f) xvi. Method performance?				
4.2.8.5	f) xvii. Pollution prevention?				

Section Reference	Question	Yes	No	NA	Comments
4.2.8.5	f) xviii. Data assessment and acceptance criteria for quality control measures?				
4.2.8.5	f) xix. Corrective actions for out-of-control data?				
4.2.8.5	f) xx. Contingencies for handling out-of-control or unacceptable data?				
4.2.8.5	f) xxi. Waste management?				
4.2.8.5	f) xxii. References?				
4.2.8.5	f) xxiii. Any tables, diagrams, flowcharts and validation data?				
4.2.8.5	f) xxiv. Equipment/instrument maintenance?				
4.2.8.5	f) xxv. Computer hardware and software?				
4.2.8.5	f) xxvi. Troubleshooting?				
4.2.8.5	g) Are all technical SOPs (e.g., sample preparation, analytical procedures, sample storage, or sample receipt) reviewed for accuracy and adequacy at least annually, and updated if necessary?				
4.2.8.5	g) Are all SOP reviews conducted by personnel having the pertinent background, recorded, and made available for assessment?				
4.3	**Document Control**				
4.3.1	Has the laboratory established 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?				
4.3.2.1	Are all documents issued to laboratory personnel as part of the management system reviewed and approved for used by authorized personnel prior to issue?				
4.3.2.1	Is there a master list (or equivalent procedure) identifying the current revision status and distribution of documents in the management system?				
4.3.2.1	Is this master list readily available to preclude the used of invalid and/or obsolete documents?				

Section Reference	Question	Yes	No	NA	Comments
4.3.2.2.	a. Does the document control procedure(s) adopted ensure that authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed?				
4.3.2.2.	b. Does the document control procedure(s) adopted ensure that documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements?				
4.3.2.2.	c. Does the document control procedure(s) adopted ensure that invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?				
4.3.2.2.	d. Does the document control procedure(s) adopted ensure that obsolete documents retained for either legal or knowledge presentation purposes are suitable marked?				
4.3.2.2.	e. Are affected personnel notified of changes to management systems documents and supporting procedures, including technical documents?				
4.3.2.2.	f. Are reviews (internal or external) of management system documentation maintained and made available for assessment?				
4.3.2.2.	g. Are any documents providing instructions to laboratory personnel (e.g., operator aids) considered part of the management system and are subject to document control procedures?				
4.3.2.3	Are management system documents generated by the laboratory uniquely identified?				
4.3.2.3	Does this identification include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies)?				
4.3.3.1	Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise?				
4.3.3.1	Does designated personnel have access to pertinent background upon which to base their review and approval?				
4.3.3.2	Where practicable, is the altered or new text identified in the document or the appropriate attachments?				

Section Reference	Question	Yes	No	NA	Comments
4.3.3.3	If the laboratory's documentation 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?				
4.3.3.3	Are amendments to documents clearly marked, initialed and dated?				
4.3.3.3	Is a revised document formally re-issued as soon as practicable?				
4.3.3.4	Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?				
4.4	**Review of Requests, Tenders and Contracts**				
4.4.1	Has the laboratory established and maintained procedures for the review of requests, tenders and contracts?				
4.4.1	Are these procedures maintained?				
4.4.1	a) Do the policies and procedures for reviews leading to a contract for environmental testing ensure that the requirements, including the methods to be used, are adequately defined, documented and understood?				
4.4.1	b) Do the policies and procedures for reviews leading to a contract for environmental testing and/or calibration ensure that the laboratory has the capability and resources to meet the requirements?				
4.4.1	c) Do the policies and procedures for reviews leading to a contract for environmental testing ensure that the appropriate environmental test method is selected and capable of meeting the clients' requirements?				
4.4.1	Are any differences between the request or tender & the contract resolved before any work commences?				
4.4.1	Is each contract acceptable to both the laboratory and the customer?				
4.4.2	Are records of reviews, including any significant changes maintained?				
4.4.2	Are records also maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract?				

Section Reference	Question	Yes	No	NA	Comments
4.4.2	Note: For review of routine and other simple tasks, the date and the identification (e. g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced environmental testing and/or calibration tasks, a more comprehensive record should be maintained. (5.4.4.2).				
4.4.3	Does the review cover any work that is subcontracted by the laboratory?				
4.4.4	Is the client informed of any deviation from the contract?				
4.4.4.1	Are waivers from QSM requirements requested in writing from the appropriate DoD Chemist or Contractor Project Chemist (however named) on a project-specific basis and does it include technical justification relating to the specific project for the waiver. Is documentation of approval for the waiver maintained by the laboratory and is it readily available for review?				
4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated?				
4.4.5	Are any contract amendments communicated to all affected personnel?				
4.5	**Subcontracting of Tests and Calibrations**				
4.5.1	When a laboratory subcontracts work, whether because of unforeseen reasons (workload, need for further expertise or temporary incapacity) or on a continuing basis (permanent subcontracting, agency or franchising arrangements), is this work placed with a competent subcontractor?				
4.5.2	Does the laboratory have a policy of advising the client of the arrangement in writing and, when possible, gain the approval of the clients, preferably in writing?				
4.5.3	Does the laboratory have a policy for the responsibility to the client for the subcontract's work, except in the case where the client or a regulatory authority specified which subcontract is to be used?				

Section Reference	Question	Yes	No	NA	Comments
4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests?				
4.5.4	Does the laboratory maintain a record of evidence of compliance with this standard for the work in question?				
4.5.5	When a laboratory subcontracts work, is the work placed with a laboratory accredited to the 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?				
4.5.5	Is the laboratory performing the subcontracted work indicated in the final report?				
4.5.5	Does the laboratory make a copy of the subcontractor's report available to the client when requested?				
4.5.6	Does the laboratories ensure and document that subcontracted (sub-tier) laboratories meet the requirements of this standard?				
4.5.7	Are subcontracted laboratories performing analytical services in support of Environmental Restoration projects accredited in accordance with the DoD ELAP?				
4.5.8	Do subcontracted laboratories receive project-specific approval from the DoD customer before any samples are analyzed?				
4.5.9	Are the requirements for subcontracting laboratories also applied to the use of any laboratory under the same corporate umbrella, but at a different facility or location?				
4.5.10	Do all subcontracted or outsourced management systems elements (such as data review) or outsourced personnel comply with the laboratory's overall management system, and do they comply with the requirements of this standard, and are subject to review/approval by the DoD~~/DOE~~ customer?				
4.6	**Purchasing Services and Supplies**				
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 environmental tests?				

Section Reference	Question	Yes	No	NA	Comments
4.6.1	Do procedures exist for the purchase, reception, & storage of reagents & consumable materials relevant for the environmental tests?				
4.6.1	Do records for services and supplies that may affect the quality of environmental tests include the following, where applicable:				
4.6.1	a) Date of receipt?				
4.6.1	b) Expiration date?				
4.6.1	c) Source?				
4.6.1	d) Lot or serial number?				
4.6.1	e) Calibration and verification records?				
4.6.1	f) Accreditation or certification scopes/certificates?				
4.6.1	(Guidance) Examples of services and supplies that may affect the quality of environmental tests include, but are not limited to, balance calibration, solvents, standards, and sample containers.				
4.6.2	Does the laboratory ensure that purchased supplies, reagents and consumable materials that affect quality are not used until they have been inspected or otherwise verified as complying with requirements defined in the methods for the environmental tests concerned?				
4.6.2	Are the services and supplies used compliant with specified requirements?				
4.6.2	Are records maintained of action taken to check compliance?				
4.6.3	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered?				
4.6.3	Are these purchasing documents reviewed & approved for technical content prior to release?				
4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies and services that affect the quality of testing and calibration?				
4.6.4	Are records maintained of the evaluations?				
4.6.4	Is a list of those approved maintained?				
4.7	**Service to the Customer**				

Section Reference	Question	Yes	No	NA	Comments
4.7.1	Does the laboratory afford customers or their representative's cooperation to clarify the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers?				
4.7.2	Does the laboratory maintain and document communication with the client for the purposes of seeking feedback, both positive and negative, and clarifying customer requests.				
4.7.2	Is the feedback used and analysed to improve the management system, testing and calibration activities and customer service?				
4.8	**Complaints**				
4.8	Does the laboratory have a policy and procedure for the resolution of complaints received from customers or other parties?				
4.8	Are records maintained of all complaints and of the investigations and corrective actions taken?				
4.9	**Control of Nonconforming Testing and/or Calibration Work**				
4.9.1	Does the laboratory have a policy and procedures that are implemented when any aspect of its environmental testing, or the results of this work, does not conform to its own procedures or the agreed requirements of the client?				
4.9.1.	a. Do the policy and procedures for nonconforming work ensure that 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?				
4.9.1.	b. Do the policy and procedures for nonconforming work ensure that an evaluation of the significance of the nonconforming work is made?				
4.9.1.	c. Do the policy and procedures for nonconforming work ensure that corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work?				
4.9.1.	d. Do the policy and procedures for nonconforming work ensure that where the data quality is or may be impacted, the client is notified?				

Section Reference	Question	Yes	No	NA	Comments
4.9.1.	e. Do the policy and procedures for nonconforming work ensure that the responsibility for authorizing the resumption of work is defined?				
4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are the corrective action procedures given in 4.10 promptly followed?				
4.9.3	Does the laboratory upon discovery, notify within 15 business days all affected customers of potential data quality issues resulting from nonconforming work?				
4.9.3	Is a notification performed according to a written procedure?				
4.9.3	Are records of corrections taken to resolve the nonconformance submitted to the customer(s) within 30 business days of discovery?				
4.9.4	Does the DoD ELAP laboratory report any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7 of the DoD QSM, to their AB within 15 business days of discovery. Discovery includes findings of such inappropriate practices by laboratory staff or customer stakeholders.				
4.9.4	Does the DoD ELAP laboratory submit records of associated corrections taken or proposed corrective actions to their AB within 30 business days of discovery.				
4.9.4	Note: The respective AB will then have the responsibility of informing the EDQW of the laboratory's deviation from the requirements of the QSM. If the AB is not notified within 15 business days the AB will immediately suspend the laboratory's DoD ELAP accreditation. The respective ABs and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties.				
4.10	**Improvement**				
4.10.	Has the laboratory improved the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?				
4.11	**Corrective Action**				
4.11.1	Does the laboratory have an established policy and procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified?				

Section Reference	Question	Yes	No	NA	Comments
4.11.1	Has the laboratory designated appropriate authorities for implementing corrective action in the above situations?				
4.11.2	Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?				
4.11.3	Where corrective action is needed, does the laboratory identify potential corrective actions?				
4.11.3	Does the laboratory select and implement the action(s) most likely to eliminate the problem and prevent recurrence?				
4.11.3	Are corrective actions made to a degree appropriate to the magnitude and the risk of the problem?				
4.11.3	Does the laboratory document and implement any required changes resulting from corrective action investigations?				
4.11.4	Does the laboratory monitor the results to ensure that the corrective actions taken are effective?				
4.11.5	Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this Standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?				
4.11.6	Does the laboratory documented procedure(s) to address 4.11.1 and 4.11.3 through 4.11.5?				
4.11.6	Do the procedure(s) include (a & b):				
4.11.6	a) Which individual(s) or positions are responsible for assessing each QC data type?				
4.11.6	b) Which individual(s) or positions are responsible for initiating and/or recommending corrective actions?				
4.11.7	Does the cause analysis described in Section 4.11.2 applies to failures that indicate a systematic error?				
4.11.8	Does the laboratory have and use a record system for tracking corrective actions to completion and for analyzing trends to prevent the recurrence of the nonconformance?				

Section Reference	Question	Yes	No	NA	Comments
4.11.8	Are approved corrective actions developed to address findings during DoD ELAP assessments implemented?				
4.11.8	Are any changes to approved corrective action plans approved by the DoD ELAP Accreditation Bodies~~, as appro~~priate?				
4.12	**Preventive Action**				
4.12.1	Are needed improvements and potential sources of nonconformities, either technical or concerning the management system, identified?				
4.12.1	Are records of preventive actions maintained for review?				
4.12.1	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?				
4.12.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?				
4.13	**Control of Records**				
4.13.1.1	Has the laboratory established procedures for: - identification? - collection? - indexing? - access? - filing? - storage? - maintenance? - disposal? of all quality and technical records.				
4.13.1.1	Does the laboratory maintain these procedures?				
4.13.1.1	Do the quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?				
4.13.1.2	Are all records legible?				

Section Reference	Question	Yes	No	NA	Comments
4.13.1.2	Are all records 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?				
4.13.1.2	Are the retention times established?				
4.13.1.3	Are all records held secure and in confidence?				
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?				
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?				
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?				
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?				
4.13.2.2	Are observations, data and calculations recorded at the time they are made?				
4.13.2.2	Are they identifiable to the specific task?				
4.13.2.3	When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and the correct value entered alongside?				
4.13.2.3	Are all such alterations to records signed or initialed by the person making the correction?				
4.13.2.3	In the case of electronic records, are equivalent measures taken to avoid loss or change of original data?				
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?				

Section Reference	Question	Yes	No	NA	Comments
4.13.3	a) Does the system produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts?				
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?				
4.13.3	c) Are records available to the accreditation body?				
4.13.3	d) Are records that are stored only on electronic media supported by the hardware and software necessary for their retrieval?				
4.13.3	e) Is the access to archived information documented with an access log?				
4.13.3	f) Does the laboratory maintain the following data necessary for the historical reconstruction:				
4.13.3	f) i. Is all raw data, whether hard copy or electronic, for calibrations, samples and quality control measures including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records) maintained?				
4.13.3	f) ii. Is 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 documented?				
4.13.3	f) iii. Are laboratory sample ID code used?				
4.13.3	f) iv. Is the Date of analysis recorded?				
4.13.3	f) v. Is the time of analysis is required if the holding seventy-two hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations)?				
4.13.3	f) vi. Instrumentation identification and instrument operating conditions/parameters (or Reference to such data)?				
4.13.3	f) vii. All manual calculations?				
4.13.3	f) viii. Analyst's or operator's initials/signature or electronic identification?				

Section Reference	Question	Yes	No	NA	Comments
4.13.3	f) ix. Sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents?				
4.13.3	f) x. Test results?				
4.13.3	f) xi. Standard and reagent origin, receipt, preparation, and use?				
4.13.3	f) xii. Calibration criteria, frequency and acceptance criteria?				
4.13.3	f) xiii. Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions?				
4.13.3	f) xiv. Quality control protocols and assessment?				
4.13.3	f) xv. Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries?				
4.13.3	f) xvi. Method performance criteria including expected quality control requirements?				
4.13.3	f) xvii. Proficiency test results?				
4.13.3	f) xviii. Records of demonstration of capability for each analyst?				
4.13.3	f) xix. A record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record?				
4.13.3	g) Are all generated data, except those that are generated by automated data collection systems, recorded legibly in permanent ink?				
4.13.3	g) i. Is the individual making corrections to records recording date and initials to the correction?				
4.13.3	g) ii. Corrections due to reasons other than transcription errors shall specify the reason for the correction?				
4.13.3	g) iii) Do records for changes made to data (either hardcopy or electronic) include the identification of the person who made the change and the date of change?				
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?				

Section Reference	Question	Yes	No	NA	Comments
4.13.3	h) In addition, are appropriate regulatory and state legal requirements concerning laboratory records followed?				
4.13.4	Do the permanent, bound laboratory notebooks (logbooks) or notebooks have measures in place to prevent the removal or addition of pages?				
4.13.4	Do the permanent, bound logbooks have the following:				
4.13.4	a) Are laboratory notebook pages -numbered, and are all entries signed or initialed and dated by the person responsible for performing the activity at the time the activity is performed?				
4.13.4	a) Are all entries recorded in chronological order?				
4.13.4	b) Is the person responsible for performing the closure, the one who performed the last activity recorded?				
4.13.4	b) Are all notebook pages closed when the activities recorded are completed or carried over to another page?				
4.13.4	b) Does closure occur at the end of the last activity recorded on a page, as soon as practicable thereafter?				
4.13.4	b) Do satisfactory records of closure include analyst initials and date?				
4.13.4	c) Does each laboratory notebook have a unique serial number clearly displayed?				
4.13.5	Does the laboratory have procedures for the independent review of technical and quality records to ensure they are legible, accurate, and complete?				
4.13.6	Has the laboratory established a review frequency for all records such as laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, verification, validation, and archival?				
4.13.6	Are records of the reviews maintained and made available for review?				
4.13.7	If not self-explanatory (e.g., a typo or transposed number), do corrections to technical and quality records include a justification for the change?				
4.13.8	Does the records control system SOP address the requirements for access to and control of the files, including accountability for any records removed from storage?				
4.13.9	Are all SOPs archived for historical reference, per regulatory or customer requirements?				

Section Reference	Question	Yes	No	NA	Comments
4.13.9	Does the laboratory have a procedure for permanent laboratory closure and disposal of any remaining records associated with DoD~~/DOE~~ analytical data?				
4.14	**Internal Audits**				
4.14.1	Does the laboratory periodically, in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this standard?				
4.14.1	NOTE: The cycle for internal auditing should normally be completed in one year.				
4.14.1	Does the internal audit program address all elements of the management system, including the testing and/or calibration activities?				
4.14.1	Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management?				
4.14.1	Are such audits performed by trained personnel who are, wherever resources permit, independent of the activity to be audited?				
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?				
4.14.2	Does the laboratory notify customers in writing if investigations show that the laboratory results may have been affected?				
4.14.2	Does the laboratory notify DoD clients within fifteen (15) business days of discovery of any investigation that casts doubt upon the validity of test results?				
4.14.3	Are the following recorded: area of activity audited? audit findings? corrective actions that arise?				
4.14.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?				
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?				
4.14.5	b) Does the laboratory management ensure that these actions are discharged within the agreed time frame?				

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

Section Reference	Question	Yes	No	NA	Comments
4.15.1	Does the review take account of: - the suitability of policies and procedures? - reports from managerial and supervisory personnel? - the outcome of recent internal audits? - corrective and preventive actions? - assessments by external bodies? - the results of inter-laboratory comparisons or proficiency tests? - changes in the volume and type of work? - customer feedback? - complaints? - recommendations for improvement? - other relevant factors, such as quality control activities, resources and staff training?				
4.15.2	Are findings from management reviews and ensuing actions recorded?				
4.15.2	Does management ensure that those actions are carried out within an appropriate and agreed timescale?				
4.15.3	Is the Management review completed on an annual basis?				
4.16	**Data Integrity Investigations**				
4.16	Are all investigations resulting from data integrity issues conducted in a confidential manner until they are completed?				
4.16	Are investigations resulting from data integrity documented, as well as any notifications made to clients receiving any affected data?				
4.16	Does the DoD ELAP laboratory report any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7 of the DoD QSM, to their AB within 15 business days of discovery?				
4.16	Does the DoD ELAP laboratory submit records of associated corrections taken or proposed corrective actions to their AB within 30 business days of discovery?				
4.16	Note: The respective AB will then have the responsibility of informing the EDQW of the laboratory's deviation from the requirements of the QSM. The respective ABs and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties.				

Section Reference	Question	Yes	No	NA	Comments
5	**TECHNICAL REQUIREMENTS**				
5.1	**General**				
5.1.1.	Does the laboratory determine correctness and reliability of the environmental tests include contributions from:				
5.1.1.	Human factors (5.2)?				
5.1.1.	Accommodation and environmental conditions (5.3)?				
5.1.1.	Environmental test methods and method validation (5.4)?				
5.1.1.	Equipment (5.5.5)?				
5.1.1.	Measurement traceability (5.6)?				
5.1.1.	Sampling (5.7)?				
5.1.1.	The handling of samples (5.8)?				
5.1.2	Does the laboratory take account of the factors that contribute to the total uncertainty of measurement in developing environmental test methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses?				
5.2	**Personnel**				
5.2.1	Does the laboratory management ensure the competence of all who:				
5.2.1	- operate specific equipment?				
5.2.1	- perform tests and/or calibrations?				
5.2.1	- evaluate results?				
5.2.1	- sign test reports and calibration certificates?				
5.2.1	NOTE: The personnel responsible for the opinions and interpretation in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing, also have relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; knowledge of the general requirements expressed in the legislation and standards; understanding of the significance of deviations found with regard to the normal use of the items concerned.				

Section Reference	Question	Yes	No	NA	Comments
5.2.1	When using staff undergoing training, is appropriate supervision provided?				
5.2.1	Are those personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required?				
5.2.2	Does the management formulate goals with respect to the education, training and skills of the laboratory personnel?				
5.2.2	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?				
5.2.2	Is the effectiveness of the training actions taken evaluated?				
5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory?				
5.2.3	Where contracted and additional technical and key support personnel are used, does the laboratory ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system?				
5.2.4	Does the laboratory maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations?				
5.2.4	Do Job descriptions, as a minimum, must include as a minimum the elements in the note of 5.2.4?				
5.2.4	-responsibilities for performing tests/calibrations?				
5.2.4	-responsibilities for planning and evaluation of results of tests/calibrations?				
5.2.4	-responsibilities for reporting opinions and interpretations?				
5.2.4	-responsibilities for method modifications and development and validation of new methods?				
5.2.4	-expertise/experience required?				
5.2.4	-qualifications/training programs?				
5.2.4	-managerial duties				
5.25	Does management authorize specific personnel to perform particular types of sampling, environmental testing, to issue test reports, to give opinions and interpretations and to operate particular types of equipment?				

Section Reference	Question	Yes	No	NA	Comments
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?				
5.2.6.1	Does the laboratory meet the applicable requirements for technical managers as listed below:				
5.2.6.1	a. Any technical manager of an accredited environmental laboratory that engaged in chemical analysis 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 year of experience?				
5.2.6.1	b. Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, 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? Note: In addition, the person shall have at least two (2) years of experience performing such analysis.				
5.2.6.1	c. Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis, a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen 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? Note: A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.				

Section Reference	Question	Yes	No	NA	Comments
5.2.6.1	c. 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. Note: In addition, each person shall have one (1) year of experience in microbiological analyses.				
5.2.6.1	d. Any technical manager of an accredited environmental laboratory engaged in radiological analysis 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. Note: A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.				
5.2.6.1	e. Does the laborartory ensure that the technical manager(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers meet the following technical requirements?				
5.2.6.1	e) 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.				
5.2.6.1	e) 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 year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.				

Section Reference	Question	Yes	No	NA	Comments
5.2.6.1	e) 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.				
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.				
5.2.6.1	**Technical Manager Qualification Exceptions**				
5.2.6.2	a. Does full-time employees of the drinking water or sewage treatment facility hold a valid treatment plant operator's certificate appropriate to the nature and size of such facility and do they meet the educational requirements as the technical manager?				
5.2.6.2	a. Does the technical manager have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit? Note: Such accreditation for a drinking water or sewage treatment facility shall be limited to the scope of that facility's regulatory permit.				
5.2.6.2	b. Does full-time employee of an industrial waste treatment facility have 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? Note: Such accreditation for an industrial waste treatment facility shall be limited to the scope of that facility's regulatory permit.				
5.2.6.2	c. Do persons who do not meet the education credential requirements but possess the requisite experience of 5.2.6.1 qualify as technical manager(s) from to the following conditions:				

Section Reference	Question	Yes	No	NA	Comments
5.2.6.2	c) 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?				
5.2.6.2	c) 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?				
5.2.6.2	c) 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?				
5.2.7	Is data integrity training provided as a formal part of new employee and is it provided on an annual basis for all current employees?				
5.2.7	Are topics covered documented in writing and provided to all trainees?				
5.2.7	Does data integrity training require emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient?				
5.2.7	Are employees required to understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution?				
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?				
5.2.7	At a minimum, are the following topics and activities included:				
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?				
5.2.7	b) training, including discussion regarding all data integrity procedures?				

Section Reference	Question	Yes	No	NA	Comments
5.2.7	c) data integrity training documentation?				
5.2.7	d) in-depth data monitoring and data integrity procedure documentation?				
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?				
5.2.7	Does top management acknowledge its support for data integrity by implementing the specific requirements of the laboratory's data integrity program?				
5.2.7	To facilitate the implementation of this program, the following practices are prohibited:				
5.2.7	a) Fabrication, falsification, or misrepresentation of data?				
5.2.7	a) i) Creating data for an analysis that was not performed (dry lab)?				
5.2.7	a) ii) Creating information for a sample that was not collected (dry lab)?				
5.2.7	a) iii) Using external analysts, equipment, and/or laboratories to perform analyses when not allowed by contract?				
5.2.7	b) Improper clock setting (time traveling) or improper date/time recording?				
5.2.7	b) i) Resetting the internal clock on an instrument to make it appear that a sample was analyzed within holding time when in fact it was not?				
5.2.7	b) ii) Changing the actual time or recording a false time to make it appear that holding times were met, or changing the times for sample collection, extractions or other steps to make it appear that holding times were met?				
5.2.7	c) Unwarranted manipulation of samples, software, or analytical conditions?				
5.2.7	c) i) Unjustified dilution of samples?				
5.2.7	c) ii) Manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria?				
5.2.7	c) iii) Changing the instrument conditions for sample analysis from the conditions used for standard analysis (e.g., changing EM voltage)?				

Section Reference	Question	Yes	No	NA	Comments
5.2.7	c) iv) Unwarranted manipulation of computer software (e.g., forcing calibration or QC data to meet criteria, removing computer operational codes such as the M" flag, inappropriately subtracting background, or improperly manipulating the chromatographic or spectrophotometric baseline)?				
5.2.7	c) v) Turning off, or otherwise disabling, electronic instrument audit/tracking functions?				
5.2.7	d) Misrepresenting or misreporting QC samples?				
5.2.7	d) i) Representing spiked samples as being digested or extracted when this has not been done?				
5.2.7	d) ii) Substituting previously generated runs for a non-compliant calibration or QC run to make it appear that an acceptable run was performed?				
5.2.7	d) iii) Failing to prepare or analyze method blanks and the laboratory control sample (LCS) in the same manner that samples were prepared or analyzed?				
5.2.7	d) iv) Tampering with QC samples and results, including over spiking and adding surrogates after sample extraction?				
5.2.7	d) v) Performing multiple calibrations or QC runs (including CCVs, LCSs, spikes, duplicates, and blanks) until one meets criteria, rather than taking needed, corrective action, and not documenting or retaining data for the other unacceptable data?				
5.2.7	d) vi) Deleting or failing to record non-compliant QC data to conceal the fact that calibration or other QC analyses were non-compliant?				
5.2.7	e) Improper calibrations?				
5.2.7	e) i) Discarding points in the initial calibration to force the calibration to be acceptable?				
5.2.7	e0 ii) Discarding points from an MDL study to force the calculated MDL to be higher or lower than the actual value?				
5.2.7	e) iii) Using an initial calibration that does not correspond to the actual run sequence to make continuing calibration data look acceptable when in fact is was not?				

Section Reference	Question	Yes	No	NA	Comments
5.2.7	e) iv) Performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to meet QC criteria or to avoid corrective action?				
5.2.7	f) Concealing a known analytical or sample problem?				
5.2.7	g) Concealing a known improper or unethical behavior or action?				
5.2.7	h) Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official?				
5.3	**Accommodation and Environmental Conditions**				
5.3.1	Are laboratory facilities for environmental testing, including but not limited to energy sources, lighting and environmental conditions, such as to facilitate correct performance of the environmental tests?				
5.3.1	Is particular care taken when sampling and environmental tests are undertaken at sites other than a permanent laboratory facility?				
5.3.1	Are the technical requirements for accommodation and environmental conditions that can affect the results of environmental tests documented?				
5.3.2	For these environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of results, does the laboratory:				
5.3.2	-monitor?				
5.3.2	-control?				
5.3.2	- record?				
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?				
5.3.2	Are environmental tests and calibrations stopped when the environmental conditions jeopardize the results of the environmental tests?				
5.3.3	Is there effective separation between neighboring areas in which there are incompatible activities?				

Section Reference	Question	Yes	No	NA	Comments
5.3.3	a) When cross-contamination is a possibility, are samples suspected of containing high concentrations of target analytes isolated from other samples?				
5.3.3	b) Are storage blanks stored with all volatile organics samples, regardless of suspected concentration levels?				
5.3.3	b) Are samples suspected of containing high concentrations of volatile organics isolated from other volatile organics samples?				
5.3.3	b) Are storage blanks used to determine if cross-contamination may have occurred?				
5.3.3	b) Does the laboratory have documented procedures and criteria for evaluating storage blanks, appropriate to the types of samples being stored?				
5.3.3	b) Are storage blanks stored in the same manner as the customer samples and are they analyzed and reviewed at a minimum, every 14 days?				
5.3.3	c) If contamination is discovered, does the laboratory have corrective action plan in place to identify the root cause and eliminate the source; determine which samples may have been impacted and implement measures to prevent recurrence?				
5.3.4	Is access to and use of areas affecting the quality of the environmental tests controlled?				
5.3.4	Does the laboratory determine the extent of control based on its particular circumstances?				
5.3.5	Are measures taken to ensure good housekeeping in the laboratory?				
5.3.5	Are special procedures prepared where necessary?				
5.4	**Test and Calibration Methods and Method Validation**				
5.4.1	Does the laboratory use appropriate methods and procedures for all environmental tests and/or calibrations within its scope, including 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?				

Section Reference	Question	Yes	No	NA	Comments
5.4.1	Does the laboratory have instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples where the absence of such instructions could jeopardize the results of environmental tests?				
5.4.1	Are all instructions, standards, manuals and reference data relevant to the work of the laboratory kept up to date and made readily available to personnel?				
5.4.1	Do deviations from environmental test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client?				
5.4.2	Does the laboratory use methods for environmental testing, including methods for sampling, which meet the needs of the client and which are appropriate for the environmental tests it undertakes?				
5.4.2	Are methods published in international, regional or national standards used if possible?				
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?				
5.4.2.	When necessary, is the standard supplemented with additional details to ensure consistent application?				
5.4.2.	When the use of specific methods for a sample analysis are mandated or requested, are only those methods used?				
5.4.2.	When the client does not specify the method to be used or where methods are employed that are not required, are the methods fully documented and validated?				
5.4.2.	Is the client informed as to the method chosen?				
5.4.2.	Does the laboratory inform the client when the method proposed by the client is considered to be inappropriate or out of date?				
5.4.3	Is the introduction of environmental test methods developed by the laboratory for its own use a planned activity?				
5.4.3	Is the introduction of environmental test methods assigned to qualified personnel equipped with adequate resources?				

Section Reference	Question	Yes	No	NA	Comments
5.4.3	Are plans updated as development proceeds-?				
5.4.3	Is effective communication amongst all personnel involved ensured?				
	Estimation of Analytical Uncertainty				
5.4.6	Does the Environmental testing laboratories have a procedure(s) for estimating analytical uncertainty?				
5.4.6	Is the quality control measurement data used to determine analytical uncertainty?				
5.4.6	a) Does the laboratory attempt to identify all components of analytical uncertainty and make a reasonable estimation?				
5.4.6	a) And does the laboratory ensure that the form of data reporting does not give a wrong impression of the uncertainty?				
5.4.6	a) Is the reasonable estimation of uncertainty based on knowledge of method performance and previous experence?				
5.4.6	a) When estimating the analytical uncertainty,are all uncertainty components which are of importance in the given situation taken into account?\				
5.4.6	b) In cases where a well recognized test method specifies limits and the form of presentation of calculated results, has the laboratory followed the test method and reporting instructions?				
5.4.6	c) The laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control.				
5.4.6	c) As stated in Section 5.10.3.1.c, do the test reports include a statement of the estimated uncertainty of measurement only when required by client instruction?				
5.4.6	c) If a project requires measurement uncertainty to be reported, does the laboratory report the estimated uncertainty based on project-specific procedures or, if not available, any other scientifically valid and documented procedures?				
5.4.6	Note: A laboratory may report the in-house, statistically-derived LCS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to analytical uncertainty at a 99% confidence level.				

Section Reference	Question	Yes	No	NA	Comments
5.4.6	c) For testing laboratories, do they ensure that the equipment used can provide the analytical portion of measurement uncertainty needed by the customer?				
5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner?				
5.4.7.1	a. Does the laboratory have established SOPs to ensure that the reported data are free from transcription and calculation errors?				
5.4.7.1	b. Does the laboratory have established SOPs to ensure that all quality control measures are reviewed, and evaluated before data are reported?				
5.4.7.1	c. Does the laboratory have established SOPs addressing manual calculations?				
5.4.7.1	d. Does the laboratory have established SOPs addressing manual integrations?				
5.4.7.1	When manual integrations are performed, do raw data records include a complete audit trail for those manipulations (i.e., Are the chromatograms obtained before and after the manual integration retained to permit reconstruction of the results)?				
5.4.7.1	Note: This requirement applies to all analytical runs including calibration standards and QC samples.				
5.4.7.1	Does the person performing the manual integration sign and date each chromatogram and document the rationale for performing manual integration (electronic signature is acceptable)?				
5.4.7.1	Does the laboratory electronically maintained records of manual integrations meet all requirements, including signature requirements?				
5.4.7.1	Can the results be historically reconstructed?				
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 (a-c):				
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?				

Section Reference	Question	Yes	No	NA	Comments
5.4.7.2	c) NOTE: Commercial off-the-shelf software is sufficiently validated. However, lab software configuration or modifications should be validated as in 5.4.7.2a.				
5.4.7.2	b) for protecting the data, procedures are:				
5.4.7.2	-established?				
5.4.7.2	-implemented?				
5.4.7.2	b) Do such procedures include, but are not limited to:				
5.4.7.2	-integrity and confidentiality of data entry or collection?				
5.4.7.2	-data storage?				
5.4.7.2	-data transmission?				
5.4.7.2	-data processing?				
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?				
5.4.7.2	d) Does the laboratory have a procedure to ensure individual user names and passwords are required for all LIMS users?				
5.4.7.2	d) Are LIMS passwords changed on a regular basis, at a minimum annually?				
5.4.7.2	e) Upon employment, are laboratory employees given initial training in computer security awareness and have ongoing refresher training on an annual basis ?				
5.4.7.2	e) Are records of the training maintained and available for review?				
5.4.7.2	f) Are periodic inspections (at least annually) of the LIMS being performed by the Quality Manager or designee to ensure the integrity of electronic data?				
5.4.7.2	f) Does the Quality Manager or designee maintain records of inspections and submit reports to laboratory management, noting any problems identified with electronic data processing stating the corrective actions taken?				
5.4.7.2	g) Does the laboratory have a procedure to notify the customer prior to changes in LIMS software or hardware configuration that will adversely affect customer electronic data?				

Section Reference	Question	Yes	No	NA	Comments
5.4.7.2	h) Are spreadsheets used for calculations verified before initial use and after any changes to equations or formulas, including software revision upgrades, and are records available for review?				
5.4.7.2	h) Are formula cells write-protected to minimize inadvertent changes to the formulas?				
5.4.7.2	h) Do printouts from any spreadsheets include all information used to calculate the data?				
5.4.7.2	i) Does the laboratory have SOPs for:				
5.4.7.2	i) i. Software development methodologies that are based on the size and nature of the software being developed?				
5.4.7.2	i) ii. Testing and QC methods to ensure that all software accurately performs its intended functions, including:				
5.4.7.2	i) ii. a. Acceptance criteria?				
5.4.7.2	i) ii. b. Tests to be used?				
5.4.7.2	i) ii. c. Personnel responsible for conducting the tests?				
5.4.7.2	i) ii. d. Records of test results?				
5.4.7.2	i) ii. e. Frequency of continuing verification of the software?				
5.4.7.2	i) ii. f. Test review and approvals?				
5.4.7.2	i) iii. Software change control methods that include instructions for requesting, authorizing,testing (to include quality control), approving, implementing and establishing thepriority of software changes. The requirements to be met by each software change must be documented?				
5.4.7.2	i) iv. Software version control methods that record the software version currently used? Data sets are recorded with the date and time of generation and/or the software version used to generate the data set?				
5.4.7.2	i) v. Maintaining a historical file of software, software operating procedures, software changes, and software version numbers				
5.4.7.2	i) vi. Defining the acceptance criteria, testing, records, and approval required for changes to LIMS hardware and communication equipment				
5.4.7.2	j) Are records available in the laboratory to demonstrate the validity of laboratory generated software, and include:				

Section Reference	Question	Yes	No	NA	Comments
5.4.7.2	j) i. Software description and functional requirements?				
5.4.7.2	j) ii. Listing of algorithms and formulas?				
5.4.7.2	j) iii. Testing and QA records?				
5.4.7.2	j) iv. Installation, operation and maintenance records?				
5.4.7.2	k) Do Electronic Data Security measures must ensure the following:				
5.4.7.2	k) i. Individual user names and passwords have been implemented?				
5.4.7.2	k) ii. Operating system privileges and file access safeguards are implemented to restrict the user of the LIMS data to users with authorized access?				
5.4.7.2	k) iii. All LIMS Users are trained in computer awareness security on an annual basis?				
5.4.7.2	k) iv. System events, such as log-on failures or break-in attempts are monitored?				
5.4.7.2	k) v. The electronic data management system is protected from the introduction of computer viruses?				
5.4.7.2	k) vi. System backups occur on a regular and published schedule and can be performed by more than one person within an organization?				
5.4.7.2	k) vii. Testing of the system backups must be performed and recorded to demonstrate that the backup systems contain all required data?				
5.4.7.2	k) viii. Physical access to the servers is limited by security measures such as locating the system within a secured facility or room, and/or utilizing cipher locks or key cards?				
	Equipment				
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)?				
5.5.1	In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of this Standard are met?				

Section Reference	Question	Yes	No	NA	Comments
5.5.1	Is equipment and its software used for testing, calibration and sampling capable of achieving the accuracy required?				
5.5.2	Does it comply with specifications relevant to the tests and/or calibrations concerned?				
5.5.2	Have calibration programs been established for key quantities or values of the instruments where these properties have a significant effect on the results?				
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?				
5.5.2	Is it checked and/or calibrated before use?				
5.5.3	Is equipment operated by authorized personnel?				
5.5.3	Are current instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer) readily available for use by the appropriate laboratory personnel?				
5.5.4	Is each item of equipment and its software used for environmental testing and calibration that is significant to the result, uniquely identified, when practicable?				
5.5.5	Are records of each item of equipment and its software significant to the tests and/or calibrations performed maintained?				
5.5.5	Do the maintenance records include at least the following:				
5.5.5	a. The identity of the item of equipment and its software?				
5.5.5	b. The manufacturer's name, type identification, and serial number or other unique identification?				
5.5.5	c. Checks that equipment complies with the specification (see 5.5.5.2)?				
5.5.5	d. The current location?				
5.5.5	e. The manufacturer's instructions, if available or reference to their location?				
5.5.5	f. Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?				

Section Reference	Question	Yes	No	NA	Comments
5.5.5	g. The maintenance plan, where appropriate, and maintenance carried out to date; documentation on all routine and non-routine maintenance activities and reference material verifications?				
5.5.5	h. Date placed in service?				
5.5.5	i. Condition when received (e.g., new, used, reconditioned)?				
5.5.5	j. Operational status?				
5.5.5	k. Instrument configuration and settings?				
5.5.6	Does the laboratory have procedures covering the following to ensure proper functioning and in order to prevent contamination or deterioration:				
5.5.6	-safe handling?				
5.5.6	-transport?				
5.5.6	-storage?				
5.5.6	-use and planned maintenance of measuring equipment?				
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?				
5.5.7	Is the equipment isolated to prevent its use or clearly labeled or marked as being out of service, until it has been repaired and shown by calibration or test to perform correctly?				
5.5.7	Does the laboratory examine the effect of the defect or departure from specified limits on previous environmental tests and institute the "Control of nonconforming work" procedure as required by 4.9?				
5.5.8	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded or otherwise identified to indicate the status of calibration including the date when last calibrated and the date or expiration criteria when recalibration is due?				
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?				

Section Reference	Question	Yes	No	NA	Comments
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?				
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?				
5.5.12	Is test equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test results?				
5.5.13.1	Are all devices that are not be the actual test instrument, but are necessary to support laboratory operations, including, 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 volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices), that have quantitative results that are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume, verified or calibrated?				
5.5.13.1	a) Are all support equipment maintained in proper working order?				
5.5.13.1	a) Are the records of all repair and maintenance activities, including service calls, shall be kept?				
5.5.13.1	a) Does the laboratory have procedures for recording catastrophic failure of support equipment (e.g., refrigerators, freezers) and addresses identification of affected samples and customer notification?				
5.5.13.1	b) Are all support equipment calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use?				
5.5.13.1	b) Are the results of such calibration or verification within the specifications required of the application for which this equipment is used or:				
5.5.13.1	b) i. the equipment shall be removed from service until repaired; or				
5.5.13.1	b) ii. the laboratory shall maintain records of established correction factors to correct all measurements?				

Section Reference	Question	Yes	No	NA	Comments
5.5.13.1	c) Are raw data records retained to document equipment performance?				
5.5.13.1	d) On each day the equipment is used, balances, ovens, refrigerators, freezers and water baths are they checked and documented? Is the acceptability for use or continued use documented according to the needs of the analysis or application for which the equipment is being used?				
5.5.13.1	d. Are checks performed in the expected use range, using reference standards that are obtained, where available, from an accredited third party or a NMI (e.g., NIST) traceable to the SI, International System of Units?				
5.5.13.1	e) Are Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) checked for accuracy on a quarterly basis?				
5.5.13.1	f) Are results of calibration and verification of support equipment within the specifications required of the application for which this equipment is used and/or the equipment is removed from service until repaired?				
5.5.13.1	f) Are calibration and verification records, including those of established correction factors must be maintained.				
5.5.13.1	f) In the absence of method-specific requirements, the minimum requirements are as follows:				
5.5.13.1	Performance Check for Balance calibration check: [Using two standard weights that bracket the expected mass] Frequency : Daily prior to use & Acceptance Criteria: Top-loading balance: ± 2% or ± 0.02 g, whichever is greater & Analytical balance: ±0.1% or ±0.5 mg, whichever is greater?				
5.5.13.1	Performance Check: Verification of standard mass [Using weights traceable to the International System of Units (SI) through a NMI; Frequency: Every 5 years; Acceptance Criteria: Certificate of Calibration from ISO/IEC 17025 accredited calibration laboratory?				
5.5.13.1	Performance Check: Monitoring of refrigerator/freezer temperature; Frequency: Daily (i.e. 7 days per week) [use MIN/MAX thermometers or data loggers equipped with notification of out of control event capabilities if personnel not available to record daily]; Acceptance Criteria: Refrigerators: 0˚C to 6˚C, Freezers: ≤-10˚C?				

Section Reference	Question	Yes	No	NA	Comments
5.5.13.1	Frequency: If a notification has been sent to laboratory personnel for out of control conditions,does the laboratory respond with corrective actions within 24 hours of sent notification or the client of the affected samplesis notified?				
5.5.13.1	Performance Check: Thermometer verification check [Using a thermometer traceable to the SI through an NMI] [Performed at two temperatures that bracket the target temperature(s). Assume linearity between the two bracketing temperatures.] [If only a single temperature is used, at the temperature of use]; Frequency: Liquid in glass: Before first use and annually, Electronic: Before first use and quarterly; Acceptance Criteria: Apply correction factors or replace thermometer?				
5.5.13.1	Performance Check: Volumetric lab ware; Frequency: Class B: By lot before first use, Class A and B: Upon evidence of deterioration; Acceptance Criteria: Bias: Mean within ±2% of nominal volume, Precision: RSD ≤1% of nominal volume (based on 10 replicate measurements)?				
5.5.13.1	Performance Check: Non-volumetric lab ware [Applicable only when used for measuring initial sample volume and final extract/ digestates volume]; Frequency: By lot before first use or upon evidence of deterioration; Bias: Mean within ±3% of nominal volume, Precision: RSD ≤3% of nominal volume (based on 10 replicate measurements)?				
5.5.13.1	Performance Check: Mechanical volumetric pipette; Frequency: Daily before use; Bias: Mean within ±2% of nominal volume, Precision: RSD ≤1% of nominal volume (based on minimum of 3 replicate measurements), [Note: for variable volume pipettes, the nominal volume is the volume of use]?				
5.5.13.1	Performance Check: Glass microliter syringe; Frequency: Upon receipt and upon evidence of deterioration; General Certificate of Bias & Precision upon receipt Replace if deterioration is evident?				
5.5.13.1	Performance Check: Drying oven temperature check; Frequency: Daily prior to and after use; Acceptance Criteria: Within ±5% of set temperature?				
5.5.13.1	Performance Check: Water purification system; Frequency: Daily prior to use; Acceptance Criteria: Per Laboratory SOP?				

Section Reference	Question	Yes	No	NA	Comments
5.5.13.1	Performance Check: Radiological Survey Equipment; Frequency: Daily prior to use; Acceptance Criteria: Per Laboratory SOP?				
5.5.13.1	**Measurement Traceability**				
5.6	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?				
5.6.1	Does the laboratory have an established program and procedure for the calibration of its equipment?				
5.6.2.1.1	Does a calibration laboratory establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI measurement units?				
5.6.2.1.1	Is the link to SI units achieved by reference to national measurement standards?				
5.6.2.1.1	Are the national measurement standards primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or;				
5.6.2.1.1	Are they secondary standards (standards calibrated by another national metrology institute)?				
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?				
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?				
5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units. In these cases, does calibration provide confidence in measurements by establishing traceability to appropriate measurement standards such as:				
5.6.2.1.2	the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material?				

Section Reference	Question	Yes	No	NA	Comments
5.6.2.1.2	the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned?				
5.6.2.1.2	Does the laboratory participate in a suitable program of proficiency testing? (Assessor must provide copies of PT reports in package.)				
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				
5.6.2.2.1	When the above situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?				
5.6.2.2.1	Where traceability of measurements to SI units is not possible or not relevant, are the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards required?				
5.6.3.1	Does the laboratory have a program and procedure for the calibration of its reference standards?				
5.6.3.1	Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1?				
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?				
5.6.3.1	Are reference standards calibrated before and after any adjustment?				
5.6.3.1	Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?				
5.6.3.2	Are internal reference materials checked as far as is technically and economically practicable?				
5.6.3.3	Are checks carried out to maintain confidence in the status of reference, primary, transfer or working standards and reference materials according to defined procedures and schedules?				
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?				

Section Reference	Question	Yes	No	NA	Comments
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?				
5.6.4.1	a) Reference Standards: Where commercially available, is there traceability to a national standard of measurement?				
5.6.4.1	b) Reference Materials: Where possible, is there traceability to national or international standards of measurement or to national or international standard reference materials? Are Internal reference materials checked as far as is technically and economically practicable?				
5.6.4.2	Does the laboratory have documented procedures for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory?				
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?				
5.6.4.2	a).Do records for standards, reagents, and reference materials include lot numbers?				
5.6.4.2	a) Is the documentation for reagents and solvents checked to ensure that the stated purity will meet the intended use and do the supporting records of the checks filed in a manner that is retrievable?				
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?				
5.6.4.2	Note: If an expiration date is not provided by the manufacturer or vendor it is not required.				
5.6.4.2	c)Are Records maintained on standard, reference material, and reagent preparation?				

Section Reference	Question	Yes	No	NA	Comments
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?				
5.6.4.2	d) Do all containers of prepared standards, reference materials, and reagents bear a unique identifier and expiration date?				
5.6.4.2	d) Do expiration date of the prepared standard exceed the expiration date of the primary standard?				
5.6.4.2	d) Do all containers of prepared standards used bear a preparation date?				
5.6.4.2	e) Are procedures in place to ensure prepared reagents meet the requirements of the method?				
5.6.4.2	f) Are standards, reference materials, and reagents used after their expiration dates only if their reliability is verified by the laboratory?				
5.6.4.2	f) If a standard exceeds its expiration date and is not re-certified, does the laboratory remove the standard or clearly designate it as acceptable for qualitative purposes only?				
5.6.4.2	g) Are Standards and reference materials stored separately from samples, extracts, and digestates and protected in an appropriate cabinet or refrigerator				
	Sampling				
5.7.1	Does the laboratory have a sampling plan and procedure for sampling when it carries out sampling of substances, materials or products for subsequent environmental testing?				
5.7.1	Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken?				
5.7.1	Are sampling plans, whenever reasonable, based on appropriate statistical methods?				
5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the environmental test and calibration results?				

Section Reference	Question	Yes	No	NA	Comments
5.7.1	Where subsampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures and appropriate techniques to obtain representative sub-samples?				
5.7.1	Does the sample handling procedures address laboratory practices for recording the presence of extraneous materials (e.g., rocks, twigs, vegetation) present in samples in the case of heterogeneous materials?				
5.7.1	To avoid preparing non-representative samples, does the laboratory not "target" within a relatively small mass range (e.g., 1.00 ± 0.01 g)?				
5.7.1	Does the laboratory not manipulate the sample material so the sample aliquot weighs exactly 1.00g ± 0.01g, as an example?				
5.7.1	Is the handling of multiphase samples addressed in a specific sampling procedures, as appropriate?				
5.7.1	Does the laboratory's sampling procedures comply with recognized consensus standards (for example, ASTM standards or EPA's Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples (EPA/600/R-03/027)) where available?				
5.7.2	Are client required deviations, additions or exclusions from the documented sampling procedure, recorded in detail with the appropriate sampling data?				
5.7.2	Are any required deviations, additions, or exclusions (to sampling plans) communicated to the appropriate personnel?				
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 done?				
5.7.3	Do these records include:				
5.7.3	- the sampling procedure used?				
5.7.3	- the identification of the sampler?				
5.7.3	- environmental conditions (if relevant)?				
5.7.3	- diagrams or other equivalent means to identify the sampling locations as necessary?				
5.7.3	If appropriate, the statistics the sampling procedures are based upon?				

Section Reference	Question	Yes	No	NA	Comments
5.7.4	a) does the Documentation include the date and time of sampling?				
5.7.4	b) Any deviations from sampling procedures shall be documented?				
	Handling of Test and Calibration Items				
5.8.	Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of samples, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the client, including:				
5.8.1	Are the personnel dealing with radioactive samples trained in radioactive sample receipt, radioactive waste management, radioactive materials shipping (49 CFR 172) and handling, and radioactive material control?				
5.8.2	Does the laboratory have a system for identifying samples?				
5.8.2	Is the sample identification retained throughout the life of the sample in the laboratory?				
5.8.2	Does the laboratory have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time?				
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?				
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?				
5.8.3	Upon receipt of the sample(s) is the condition, including any abnormalities or departures from normal or specified conditions as described in the environmental test method, recorded?				
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?				
5.8.3	Is the discussion recorded?				
5.8.3	Does the laboratory have a procedure addressing instances when it receives samples that require non-routine or additional sample preparation steps?				

Section Reference	Question	Yes	No	NA	Comments
5.8.4	Does the laboratory have procedures and appropriate facilities for avoiding deterioration, contamination, loss or damage to the sample during storage, handling, preparation and testing?				
5.8.4	Are handling instructions provided for the item followed (a - d)?				
5.8.4	When items have to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?				
5.8.4	Where at 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?				
5.8.4	a. Does the laboratory have SOP(s) in place to address the use of ventilation hoods or suitable containment for opening shipping containers, radiation screening of samples, laboratory notification, and labeling requirements for radioactive samples?				
5.8.4	c. Are shipping containers and packaging opened inside a ventilation hood or other designated area that provides adequate ventilation for personnel?				
5.8.4	c. Are all shipping containers from known radiological areas surveyed for radiological contamination on all external surfaces?				
5.8.4	c. Has the laboratory developed and implemented administrative policies for the receipt of radiological shipping containers and samples?				
5.8.4	c. Are radiological surveys of sample shipping containers performed as soon as possible from the time of receipt by the laboratory?				
5.8.4	d.. Are Instrumentation and equipment used for monitoring the following;				
5.8.4	d) i) Maintained and calibrated on an established frequency?				
5.8.4	d) ii) Appropriate for the type(s), levels, and energies of the radiation encountered?				
5.8.4	d) iii) Appropriate for existing environmental conditions?				
5.8.4	d) iv) Routinely tested for operability (10 CFR 835.401(b))?				
5.8.4	e. Does the laboratory have a system in place to record incidents involving spillage of customer samples or significant spillage of chemicals?				
5.8.5	The following are essential to ensure the validity of the laboratory's data:				

Section Reference	Question	Yes	No	NA	Comments
5.8.5	a) Does the laboratory have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time? And does the system include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates?				
5.8.5	b) Does the laboratory code maintain an unequivocal link with the unique field ID code assigned to each sample?				
5.8.5	c) Is the laboratory ID code placed as a durable mark on the sample container?				
5.8.5	d) Is the laboratory ID code entered into the laboratory records and does the link associate the sample with related laboratory activities such as sample preparation?				
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, is the laboratory ID code the same as the field ID code?				
5.8.6	Does the laboratory have a written sample acceptance policy, and does it includes the following?				
5.8.6	a) proper, full, and complete documentation, which includes sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample?				
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?				
5.8.6	c) use of appropriate sample containers?				
5.8.6	d) adherence to specified holding times?				
5.8.6	e) sufficient sample volume to perform the necessary tests?				
5.8.6	f) procedures to be used when samples show signs of damage, contamination or inadequate preservation?				

Section Reference	Question	Yes	No	NA	Comments
5.8.6	g) qualification of any data that do not meet the above requirements?				
5.8.6	h) Does the laboratory have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected?				
5.8.7;1	Has the laboratory implement procedures for verifying and documenting preservation?				
5.8.7.1	a) Is sample temperature measurement verified through the use of one or more temperature blanks for each shipping container, if provided?				
5.8.7.1	a) If a temperature blank is not available, are other temperature measurement procedures used?				
5.8.7.1	b) Does the laboratory refer to the Chain of Custody (COC) for the matrix definition? In the case where the matrix is not identified on the COC, does the laboratory contact the customer prior to proceeding?				
5.8.7.1	c) Is Chemical preservation checked at the time of sample receipt for all samples, unless it is not technically acceptable to check preservation upon receipt (e.g., VOA samples)?				
5.8.7.1	c) If any of the following conditions exist, is the chemical preservation rechecked in the laboratory:				
5.8.7.1	i Continued preservation of the sample is in question (e.g., the sample may not be compatible with the preservation)?				
5.8.7.1	ii) Deterioration of the preservation is suspected?				
5.8.7.1	d) Does the laboratory have procedures in place that ensure that the appropriate laboratory personnel are notified when samples are received with a quick turn-around time request, short hold times, or a short amount of hold time is remaining?				
5.8.7.2	If the sample does not meet the sample receipt acceptance criteria listed in this Standard, does the laboratory can either (a-b):				
5.8.7.2	a) retain correspondence and/or records of conversations concerning the final disposition of rejected samples?				

Section Reference	Question	Yes	No	NA	Comments
5.8.7.2	b) fully document any decision to proceed with the analysis of samples not meeting acceptance criteria?				
5.8.7.2	b) i. Are the condition of these samples noted on the chain of custody or transmittal form and laboratory receipt documents?				
5.8.7.2	b) ii. Is the analysis data appropriately qualified on the final report?				
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?				
5.8.7.3	a) Does the sample receipt log record the following:				
5.8.7.3	a) i. client/project name?				
5.8.7.3	a) ii. date and time of laboratory receipt?				
5.8.7.3	a) iii. unique laboratory ID code (see Section 5.12.1.b)i.)?				
5.8.7.3	a) iv. signature or initials of the person making the entries?				
5.8.7.3	b) During the login process, is the following information unequivocally linked to the log record or included as a part of the log? If such information is recorded/documented elsewhere, are the records part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample?				
5.8.7.3	NOTE: The placement of the laboratory ID number on the sample container is not considered a permanent record.				
5.8.7.3	b) i. Is the field ID code, which identifies each sample, shall be linked to the laboratory ID code in the sample receipt log?				
5.8.7.3	b) ii. Is the date and time of sample collection shall be linked to the sample and to the date and time of receipt in the laboratory?				
5.8.7.3	b) iii. Is the requested analyses (including applicable approved method numbers) linked to the laboratory ID code?				
5.8.7.3	b) iv. Are the comments resulting from inspection for sample rejection linked to the laboratory ID code?				
5.8.7.4	Are all documentation, such as memos, chain of custody, or transmittal forms that are transmitted to the laboratory by the sample transmitter, retained?				

Section Reference	Question	Yes	No	NA	Comments
5.8.7.5	Is a complete chain of custody record form, if utilized, maintained?				
5.8.8	Legal chain of custody procedures are used for evidentiary or legal purposes. If a client specifies that a sample is to be used for evidentiary purposes, then does the laboratory have a written SOP for how that laboratory will carry out legal chain of custody?				
5.8.8	a) When the legal Chain of Custody (COC) protocols are not provided by a state or federal program and legal custody is required to be maintained for a given project, is the following protocols incorporated?				
5.8.8	Do the legal COC protocol records establish an intact, continuous record of the physical possession, storage and disposal of used sample containers, collected samples, sample aliquots, and sample extracts or digestates, collectively referred to below as “samples”?				
5.8.8	i: Is the sample in someone's custordy if the following is in place (a-d)?				
5.8.8	a. It was in one’s actual physical possession?				
5.8.8	b. It was in one’s view, after being in one’s physical possession?				
5.8.8	c. It was been in one’s physical possession and then locked or sealed so that no one can tamper with it?				
5.8.8	d. It was kept in a secure area, restricted to authorized personnel only?				
5.8.8	ii. Do the COC records identify all individuals who physically handled individual samples?				
~~**5.8.8**~~	~~f. Does the Legal COC begin at the point established by the federal or state oversight program?~~				
~~**5.8.8**~~	~~g. Do the COC forms remain with the samples during transport or shipment?~~				
~~**5.8.8**~~	~~h. If shipping containers and/or individual sample containers are submitted with sample custody seals and any seals are not intact, does the custodian note this on the COC?~~				
~~**5.8.8**~~	~~j. Once received by the laboratory, are laboratory personnel responsible for the care and custody of the sample, and are they able to testify that the sample was in their possession and within view or secured in the laboratory at all times?~~				

Section Reference	Question	Yes	No	NA	Comments
~~5.8.8~~	~~Note: This includes from the moment it was received from the custodian until the time that the analyses are completed until the time that the sample is disposed.~~				
5.8.8	b) Are tracking records maintained until final disposition or return of samples to the customer?				
5.8.8	b) Do tracking records include, by direct entry or linkage to other records:				
5.8.8	i) Time of day and calendar date of each transfer or handling?				
5.8.8	ii) Signatures of all personnel who physically handled the samples and parent organization and physical address?				
5.8.8	iii) All information necessary to produce unequivocal, accurate reports that record the laboratory activities associated with sample receipt, preparation, analysis?				
5.8.8	iv) Common carrier records?				
5.8.9	a) Are Samples stored according to the conditions specified by preservation protocols?				
5.8.9	a) i. Are samples that require thermal preservation stored under refrigeration that is +/- 2℃ of the specified preservation temperature unless regulatory or method specific criteria exist? For samples with a specified storage temperature of 4℃, storage at a temperature above the freezing point of water to 6℃ shall be acceptable?				
5.8.9	a) ii. Are samples stored away from all standards, reagents, and food? Are samples stored in such a manner to prevent cross contamination?				
5.8.9	b) Are sample fractions, extracts, leachates and other sample preparation products stored according to Section 5.8.9 a) or according to specifications in the method?				
5.8.9	c) Does the laboratory have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products?				
5.8.9	i) Does disposal of the physical sample occur only with the concurrence of the customer who submitted the sample if those samples are disposed of prior to any project specified time limit?				

Section Reference	Question	Yes	No	NA	Comments
5.8.9	ii)Are all conditions of disposal and all records and correspondence concerning the final disposition of the physical sample recorded and retained?				
5.8.9	i) Are samples that are completely consumed during analysis recorded as such for their final disposition?				
~~**5.8.9**~~	~~Do records indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to customer), and the name of the individual who performed the task?~~				
5.8.9	d) Is the access to all evidentiary samples and subsamples controlled and recorded for all samples associated with legal chain of custody:				
5.8.9	d) i) Is a clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside designated as a custody room?				
5.8.9	d) ii) Where possible, are the distribution of samples to the analyst performing the analysis must be made by the custodian(s)?				
5.8.9	d) iii) Does the laboratory area maintain a secured area, restricted to authorized personnel only?				
5.8.9	d) iv) Once the sample analyses are completed, are the unused portion of the sample, together with all identifying labels, must be returned to the custodian?				
5.8.9	d) iv) Is the returned sample retained in the custody room until permission to dispose of the sample is received by the custodian or other authority?				
5.8.9	e) Are transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for legal COC for all samples associated with legal chain of custody?				
	Assuring the Quality of Test and Calibration Results				
5.9.1	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken?				
5.9.1	Are Quality control samples processed in the same manner as field samples and are they must analyzed and reported with their associated field samples?				

Section Reference	Question	Yes	No	NA	Comments
5.9.1	Are the data resulting from quality control procedures recorded in such a way that trends are detectable and, where practicable, are statistical techniques applied to the reviewing of the results?				
5.9.1	Is the quality control monitoring planned and reviewed?				
5.9.1	Are quality control samples processed in the same manner as field samples? Are they analyzed and reported with their associated field samples?				
5.9.2	Is quality control data analyzed and, where it is found outside pre-defined criteria, planned action taken to correct the problem and to prevent incorrect results from being reported?				
5.9.3	These general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., asbestos, chemical, microbiological, radiological, toxicity) and are further described in Technical Modules. The standards for any given test type shall assure that the applicable principles are addressed:				
5.9.3	a) Does the laboratories have detailed written protocols in place to monitor the following quality controls:				
5.9.3	a) 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?				
5.9.3	a) ii. tests to define the variability and/or repeatability of the laboratory results such as replicates?				
5.9.3	a) 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?				
5.9.3	a) iv. measures to evaluate method capability, such as limit of detection and limit of quantitation or range of applicability such as linearity?				
5.9.3	a) 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?				
5.9.3	a) vi. selection and use of reagents and standards of appropriate quality?				

Section Reference	Question	Yes	No	NA	Comments
5.9.3	a) vii. measures to assure the selectivity of the test for its intended purpose?				
5.9.3	a) 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?				
5.9.3	b) Are all quality control measures assessed and evaluated on an on-going basis and quality control acceptance criteria used?				
5.9.3	c) Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?				
5.9.3	Are quality control protocols specified by the laboratory's SOP followed (see Section 4.2.8.5 in this Standard)?				
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?				
5.9.3	When it is not apparent which is more stringent, are the QC in the mandated method or regulations is to be followed?				
	Reporting the Results				
5.10.	Are the results of each test, or series of environmental tests carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the environmental test methods?				
5.10.1	In the case of environmental tests or calibration results performed for internal clients, or in the case of a written agreement with the client, are the results reported in a simplified way?				
5.10.1	Is any information listed in.5.10.2 to 5.10.4 which is not reported to the client readily available in the laboratory which carried out the environmental tests results?				
5.10.1	Does the report include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used? (This information is normally that required by 5.10.2 and 5.10.3 or 5.10.4.)				

Section Reference	Question	Yes	No	NA	Comments
5.10.1	Does the laboratory have a written procedure for communicating with the customer for the purpose of establishing project-specific data reporting requirements including:				
5.10.1	1) conventions for reporting results below the LOQ?				
5.10.1	2) specification for the use of data qualifiers?				
5.10.1	Is the basis for the use of all data qualifiers adequately explained in the test report?				
5.10.2	Does each test report include at least the following information, unless the laboratory has valid reasons for not doing so, as indicated by 5.10.2.a and b?				
5.10.2	a. A title (e.g. "Test Report," "Certificate of Results," or "Laboratory Results")?				
5.10.2	b. The name and address of the laboratory, the location where the environmental tests were carried out, if different from the address of the laboratory, and phone number with name of contact person for questions?				
5.10.2	b) Is the name of a contact person and their phone number included in the laboratory information?				
5.10.2	c. Unique identification of the test report (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?				
5.10.2	c) The total number of pages listed on the first page or the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers?				
5.10.2	c) Each page is identified with the unique report identification?				
5.10.2	c) The pages are identified as a number of the total report pages (e.g. 3 of 10, 1 of 20)?				
5.10.2	d. The name an address of the client and project name on the test reports?				
5.10.2	e. Identification of the method used?				
5.10.2	f. a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?				

Section Reference	Question	Yes	No	NA	Comments
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?				
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?				
5.10.2	i. the test or calibration results with, where appropriate, the units of measurement?				
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?				
5.10.2	k. where relevant, a statement to the effect that the results relate only to the items tested or calibrated?				
5.10.2	l. Any failures identified?				
5.10.2	m. For Whole Effluent Toxicity, identification of the statistical method used to provide data?				
5.10.2	n . The date of issuance?				
5.10.2	o. For solid samples, a statement of whether the results are based on a dry weight or wet weight basis?				
5.10.2	NOTE: Hard copies of test reports and calibration certificates should also include the page number and total number of pages. Labs should include a statement specifying report/certificate shall not be reproduced except in full, without written approval by the laboratory.				
5.10.3	Where it is necessary for the interpretation of the test results, does the test report also include the following:				
5.10.3.1	a. Deviations from (such as failed quality control), additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions and any nonstandard conditions that may have affected the quality of results, including the use and definitions of data qualifiers?				

Section Reference	Question	Yes	No	NA	Comments
5.10.3.1	b. Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature?				
5.10.3.1	c. Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed when a client's instruction so requires?				
5.10.3.1	d. Where appropriate and needed, opinions and interpretations?(See 5.10.5)				
5.10.3.1	e. Additional information which may be required by specific methods, clients or groups of clients?				
5.10.3.1	f. Information on any non-standard conditions that may have affected the quality of the results, including the use and definitions of data qualifiers?				
5.10.3.1.1	g. Where management system requirements are met, a statement of compliance/noncompliance requirements and/or specifications, including identification of test results derived from any sample that did not meet sample acceptance requirements such as improper container, holding time, or temperature?				
5.10.3.1.1	In the absence of project-specific requirements, are the minimum standard data qualifiers listed below used by the laboratory:				
5.10.3.1.1	U – Analyte was not detected and is reported as less than the LOD or as defined by the client. The LOD has been adjusted for any dilution or concentration of the sample.?				
5.10.3.1.1	J – The reported result is an estimated value (e.g., matrix interference was observed or the analyte was detected at a concentration outside the calibration range)?				
5.10.3.1.1	B – Blank contamination. The recorded result is associated with a contaminated blank?				

Section Reference	Question	Yes	No	NA	Comments
5.10.3.1.1	N – Non-target analyte. The analyte is a tentatively identified compound using mass spectrometry or any non-customer requested compounds that are tentatively identified?				
5.10.3.1.1	Q – One or more quality control criteria failed (e.g., LCS recovery, surrogate spike recovery or CCV)?				
5.10.3.1.1	If the laboratory uses additional data qualifiers, or different letters or symbols to denote the qualifiers listed above, are they appropriately defined and their use consistent with project-specific requirements (e.g., this document, the contract, and project-planning documents)?				
5.10.3.2	Do test reports containing the results of sampling include the following, where necessary for the interpretation of test results:				
5.10.3.2	a. The date of sampling?				
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)?				
5.10.3.2	c. The location of sampling, including any diagrams, sketches or photographs?				
5.10.3.2	d. A reference to the sampling plan and procedures used?				
5.10.3.2	e. Details of any environmental conditions during sampling that may affect the interpretation of the test results?				
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?				
5.10.5	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made?				
5.10.5	Are opinions and interpretations clearly marked as such in a test report?				
5.10.5	When included, are opinions and interpretations only contained in the case narrative?				
5.10.6	Does the subcontractor report the results either in writing or electronically?				
5.10.6	Does the laboratory make a copy of the subcontractor's report available to the client when requested by the client?				

Section Reference	Question	Yes	No	NA	Comments
~~**5.10.6**~~	~~When the test report contains results of tests performed by subcontractors, are these results clearly identified by subcontractor name or applicable accreditation number?~~				
5.10.7	In the case of transmission of environmental test results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this Standard met and ensure that all reasonable steps are taken to preserve confidentiality?				
5.10.8	Is the format of the report designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse?				
5.10.9	Are material amendments to a test report/calibration certificate after issue made only in the form of a further document, data transfer, including a statement equivalent to “Supplement to Test Report (or Calibration Certificate)”?				
5.10.9	Do such amendments meet all the requirements of this standard?				
5.10.9	When it is necessary to issue a complete new test report or calibration certificate, is this uniquely identified?				
5.10.9	Does this contain a reference to the original that it replaces?				
5.10.9	Do such test report amendments meet all the requirements of this Standard?				
5.10.10	When it is necessary to issue a complete new test report, is this uniquely identified and does it contain a reference to the original that it replaces?				
5.10.10	Some regulatory reporting requirements or formats such as monthly operating reports may not require all items listed, in those cases does the laboratory provide all the required information to their client for use in preparing such regulatory reports?				
5.10.10	~~Note:~~ Laboratories operated solely to provide data for compliance purposes (in-house or captive laboratories) shall have all applicable information specified in Section 5.10 readily available for review by the accreditation body. However, formal reports detailing the information are not required if:				
5.10.10	a) Is the in-house laboratory itself responsible for preparing the regulatory reports?				

Section Reference	Question	Yes	No	NA	Comments
5.10.10	b) Does the laboratory provides information to another individual within the organization for preparation of regulatory reports?				
5.10.10	b) Does the facility management ensure that the appropriate report items are in the report to the regulatory authority, if such information is required?				
5.10.10	c) see Section 5.10.1, paragraph 3?				
5.10.10	a) The date and time of sample collection, preparation, and analysis are required to be included as part of the laboratory report, regardless of the length of holding time. If the time of the sample collection is not provided, does the laboratory assume the most conservative time of day? For the purpose of batch processing, are the start and stop dates and times of the batch preparation recorded?				
5.10.11	a) Is the time of sample preparation and/or analysis recorded, if the required holding time for either activity is less than or equal to seventy-two hours?				
5.10.11	b) Are results reported on a basis other than as received (e. g., dry weight)?				
5.10.11	c) Are any non-accredited tests clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables?				
5.10.11	d) Are there clear identification of numerical results with values outside the calibration range?				
5.10.11	d) Are the date and time of sample collection, preparation, and analysis are required to be included as part of the laboratory report, regardless of the length of holding time? If the time of the sample collection is not provided, does the laboratory assume the most conservative time of day? For the purpose of batch processing, are the start and stop dates and times of the batch preparation recorded?				
5.10.11	e) Is there qualification of numerical results with values outside the calibratiotion range?				
	SOP-3 Accreditation Symbol Procedure				
SOP-3	**For applicant laboratories:** Does the applicant laboratory use the PJLA Logo?				

Section Reference	Question	Yes	No	NA	Comments
SOP-3	Note Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval.				
SOP-3	**PJLA Symbol Usage for Accredited Laboratories:**				
SOP-3	Is the accredited 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 does use the actual accreditation symbol and issues an endorsed or accredited report are they specifying the following on their report in lieu of the actual symbol:				
SOP-3	accreditation number?				
SOP-3	program (i.e. medical testing)?				
SOP-3	the standard (i.e. ISO/IEC 17025:2005 and DoD ELAP)?				
SOP-3	a reference to PJLA as the accrediting body?				
SOP-3	Is the symbol reproduced in a size that is clearly distinguishable?				
SOP-3	Is the symbol reproduced in a single-color (black or a single color belonging to the house-style of the accredited lab)?				
SOP-3	Is the symbol identifiable?				
SOP-3	Is the accredited laboratory properly stating their accreditation status? “Accredited to ISO/IEC 17025:2005” or utilizing the ILAC criteria listed in the SOP-3 Procedure. (ILAC guidance not mandatory)				
SOP-3	Does the laboratory have a documented procedure outlining requirements listed in PJLA SOP-3.				
SOP-3	If the ILAC Mark is utlized, 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 occurrs				
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?				

Section Reference	Question	Yes	No	NA	Comments
SOP-3	Quotations or proposals for work (symbols may only be listed for accredited laboratories)?				
SOP-3	Was the proper accreditation symbols used and in accordance to the laboratory accredited scope?				
SOP-3	Is the accredited laboratory appropriately using the symbol by **not** placing the symbol on:				
SOP-3	Legal documents?				
SOP-3	Test or Calibrations Reports or Certificates for work that is not covered by the scope of accreditation?				
SOP-3	Documents that list sites not accredited?				
SOP-3	Tested or Calibrated Products, except calibration labels (May be misleading that PJLA has accredited the product)?				
SOP-3	If the accredited laboratory included the results of subcontracted tests or calibrations on reports or certificates can they demonstrate that they have done the following:				
SOP-3	a) obtained approval from the subcontracted laboratory?				
SOP-3	b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate?				
SOP-3	c) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate?				
	PL-1 Proficiency Testing Requirements for Applicant and Accredited Laboratories				
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 proficiency testing plan or schedule?				
PL-1	Does this plan or schedule include all items included on the scope of accreditation to be tested within a four year period?				

Section Reference	Question	Yes	No	NA	Comments
PL-1	Has the laboratory completed at least one proficiency test each year?				
PL-1	Has the proficiency plan or schedule been approved by PJLA?				
PL-1	For any unfavorable results gathered during proficiency testing, was appropriate corrective action taken?				
	PL-2 Measurement Traceability Policy				
PL-2	Does the laboratory have documented policies and procedures regarding measurement traceability and reference this traceability on test reports?				
PL-2	Does the laboratory have documented procedures detailing the verification, transport and storage of reference standards?				
PL-2	Has the laboratory employed the services of an external calibration provider(s) that are accredited to ISO/IEC 17025:2005 for the calibration(s) performed?				
PL-2	If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI?				
PL-2	Is this documented on an LF-123?				
PL-2	Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed?				
	PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories				
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?				

Section Reference	Question	Yes	No	NA	Comments
PL-3	Does the laboratories documented procedure for estimating uncertainty include a definition of the method used to determine significance of each potential uncertainty contributor?				
PL-3	Does the laboratories documented procedure for estimating uncertainty include a definition of the method used to account for uncertainty when making a statement of compliance?				
PL-3	**Appendix A**				
Appendix A	**Reporting Requirements**				
Appendix A	In the absence of client specified reporting criteria, are the reporting requirements outlined below used for hard-copy data reports or electronic versions of hard-copy data (such as pdf)?				
Appendix A	Note: This includes mandatory requirements for all printed data reports, and requirements for data reports requiring third party data review or validation. Optional reporting requirements are those that may be required by a specific project, depending upon their needs.				
Appendix A	Are the following required elements included:				
Appendix A	- cover sheet?				
Appendix A	- table of contents?				
Appendix A	- case narrative?				
Appendix A	- analytical results?				
Appendix A	- sample management records?				
Appendix A	- Quality Assessment/Quality Control (QA/QC) information?				
Appendix A	- Data reports for third party review or validation?				
Appendix A	**1.0 Cover Sheet**				
Appendix A	Does the cover sheet specify the following information?				
Appendix A	· Title of report (i.e., test report, test certificate)?				
Appendix A	· Name and location of laboratory (to include a point of contact, phone and facsimile numbers, and e-mail address)?				

Section Reference	Question	Yes	No	NA	Comments
Appendix A	· Name and location of any subcontractor laboratories, and appropriate test method performed (information can also be located in the case narrative as an alternative)?				
Appendix A	· Unique identification of the report (such as serial number)?				
Appendix A	· Client name and address?				
Appendix A	· Project name and site location?				
Appendix A	· Statement of data authenticity and official signature and title of person authorizing report release, date of issuance?				
Appendix A	· Amendments to previously released reports that clearly identify the serial number for the previous report and state the reason(s) for reissuance of the report?				
Appendix A	· Total number of pages?				
Appendix A	**2.0 Table of Contents**				
Appendix A	Are the laboratory data packages organized in a format that allows for easy identification and retrieval of information?				
Appendix A	Is an index or table of contents included for this purpose?				
Appendix A	**3.0 Case Narrative**				
Appendix A	Is a case narrative included in each report?				
Appendix A	Is the purpose of the case narrative is to:				
Appendix A	· Describe any abnormalities deviations and failures that may affect the analytical results?				
Appendix A	· Summarize any issues in the data package that need to be highlighted for the data user to help them assess the usability of the data?				
Appendix A	· Provide a summary of samples included in the report with the methods employed in order to assist the user in interpretation?				
Appendix A	-Does the case narrative provide (Information need not be repeated if noted elsewhere in the data package)?				
Appendix A	-A table(s) summarizing samples received, providing a correlation between field sample numbers and laboratory sample numbers, and identifying which analytical, preparation, and clean-up methods were performed?				

Section Reference	Question	Yes	No	NA	Comments
Appendix A	-If multiple laboratories performed analyses, are the names and locations of each laboratory shall be associated with each sample?				
Appendix A	-A list of samples that were received but not analyzed?				
Appendix A	-Date of samples received?				
Appendix A	-Sample preservation and condition at receipt?				
Appendix A	-A description of extractions or analyses that are performed out of holding times?				
Appendix A	-A definition of all data qualifiers or flags used?				
Appendix A	-Identification of deviations of any calibration standards or QC sample results from appropriate acceptance limits and a discussion of the associated corrective actions taken by the laboratory?				
Appendix A	-Identification of multiple sample runs with reason(s) identified (e.g., dilutions or multiple cleanups)?				
Appendix A	-Identification of samples and analytes for which manual integration was necessary includig the justification?				
Appendix A	-Appropriate notation of any other factors that could affect the sample results (e.g., air bubbles in volatile organic compounds (VOC) sample vials, excess headspace in soil VOC containers, the presence of multiple phases, sample temperature or pH excursions, VOC containers, the presence of multiple phases, sample temperature or pH excursions, and container type or volume)?				
Appendix A	**4.0 Analytical Results**				
Appendix A	Do the results for each sample contain the following information at a minimum: (Information need not be repeated if noted elsewhere in the data package):				
Appendix A	· Project name and site location?				
Appendix A	· Field sample ID number as written on custody form?				
Appendix A	· Laboratory sample ID number?				
Appendix A	· Preparation batch number(s)?				
Appendix A	· Matrix (soil, water, oil, air, etc.)?				
Appendix A	· Date and time sample collected?				

Section Reference	Question	Yes	No	NA	Comments
Appendix A	· Date and time sample prepared?				
Appendix A	· Date and time sample analyzed?				
Appendix A	· Method numbers for all preparation, cleanup, and analysis procedures employed?				
Appendix A	· Analyte or parameter with the Chemical Abstracts Service (CAS) Registry Number if available?				
Appendix A	· Sample aliquot analyzed?				
Appendix A	· Final extract volume?				
Appendix A	· Identification of analytes in which manual integration occurred, including the cause and justification?				
Appendix A	· Analytical results with correct number of significant figures?				
Appendix A	· Detection Limit, Limit of Detection, and Limit of Quantitation associated with sample results and adjusted for sample-specific factors (e.g., aliquot size, dilution/concentration factors, and moisture content)?				
Appendix A	· Any data qualifiers assigned?				
Appendix A	· Concentration units?				
Appendix A	· Dilution factors?				
Appendix A	· All multiple sample run results shall be reported?				
Appendix A	· Percent moisture or percent solids (all soils are to be reported on a dry weight basis)?				
Appendix A	· Statements of the estimated uncertainty of test results?				
Appendix A	**5.0 Sample Management Records**				
Appendix A	Do the Sample Management records include the documentation accompanying the samples, such as:				
Appendix A	· Chain-of-custody records?				
Appendix A	· Shipping documents?				
Appendix A	· Records generated by the laboratory which detail the condition of the samples upon receipt at the laboratory (e.g., sample cooler receipt forms, cooler temperature, and sample pH)?				

Section Reference	Question	Yes	No	NA	Comments
Appendix A	· Telephone conversation or e-mail records associated with actions taken or quality issues?				
Appendix A	· Records of sample compositing done by the laboratory?				
Appendix A	**QA/QC Information**				
Appendix A	Does the minimum laboratory internal QC data package include:				
Appendix A	· Method blank results?				
Appendix A	· Percent recoveries for Laboratory Control Sample (LCS), Laboratory Control Sample?				
Appendix A	· Duplicates (LCSD), Matrix spike (MS), and Matrix Spike Duplicates (MSD)?				
Appendix A	· MSD or matrix duplicate Relative percent differences (RPD)?				
Appendix A	· Surrogate percent recoveries?				
Appendix A	· Tracer recoveries?				
Appendix A	· Spike concentrations for LCS, MS, surrogates?				
Appendix A	· QC acceptance criteria for LCS, MS, surrogates?				
Appendix A	Post-Digestion Spike (PDS) recoveries?				
Appendix A	· In-house or project specified LCS control limits, as applicable?				
Appendix A	· Serial dilutions (SD) percent difference?				
Appendix A	· Batch numbers (preparation, analysis, and cleanup)?				
Appendix A	**7.0 Data Reports for Third Party Review or Validation**				
Appendix A	Note: The data validation guidelines established in other Department of Defense/Department of Energy guidance or project-specific guidelines may have distinct reporting formats. The appropriate QAPP should be consulted to determine what type (stage) of data package is required.				
Appendix A	Does the laboratory report the following requirements for each stage (formerly level) of data package:				
Appendix A	· A cover sheet, table of contents, and case narrative including all of the information specified in the above sections are required for all stages of data reports.				

Section Reference	Question	Yes	No	NA	Comments
Appendix A	· Stage 1: Sample results forms, chain of custody, laboratory receipt checklist?				
Appendix A	· Stage 2A: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms?				
Appendix A	- Stage 2B: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms, instrument QC forms, instrument and preparation logs?				
Appendix A	- Stage 3: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms, instrument QC forms, instrument and preparation logs, instrument quantitation forms (raw data)?				
Appendix A	·Stage 4: Sample results forms, chain of custody, laboratory receipt checklist, sample related method QC forms, instrument QC forms, instrument and preparation logs, instrument quantitation forms (raw data), instrument chromatograms and spectra.				
Appendix A	· In addition, standards traceability must be included in Stages 3 and 4 if a legal chain of custody is required?				
	Appendix B				
	Quality Control Requirements				
Appendix B	Are the QC requirements defined in Appendix B followed by the laboratory for the SW-846 methods?				
	Appendix C				
	Control Limits and Requirements				
Appendix C	Does the laboratory use control limits that are within the limits found in Appendix C?				
	APPENDIX D: Non-Destructive Assay (NDA)				
Appendix D	**1.0 Quality Assurance**				
Appendix D	**1.1 NDA System Calibration**				
Appendix D	Are the procedures developed and implemented for NDA measurement system calibration methods and processes?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Note: The “initial calibration” is that fundamental calibration that addresses and accounts for the response of an NDA measurement system to radioactive materials present in the waste containers or process components of interest (measurement items).				
Appendix D	Note: The “calibration confirmation” is a thorough corroboration of the “initial calibration” using traceable working reference materials (WRMs) and representative waste matrix/ process component configurations.				
Appendix D	Note: The “calibration verification” is a periodic verification of the “initial calibration” to ensure on-going long-term data quality compliance through the period of NDA operations.				
Appendix D	This allows the NDA measurement organization autonomy in devising and implementing techniques and analytical procedures for these three calibration definitions.				
Appendix D	Does the NDA measurement organization demonstrate the calibration and associated uncertainty is compliant with applicable client and/or end-user requirements initially and throughout the contract period?				
Appendix D	**1.1.1 Initial NDA System Calibration**				
Appendix D	Is the NDA measurement system “initial calibration” performed to ensure the measurement system response provides valid data of known and documented quality?				
Appendix D	Are calibrations performed using traceable WRMs obtained from suppliers maintaining a nationally recognized reference base and an accredited measurement program?				
Appendix D	Does the laboratory have full documentation of the calibration technique, process, and results?				
Appendix D	For cases where there is an insufficient number and denomination of traceable radioactive material standards to support the “initial calibration”, can the NDA organization develop alternate calibration strategies based on available resources?				
Appendix D	Are alternate strategies clearly documented and technically justifiable?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Is the development and establishment of an "initial calibration" address the following as applicable? :				
Appendix D	a) Are SOPs in place to specify steps/activities necessary to develop and determine the "initial calibration" including but not limited to, specification of traceable radioactive sources or their alternates, geometrical positioning of sources, traceable source/matrix media configurations, acquisition of NDA system response data, computational methods, analysis of response data to determine a robust calibration, calibration acceptance criteria, calibration applicability and qualifiers and calibration uncertainty?				
Appendix D	b) Is the "initial calibration" performed through the use of traceable working reference materials, unless exceptions have been stipulated and documented?				
Appendix D	b) For mass calibrations (i.e., calibrations that use a direct measurement of the same isotopes, matrices, and containers that will subsequently be measured in unknown items), do the radioactive material mass and matrix characteristics span and bracket the range of anticipated values for the measurement items?				
Appendix D	b) For calibrations based on instrument response modeling, is there sufficient information provided in the method description and calibration regimen to assure that the calibration measurements and model appropriately spans and brackets the anticipated analysis space?				
Appendix D	(e.g., provide mechanisms to account for anticipated geometries, radioactive material mass, chemical composition, and matrix characteristics)				
Appendix D	b) For enrichment determinations using the enrichment meter technique, does the initial calibration span the range of enrichments in anticipated unknown item measurements?				
Appendix D	c) Is the measurement uncertainty associated with the application of the "initial calibration" established using a sound and technically defensible technique?				
Appendix D	c) Are the methods for the estimation of total measurement uncertainty (TMU) shall be developed and documented?				

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

Section Reference	Question	Yes	No	NA	Comments
Appendix D	f) Does the NDA organization document this number and their denominations in a calibration SOP or other applicable document?				
Appendix D	f) This requirement does not necessarily apply to NDA methods that rely on modeling.				
Appendix D	f) Is the method used to assure that the calibration and model appropriately spans and brackets the anticipated analysis space (e.g., provide mechanisms to account for anticipated geometries, radioactive material mass, chemical composition, and matrix characteristics) as per item (b) above technically justified and documented?				
Appendix D	f) The For NDA methods that do not necessarily require calibration with source material similar in nature to the waste or process items (e.g., neutron counting), are those source(s) used still required to be traceable?				
Appendix D	f) However, is the accounting of the efficiency variation because of the composition of the actual radioactive material shall be assessed and corrected for (e.g., Californium (252Cf) fission neutron spectrum counter efficiency versus uranyl fluoride (UO2F2) neutron spectrum efficiency.)				
Appendix D	g) Is the “initial calibration” process clearly documented including the calibration measurement configurations, data acquisition parameters, acquired data, data reduction methods, resultant calibration factors or expressions, statistical analyses and uncertainties?				
Appendix D	g) Do the records containing information pertinent to the calibration process that are retained include following:				
Appendix D	g) 1) WRM and/or surrogate waste matrix configurations used to acquire instrument response data, calibration determination techniques?				
Appendix D	g) 2) SOP(s) used?				
Appendix D	g) 3) data acquisition parameters?				
Appendix D	g) 4) NDA system identification?				
Appendix D	g) 5) analytical software used?				
Appendix D	g) 6) traceable standard identifications?				
Appendix D	g) 7) analytical support equipment information?				
Appendix D	g) 8) electronic file storage locations?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	g) Are the records sufficient to allow reproduction of the "initial calibration"?				
Appendix D	h) Is the initial calibration re-established when repairs or changes are made to the measurement system that are likely to affect one or more calibration parameters?				
Appendix D	**1.1.2 Calibration Confirmation**				
Appendix D	Is a confirmation of the "initial" NDA measurement system calibration performed?				
Appendix D	In this context, does confirmation mean the "initial calibration" assessed and determined is correct and true by the objective collection of evidence supporting the calibration was properly established?				
Appendix D	a) Is this recommended method used to assemble test item(s) consisting of traceable source/matrix configuration(s) nominally representative of the waste form and/or process components to be characterized?				
Appendix D	a) Do they contain a known and traceable radioactive element/isotope, mass/activity and/or enrichment in a known and representative matrix configuration?				
Appendix D	a) Are the confirmation test item(s) then measured using the "initial calibration" of the NDA system?				
Appendix D	a) Is the number of differing tests item configurations used to confirm the calibration determined by the NDA organization and documented?				
Appendix D	a) Does the reported "calibration confirmation" measurement result agree with criteria as established by the NDA organization, with the known element/isotope, mass/activity and/or enrichment of the confirmation test item(s)?				
Appendix D	a) Does the NDA organization acceptance criterion not exceeding the criteria as presented in Section 1.1.3 unless technically justified and documented?				
Appendix D	b) Are the radioactive sources used for "calibration confirmation" purposes, to the extent practicable, representative of the actual radioactive material compositions and chemical compounds as found in the measurement item inventory of interest?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	c) Are radioactive material standards used for “calibration confirmation” traceable to a nationally recognized reference base (e.g., National Institute of Standards and Technology [NIST] or New Brunswick Laboratory [NBL])?				
Appendix D	c) Are the traceable standards used for “calibration confirmation” related to (from the same feedstock or lineage) those used to perform the “initial calibration”?				
Appendix D	d) Is calibration confirmation acceptance assessed through the degree of agreement between the known “calibration confirmation“ test item value and that as per the NDA confirmation measurement result?				
Appendix D	d) Is the NDA organization to determine and document representative “calibration confirmation” source/matrix surrogate configuration(s)?				
Appendix D	d) Does the NDA organization also develop “calibration confirmation” bias and precision acceptance criteria specific to the NDA system and measurement items under consideration?				
Appendix D	Note: Recommended “calibration confirmation” acceptance criteria are delineated in Section 1.1.3.				
Appendix D	e) Are the calibration confirmation results outside NDA organization defined acceptance criteria requiring implementation of corrective action(s) as applicable?				
Appendix D	e) Calibration confirmation results are not to exceed the maximum allowable acceptance criteria of Section 1.1.3 unless the NDA organization has specifically determined and documented greater limits with the requisite technical justification.				
Appendix D	f) For the case where a corrective action was required and subsequently implemented, is the “calibration confirmation” process repeated?				
Appendix D	f) Are the acceptable results obtained and documented before the NDA system is considered operational?				
Appendix D	f) Where a “calibration confirmation” failure was determined to be due to a minor issue (e.g., wrong constant, wrong efficiency file, or an inappropriate test item), does the entire “calibration confirmation” measurement regimen need to be repeated?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	f) Was this acceptable to the laboratory provided it is the true cause of the failure?				
Appendix D	f) Are all corrective actions and their effects, supporting data, results, etc., documented and retained?				
Appendix D	g) In the case where the "calibration confirmation" was acceptable for certain types or categories of radioactive material/waste matrix configurations, but unacceptable for other categories with distinctly different source/matrix properties, is conditional acceptance of the "calibration confirmation" made?				
Appendix D	g) Does the NDA organization, however, clearly identify which categories of source/matrix configurations are approved for NDA measurement and which are not?				
Appendix D	g) Is the technical basis for accepting certain source/matrix categories documented and available for review?				
Appendix D	g) Are recalibration or corrective action efforts implemented and documented for source/matrix categories that do not meet acceptance criteria for "calibration confirmation"?				
Appendix D	h) Is the "calibration confirmation" process performed following an initial calibration or where indications warrant a re-assessment of the "initial calibration", e.g., the source/matrix configuration of measurement items varies relative to the source/matrix configurations used to develop the "initial calibration"?				
Appendix D	h) Additional causes for a performing a "calibration confirmation" include: 1) major NDA system repairs or modifications, 2) replacement of NDA measurement system components, e.g., detector, neutron generator or supporting electronic components that have the potential to affect data quality, 3) re-calibration, 4) significant changes to the NDA system software				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	i) Do the records retained permit reconstruction of any NDA measurement system "calibration confirmation"(e.g., NDA method, measurement system configuration, confirmation date, primary radioactive isotope(s), mass or concentration and response, calibration factor(s), or equations/coefficients used to convert NDA instrument response to mass/concentration)?				
Appendix D	i) Does documentation explicitly connect the "calibration confirmation" data/records to the "initial calibration"?				
Appendix D	**1.1.3 Calibration Confirmation Acceptance Criteria**				
Appendix D	a) Are bias and precision limits used to determine the acceptability of "calibration confirmation" measurements?				
Appendix D	a) Are the specified limits "upper limits" to be applied to all NDA measurement techniques over all matrix configurations?				
Appendix D	a) Are the recommended "calibration confirmation" limits not specifically tied to end-user requirements, or are nominal performance levels expected of NDA systems?				
Appendix D	a) Is failure to comply with these biases and precision limits as an indicator that more capable measurement techniques need to be developed?				
Appendix D	b) Are NDA measurement system bias and precision determined through the acquisition of replicate measurements using matrix container and/or process component mock-ups combined with traceable WRMs?				
Appendix D	b) Are the source/matrix configurations representative of the actual measurement item population of interest?				
Appendix D	b) Is the number of different source/matrix test configurations and replicate measurements of each determined by the NDA organization and documented?				
Appendix D	Note: The "calibration confirmation" bias is to be determined in terms of %Bias [(mean measured value - known value)/known value]*100 or %R (mean measured value/known value)*100. The bias shall not be outside the limits as per Table -1 at the 95% confidence level.				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	c) Precision is reported as percent relative standard deviation (% RSD). The %RSD shall not exceed the value listed in the last row of Table -1 for twenty replicate measurements of the "calibration confirmation" source/matrix test item(s). Equivalent %RSD limits for a number of different replicate values are tabulated in Table -2.				
Appendix D	**1.1.4 Calibration Verification**				
Appendix D	Does the laboratory's "calibration verification" test item(s) meet the bias acceptance criteria delineated in Section 1.1.3?				
Appendix D	Are "calibration verification" performed at least once every five operational days for each measurement system and calibration in use?				
Appendix D	Is a five day operational period defined as a rolling tally of five days where NDA operations were in effect, not necessarily consecutive?				
Appendix D	Is the start point for the five day operational period from the start of approved operations or the first operational day after the previous rolling five day tally was completed?				
Appendix D	Is the five day operational "calibration verification" requirement extended to a maximum of thirty operational days provided the NDA organization demonstrate and technically justify the long term stability of the NDA system per established acceptance criteria?				
Appendix D	Are calibration verification test items typically selected from or assembled from the traceable standards and matrix containers or process component mock-ups used in the "calibration confirmation" process?				
Appendix D	Is the "calibration verification" test item to be submitted to NDA operations in a "blind" manner, where applicable, and processed through the measurement routine as though it was an actual measurement item?				
Appendix D	Are the "calibration verification" tests items selected and/or configured and submitted such that during a 12-month period the operational space of the NDA system "initial calibration" is spanned?				
Appendix D	Is the "calibration verification" a point check in the calibration realm?				
Appendix D	Do the laboratory's "calibration verification" configurations vary over the operational space?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Does acceptable performance for a "calibration verification" measurement result in terms of bias, trending measures and so forth determined and documented by the NDA organization?				
Appendix D	Is a CAP for out-of-control "calibration verification" results prepared by the NDA organization?				
Appendix D	Does the CAP include a provision requiring the evaluation of measurement item data potentially affected by the failed "calibration verification" measure?				
Appendix D	Is the "calibration verification" protocol, monitoring, acceptance criteria, action levels, etc., clearly documented and readily available for review?				
Appendix D	Is the calibration verification data control charted and monitored for trends over time?				
Appendix D	Does the NDA organization utilize other methods of "calibration verification" provided they are technically justifiable and documented?				
Appendix D	**1.2 NDA Method Detection Limit**				
Appendix D	Is methodology in place to determine NDA measurement system detection limit for those radionuclides specified per the client/end-user requirements?				
Appendix D	Is the methodology re-determined each time there is a significant change in the measurement method or matrix configuration?				
Appendix D	Do instruments performing low-level waste discrimination measurements have a minimum detectable activity (MDA)/lower limit of detection (LLD) sufficient to meet the acceptance criteria?				
Appendix D	Is the methodology for determination of the MDA/LLD documented by the NDA organization?				
Appendix D	Does the LLD level of radioactivity, if present, yield a measured value greater than the critical level (Lc) with a 95% probability, where the Lc is defined as that value which measurements of the background will exceed with 5% probability (the LLD may be defined in a different manner to comply with specific client needs)?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Because the LLD is a measurement- based parameter, it is not feasible to calculate LLDs for radionuclides that are not determined primarily by measurement, e.g., 99Tc; does NDA organization derive the equivalent of an LLD (i.e., a reporting threshold for a radionuclide(s) when technically justified)?				
Appendix D	Is the value based on decay kinetics, scaling factors, or other scientifically based relationships and must be adequately documented in site records?				
Appendix D	**1.3 Infinite Thickness**				
Appendix D	For a given radioactive material thickness (deposit or buildup), is the thickness reached beyond which there is no increase in counts for an increase in thickness?				
Appendix D	At this point, infinite thickness has been reached. Is the phenomenon typically only observed in gamma-ray counting?				
Appendix D	Does the NDA organization have a documented process for identifying infinite thickness when performing measurements?				
Appendix D	**1.4 NDA Measurement Uncertainty**				
Appendix D	Does the NDA organizations have and apply methods and procedures for estimating total measurement uncertainty (TMU) for all reported values?				
Appendix D	Does the NDA organization perform a preliminary identification of uncertainty components and produce measurement uncertainty estimates for the waste population to be characterized prior to generating characterization data for the client/end-user?				
Appendix D	Does the estimate of the measurement have uncertainty for the measurement item inventory of interest performed and documented?				
Appendix D	Is the estimate based on knowledge of the measurement method performance and make use of previous experience and validation data from similar measurement apparatus and configurations when available?				
Appendix D	Are the estimated measurement uncertainties evaluated per client and/or end-user needs and requirements?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Is the method used to calculate TMU for the purpose of demonstrating compliance with client and/or end-user requirements documented and technically justified?				
Appendix D	Does the NDA organization have a method to determine total measurement uncertainty for each NDA system employed including:				
Appendix D	a) Is there a development of a document or plan that delineates the approach to TMU determination, defines measurement uncertainty components, and determines a method for acquiring data/information on components of variance and processing of acquired data and information to arrive at technically defensible TMU for the measurement item population of interest?				
Appendix D	b) Is there a procedure or applicable document that provides specific direction on the acquisition of NDA system measurement data for use in deriving the TMU?				
Appendix D	c) Is there a produce documentation that clearly describes the processing of acquired data, accounting for all significant variables, and the application of methods to determine the TMU?				
Appendix D	d) Is the TMU clearly define how it is expressed? (e.g., 95% confidence level, percent, one- sigma, etc.)				
Appendix D	e) Is the TMU determination method clearly documented?				
Appendix D	e) Are NDA organizations that utilize commercial off-the-shelf data analysis and uncertainty software still accountable to produce clear documentation of the TMU approach, components of variance, and technique for arriving at the TMU value?				
Appendix D	**1.5 NDA Measurement Traceability**				
Appendix D	Are the calibrations of NDA instrumentation and support measurement devices (e.g., weight scale), used for NDA characterization purposes have traceable calibrations established and documented before being put into service?				

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

Section Reference	Question	Yes	No	NA	Comments
Appendix D	e) 1) Is the standard sent to a qualified facility maintaining measurement systems traceable to a certified reference material (CRM) for a determination of the standard attribute of interest?				
Appendix D	e) 1) Is the standard simply given an updated attribute value and returned to the NDA organization with a revised or new certificate?				
Appendix D	e) 2) Are the methods cross-compared the standard with another traceable standard possessing the same attribute in a calibrated and operational measurement system?				
Appendix D	e) 2) Does an evaluation of the results produce a verification of the standard that is about to or has expired?				
Appendix D	e) 2) Does the NDA organization determine the acceptable uncertainty in the verified value relative to the NDA characterization process at hand?				
Appendix D	e) Is the verification method used and standard verification acceptability criteria documented?				
Appendix D	e) Are the results of the verification are to be documented and maintained as a QA record?				
Appendix D	f) Do the WRM Certificates of Traceability contain information and data that clearly details traceability to a CRM?				
Appendix D	g) Are checks needed to maintain confidence in the status of WRMs carried out according to defined procedures and schedules?				
Appendix D	h) Does the NDA service provider have procedures for the safe handling, transport, storage and use of WRMs in order to prevent contamination or deterioration and protect their integrity?				
Appendix D	**1.6 NDA Measurement System Software**				
Appendix D	Are software quality assurance (SQA) requirements implemented by NDA organizations that utilize software as part of NDA waste characterization, developed in-house or acquired?				
Appendix D	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of NDA measurement data, does the NDA organization have documentation or SOPs for software related activities?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Does this documentation includes but is not limited to the following as applicable? :				
Appendix D	a) For software acquired from a commercial vendor or other third party, evidence of software quality control (QC), is verification and validation (V&V) and other pertinent data acquired and maintained by the NDA organization?				
Appendix D	a) Is software verification the processes of evaluating software to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase (IEEE-STD-610)?				
Appendix D	a) Is software validation the process of evaluating software during or at the end of the development process to determine whether it satisfies specified requirements? (IEEE-STD-610)				
Appendix D	b) For software developed or modified in-house by the NDA organization, is software development planning and QA controls identified in documented plans?				
Appendix D	Are the following activities addressed in such plans/procedures:				
Appendix D	b) 1) Software development and testing,?				
Appendix D	b) 2) Software V&V?				
Appendix D	b) 3) Software configuration control?				
Appendix D	b) 4) Software operation and maintenance?				
Appendix D	c) Is computer software developed by the NDA organization documented per applicable software development quality standards?				
Appendix D	c) Do the standards include e the following documentation:				
Appendix D	c) 1) Software specification document?				
Appendix D	c) 2) Software design document?				
Appendix D	c) 3) Software test plan?				
Appendix D	c) 4) Software V&V document				
Appendix D	c) 4) If used are NDA organization developed software and/or modifications to commercial software must be validated?				
Appendix D	c) 4) Were installation and operability checks performed?				
Appendix D	d) Is software change procedures include requirements for the requesting, testing, quality assurance, approving, and implementation of changes?				

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

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

Section Reference	Question	Yes	No	NA	Comments
Appendix D	a) Are uncertainties reported when using ratios and scaling factors used include the uncertainty in the ratio or scaling factor?				
Appendix D	a) The type and quantity of supporting documentation may vary by waste stream but does it compile a written record that includes a summary identifying all sources of information used to delineate the waste stream's isotopic distribution or radionuclide scaling factors?				
Appendix D	a) Is the basis and rationale for the delineation clearly summarized in an AK report and traceable to referenced documents?				
Appendix D	a) Are assumptions made in this rationale identified?				
Appendix D	a) Is following information included as part of the AK written record:				
Appendix D	a) 1) Map of the site with the areas and facilities involved in waste generation and process equipment identified,?				
Appendix D	a) 2) Facility mission description as related to radionuclide-bearing materials and their management (e.g., routine production, fuel research and development, and experimental processes)?				
Appendix D	a) 3) Description of the specific site locations (such as the area or building) and operations relative to the isotopic composition of the uranium bearing wastes and process components they generated?				
Appendix D	a) 4) Waste identification or categorization schemes used at the facility relevant to the waste material's isotopic distribution (e.g., the use of codes that correlate to a specific isotopic distribution and a description of the isotopic/radionuclide composition of each waste stream)?				
Appendix D	a) 5) Information regarding the waste's physical and chemical composition that could affect the isotopic distribution (e.g., processes used to remove ingrown daughters or alter its expected contribution based solely on radioactive decay kinetics)?				
Appendix D	a) 6) Statement of all numerical adjustments applied to derive the material's isotopic distribution (e.g., scaling factors, decay/in-growth corrections and secular equilibrium considerations)?				
Appendix D	a) Is the documentation sufficient to enable independent calculation of the scaling factor or ratio of interest?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	b) Supplemental AK Information				
Appendix D	b) Is the supplemental AK information obtained dependent on availability?				
Appendix D	b) Is information collected as appropriate to support contentions regarding the waste's isotopic distribution?				
Appendix D	b) Is this information used to compile the waste's AK written record?				
Appendix D	b) Does supplemental AK documentation that is used include information from the following sources:				
Appendix D	b) 1) Safeguards and security, materials control and accountability, and other nuclear materials control systems or programs and the data they generated?				
Appendix D	b) 2) Reports of nuclear safety or criticality, accidents/excursions involving the use of special nuclear material (SNM), or nuclear material?				
Appendix D	b) 3) Waste packaging procedures, waste disposal, building or nuclear material management area logs or inventory records, and site databases that provide information on SNM or nuclear materials?				
Appendix D	b) 4) Test plans, research project reports, or laboratory notebooks that describe the radionuclide content of materials used in experiments?				
Appendix D	b) 5) Information from site personnel (e.g., documented interviews), and 6) Historical analytical data relevant to the isotopic distribution of the waste stream?				
Appendix D	c) AK Discrepancy Resolution				
Appendix D	c) If there is any form of discrepancy between AK information related to isotopic ratios or composition, is the NDA organization responsible for having the sources of the discrepancy evaluated to determine information credibility?				
Appendix D	c) Is information not credible or information that is limited in its applicability to the NDA characterization effort will be identified as such, and the reasons for dismissing it will be justified in writing.				
Appendix D	c) Are limitations concerning the information documented in the AK record and summarized in the AK report?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	c) In the event the discrepancy cannot be resolved, did the site perform direct measurements for the impacted population of containers or process items?				
Appendix D	c) If discrepancies "result in a change to the original determinations, is the AK summary updated?				
Appendix D	**1.8 NDA Data Reporting, Review, and Verification**				
Appendix D	a) NDA Measurement Data Reporting				
Appendix D	a) Is the NDA organization to document individual NDA measurement item results in a standard report format? For each NDA measurement item (waste container/ process component) is there a separate report? Do the NDA measurement item reports contain or reference the location of information sufficient to fully describe all input data, NDA measurement configuration information, acquisition parameters, analysis technique, software version, QC data, etc. to allow reconstruction of the reported results?				
Appendix D	Does the NDA reports include the following:				
Appendix D	a) NDA Measurement Date Reporting				
Appendix D	1) Report title (e.g., "NDA Measurement Item Report"), Name of NDA organization, Client contact name for which report is to be delivered and NDA service provider point of contact responsible for ensuring the submittal of the report in the approved manner, and Identification of project name, site, or facility NDA measurement items are associated with.				
Appendix D	Measurement item identification and QC information				
Appendix D	2) Measurement item identification/designator and other identifiers/designations as applicable (e.g., the clients own identifier), Date(s) of NDA data acquisition, Analysis, background, and QC file names, Measurement item description, NDA field worksheet file name, log name, or other identifier, Gross/net weight, if applicable, NDA measurement live time, and Location of NDA measurement system, site name, facility name, building name, and other identifying information?				
Appendix D	3) Primary radionuclide measurement results:				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Primary NDA measurement quantitation method (e.g., gamma, neutron), Primary radioisotopes and their associated TMU s in appropriate units, (for example, gram, activity, activity concentration, MDA, and % uncertainty), Total radionuclide mass, activity, concentration, and associated TMU, 235U fissile gram equivalent and associated TMU (gram), and Other primary quantities such as uranium enrichment weight percent (wt%) and associated wt% TMU.?				
Appendix D	4) NDA acquisition and analysis information:				
Appendix D	NDA detector or system identification, Name of ancillary data and/or information sheets associated with the NDA measurement item. These are often called NDA Field Worksheets and contain information pertinent to the analysis of the acquired data such as container fill height and measurement configuration (e.g., detector to item distance and operator signature/date), Identification of real time radiography examination files, if applicable, The acquisition software identification and version, and Analysis software identification and version.?				
Appendix D	5) Comment/Narrative section including:				
Appendix D	Name or reference to procedures used to acquire the NDA measurement data analyze the data, and acquire supporting data/information used in analysis?				
Appendix D	Name or reference to QC procedures utilized in the acquisition and processing of the data, Identification or reference to WRM and check source(s) used for calibration and/or QC activities, Identification of or reference to calibration procedures and records and/or location?				
Appendix D	If not specified elsewhere, definition of the quoted uncertainties (i.e., one σ, two σ). When TMU is reported differently on the batch cover sheet of the IMS, the method of expressing TMU shall be specified on the NDA measurement item report sheet or the applicable procedures referenced?				
Appendix D	The NDA measurement item report is to have the analyst signature and date and the independent technical reviewer signature and date?				
Appendix D	b) NDA Data Review				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Is all NDA measurement data reviewed and approved by qualified personnel prior to being reported?				
Appendix D	At a minimum, is the data and analysis reviewed by an independent technical reviewer (a second qualified person)?				
Appendix D	Is this reviewer an individual other than the data generator (analyst) who is qualified to have performed the initial work?				
Appendix D	Did the technical reviewer verify, at a minimum, the following information:				
Appendix D	1) Are NDA measurement system QC results within established control limits and, if not, has the data been appropriately dispositioned using the nonconformance process?				
Appendix D	1) Does this include a complete summary of qualitative and/or quantitative data for all items with data flags or qualifiers?				
Appendix D	2) Are “calibration verification” measurements performed and reviewed as acceptable?				
Appendix D	3) Are NDA system data acquisitions and reductions conducted in a technically correct manner in accordance with current methods (verification of procedure and revision)?				
Appendix D	4) Are calculations performed outside of software that is in the software QA program reviewed by a valid calculation program, a periodic spot check of verified calculation programs (not required with every report) and/or 100 percent check of all hand calculations?				
Appendix D	5) Are proper constants such as half-lives, branching ratios, attenuation values, neutron yields, gamma libraries used?				
Appendix D	6) Is data reported in the proper units and correct number of significant figures?				
Appendix D	7) Are the values verifiable to within rounding or significant difference discrepancies rectified prior to completion of independent technical review?				
Appendix D	8) Is the data reviewed for transcription errors?				
Appendix D	9) Are the calibrations documented?				
Appendix D	10) Are the standards used traceable to nationally recognized certificates?				
Appendix D	c)NDA Data Verification				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	1) Are batch data reports prepared for each measurement batch on standard form (hard copy or electronic equivalent)?				
Appendix D	1) Do batch data reports at a minimum include the following:				
Appendix D	1) NDA organization name, NDA measurement system identification, batch number, NDA measurement item identifications included in the batch, date and signature release by authorized personnel?				
Appendix D	1) Table of contents?				
Appendix D	1) QC data, backgrounds, replicate data, and control charts, etc., for the relevant batch time period?				
Appendix D	1) Does data verification per the NDA service provider QA Plan, and as per applicable procedures?				
Appendix D	2) Are batch reports reviewed and approved by qualified personnel before being submitted?				
Appendix D	2) Are only appropriately trained and qualified personnel allowed to perform data verification/review?				
Appendix D	2) Do verification reviews shall ensure:				
Appendix D	a) The QC documentation for the batch report is complete and includes as applicable a list of containers in the set or batch and applicable set or batch QC results?				
Appendix D	b) Data were collected as described in the planning documents and are complete and correct. Are all batch data reports approved by the project manager or designee?				
Appendix D	b) Does the project manager verify at a minimum the following information:				
Appendix D	b) i. Are data generation-level verification performed by a second qualified person and appropriate signature release?				
Appendix D	b) ii. Are batch review checklists complete?				
Appendix D	b) iii-iv. Are batch reports complete and data are properly reported (e.g., data are reported in the correct units and with the correct number of significant figures), and Data comply with program objectives?				
Appendix D	Do results of the review require that qualifiers be placed on the use of the data?				

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

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Does the measurement control program provide for the administration, evaluation, and control of measurement processes? Is the design of the measurement control program is to ensure the NDA measurement process provides data of sufficient quality (i.e., the measurement system is in control per defined criteria)? Does the NDA organization then make and document qualifying statements about the suitability and validity of measurement data as generated for the client and/or end-user?				
Appendix D	Are QC measurements to be performed in conjunction with and related to a batch of NDA measurement items?				
Appendix D	Do out of control performance checks for a given NDA instrument cause the batch data to be considered suspect? Are corrective actions in place to evaluate the measurement item results for the affected batch?				
Appendix D	**2.1 QC Procedures**				
Appendix D	Are the NDA organization procedures implementing applicable QCs for monitoring the validity of NDA measurements and the analytical results? Does the NDA QA program specify qualitative and quantitative acceptance criteria for the QC checks? Do the NDA QC measures and acquired information/data documented or logged in such a way that trends are detectable? Are statistical techniques applied to the evaluation of acquired QC data and action levels specified? Are procedures also in place to implement the corrective action process when QC criteria are not satisfied? Is the QC program periodically reviewed?				
Appendix D	In addition, does the NDA service provider address the following:				
Appendix D	a) Is development of a QC plan with clearly defined roles and responsibilities? Do the QC program assure objectivity and independence of action? Is the person assigned responsibility for the QC program knowledgeable of the measurement system being controlled, statistical QC, and the process being monitored? Is the organization providing sufficient separation of functions to avoid any conflict of interest?				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	b) Is acquisition and maintenance of suitable WRMs and check sources to monitor measurement system performance during NDA characterization operations? Are records concerning specification and acquisition of standards and sources, including an assessment of their uncertainties and procurement documented and retained?				
Appendix D	c) Do QC checks include a means to evaluate the variability and/or repeatability of NDA measurement results?				
Appendix D	d) Are determination of measurement parameters and acceptance criteria necessary to ensure the accuracy of the NDA method using daily performance checks and analysis of performance check data (e.g., control charts, trending analysis, and replicate measurements)?				
Appendix D	e) Are QC protocols as specified in the NDA organization method manual and/or procedure(s) followed?				
Appendix D	f) Are QC measurement parameter action levels established and documented?				
Appendix D	g) Are written procedures developed and documented to address out-of-control conditions and the subsequent re-qualification of the instrument?				
Appendix D	**2.2 NDA QC Requirements**				
Appendix D	a) Are backgrounds Measurements performed and recorded for neutron and gamma systems for each system in use at least once per day and twice for each batch?				
Appendix D	a) Does the once per day background measurement can serve as the beginning or ending background measurement required for the batch?				
Appendix D	a) Do the two background measurements for each batch bracket the start and end of the batch, one at the beginning of the batch and one at the end of the batch, unless technical justification to do otherwise is developed and documented?				
Appendix D	a) Is the count time for neutron and gamma background checks at least as long as the measurement count time unless otherwise specified and documented by an appropriately qualified individual?				

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

Section Reference	Question	Yes	No	NA	Comments
Appendix D	b) Do performance checks, as applicable, also be acquired on support equipment? Are the recorded performance measurements checks monitored using control charts or tolerance charts to ensure the instrument performance is within statistical control?				
Appendix D	c) Are replicate Measurements used to determine the repeatability of a measurement system that represents the intrinsic instrument variability? Is repeatability variance a short-term variance usually dominated by counting statistics?				
Appendix D	c) Is the replicate measurement acquired by randomly selecting one measurement item that has been processed through the NDA system for the batch?				
Appendix D	c) Is data analysis performed independently for the two measurements? Is the second measurement of the item performed any time before the start of the next data set or batch?				
Appendix D	c) If an acceptable RPD, less than or equal to 25% or other criteria specifically requested by the client, is a control chart of the RPD maintained for trending analysis?				
Appendix D	Are procedures established for the collection, processing and periodic evaluation of replicate data?				
Appendix D	Are alternate methods for determining repeatability and assessing its acceptability implemented by the NDA organization provided they are technically justifiable, documented and available for review?				
Appendix D	Is the replicate data monitored using control charts or tolerance charts to ensure the instrument reproducibility is within statistical control?				
Appendix D	If the check source is not traceable, is it correlated with a traceable source or well known, characterized and documented?				
Appendix D	Are all performance data monitored on an as-recorded basis and over time using control charts and trending techniques?				
Appendix D	**3.0 QC Action Levels and Response**				

Section Reference	Question	Yes	No	NA	Comments
Appendix D	Are quality control measurements performed on a periodic basis as prescribed above and evaluated relative to established acceptance criteria? Are quality control measurements also be reviewed and evaluated over time to determine continued acceptability of the assay system and to monitor trends?				
Appendix D	If daily quality control checks yield results that are outside the acceptable range(s), is the required responses in Table -3 followed.?				
Appendix D	Are all control limits and associated actions documented and maintained? Refer to Table -3 Range of Applicability.				
Appendix D	**VOLUME 1, MODULE 3**				
	QS Asbestos Testing				
	Method Validation				
1.5	Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope and amplifications and modification of reference methods?				
1.5	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
1.5	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
1.5	Does the laboratory participate in a suitable program of proficiency testing? (Assessor must provide copies of PT reports in package.)				
	Demonstration of Capability (DOC)				
1.6	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (per Section 1.6.2)?				
1.6.1	Were ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) required?				
1.6.1	Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				

Section Reference	Question	Yes	No	NA	Comments
1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
1.6.1	**Initial DOC**				
1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
1.6.2	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
1.6.2.1	a) analyst(s) involved in preparation and/or analysis?				
1.6.2.1	b) matrix?				
1.6.2.1	c) analyte(s), class of analyte(s), or measured parameter(s)?				
1.6.2.1	d) identification of method(s) performed?				
1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number?				
1.6.2.1	f) date(s) of analysis?				
1.6.2.1	g) summary of analyses, including information outlined in Section 1.6.2.2.c?				
1.6.2.2	If the method or regulation does not specify a DOC, does the laboratory use the procedure stated in 1.6.2.2 a to f? (1.6.2.2.e.i is not allowed for DoD)				
1.6.2.2	Does the laboratory document other approaches to initial DOC, and are they adequate?				
	Ongoing DOC				
1.6.3.1	Does the laboratory have a documented procedure describing ongoing demonstration of capability?				
1.6.3.1	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard?				

Section Reference	Question	Yes	No	NA	Comments
1.6.3.1	Does the laboratory use one of the following for ongoing DOC:				
1.6.3.2	a) acceptable performance of a blind sample (single blind to the analyst)?				
1.6.3.2	NOTE: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the test.				
1.6.3.2	b) another initial DOC?				
1.6.3.2	c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy?				
1.6.3.2	c) Does the laboratory determine the acceptable limits for precision and accuracy prior to analysis?				
1.6.3.2	c) Does the laboratory tabulate or be able to readily retrieve four (4) consecutive passing laboratory control samples (LCS) for each method for each analyst each year?				
1.6.3.2	d) a documented process of analyst review using QC samples?				
1.6.3.2	d) Are QC samples reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
1.6.3.2	e) If a) through d) are not technically feasible, then does the laboratory perform analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method)?				
	Technical Requirements				
1.7	Calibration				
1.7.1	If NIST standard reference materials (SRM) specified are unavailable, does the laboratory substitute an equivalent reference material with a certificate of analysis?				
1.7.1.1	Transmission Electron Microscopy				
1.7.1.1.1	Water and Wastewater				
1.7.1.1.1	Are all calibrations performed under the same analytical conditions used for routine asbestos analysis and are they recorded in a notebook and include date and analyst's signature?				
1.7.1.1.1	**a) Magnification Calibration**				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1.1	a) Is Magnification calibration done at the fluorescent screen, with the calibration specimen at the eucentric position, at the magnification used for fiber counting?				
1.7.1.1.1	a) Is a logbook maintained with the dates of the calibration recorded, the calibrated maginifcation, and the analysts signature or initials?				
1.7.1.1.1	a) Are Calibrations performed monthly?				
1.7.1.1.1	a) Is Calibration data displayed on control charts?				
1.7.1.1.1	Is a logbook or electronic record maintained with the calibrated magnification, the date of calibration, and the analyst's signature or initials recorded?				
1.7.1.1.1	**b) Camera Constant**				
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?				
1.7.1.1.1	b)Is the diffraction specimen at the eucentric position for this calibration?				
1.7.1.1.1	b)Does the calibration allow accurate (<10% variation) measurement of layer-line spacing on the medium used for routine measurement? (i.e., the phosphor screen or camera film)				
1.7.1.1.1	b)Does the calibration allow accurate (<5% variation) measurement of zone axis SAED patterns on permanent media? (e.g., film)				
1.7.1.1.1	b)Where non-asbestiform minerals internal camera constant standard such as gold, are they deposited and measured on each sample to facilitate accurate indexing of zone axis SAED patterns?				
1.7.1.1.1	b) Are Calibrations performed monthly?				
1.7.1.1.1	b) Is Calibration data displayed on control charts?				
1.7.1.1.1	**c) Spot Size**				
1.7.1.1.1	c) Is the diameter of the smallest beam spot at crossover less than 250 nm as calibrated quarterly?				
1.7.1.1.1	c) Is Calibration data displayed on control charts?				
1.7.1.1.1	**d) Beam Dose**				
1.7.1.1.1	d) Is the beam dose calibrated?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1.1	d) Is the electron diffraction pattern from a single fibril >1 µm in length from a NIST SRM chrysotile sample is stable in the electron beam dose for at least 15 seconds?				
1.7.1.1.1	**e) Energy Dispersive X-Ray Analysis (EDXA) System**				
1.7.1.1.1	e) 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?				
1.7.1.1.1	e) i) Is the calibration of the x-ray energy checked prior to each analysis of samples and recalibrated if out of the specified range?				
1.7.1.1.1	e) 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?				
1.7.1.1.1	e) 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?				
1.7.1.1.1	e) iii) Is NIST SRM 2063a used for Mg, Si, Ca, Fe, and k-factors for Na and Al are obtained from suitable materials such as albite, kaersutite, or NIST SRM 99a?				
1.7.1.1.1	e) 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.				
1.7.1.1.1	e) iii). Is the k-factor relative to Si for Na between 1.0 and 4.0, for Mg; Fe between 1.0 and 2.0, and Al and Ca between 1.0 and 1.75?				
1.7.1.1.1	e) iii). Is the k-factor for Mg relative to Fe 1.5 or less?				
1.7.1.1.1	e) iii). Is Calibration data displayed on control charts?				
1.7.1.1.1	e) iv). Is the detector resolution checked quarterly to ensure a full-width half maximum resolution of <175 eV at Mn Kα (5.90 keV)?				
1.7.1.1.1	e) iv). Is Calibration data displayed on control charts?				
1.7.1.1.1	e) v) Are the portions of a grid in a specimen holder for which abnormal x-ray spectra are generated under routine asbestos analysis conditions determined? Are these areas avoided in asbestos analysis?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1.1	e) 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?				
1.7.1.1.1	**f) Low Temperature Asher**				
1.7.1.1.1	f) Is the low temperature asher calibrated quarterly by determining a calibration curve for the weight vs. ashing time of collapsed mixed-cellulose ester (MCE) filters?				
1.7.1.1.1	f) Is Calibration data displayed on control charts?				
1.7.1.1.1	**g) Grid Openings**				
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?				
1.7.1.1.1	g) Is the variation in the calibration measurements (2s) is <5% of the mean calibration value?				
1.7.1.1.2	**Air**				
1.7.1.1.2	Are all calibrations performed in accordance with Section 1.7.1.1.1, with the exception of magnification?				
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?				
1.7.1.1.2	Is a logbook maintained with the dates of the calibration recorded?				
1.7.1.1.2	Are calibrations performed monthly to establish the stability of magnification?				
1.7.1.1.2	Is the phase-shift detection limit of the microscope checked daily or after modification?				
1.7.1.1.3	**Bulk Samples**				
1.7.1.1.3	All calibrations performed in accordance with Section 1.7.1.1.1?				
1.7.1.2	Phase Contrast Microscopy				
1.7.1.2	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?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.2.1	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?				
1.7.1.2.1	Does the procedure assures that the minimum detectable fiber diameter (<ca. 0.25µm) for this microscope is achieved?				
1.7.1.2.2	Prior to ordering the Walton-Beckett graticule, is a calibration, in accordance with NIOSH 7400, Issue 2, 15 August 1994, Appendix A, performed to obtain a counting area 100 µm in diameter at the image plane?				
1.7.1.2.2	Is the phase-shift detection limit of the microscope checked daily and after modification?				
1.7.1.2.3	Is the diameter, dc (mm), of the circular counting area and the disc diameter specified when ordering the graticule?				
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?				
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)?				
1.7.1.2.3	Is a recalibration of field diameter required when there is a change in interpupillary distance (i.e., change in analyst)?				
1.7.1.2.3	Is the acceptable range for field area 0.00754 mm2 to 0.00817 mm2?				
1.7.1.2.3	Is the actual field area documented and used?				
1.7.1.3	**Polarized Light Microscopy**				
1.7.1.3.1	**Microscope Alignment**				
1.7.1.3.1	Are both stereoscope and polarized light microscopes aligned and checked for function and optimized for correct operation before every use by every analyst?				
1.7.1.3.1	Are all aligments and function checks documented in the proper logbook or electronic record?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.3.1	a) Are both stereoscope and polarized light microscope aligned and checked for function and optimized for correct operation before every use by every analyst?				
1.7.1.3.1	b) Are all alignments and function checks documented in the proper log book or electronic record?				
1.7.1.3.2	**Refractive Index Liquids.**				
1.7.1.3.2	Are series of nD = 1.49 through 1.72 in intervals less than or equal to 0.005?				
1.7.1.3.2	Are the Refractive index liquids for dispersion staining, high-dispersion series 1.550, 1.605, 1.680?				
1.7.1.3.2	Is the accurate measurement of the refractive index (RI) of a substance requires the use of calibrated refractive index liquids?				
1.7.1.3.2	Are the Refractive index liquids calibrated at first use and semiannually, or next use, whichever is less frequent, to an accuracy of 0.004, with a temperature accuracy of 2℃ using a refractometer or RI glass beads?				
	Quality Control				
1.7.2.1	**Negative Controls**				
1.7.2.1.1	**Transmission Electron Microscopy**				
1.7.2.1.1	a) Water and Wastewater				
1.7.2.1.1	a) i. Are blank determinations made prior to sample collection?				
1.7.2.1.1	a) i. When using polyethylene bottles, is one (1) bottle from each batch, or a minimum of one from each twenty-four (24) tested for background level?				
1.7.2.1.1	a) i. When using glass bottles, are four (4) bottles from each twenty-four (24) tested?				
1.7.2.1.1	a) i. Is an acceptable bottle blank level defined as < 0.01 Million Fibers per Liter (MFL) > 10 µm?				
1.7.2.1.1	a) ii. Is a process blank sample consisting of fiber-free water run before the first field sample?				
1.7.2.1.1	a) ii. Is the quantity of water > 10 mL for a 25-mm diameter filter and > 50 mL for a 47-mm diameter filter?				
1.7.2.1.1	b) Air				
1.7.2.1.1	b) i. Is a blank filter prepared with each set of samples?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.1.1	b) i. Is a blank filter left uncovered during preparation of the sample set and is a wedge from that exposed blank filter prepared alongside wedges from the sample filters?				
1.7.2.1.1	b) i. At minimum, is a blank filter analyzed for each twenty (20) samples analyzed?				
1.7.2.1.1	b) ii. Is the maximum contamination on a single blank filter no more than 53 structures/mm2 and the is the Maximum average contamination for all blank filters no more than 18 structures/mm2?				
1.7.2.1.1	c) Bulk Samples				
1.7.2.1.1	c) 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?				
1.7.2.1.1	c) 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?				
1.7.2.1.1	c) ii. Does the laboratory maintain a list of non-asbestos fibers that can be confused with asbestos?				
1.7.2.1.1	c) ii.. Does the list include crystallographic and/or chemical properties that disqualify each fiber being identified as asbestos?				
1.7.2.1.1	c) 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?				
1.7.2.1.2	**Phase Contrast Microscopy**				
1.7.2.1.2	Are at least two field blanks (or 10% of the total samples, whichever is greater) submitted for analysis with each set of samples?				
1.7.2.1.2	Are field blanks handled in a manner representative of actual handling of associated samples in the set with a single exception for air which is drawn through the blank sample?				
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?				
1.7.2.1.2	Are results from field blank samples used in the calculation to determine final airborne fiber concentration?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.1.2	Is the identity of blank filters unknown to the counter until all counts have been completed?				
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?				
1.7.2.1.3	**Polarized Light Microscopy**				
17.2.1.3	a) Friable Materials. Is at least one (1) blank slide prepared daily or with every fifty (50) samples analyzed, whichever is less?				
17.2.1.3	a) Is it prepared by mounting a sub-sample of an isotropic verified non-asbestos-containing material (non-ACM) (e.g., fiberglass in SRM 1866) in a drop of immersion oils normally used on a clean slide, rubbing preparation tools (forceps, dissecting needles, etc.) in the mount and placing a clean coverslip on the drop?				
17.2.1.3	a) Is the entire area under the coverslip scanned to detect any asbestos contamination?				
17.2.1.3	a) Is a similar check made after every twenty (20) uses of each piece of homogenization equipment?				
17.2.1.3	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)				
17.2.1.3	b) Non-Friable Materials. Is at least one (1) non-ACM non-friable material prepared and analyzed with every twenty (20) samples analyzed?				
17.2.1.3	b) Does the non-ACM through the full preparation and analysis regimen for the type of analysis being performed?				
	Test Variability/Reproducibility				
1.7.3.1	Transmission Electron Microscopy				
1.7.3.1	Are Quality assurance analyses performed regularly covering all time periods, instruments, tasks, and personnel?				
1.7.3.1	Are the selection of samples random and samples of special interest are included in the selection of samples for quality assurance analyses?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.1	When possible, are the checks on personnel performance executed without their prior knowledge?				
1.7.3.1	Are a disproportionate number of analyses not being performed prior to internal or external audits?				
1.7.3.1	Note: It is recommended that a laboratory initially be at 100% quality control (all samples re-analyzed). The proportion of quality control samples can later be lowered gradually, as control indicates, to a minimum of 10%.				
1.7.3.1.1	Water and Wastewater				
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?				
1.7.3.1.1	Are Quality assurance analyses postponed during periods of heavy workloads?				
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?				
1.7.3.1.1	Is the precision of analyses related to concentration?				
1.7.3.1.1	Note: Relative standard deviations (RSD) for amphibole asbestos decreased from 50% at 0.8 MFL to 25% at 7 MFL in inter-laboratory proficiency testing, while RSD for chrysotile was higher, 50% at 6 MFL. a)				
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?				
1.7.3.1.1	a) Are the results within 1.5x of Poisson standard deviation, and is it performed at a frequency of one (1) per one hundred (100) samples?				
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?				
1.7.3.1.1	b) Are the second aliquot of sample results within 2.0x of Poisson standard deviation, and is it performed at a frequency of one (1) per one hundred (100) samples?				
1.7.3.1.1	c) Verified Analyses. Is a second, independent analysis performed on the same grids and grid openings used in the original analysis of a sample?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.1.1	c) Do the two sets of results compared according to Turner and Steel (NISTIR 5351), and is it performed at a frequency of one (1) per twenty (20) samples?				
1.7.3.1.1	c) Do the Qualified analysts maintain an average of ≥ 80% true positives, ≤ 20% false negatives, and ≤ 10% false positives?				
1.7.3.1.2	**Air**				
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?				
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?				
1.7.3.1.2	b) Are the limits derived from the allowable false positives and false negatives given in Section 1.7.3.1.1.c, Verified Analysis, below?				
1.7.3.1.2	b) Is SRM 1876b analyzed at a minimum of once per year by each TEM analyst?				
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?				
1.7.3.1.2	d) Are Inter-laboratory analyses performed to detect laboratory bias? Does the frequency of inter-laboratory verified analysis correspond to a minimum of one (1) per two hundred (200) grid square analyses for client?				
1.7.3.1.2	e) If more than one TEM is used for asbestos analysis,are intermicroscope analyses performed to detect instrument bias?				
1.7.3.1.2	e)i. Replicate. Is a second, independent analysis performed in accordance with Section 1.7.3.1.1.a?				
1.7.3.1.2	e)ii Duplicate. Is a second wedge from a sample filter prepared and analyzed in the same manner as the original preparation of that sample? Are results within 2.0x of Poisson standard deviation? Is this performed at a frequency of one (1) per one hundred (100) samples?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.1.2	e)iii Verified Analyses.Is a second, independent analysis performed on the same grids and grid openings in accordance with Section 1.7.3.1.1.c?]				
1.7.3.1.3	**Bulk Samples**				
1.7.3.1.3	Note: Bulk samples with low (< 10%) asbestos content are the most problematic.				
1.7.3.1.3	Are at least 30% of a laboratory's QC analyses performed on samples containing from 1% to 10% asbestos?				
1.7.3.1.3	a) Is at least one (1) out of fifty (50) samples reanalyzed by the same analyst?				
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?				
1.7.3.1.3	b) Is at least one (1) out of fifteen (15) samples reanalyzed by another analyst?				
1.7.3.1.3	Note: Inter-analyst results will require additional reanalysis, possibly including another analyst, to resolve discrepancies when classification (ACM vs. non-ACM) errors occur, when asbestos identification errors occur, or when inter-analyst precision is found to be unacceptable.				
1.7.3.1.3	c) Does the laboratory participate in round robin testing with at least one (1) other laboratory?				
1.7.3.1.3	c) Are samples sent to this other laboratory at least four (4) times per year?				
1.7.3.1.3	c) Are the samples previously analyzed as QC samples?				
1.7.3.1.3	c) Are the results of the analyses assessed in accordance with QC requirements?				
1.7.3.1.3	c) Do the QC requirements address misclassifications (false positives, false negatives) and misidentification of asbestos types?				
1.7.3.1.3	d) Are Inter-laboratory analyses performed to detect laboratory bias?				
1.7.3.1.3	d) Does the frequency of inter-laboratory verified analysis correspond to a minimum of one (1) per two hundred (200) grid square analyses for clients?				
1.7.3.1.3	e) If more than one TEM is used for asbestos analysis, are intermicroscope analyses performed to detect instrument bias?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.1.3	e) i. Replicate. Is a second, independent analysis performed in accordance with Section 1.7.3.1.1.a?				
1.7.3.1.3	e) ii. Duplicate. Is a second wedge from a sample filter prepared and analyzed in the same manner as the original preparation of that sample?				
1.7.3.1.3	Are results of second aliquot of sample within 2.0x of Poisson standard deviation, and is it performed at a frequency of one (1) per one hundred (100) samples?				
1.7.3.1.3	e) iii. Verified Analyses. Is a second, independent analysis performed on the same grids and grid openings in accordance with Section 1.7.3.1.1.c?				
1.7.3.1.3	**Phase Contrast Microscopy**				
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?				
1.7.3.2	a) Does each laboratory participate in round robin testing at least once every six months with at least all the other laboratories in its inter-laboratory quality assurance group?				
1.7.3.2	a) Does each laboratory submit slides typical of its own workload for use in the program?				
1.7.3.2	a) Are the round robin results analyzed using appropriate statistical methodology?				
1.7.3.2	a) Are results of the round robin QA program posted in each laboratory to keep the microscopists informed?				
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?				
1.7.3.2	b) Are reference slides prepared using well-behaved samples taken from the laboratory workload?				
1.7.3.2	b) Are fiber densities cover the entire range routinely analyzed by the laboratory?				
1.7.3.2	b) Are prepared slides counted by all analysts to establish an original standard deviation and corresponding limits of acceptability?				

Section Reference	Question	Yes	No	NA	Comments
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?				
1.7.3.2	b)Are Intra- and inter-analyst precision estimated from blind recounts on reference samples?				
1.7.3.2	b)Is the Inter-analyst precision posted in each laboratory to keep the microscopists informed?				
1.7.3.2	Note: It is recommended that the labels on the reference slides be periodically changed so that the analysts do not become familiar with the samples.				
1.7.3.2	**Polarized Light Microscopy**				
1.7.3.3	Refer to Section 1.7.3.1.3				
	Other Quality Control Measures				
1.7.4.1	**Transmission Electron Microscopy**				
1.7.4.1	**a) Water and Wastewater**				
1.7.4.1	a) i) Are filter preparations made from all six (6) asbestos types from NIST SRMs 1866 and 1867?				
1.7.4.1	a) i)Do the filter preparations have concentrations between one (1) and twenty (20) structures (>10µm) per 0.01 mm2?				
1.7.4.1	a) i) Is one of filter preparations analyzed independently at a frequency of one (1) per one hundred (100) samples analyzed?				
1.7.4.1	a) 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?				
1.7.4.1	a) ii) Is NIST SRM 1876b analyzed annually by each analyst?				
1.7.4.1	a) ii) Are results evaluated in accordance with limits published for that SRM?				
1.7.4.1	**b) Air**				
1.7.4.1	b) i) Are filter preparations made from all six (6) asbestos types in accordance with Section 1.7.4.1.a)i?				
1.7.4.1	b) ii) Is NIST SRM 1876b analyzed annually?				
1.7.4.1	**c) Bulk Samples**				

Section Reference	Question	Yes	No	NA	Comments
1.7.4.1	c) i) Are all analysts able to correctly identify the six (6) regulated asbestos types (chrysotile, amosite, crocidolite, anthophyllite, actinolite, and tremolite)?				
1.7.4.1	c) ii) Are standards for the six (6) asbestos types listed available from NIST (SRMs 1866 and 1867) in the laboratory?				
1.7.4.1	**Phase Contrast Microscopy**				
1.7.4.2	Test for Non-Random Fiber Distribution				
1.7.4.2	a) Are blind recounts by the same analyst performed on 10% of the filters counted?				
1.7.4.2	a) Does a person other than the counter re-label slides before the second count?				
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?				
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?				
1.7.4.2	a) Are all rejected paired counts discarded?				
1.7.4.2	b) It is not be necessary to use this statistic on blank recounts.				
1.7.4.2	b) 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)?				
1.7.4.2	**Polarized Light Microscopy**				
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 whether a standard or reference sample that has been routinely resubmitted to determine analyst's precision and accuracy?				
1.7.4.3	Note: A set of Friable Material samples can be accumulated from proficiency testing samples with predetermined weight compositions or from standards generated with weighed quantities of asbestos and other bulk materials.				

Section Reference	Question	Yes	No	NA	Comments
1.7.4.3	a) Do at least half of the reference samples submitted for this QC contain between 1 and 10% asbestos?				
1.7.4.3	b) Is at least one (1) out of one hundred (100) samples verified quantitative standard that has routinely been resubmitted to determine analyst precision and accuracy?				
1.7.4.3	**Analytical Sensitivity**				
1.7.5	Transmission Electron Microscopy				
1.7.5.1	**Water and Wastewater**				
1.7.5.1.1	Is an analytical sensitivity of 200,000 fibers per liter (0.2 MFL) required for each sample analyzed?				
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?				
1.7.5.1.1	Note: The value will depend on the fraction of the filter sampled and the dilution factor (if applicable).				
1.7.5.1.1	**Air**				
1.7.5.1.2	Is an analytical sensitivity of 0.005 structures/cm2 required for each sample analyzed?				
1.7.5.1.2	Is analytical sensitivity defined as the airborne concentration represented by the finding of one asbestos structure in the total area of filter examined?				
1.7.5.1.2	Note: The value will depend on the effective surface area of the filter, the filter area analyzed, and the volume of air sampled.				
1.7.5.1.2	**Bulk Samples**				
1.7.5.1.3	Is the range dependent on the type of bulk material being analyzed?				
1.7.5.1.3	Is the sensitivity as low as 0.0001%?				
1.7.5.1.3	**Phase Contrast Microscopy**				
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?				
1.7.5.2	Is an ideal counting range on the filter 100 to 1300 fibers/mm2?				
1.7.5.2	Is the limit of detection (LOD) estimated to be 5.5 fibers per 100 fields or 7 fibers/mm2?				

Section Reference	Question	Yes	No	NA	Comments
1.7.5.2	Is the LOD in fiber/cc depend on sample volume and quantity of interfering dust but <0.01 fiber/cm2 for atmospheres free of interferences?				
1.7.5.2	**Polarized Light Microscopy**				
1.7.5.3	Does the laboratory utilize a method that provides a limit of detection that is appropriate and relevant for the intended use of the data?				
1.7.5.3	Is the Limit of detection determined by the protocol in the method or applicable regulation?				
1.7.5.3	**Quality of Standards and Reagents**				
1.7.6	**Transmission Electron Microscopy**				
1.7.6.1	a) Has the quality control program establish and maintain provisions for asbestos standards?				
1.7.6.1	b) Are reference standards that are used in an asbestos laboratory obtained from NIST, EPA, or suppliers who participate in supplying NIST standards or NIST traceable asbestos?				
1.7.6.1	b)Are any reference standards purchased outside the United States traceable back to each country's national standards laboratory?				
1.7.6.1	b)Do the commercial suppliers of reference standards conform to ANSI N42.22 to assure the quality of their products?				
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?				
1.7.6.1	d) Are all reagents used analytical reagent grade or better?				
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?				
1.7.6.1	**Phase Contrast Microscopy**				

Section Reference	Question	Yes	No	NA	Comments
1.7.6.2	Are 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) utilized as reference samples (refer to Section D.6.2.2 b) to standardize the optical system and analyst?				
1.7.6.2	Do all testing reagents and devices (except standards) (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)?				
1.7.6.2	**Polarized Light Microscopy**				
1.7.6.3	Refer to Section 1.7.6.1.				
	Data Acceptance/Rejection Criteria				
1.7.7	Transmission Electron Microscopy				
1.7.7.1	Water and Wastewater				
1.7.7.1.1	a) Is the concentration of asbestos in a given sample shall be calculated in accordance with EPA/600/R-94/134, Method 100.2, Section 12.1?				
1.7.7.1.1	b) Measurement Uncertainties.				
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?				
1.7.7.1.1	Air				
1.7.7.1.2	a) Is the concentration of asbestos in a given sample shall be calculated in accordance with the method utilized?				
1.7.7.1.2	Measurement Uncertainties				
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?				
1.7.7.1.2	Bulk Samples				
1.7.7.1.3	a) Is the concentration of asbestos in a given sample shall be calculated in accordance with the method utilized? (e.g., EPA/600/R-93/116, July 1993)				

Section Reference	Question	Yes	No	NA	Comments
1.7.7.1.3	b) Are 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?				
1.7.7.1.3	b) Do standard deviations range from 20% to 60% for residues with lower asbestos content?				
1.7.7.2	**Phase Contrast Microscopy**				
1.7.7.2	Is the airborne fiber concentration in a given sample calculated in accordance with NIOSH 7400, Issue 2, 15 August 1994, Sections 20 and 21?				
1.7.7.2.1	Does the laboratory calculate and report the intra laboratory and inter-laboratory relative standard deviation with each set of results (NIOSH 7400, Issue 2, 15 August 1994)?				
1.7.7.2.2	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”?				
1.7.7.2.3	Are fiber counts outside the 100-1300 fibers/mm2 range reported as having “greater than optimal variability” and as being “probably biased”?				
1.7.7.2.3	**Polarized Light Microscopy**				
1.7.7.3	Is the concentration of asbestos in a given sample calculated in accordance with the method utilized? (e.g., EPA/600/R-93/116, July 1993)				
1.7.7.3.1	Are precision and accuracy determined by the individual laboratory for the percent range involved?				
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?				
1.7.8.1	**Constant and Consistent Test Conditions Sample and Sampling Requirements**				
1.7.8	Are samples transported to the laboratory as soon as possible after collection?				
1.7.8.1	Is the date and time of sampling noted on submittal forms?				
1.7.8.1	Are the names of the collectors with their signatures and the site included on the chain-of-custody forms?				

Section Reference	Question	Yes	No	NA	Comments
1.7.8.2	Has the laboratory establish and adhere to written procedures to minimize the possibility of cross contamination between samples?				
	Volume 1 Module 4				
	Chemical Testing				
	Method Validation				
1.5.1	**1.5.1 DoD/DOE (Requirement) Validation of Methods**				
1.5.1	a) Does the laboratory validate reference methods via the procedures specified in Sections 1.5.2 and 1.5.3?				
1.5.1	b) Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use?				
1.5.1	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
1.5.1	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
1.5.1	In the absence of other specifications, are the minimum requirements for method validation are given in Sections 1.5.2, 1.5.3 and 1.5.4?				
1.5.1	c) Is the laboratory evaluating modified reference methods and non-standard methods (including laboratory developed methods) using quality control procedures and acceptance criteria that are consistent with those of similar standard methods or technologies, andthe evaluation includes the following:				
1.5.1	c) i) Scope?				
1.5.1	c) ii) Calibration?				
1.5.1	c) iii) Interferences/Contamination?				
1.5.1	c) iv) Analyte identification?				
1.5.1	c) v) Analyte quantitation?				
1.5.1	c) vi) Selectivity?				
1.5.1	c) vii) Sensitivity?				

Section Reference	Question	Yes	No	NA	Comments
1.5.1	c) viii) Precision?				
1.5.1	c) ix) Bias?				
1.5.1	d) Is the use of any modified reference method or non-standard methods being approved by DoD/DOE personnel?				
1.5.1	e) Are methods validated when substantive modifications are made to reference methods (i.e., stoichiometry, technology, mass tuning acceptance criteria, quantitation ions, compressing digestion or extraction timeframes, reducing reagent or solvent volumes, changing solvents, or compressing instrument runtimes)?				
1.5.1	DoD/DOE allows method modifications as described in the November 20, 2007 USEPA Memorandum on method flexibility				
1.5.1	Are the methods that are not published in the Standard Methods for the Examination of Water and Wastewater or Multi-Agency Radiological Laboratory Analytical Protocols Manual, or published in recognized entities such as USEPA, USDOE, ASTM, or NIOSH considered non-standard methods?				
	Limit of Detection and Limit of Quantitation				
1.5.2	**DoD/DOE (Requirement)**				
1.5.2	Note: If the laboratory is not reporting a value below the Limit of Quantitation, a Limit of Detection study is not required				
1.5.2.1	Does the laboratory utilize a method that provides an LOD that is appropriate and relevant for the intended use of the data?				
1.5.2.1	If a mandated method or regulation includes protocols for determining detection limits, are they followed?				
1.5.2.1	Does the laboratory document how LODs were derived from the determinations?				
1.5.2.1	Are all sample-processing and analysis steps of the analytical method included in the determination or validation of the LOD?				
1.5.2.1	a) When required, does the laboratory determine or verify the LOD for the method for each target analyte of concern in the quality system matrices?				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1	b) Is the validity of the LOD verified by detection (a value above zero) of the analyte(s) in a QC sample in each quality system matrix?				
1.5.2.1	b) Does the QC sample contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests?				
1.5.2.1	b) Is the verification performed on every instrument that is to be used for analysis of samples and reporting of data?				
1.5.2.1	b) Is the validity of the LOD verified as part of the LOD determination process?				
1.5.2.1	b) Is the verification done prior to the use of the LOD for the sample analysis?				
1.5.2.1	b) Does the laboratory establish a detection limit (DL) using accepted, published methodologies from recognized entities such as USEPA, USDOE, ASTM, or NIOSH for each suite of analyte-matrix-method, including surrogates?				
1.5.2.1	b) Is the DL used to determine the LOD for each analyte and matrix as well as for all preparatory and cleanup methods routinely used on samples?				
1.5.2.1	c) Does the laboratory have readily available, if require, an LOD study for any component which spiking solutions or quality control sample are available?				
1.5.2.1	d) Is the LOD initially determined for the compounds of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or is the LOD performed in the quality system matrix of interest?				
1.5.2.1	e) Is the LOD performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis?				
1.5.2.1	f) Does each preparation method listed on the scope of accreditation have quarterly LOD/LOQ verifications?				
1.5.2.1	f) However, do all possible combinations of preparation and cleanup techniques have the required LOD/LOQ verifications?				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1	f) If LOD/LOQ verifications are not performed on all combinations, does the laboratory base the LOD/LOQ verifications on the worst case basis (preparation method with all applicable cleanup steps)?				
1.5.2.1	f) After each DL determination, does the laboratory establish the LOD by spiking a quality system matrix at a concentration of at least 2 times but no greater than four times the DL?				
1.5.2.1	f) Does the spike concentration establish the LOD?				
1.5.2.1	f) Are the spike concentration at which the LOD is established verified?				
1.5.2.1	f) Is the LOD specific to each suite of analyze, matrix, and method (including sample preparation)?				
1.5.2.1	f) Are the following requirements applied to the initial LOD establishment and to the LOD verifications?				
1.5.2.1	f) i) Does the apparent signal to noise (S/N) ratio at the LOD at least three and do the results meet all method requirements for analyte identification (e.g., ion abundance, second column confirmation, or pattern recognition)?				
1.5.2.1	f) i) For data systems that do not provide a measure of noise, is the signal produced by the verification sample a result that is at least three standard deviations greater than the mean method blank concentration?				
1.5.2.1	f) ii) If the LOD verification fails, does the laboratory repeat the DL determination and LOD verification or perform and pass two consecutive LOD verifications at a higher spike concentration and set the LOD at the higher concentration?				
1.5.2.1	f) iii) Does the laboratory maintain documentation for all DL determinations and LOD verifications?				
1.5.2.1	f) iv) Are the DL and LOD reported for all analyte-matrix-methods suites, unless it is not applicable to the test or specifically excluded by project requirements?				
1.5.2.1	g) Is the LOD verified quarterly?				
1.5.2.1	g) In situations where methods are setup and used on an infrequent basis, does the laboratory choose to perform LOD verifications on a one per batch basis?				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1	g) Is all verification data in compliance, reported, and available for review?				
	Limit of Quantitation (LOQ)				
1.5.2.2	a) Are all sample-processing and analysis steps of the analytical method included in the determination of the LOQ?				
1.5.2.2	b) The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not available or otherwise inappropriate (e.g., pH)				
1.5.2.2	c) Does the laboratory procedure for establishing the LOQ empirically demonstrate precision and bias at the LOQ for each suite of analyte-matrix-method, including surrogates?				
1.5.2.2	c) Do the LOQ and associated precision and bias meet client requirements and are they reported?				
1.5.2.2	c) For DoD~~/DOE~~ projects, is the LOQ set within the calibration range, including the lowest calibration level?				
1.5.2.2	d) When an LOD is determined or verified by the laboratory, is the LOQ above the LOD?				
1.5.2.2	e) Is the LOQ verified annually for each quality system matrix, technology, and analyte?				
1.5.2.2	Note: the annual LOQ verification is not required if the LOD was determined or verified annually on that instrument.				
1.5.2.2	e) For DoD, at a minimum, is the LOQ verified quarterly?				
1.5.2.2	e) In situations where methods are setup and used on an infrequent basis, does the laboratory choose to perform LOQ verifications on a one per batch basis in lieu of quarterly verification, prior to sample analysis.?				
	Evaluation of Precision and Bias				
1.5.3	a) Reference Methods.				
1.5.3	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?				

Section Reference	Question	Yes	No	NA	Comments
1.5.3	b) Non-Reference Methods.				
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?				
1.5.3	b) Does the laboratory compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory?				
1.5.3	b) Are precision and bias measurements used evaluate the method across the analytical calibration range of the method?				
1.5.3	b) Does the laboratory also evaluate precision and bias in the relevant quality system matrices and process the samples through the entire measurement system for each analyte of interest?				
1.5.3	**Evaluation of Selectivity**				
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?				
	Demonstration of Capability (DOC)				
1.6.1	Prior to acceptance and institution of any method for which data will be reported, a satisfactory initial DOC is required (see Section 1.6.2)?				
1.6.1	Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) is required?				
1.6.1	In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the ongoing DOC shall be acceptable as an initial DOC.				

Section Reference	Question	Yes	No	NA	Comments
1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
1.6.1	For the initial DOC, are appropriate records as discussed in Section 1.6.2 completed?				
1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
1.6.1	Are all demonstrations documented? All data applicable to the demonstration shall be retained and readily available at the laboratory?				
1.6.1	Is all data applicable to the demonstration retained and readily available at the laboratory?				
	Initial DOC				
1.6.2	a) Does the laboratory have a documented procedure for performing the initial demonstration of capability (DOC) for methods used?				
1.6.2	b) Are changes in any condition that could potentially affect the precision and bias, sensitivity, or selectivity of the output (e.g., a change in the detector, column type, matrix, method revision, or other components of the sample analytical system) result in a new initial DOC?				
1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
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:				
1.6.2.1	a) analyst(s) involved in preparation and/or analysis?				
1.6.2.1	b) matrix?				
1.6.2.1	c) analyte(s), class of analyte(s), or measured parameter(s)?				
1.6.2.1	d) identification of method(s) performed?				
1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number?				
1.6.2.1	f) date(s) of analysis?				
1.6.2.1	g) summary of analyses, including information outlined in Section 1.6.2.2.c?				

Section Reference	Question	Yes	No	NA	Comments
1.6.2.2	If the method or regulation does not specify an initial DOC, is the laboratory following an acceptable procedure?				
1.6.2.2	It is the responsibility of the laboratory to document other adequate approaches for performing an initial DOC?				
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 limit of quantitation?				
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?				
1.6.2.2	c) Does the laboratory use all of the results to calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same units) for each parameter of interest? When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?				
1.6.2.2	d) Do all of the laboratory's paramaeters meet the acceptance criteria?				
1.6.2.2	e) When one or more of the tested parameters fail at least one of the acceptance criteria, did the analyst follow the proceeding according to i) or ii) below?				
1.6.2.2	e) i. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with b) above.				
1.6.2.2	e) ii. Beginning with b) above, repeat the test for all parameters that failed to meet criteria.				
1.6.2.2	f) If repeated failure occurs has the laboratory located and corrected the source of the problem and repeat the test for all compounds of interest beginning with b).				
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, did the laboratory perform an initial demonstration for that analyte?				

Section Reference	Question	Yes	No	NA	Comments
	Ongoing DOC				
1.6.3	Does the laboratory have a documented procedure describing ongoing DOC?				
1.6.3.1	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
1.6.3.1	It is the responsibility of the laboratory to document other adequate approaches for performing an ongoing DOC?				
1.6.3.2	Does the laboratory use one of the following to perform on-going DOC (a - e):				
1.6.3.2	a) acceptable performance of a blind sample (single blind to the analyst)?				
1.6.3.2	Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests.				
1.6.3.2	b) another initial DOC?				
1.6.3.2	c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy?				
1.6.3.2	c) Does the laboratory determine the acceptable limits for precision and accuracy prior to analysis?				
1.6.3.2	c) Does the laboratory tabulate or have the ability to readily retrieve four (4) consecutive passing LCSs for each method for each analyst each year?				
1.6.3.2	d)a documented process of analyst review using quality control (QC) samples?				
1.6.3.2	d) Are QC samples reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
1.6.3.2	e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) performed?				
	Technical Requirements				
1.7.1.1	**Instrument Calibration**				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1	If more stringent standards or requirements are included in a mandated method or by regulation, does the laboratory demonstrate that such requirements are met?				
1.7.1.1	If it is not apparent which Standard is more stringent, are the requirements of the regulation or mandated method followed?				
1.7.1.1	Are the following essential elements of initial instrument calibration performed?				
1.7.1.1	a) Are the details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics included or referenced in the method SOP?				
1.7.1.1	a)When initial instrument calibration procedures are referenced in the method, is the referenced material retained by the laboratory and be available for review?				
1.7.1.1	b) Is sufficient raw data records retained to permit reconstruction of the initial instrument calibration (e.g., calibration date, method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration)?				
1.7.1.1	c) Are sample results quantitated from the initial instrument calibration and not quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program?				
1.7.1.1	d) Are all initial instrument calibrations verified with a standard obtained from a second manufacturer prior to analyzing any samples?				
1.7.1.1	d) Is traceability to a national standard, when commercially available?				
1.7.1.1	d) Is the use of a standard from a second lot obtained from the same manufacturer (independently prepared from different source materials) acceptable for use as a second source standard?				
1.7.1.1	d) Is the concentration of the second source standard at or near the midpoint of the calibration range?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1	d) Are the acceptance criteria for the initial calibration verification at least as stringent as those for the continuing calibration verification?				
1.7.1.1	e) Is the criteria for the acceptance of an initial instrument calibration established (e.g., correlation coefficient or relative percent difference)?				
1.7.1.1	e) Is the criteria used appropriate to the calibration technique employed?				
1.7.1.1	f) Is the lowest calibration standard at or below the LOQ? Note: Any data reported below the LOQ shall be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or explained in the narrative?				
1.7.1.1	f) Is any data reported below the LOQ considered to have an increased quantitative uncertainty and is it reported using defined qualifiers or explained in the narrative?				
1.7.1.1	g) Is the highest calibration standard at or above the highest concentration for which quantitative data are to be reported?				
1.7.1.1	g) Is any data reported above the calibration range considered to have an increased quantitative uncertainty and is reported using defined qualifiers or explained in the narrative?				
1.7.1.1	g) Do the LOQ and the highest calibration standard of a multi-level calibration curve establish the calibration range?				
1.7.1.1	g)For metals analysis with a single-point calibration, do the LOQ and the calibration standard establish the calibration range, which lie within the linear dynamic range?				
1.7.1.1	g) When sample response exceed the calibration range, does the laboratory dilute and reanalyze the sample (when sufficient sample volume and holding time permit) to bring results within the calibration range?				
1.7.1.1	g) For metals analysis, the laboratory may report a sample result with a response above the calibration range if the laboratory analyzes and passes (within 10% of the true value) a high level check standard that exceeds the sample concentration but is within the linear dynamic range (provided the high level check standard is analyzed in the same manner as the sample and within the same calibration).				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1	g) Are the results outside the calibration range reported as estimated values and qualified using appropriate data qualifiers that are explained in the case narrative?				
1.7.1.1	h) Does the following occur for instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard?				
1.7.1.1	h) i) Prior to the analysis of samples, is the zero point and single point calibration standard analyzed and is the linear range of the instrument established by analyzing a series of standards, one of which is at or below the LOQ?				
1.7.1.1	h) i). Do sample results within the established linear range require data qualifiers?				
1.7.1.1	h) ii) Is a zero point and single point calibration standard analyzed with each analytical batch?				
1.7.1.1	h) iii) Is a standard corresponding to the limit of quantitation analyzed with each analytical batch and does it meet the established acceptance criteria?				
1.7.1.1	h) iv) Is the linearity verified at a frequency established by the method and/or the manufacturer?				
1.7.1.1	i) if the initial instrument calibration results are outside established acceptance criteria, are corrective actions performed and all associated samples re-analyzed?				
1.7.1.1	i) If the re-analysis of the samples is not possible, is the data associated with an unacceptable initial instrument calibration reported with appropriate data qualifiers?				
1.7.1.1	j) Is the initial calibration range consist of a minimum of five calibration points for organic analytes and three calibration points for inorganic analytes and Industrial Hygiene samples?				
1.7.1.1	Note:(Except metals by ICP-AES or ICP-MS with a single point calibration or otherwise stated in the method).				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1	j) Are all reported analytes and surrogates (if applicable) included in the initial calibration?				
1.7.1.1	j) Are the reported results for all analytes and surrogates quantified using a multipoint calibration curve?				
1.7.1.1	j) Does the exclusion of calibration points without documented scientifically valid technical justification as not permitted?				
	Continuing Calibration				
1.7.2	When an initial instrument calibration is not performed on the day of analysis, is the validity of the initial calibration verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch?				
1.7.2	Are the following items essential elements of continuing instrument calibration verification?				
1.7.2	a) Are the details of the continuing instrument calibration procedure, calculations and associated statistics included or referenced in the method SOP?				
1.7.2	b) Is the calibration verified for each compound, element, or other discrete chemical species, except for multi-component analytes such as aroclors, chlordane, total petroleum hydrocarbons, or toxaphene, where a representative chemical, related substance or mixture can be used?				
1.7.2	c) Are instrument calibration verification performed:				
1.7.2	c i. at the beginning and end of each analytical batch? Note: . If an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch?				
1.7.2	c) ii. if the time period for calibration or the most recent calibration verification has expired?				
1.7.2	c) iii. for analytical systems that contain a calibration verification requirement?				
1.7.2	c) iv. Is the concentration of the CCV standard greater than the low calibration standard and less than or equal to the midpoint of the calibration range?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2	d) 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)?				
1.7.2	d) Are Continuing calibration verification records explicitly connect the continuing verification data to the initial instrument calibration?				
1.7.2	d) Are all CCVs analyzed evaluated and reported?				
1.7.2	d) If a CCV fails, is reanalysis or corrective actions taken?				
1.7.2	Are criteria for continuing instrument calibration verification established?				
1.7.2	e) i) If a CCV fails, does the laboratory immediately analyze two additional consecutive CCVs (immediately is defined as starting a consecutive pair within one hour; no samples can be run between the failed CCV and the two additional CCVs)?				
1.7.2	e) i)Does this approach allow for spurious failures of analytes to be reported without reanalysis of samples?				
1.7.2	e) i) Do corrective actions that change the dynamics of the system (e.g., clip column, clean injection port, run blanks) require that all samples since the last acceptable CCV be reanalyzed?				
1.7.2	e) ii) Do both of these CCVs meet acceptance criteria in order for the samples to be reported without reanalysis?				
1.7.2	e) iii) If the laboratory cannot immediately analyze two CCVs, then is corrective action(s) performed and repeat the CCV and all associated samples since the last successful CCV.?				
1.7.2	e) iv) Do corrective action(s) and recalibration occur if the above scenario fails?				
1.7.2	e) iv) Are all affected samples since the last acceptable CCV reanalyzed?				
1.7.2	e) v) Is the flagging of data for a failed CCV only appropriate when the affected samples cannot be reanalyzed?				
1.7.2	e) v) Does the laboratory notify the client prior to reporting data associated with a failed CCV?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3	**Quality Control**				
1.7.3	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken as specified in this Section?				
1.7.3	Are method specific Quality Control (QC) requirements located in Appendix B of this standard?				
1.7.3	Do all method QC parameters and samples follow Appendix B requirements, as appropriate?				
1.7.3	Are the Appendix B requirements considered the minimum technology based requirements for DoD accreditation?				
	Negative Control – Method Performance: Method Blank				
1.7.3.1	a) Is the method blank used to assess the samples in the preparation batch for possible contamination during the preparation and processing steps? Is the method blank processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure? Are procedures in place to determine if a method blank is contaminated? Are any affected samples associated with a contaminated method blank reprocessed for analysis or are the results reported with appropriate data qualifying codes?				
1.7.3.1	b) Is the method blank analyzed at a minimum of one (1) per preparation batch? 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?				
1.7.3.1	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?				
1.7.3.1	d) Method blanks are not applicable for certain analyses, such as pH, Conductivity, Flash Point and Temperature.				
	Positive Control – Method Performance: Laboratory Control Sample (LCS)				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.2	Is the LCS used to evaluate the performance of the total analytical system, including all preparation and analysis steps?				
1.7.3.2.1	Are results of the LCS compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is “out of control?”				
1.7.3.2.1	Are any affected samples associated with an out of control LCS reprocessed for re-analysis or the results reported with appropriate data qualifying codes?				
1.7.3.2.2	Is the LCS analyzed at a minimum of one (1) per preparation batch?				
1.7.3.2.2	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?				
1.7.3.2.2	In those instances for which no separate preparation method is used (for example, volatiles in water), is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty (20) environmental samples, not including method blanks, LCS, matrix spikes and matrix duplicates?				
1.7.3.2.3	Is the LCS quality system matrix, known to be free of analytes of interest and spiked with known concentrations of analytes?				
1.7.3.2.3	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.				
1.7.3.2.3	Is the following used in choosing components for the spike mixtures:				
1.7.3.2.3	Are the components spiked as specified by the mandated method or regulation or as requested by the client?				
1.7.3.2.3	In the absence of specified spiking components, does the laboratory spike per the following:				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.2.3	a) For those components that interfere with an accurate assessment, such as spiking simultaneously with technical chlordane, toxaphene and PCBs,is the spike used chosen that represents the chemistries and elution patterns of the components to be reported?				
1.7.3.2.3	a) Are all reported analytes spiked in the LCS (with the exception of Aroclor analysis, which is spiked per the method)?				
1.7.3.2.3	b) Does this require the preparation of multiple LCSs to avoid interferences?				
1.7.3.2.3	b) Is the concentration of the spiked compounds at or below the midpoint of the calibration if project specific concentrations are not specified?				
1.7.3.2.3	c) Has the laboratory establish LCS in-house limits that comply with the following?				
1.7.3.2.3	c) i) Are statistically-derived based on in-house historical data, using scientifically valid and documented procedures?				
1.7.3.2.3	c).ii) Meet the limits specified by the project or as stated in the method, if available?				
1.7.3.2.3	c).iii). Are control limits updated on at least an annual basis or as stated in the method, whichever is more frequent, and re-established after major changes in the analytical process (e.g., new instrumentation)?				
1.7.3.2.3	c).iv) Are based on at least 30 data points generated under the same analytical process?				
1.7.3.2.3	c).v). Are there excluded failed LCS recovery data and statistical outliers from the calculation? (Do not exclude unless there is a scientifically valid and documented reason- e.g., incorrectly made standard, instrument malfunction)				
1.7.3.2.3	c).vi) Are the control limits not greater than ± 3 times the standard deviation of the mean LCS recovery?				
1.7.3.2.3	d) Are the control charts or data analysis software maintained and used to detect trends and prevent out-of-control conditions?				
1.7.3.2.3	d) Are the control limits monitored on an on-going basis (at least quarterly) for shifts in mean recovery, changes in standard deviation, and development of trends?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.2.3	d) Does the laboratory choose representative compounds for control charts for the purpose of trend analysis?				
1.7.3.2.3	e) Does the QA Officer or designee review control charts at a specified frequency for out-of-control conditions and initiate appropriate corrective actions?				
1.7.3.2.3	e) Is the data analysis software also used for the statistical evaluation of data for trends and biases?				
1.7.3.2.3	f) Does the laboratory use its in-house statistically established LCS control limits for the purpose of trend analysis and use in-house control limits as a component in estimating measurement uncertainty?				
1.7.3.2.3	g) In the absence of client specified LCS reporting criteria, does the LCS control limits outlined in the DoD/DOE QSM Appendix C tables used when reporting data for DoD/DOE projects?				
1.7.3.2.3	g) Has the laboratory developed processes or procedures to incorporate these limits?				
1.7.3.2.3	h). Are the LCS limits specified in the DoD/DOE QSM Appendix C tables used for batch control unless project specific criteria exist?				
1.7.3.2.3	h) Are sporadic marginal Exceedences allowed for those analytes outside the 3 standard deviation control limits but still within 4 standard deviations?				
1.7.3.2.3	h) Are marginal Exceedences not allowed for those analytes determined by a project to be target analytes (i.e. “risk drivers”) without project specific approval?				
1.7.3.2.3	i) For analytes that are not listed in the DoD/DOE QSM Appendix C control limits tables, does the laboratory use their in-house control limits for batch control and data reporting?				
1.7.3.2.3	DoD Only (Requirement) For DoD ELAP accreditation				
1.7.3.2.3	j) Does the laboratory develop in-house control limits for all analytes on their scope of accreditation?				
1.7.3.2.3	j) Are the in-house control limits used for trend analysis, and batch control for those analytes not listed in the DoD/DOE QSM Appendix C LCS tables?				
	Sample Specific Controls				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.3	Does the laboratory have a documented procedure for determining the effect of the sample matrix on method performance?				
1.7.3.3	Does the procedure relate the analyses of quality system matrix specific Quality Control (QC) samples and the designed data quality indicators for a specific sample using the designated method?				
1.7.3.3	Are these controls alone used to judge laboratory performance?				
1.7.3.3	Examples of matrix-specific QC include: Matrix Spike (MS), Matrix Spike Duplicate (MSD), sample duplicates, and surrogate spikes?				
1.7.3.3	Does the laboratory 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?				
1.7.3.3	Are the results of all MS/MSDs evaluated using the same acceptance criteria used for the DoD/DOE Appendix C LCS limits or project limits, if specified?				
1.7.3.3	If the specific analyte(s) are not available in the QSM Appendix C tables, does the laboratory use their LCS in-house limits as a means of evaluating MS/MSDs?				
	Matrix Spike; Matrix Spike Duplicates				
1.7.3.3.1	a) Does the matrix-specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method?				
1.7.3.3.1	Note: The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch				
1.7.3.3.1	b) Does each preparation batch of samples contain an associated MS and MSD (or matrix duplicate (MD)) using the same matrix collected for the specific project?				
1.7.3.3.1	b) Are the requirements for MS/MSD not applicable to all methods (e.g., certain radiochemical samples, air-testing samples, classic chemistry, and industrial hygiene samples)?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.3.1	b) If adequate sample material is not available, is the lack of MS/MSDs (MDs) noted in the case narrative, and is a LCS Duplicate (LCSD) used to determine precision?				
1.7.3.3.1	b) Are additional MS/MSDs required on a project-specific basis?				
1.7.3.3.1	c) Are the MS and MSD spiked with all reported analytes (with the exception of Aroclor analysis, which is spiked per the method)?				
1.7.3.3.2	a) Are matrix duplicates defined as replicate aliquots of the same sample taken through the entire analytical procedure?				
1.7.3.3.2	a) Do the results from the analysis indicate the precision of the results for the specific sample using the selected method?				
1.7.3.3.2	a) Do the matrix duplicate provide a usable measure of sample homogeneity?				
1.7.3.3.2	a) It may also provide a measure of precision when target analytes are present?				
1.7.3.3.2	b) Is the frequency of the analysis of matrix duplicates as specified by the method or determined as part of the contract review process?				
1.7.3.3.2	c) Are matrix duplicates performed on replicate aliquots of actual samples? Is the composition usually not known?				
1.7.3.3.3	a) When required, are surrogates chosen to reflect the chemistries of the targeted components of the method and are they added prior to sample preparation/extraction?				
1.7.3.3.3	b) Except where the matrix precludes its use or when not commercially available, are surrogate compounds added to all samples, standards, and blanks for all appropriate methods?				
1.7.3.3.3	c) Are surrogate compounds chosen to represent the various chemistries of the target analytes in the method?				
1.7.3.3.3	c) Are surrogate specified by the mandated method used, and are they chosen for their being unlikely to occur as an environmental contaminant?				
1.7.3.3.3	c) Is the laboratory using deuterated analogs of selected surrogate compounds?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.3.3	d) Are surrogate spike results compared with DoD/DOE QSM Appendix C LCS limits or acceptance criteria specified by the client?				
1.7.3.3.3	d) If these criteria are not available, does the laboratory compare the results with its in-house statistically established LCS criteria?				
	Data Reduction				
1.7.3.4	Are the procedures for data reduction, such as use of linear regression, documented?				
	Reagent Quality, Water Quality and Checks				
1.7.3.5	a) In methods where the purity of reagents is not specified, is analytical reagent grade used?				
1.7.3.5	a) Are reagents of lesser purity than those specified by the method used?				
1.7.3.5	a) Is the documentation of purity available?				
1.7.3.5	b) Is the quality of water sources monitored and documented and does it meet method specified requirements?				
1.7.3.5	c) Does the laboratory verify the concentration of titrants in accordance with written laboratory procedures?				
1.7.3.5	d) Are the quality (e.g., purity) specifications for all standards and reagents (including water) documented or referenced in SOPs?				
	Selectivity				
1.7.3.6	Does the laboratory document selectivity by following the checks established within the method?				
1.7.3.6	a) Is tentative identification of an analyte occurring when a peak from a sample extract falls within the daily retention time window?				
1.7.3.6	a) Is confirmation necessary when the resu;ts are greater than DL and composition of samples is not well characterized?				
1.7.3.6	a) Are confirmation techniques including further analysis using a second column with dissimilar stationary phase, GC/MS (full scan or SIM) or HPLC/MS (if concentration permits), GC or HPLC with two different types of detectors, or by other recognized confirmation techniques?				
1.7.3.6	Note: HPLC UV-Diode Array detectors not considered confirmation for a UV detector				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.6	b) When reporting data for methods that require analyte confirmation using a secondary column or detector, are project-specific reporting requirements followed?				
1.7.3.6	b) If project specific requirements have not been specified, are the reporting requirements in the method?				
1.7.3.6	b) If the method does not include reporting requirements, does the report have the results from the primary column or detector? (Unless there is a scientifically valid and documented reason for not doing so and is concurred with by the client.)				
1.7.3.6	c) Are the DoD/DOE specific client notified of any results that are unconfirmed (e.g., confirmation was not performed or confirmation was obscured by interference)?				
1.7.3.6	c)Are the unconfirmed results identified in the test report, using appropriate data qualifier flags, and explained in the case narrative?				
1.7.3.6	c) Is the analyte presence indicated only if both original and confirmation signals are positive or if confirmation signal cannot be discerned from interference?				
	Data Acceptance/Rejection Criteria				
1.7.4	Negative Control – Method Performance: Method Blank				
1.7.4.1	Is the source of contamination investigated and measures taken to minimize or eliminate the problem?				
1.7.4.1	a) Is the method blank considered to be contaminated if:				
1.7.4.1	a) i) The concentration of any target analyte (chemical of concern) in the blank exceeds 1/2 the LOQ or is greater than 1/10th the amount measured in any associated sample, or 1/0th the regulatory limit, whichever is greater?				
1.7.4.1	a) ii) the concentration of any common laboratory contaminant in the blank exceeds the LOQ?				
1.7.4.1	b) Is the source of contamination investigates and corrective action taken if the blank contamination otherwise affects the sample results as per the method requirements or the individual project data quality objectives?				

Section Reference	Question	Yes	No	NA	Comments
1.7.4.1	b) If a method blank is contaminated as described above, then does the laboratory reprocess affected samples in a subsequent preparation batch, except when sample results are below the LOD? If insufficient sample volume remains for reprocessing, are the results reported with appropriate data qualifier?				
1.7.4.1	c) Are the samples associated with a contaminated blank evaluated as to the best corrective action for the samples (e.g.?, reprocessing or data qualifying codes)? In all cases the corrective action documented?				
1.7.4.1	c) Is the cause investigated and measures taken to minimize or eliminate the problem?				
1.7.4.1	c) Are the samples associated with a contaminated blank evaluated with corrective action for the samples (e.g.?, reprocessing or data qualifying codes)?				
1.7.4.1	c) In all cases are the corrective actions documented?				
	Positive Control – Method Performance: Laboratory Control Sample (LCS)				
1.7.4.2	a) Are the results of the individual batch LCS are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria?				
1.7.4.2	a) Does the laboratory document the calculation?				
1.7.4.2	a) Is the individual LCS compared to the acceptance criteria as published in the mandated method?				
1.7.4.2	a) Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria?				
1.7.4.2	a) Are samples analyzed along with an LCS determined to be “out of control” considered suspect and are the samples reprocessed, re-analyzed or the data reported with appropriate data qualifying codes?				
1.7.4.2	a) 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?				

Section Reference	Question	Yes	No	NA	Comments
1.7.4.2	a) 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?				
1.7.4.2	b) If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits, was corrective aciton performed? (Note: This may not indicate that the system is out of control, therefore corrective action may not be necessary)				
1.7.4.2	If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails was corrective action implemented?				
1.7.4.2	c) Was project-specific approval given when there were sporadic Marginal Exceedences for target analytes (chemicals of concern as identified by a project)?				
1.7.4.2	d) DoD considers the same analyte exceeding the LCS control limit two (2) out of three (3) consecutive LCS to be indicative of non-random behavio., Is corrective action taken and reanalysis of the LCS performed?				
1.7.4.2	Guidance: The target analytes are considered those few analytes that are critical for the success of a project (such as risk drivers) where sporadic marginal Exceedences cannot be allowed.				
1.7.4.2	Guidance: Are the Laboratories consulting with clients whenever long lists of analytes are requested for analysis to determine if marginal exceedances will be allowed.				
1.7.4.2	**Sample Specific Controls**				
1.7.4.3	a) Does laboratory document the calculation for %R, RPD or other statistical treatment used for MS/MSD calculations?				
1.7.4.3	a) Does the laboratory compare the results to the acceptance criteria as published in the mandated method?				
1.7.4.3	a) Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				

Section Reference	Question	Yes	No	NA	Comments
1.7.4.3	a) For matrix spike results outside established criteria, is corrective action documented or the data for that sample reported with appropriate data qualifying codes?				
1.7.4.3	b) Did the laboratory document the calculation for relative percent difference or other statistical treaments for Matrix Duplicates?				
1.7.4.3	b) Does the laboratory compare the results to the acceptance criteria as published in the mandated method?				
1.7.4.3	b) Did the laboratory perform corrective action for matrix duplicates results outside established criteria or was the data for that sample reported with appropriate data qualifying codes?				
1.7.4.3	b) Where there are no established criteria, did the laboratory determine internal criteria and document the method used to establish the limits?				
1.7.4.3	c) Are the results of the surrogate spikes compared to acceptance criteria as published in the mandated method?				
1.7.4.3	c) If ther are no established criteria, does the laboratory establish internal criteria and document the method used to estblish the limits?				
1.7.4.3	c) Were surrogates outside the acceptance criteria evaluated for the effect indicated for the individual sample results?				
1.7.4.3	c) Are the appropriate corrective action guided by the data quality objectives or other site-specific requirements?				
1.7.4.3	c) Are results reported from analyses with surrogate recoveries outside the acceptance criteria include appropriate data qualifiers?				
1.7.4.3	**Sample Handling**				
1.7.5	a) Are samples that require thernal presevation considered acceptable if the arrival temperature is either within 2C of the required temperature or within the method specified range? Note:				
1.7.5	Note: Samples with a specified temperature of 4C are acceptable at temperatures from just above 0C to 6C.				
1.7.5	a) i. Samples delivered to the laboratory on the same day they are collected may not meet temperature requirements. In those cases, samples shall be considered acceptable if the samples were received on ice.				

Section Reference	Question	Yes	No	NA	Comments
1.7.5	a) ii. If sample analysis is begun within 15 minutes of collection, thernal preservation is not required.				
1.7.5	a) iii. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample wihtin 15 minutes of collection.				
1.7.5	b) Does the laboratory implement procedures for checking chemical preservation of samples, such as pH or chlorine prior to or during sample preparation or analysis, with the exception of VOCs?				
1.7.5	**Volume 1 Module 5**				
	Microbiological Testing				
	Method Validation				
1.5	Does the laboratory validate non-refenece methods, laboraotry-designed/developed methods, reference methods used outside their published scope and amplications and modification of reference methods?				
1.5	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?				
1.5	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?				
1.5	Does the laboratory participate in a suitable program of proficiency testing? (Assessor must provide copies of PT reports in package.)				
1.5	Does the laboratory maintain documentation of the validation procedure while it is in use and for 5 years past the last date of use?				
1.5	If no refernece method exists, or if the data quality objectives are differenct from the refence method, does the laboratory demonstrate that the methods meets the quality objectives for the intended use?				
1.5	Does the laboratory use at least 1 know pure reference culutre at this anticipated environmental conditions, and cmpare the mthods results to that of a reference methods?				
1.5.1	Does the laboratory perform at least 10 replicate analyese with both the proposed and reference method, using the target microorganisms of choice?				

Section Reference	Question	Yes	No	NA	Comments
1.5.2	Does the laboratory verify all responses in at least the last 10 samples using mixed cutlures include the target organisms and at varying concentrations?				
1.5.3	Does the laboratory calculate the number of false positive and false negative results?				
1.5.3	**Demonstration of Capability (DOC)**				
1.6	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (per Section 1.6.2)?				
1.6.1	Were ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) required?				
1.6.1	Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				
1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
1.6.2	**Initial DOC**				
1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
1.6.2	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
1.6.2.1	a) analyst(s) involved in preparation and/or analysis?				
1.6.2.1	b) matrix?				
1.6.2.1	c) Organism(s)?				
1.6.2.1	d) identification of method(s) performed?				

Section Reference	Question	Yes	No	NA	Comments
1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number?				
1.6.2.1	f) date(s) of analysis?				
1.6.2.1	g) summary of analyses, including information outlined in Section 1.6.2.2.c?				
1.6.2.2	If the method or regulation does not specify a DOC, does the laboratory use the procedure stated in 1.6.2.2?				
1.6.2.2	Does the laboratory document other approaches to initial DOC, and are they adequate?				
1.6.2.2	**Ongoing DOC**				
1.6.3	Does the laboratory have a documented procedure describing ongoing demonstration of capability?				
1.6.3.1	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
1.6.3.1	Does the laboratory document other approaches to ongoing DOC, and are they adequate?				
1.6.3.1	Does ongoing demonstration include one of the following in 1.6.3.2 (a-f) or by performing another initial DOC?				
1.6.3.2	a) Does ongoing demonstration include the analysis of one sample or clean matrix that is fortified with a known quantity of the target organism, with results meeting the laboratory acceptance criteria for accuracy and, where applicable to the testing technique, also meeting the observational details expected for the presumptive, confirmed and completed phases defined in the method?				
1.6.3.2	b) Does ongoing demonstration include the analysis of one sample in duplicate for each target organism and test, with results meeting the laboratory acceptance criterion for precision?				
1.6.3.2	c) Does ongoing demonstration include acceptable results for one-single-blind proficiency test sample for target organisms in each field of accreditation?				

Section Reference	Question	Yes	No	NA	Comments
1.6.3.2	d) Does ongoing demonstration include performance of an alternate adequate procedure for the field of accreditation, the procedure and acceptance criteria being documented in the laboratory's quality system?				
1.6.3.2	e) Does ongoing demonstration include a documented process of analyst review using QC samples? Are QC samples reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
1.6.3.2	f) If a) through e) are not technically feasible, then does the laboratory perform analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method)?				
1.7	**Technical Requirements**				
1.7	**Initial Calibration**				
1.7.1	a) Does the laboratory have documented procedures for calibration, verification, and quality control of support equipment including conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments?				
1.7.1	a) Do these procedures refer to applicable reference methods?				
1.7.1	b) For instruments that are continuous monitors, such as in-line specific conductance meters:				
1.7.1	b) i) Does the laboratory document acceptable calibration verification at least once a month?				
1.7.1	b) ii) Are the initial calibrations being performed in a continuing calibration that is unacceptable, or is the instrument being returned to service after having been taken off line?				
1.7.1	**Continuing Calibration**				
1.7.2	Note: Reserved for specific procedures				
	Quality Control				
1.7.3.1	Sterility Checks and Method Blanks				
	a) Method Blanks				
1.7.3.1	a) Does the laboratory demonstrate the filtration equipment and filters, sample containers, and media?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.1	a) Have the reagents been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure?				
1.7.3.1	a) i) Is the filtration technique of the laboratory conducting method blanks per the analytical method?				
1.7.3.1	a) i) At a minimum is the filtration series include a beginning and ending blank?				
1.7.3.1	a) i) Does the filtration series include single or multiple filtration units?				
1.7.3.1	a) i)Have they been sterilized prior to beginning the series?				
1.7.3.1	a) ii)Is the filtration series considered ended when more than thirty (30) minutes have elapsed between successive filtrations?				
1.7.3.1	a) ii) During a filtration series are filter funnels rinsed with three (3) 20-30 ml portions of sterile rinse water after each sample filtration?				
1.7.3.1	a) ii) Are the laboratories inserting a method blank after every ten (10) samples or sanitize filtration units by UV light after each sample filtration?				
1.7.3.1	a) iii)Does the pour plate technique have method blanks of the medium being made by pouring?				
1.7.3.1	a) iii) Is there one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory?				
1.7.3.1	b. Sterility Checks				
1.7.3.1	b) i) Is the sterility check being analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory?				
1.7.3.1	b) i) Is this done prior to first use of the medium?				
1.7.3.1	b) ii) For pre-sterilized single use funnels is the sterility check performed on one funnel per lot?				
1.7.3.1	b) ii) Do laboratory-sterilized funnels have a sterility check performed on one funnel per sterilization batch?				
1.7.3.1	b) iii) Are the sterility checks on sample containers performed on at least one (1) container for each lot of purchased, pre-sterilized containers?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.1	b) iii) Are the containers prepared and sterilized in the laboratory as a sterility check is performed on one (1) container per sterilized batch with nonselective growth media?				
1.7.3.1	b) iii) Is a contracted laboratory performing the sterility checks if the laboratory does not have the requisite equipment to perform them?				
1.7.3.1	b) iii) Are all correspondence and results from a contracted laboratory retained for a period of five (5) years after the completion of the test(s)?				
1.7.3.1	b) iiv) Is the sterility check performed on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water with nonselective growth media?				
1.7.3.1	b) v) Is at least one (1) filter from each new lot of membrane filters checked for sterility with nonselective growth media?				
1.7.3.1	**Test Variability/Reproducibility**				
1.7.3.2	Are the methods that specify colony counts such as membrane filter or plated media, duplicate counts performed monthly on one positive sample, for each month that the test is performed?				
1.7.3.2	Does the laboratory have two or more analysts?				
1.7.3.2	Does each analyst count typical colonies on the same plate?				
1.7.3.2	Are counts within 10% difference?				
1.7.3.2	s the laboratory with only one (1) microbiology analyst?				
1.7.3.2	Is the same plate counted twice by the analyst and with no more than 5% difference between the counts?				
	Sample Specific Controls (where applicable)				
1.7.3.3	a. Are the matrix spikes performed per method requirement?				
1.7.3.3	b. Is the sample matrix duplicates performed per method requirements?				
1.7.3.3	**Data Reduction**				
1.7.3.4	Are the calculations, data reduction and statistical interpretations specified by each method identified and followed?				
1.7.3.4	**Quality of Standards, Reagents and Media**				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.5	Does the laboratory ensure that the quality of the reagents and media used is appropriate for the test concerned?				
1.7.3.5	a) Is the Media – Culture media prepared from commercial dehydrated powders and/or purchased ready-to-use?				
1.7.3.5	a) i) Laboratory-prepared media				
1.7.3.5	a) i) 1) Is the media prepared by the laboratory from basic ingredients tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition) prior to first use?				
1.7.3.5	a) i) 2) Is the media used within the holding time limits specified in the accredited method?				
1.7.3.5	a) i) 3) Is the detailed testing criteria information defined in the laboratory's methods, SOPs, or similar documentation?				
1.7.3.5	a) ii) Ready-to-use media				
1.7.3.5	a) ii) 1) Is the ready-to-use media used within the manufacturer's expiration date?				
1.7.3.5	a) ii) 1) Is the manufacturer's expiration date greater than those noted in Section 1.7.3.5 from the manufacturer demonstrating media quality for the extended time period?				
1.7.3.5	a) ii) 2) Is any ready-to-use media used past the expiration date verified for usability by running quality control checks comparing the media with freshly prepared media or by testing recovery with known densities of culture controls?				
1.7.3.5	b) Reagents and commercial dehydrated powders used within the shelf life of the product, and documented as per TNI Volume 1, Module 2 Quality Systems General Requirements?				
1.7.3.5	**Reagent Water**				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.5	c) i) Is the quality of the reagent water used in the laboratory, such as distilled water, deionized water or reverse-osmosis produced water monitored for bactericidal and inhibitory substances?				
1.7.3.5	c) i) Is it used in the preparation of media, solutions and buffers?				
1.7.3.5	c) ii)Is the quality of the water monitored for chlorine residual, specific conductance, total organic carbon, ammonia/organic nitrogen and heterotrophic bacteria plate count monthly (when in use)?				
1.7.3.5	c) ii) Is the maintenance performed on the water treatment system or at startup after a period of disuse longer than one month?				
1.7.3.5	c) iii) Is the analysis for metals and the Bacteriological Water Quality Test to determine presence of toxic agents or growth promoting substances performed annually?				
1.7.3.5	Note: Exception to performing the Bacteriological Water Quality Test given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.				
1.7.3.5	c) iv) Do the results of the above analyses meet the specifications of the required method and records of analyses maintained for five (5) years?				
1.7.3.5	c) v) Is reagent water purchased from an outside source and used for the preparations of media, solutions and buffers and does it meet the criteria specified?				
1.7.3.5	c) v)Is the purchased reagent water that has been in use for longer than the testing intervals specified in the accredited method either re-tested or discarded?				
1.7.3.5	d) Does the laboratory have documented records of this information?				
1.7.3.5	d) Does the documentation for media prepared in the laboratory include date of preparation, preparer's initials, type, manufacturer, lot number, final pH, expiration date, and the amount of reagents used?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.5	d) Is there 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?				
1.7.3.5	**Selectivity**				
1.7.3.6	a) Have all growth and recovery media checked to assure that the target organism(s) respond in an acceptable and predictable manner?				
1.7.3.6	b) Are the analysis results accurate, target organism identity verified as specified in the method (e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test or by the use of a completed test such as brilliant green (BG) or E. coli (EC) broth?				
1.7.3.6	c) Is the identity and traceability, reference cultures used for positive and negative controls obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body?				
1.7.3.6	c) Do microorganisms use a single preparation or culture to maintain for their intended use by documented procedures that demonstrate the continued purity and viability of the organism?				
1.7.3.6	c) i) Are the reference cultures revived (if freeze-dried) or transferred from slants and subcultures once to provide reference stocks?				
1.7.3.6	c) i) Are the reference stocks s preserved by a technique that maintains the characteristics of the strains?				
1.7.3.6	c) i) Are the reference stocks used to prepare working stocks for routine work?				
1.7.3.6	c) i) If reference stocks have been thawed, are they refrozen and re-used?				
1.7.3.6	c) ii) Have the working stocks not been sequentially cultured more than five (5) times and not be sub-cultured to replace reference stocks?				
1.7.3.6	d) Culture Controls				
1.7.3.6	**i. Negative Culture Controls**				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.6	d) i) 1) Are the negative culture controls demonstrating 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)?				
1.7.3.6	d) i) 2) Does each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory analyzed with one or more known negative culture controls (i.e. non-target organisms), as appropriate to the method?				
1.7.3.6	d) i) 2) Is this done prior to first use of the medium?				
1.7.3.6	**II. Positive Culture Controls**				
1.7.3.6	d) ii) 1) Are the positive culture controls demonstrating 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)?				
1.7.3.6	d) ii) 2) Do each pre-prepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory tested with at least one pure culture of a known positive reaction?				
1.7.3.6	d) ii) 2) Is this done prior to first use of the medium?				
1.7.3.6	**Constant and Consistent Test Conditions**				
1.7.3.7	a) Are the floors and work surfaces non-absorbent and easy to clean and disinfect?				
1.7.3.7	a) Are the work surfaces adequately sealed?				
1.7.3.7	a) Are the laboratories providing sufficient storage space, and cleaned and free from dust accumulation?				
1.7.3.7	a) Are plants, food, and drinks prohibited from the laboratory work area?				
1.7.3.7	b) i) Are the temperature-measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment at the appropriate quality to meet specification(s) in the method?				
1.7.3.7	b) i) Is the graduation of the temperature measuring devices appropriate for the required accuracy of measurement and verified to national or international standards for temperature?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.7	b) i) Is the verification performed at least annually? (See TNI Volume1, Module 2, Section 5.5.13.1).				
1.7.3.7	b) ii) Is the performance of each autoclave initially evaluated by establishing its functional properties and performance?				
1.7.3.7	Note: For example heat distribution characteristics with respect to typical uses.				
1.7.3.7	b) ii) Are the autoclaves meeting specified temperature tolerances?				
1.7.3.7	b) ii) Are there any pressure cookers used for sterilization of growth media?				
1.7.3.7	b) ii) Is the demonstration of sterilization temperature provided by use of a continuous temperature-recording device or used of a maximum registering thermometer with every cycle?				
1.7.3.7	b) ii) At least once during each month is the autoclave is used?				
1.7.3.7	b) ii) Are the appropriate biological indicators used to determine effective sterilization?				
1.7.3.7	b) ii) Is the selected biological indicator effective at the sterilization temperature and time needed to sterilize lactose-based media?				
1.7.3.7	b) ii) Is the temperature sensitive tape used with the contents of each autoclave ran to indicate that the autoclave contents have been processed?				
1.7.3.7	b) ii) Are the records of autoclave operations maintained for every cycle?				
1.7.3.7	b) ii) Do the records include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials?				
1.7.3.7	b) ii) Is the autoclave maintenance, either internally or by service contract, performed annually, and include a pressure check and verification of temperature device?				
1.7.3.7	b) ii) Are the records of the maintenance maintained in equipment logs?				
1.7.3.7	NOTE: When it has been determined that the autoclave has no leaks, pressure checks can be documented using the formula PV = nRT.				
1.7.3.7	b) ii) Is the autoclave mechanical timing device checked quarterly against a stopwatch and the actual time elapsed documented?				
1.7.3.7	b) iii) Is the volumetric equipment verified?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.7	b) iii) 1) Does the equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes verified for accuracy quarterly?				
1.7.3.7	b) iii) 2) Does the equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) verified once per lot prior to first use? (NOTE: verification can be volumetric or gravimetric.)				
1.7.3.7	b) iii) 3) Is the volume of the disposable volumetric equipment such as sample bottles, and disposable pipettes checked once per lot?				
1.7.3.7	b) iv) Are the UV instruments, used for sanitization, tested quarterly for effectiveness with an appropriate UV light meter, by plate count agar spread plates or other methods providing equivalent results such as uvcide strips?				
1.7.3.7	b) iv)Do the replace bulbs have an output that is less than 70% of original for light tests or if the count reduction is less than 99% for a plate containing 200 to 300 organisms?				
1.7.3.7	b) v) 1) Do the uniformity of temperature distribution in incubators and water baths established?				
1.7.3.7	b) v) 1) Is the temperature of incubators and water baths documented twice daily, at least four hours apart, on each day of use?				
1.7.3.7	b) v) 2) Are the ovens used for sterilization be checked for sterilization effectiveness monthly with appropriate biological indicators?				
1.7.3.7	b) v) 2) Do the records maintain for each cycle has an included date, cycle time, temperature, contents and analyst's initials?				
1.7.3.7	b) vi) 1) Does the laboratory have a documented procedure for washing labware, if applicable?				
1.7.3.7	b) vi) 1) Are the detergents designed for laboratory use used?				
1.7.3.7	b) vi) 2) Is the glassware made of borosilicate or other non-corrosive material, free of chips and cracks, and have readable measurement marks?				
1.7.3.7	b) vi) 3) Is labware that is washed and reused tested for possible presence of residues that may inhibit or promote growth of micororganisms by performing IRT annually?				

Section Reference	Question	Yes	No	NA	Comments
1.7.3.7	b) vi) 3) Is labware that is washed and reused tested for possible presence of residues that may inhibit or promote growth of micororganisms by performing IRT each time the lab changes the lot of detergent or washing products?				
1.7.3.7	b) vi) 4) Is the washed labware tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with suitable pH indicator such as bromothymol blue?				
1.7.3.7	b) vi) 4) Does the laboratory maintain record when the washed labware tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with suitable pH indicator such as bromothymol blue?				
1.7.3.7	**Data Acceptance/Rejection Criteria**				
1.7.4	Methods criteria and evaluation methods shall be used				
1.7.4	**Sample Handling**				
1.7.5	a) Does the laboratory check the arrival temprature of smaples that require thermal preservation?				
1.7.5	b) Is chlorine residual checked in the field and is the actual concentration documented with sample				
	b) When the laborotory receives samples from potable water sources that have a demonstrated history of acceptable preservation and they check a sample from each sources 1 time per month, are they complying with 1.7.5 b.i-b.iv?				
	Volume 1 Module 6				
	Radiochemical Testing				
	Method Validation				
1.5.1	Does the laboratory validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use?				
1.5.1	Is the validation as extensive as necessary to meet the needs of the given application or field of application?				

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

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

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1.1	c) MDA Calculation -i) With a Blank Population: The basic MDA calculation shall be based on the concepts developed by L. A. Currie from his paper "Limits for Qualitative Detection and Quantitative Determination, Analytical Chemistry, March, 1968, Vol. 40, or from the MARLAP Manual Chapter 20. The following general equations derived from the work of L. A. Curie can be used to calculate the MDA. i) With a Blank Population: MDA $= \frac{3.29 * S^b}{KT_s} + \frac{3}{KT_s}$ K = efficiency * $e^{-\lambda t}$ * aliquot fraction * tracer recovery*Yield TS = count time of the sample in minutes sb = standard deviation of the blank population where the blank population is in net blank counts in count time TS Use of blank populations for calculation of MDAs requires the selection of an implementation method, which includes but is not limited to: Identification of blanks to be used in the population: 1. The number of blanks to use in the population; 2. How the blank population changes; and 3. Limitations on the deletion of blanks. The method of implementation shall not introduce any statistical bias. The appropriate blank subtraction shall be the mean blank value of the blank population. The implementation of blank populations for calculation of MDAs shall be described in detail in a SOP. In the original Currie derivation, a constant factor of 2.71 was used. Since that time it has been shown and generally accepted that a constant factor of 3 is more appropriate (Multi Agency Radiation Survey & Site Investigation Manual, Aug. 2000). However, it is acceptable to use a constant of 2.71 in situations where that factor is built into instrument software without an option to use 3. In that case, obtain permission from the DoD/DOE client and document the use of 2.71 in the case narrative. ii) Without a Blank Population: MDA for samples without a blank population can be determined if based on appropriate Curie or MARLAP calculations, such as: Where: K = efficiency * e^{-1t} * aliquot fraction * tracer Recovery*Yield TS = count time of the sample in minutes TB = count time of the background in minutes b = background count rate in cpm The above equation is used when sample and background count times are different. Other equations, where sample and background count times are the same may also be used. iii) General: The above equation for MDA has the units of dpm/sample. Any other units will require appropriate conversion. Site specific requirements may be provided for other MDA formulations. MDAs for samples without a blank population can be determined if based on appropriate L. A. Currie or MARLAP calculations.				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1.1	c) i. Use of blank populations for calculation of MDAs requires the selection of an implementation method, which includes but is not limited to: a. Identification of blanks to be used in the population; b. The number of blanks to use in the population; c. How the blank population changes; and d. Limitations on the deletion of blanks. Does the method of implementation introduce any statistical bias?				
1.5.2.1.1	c) i. Is the appropriate blank subtraction the mean blank value of the blank population?				
1.5.2.1.1	c) i. Is the implementation of blank populations for calculation of MDAs described in detail in a SOP?				
1.5.2.1.1	c) i. It is acceptable to use a constant of 2.71 in situations where that factor is built into instrument software without an option to use 3. In that case, does the laboratory obtain permission from the DoD~~/DOE~~ client and document the use of 2.71 in the Case Narrative or in procedures available to the client?				
1.5.2.1.1	c) ii. Without a Blank Population: MDA for samples without a blank population can be determined if based on appropriate Currie or MARLAP calculations, such as: 3.29* Tb+Tb MDA= S B+3 K K *TS Where: K = efficiency * e -λ t * aliquot fraction * tracer Recovery*Yield TS = count time of the sample in minutes TB = count time of the background in minutes b = background count rate in cpm Is fhe above equation used when sample and background count times are different? Other equations, where sample and background count times are the same may also be used.				
1.5.2.1.1	The above equation for MDA has the units of dpm/sample. Are other units appropriately conversion. - Site specific requirements may be provided for other MDA formulations. - MDAs for samples without a blank population can be determined if based on appropriate L. A. Currie or MARLAP calculations.				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1.1	d) MDA Optimization: Does the laboratory optimize analysis parameters in order to achieve analyte MDAs less than or equal to the required detection threshold?				
1.5.2.1.1	a) Does the laboratory handle samples with elevated activities according to the following requirements: i) The appropriate aliquot size shall be determined based on the activity level in the sample. The aliquant shall be large enough to generate data, which meet the following criteria:				
1.5.2.1.1	a) The measurement uncertainty shall not be greater than 10% (1 sigma) of the sample activity.?				
1.5.2.1.1	b) The MDA for the analysis shall be a maximum of 10% of the sample activity?				
1.5.2.1.1	e) If sample-specific MDAs are calculated and reported, that shall be clearly stated in the data package?				
1.5.2.1.1	f) The definition of the MDA presupposes that an appropriate detection threshold (i.e., the decision level) has already been defined. The a probabilities assumed for the decision level shall also be used for the calculation of the MDA?				
	Decision Level (DL)				
1.5.2.1.2	Does the laboratory comply to the following DL requirements: a) In the context of analyte detection, the minimum measured value (e.g., of the instrument signal or the analyte concentration) required to give confidence that a positive (nonzero) amount of analyte is present in the material analyzed. The DL is sometimes called the critical level (Lc) or critical value (MARLAP). It is the quantity of analyte at or above which an a posteriori decision is made that a positive quantity of the analyte is present. Confidence levels may be dictated by the project. For this document, the probability of a Type I error (probability of erroneously reporting a detectable nuclide in an appropriate blank or sample) is assumed to be set at 0.05.				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.1.2	b) DL Factors and Conditions: DLs are determined a posteriori based on sample-specific sample size, count duration, tracer chemical recovery, detector background, blank standard deviation, and detector efficiency.				
1.5.2.1.2	c) The DL calculation shall be based on concepts developed by L.A. Currie "Limits for Qalitative Detection and Quantitative Determination, Analytical Chemistry, March 1968, Vol. 40, or MARLAP Chapter 20. The following general equation below can be used to calculate the DL.				
1.5.2.1.2	c) The DL can either be based on the Combined Standard Uncertainty (CSU) of the blank (preparation or method), or the standard deviation determined from a set of appropriate blanks.				
1.5.2.1.2	c) i) With Blank Population: When determined from the standard deviation of a set of appropriate blanks, the DL evaluates the level at which the blank results will not exceed more than 5% of the time (or other specified level of confidence) and may be estimated by the following equation: $DL=((t*S_b)+R_b)/(E*R*IDF*W)$ Where: DL = the decision level in disintegrations per minute per unit volume or weight (dpm/unit); S_B = the standard deviation of a set of appropriate blank net count rate after background subtraction for blanks counted for the same length of time as the sample; R_B = the average blank count rate in counts per minute (cpm); t = the student t factor for appropriate degrees of freedom and confidence level; E = the fractional detector efficiency (c/d) for the sample; R = the fractional chemical yield for the sample; IDF = the ingrowth or decay factor for the sample; and W = the weight or volume of the sample. DLs are used as the default detection threshold. Alternatively, the client may use/specify detection thresholds that meet project/site-specific requirements. DLs for samples without a blank population can be determined if based on appropriate L. A. Currie or MARLAP calculations using a CSU.				
1.5.2.1.2	ii) Without a Blank Population: DLs for samples without a blank population can be determined if based on appropriate L. A. Currie or MARLAP calculations using a CSU.				
	Required Detection Limit for Drinking Water				

Section Reference	Question	Yes	No	NA	Comments
1.5.2.2	If the laboratory analyzes drinking-water samples for Safe Drinking Water Act (SDWA) compliance monitoring do they use methods whose detection limits meet the requirements of 40 CFR 141?				
1.5.2.2	Do they meet the SDWA detection limit as defined in 40 CFR 141.25(c) as equal to the analyte concentration which can be counted with a precision of plus or minus 100% at the 95% confidence level (1.96σ where σ is the standard deviation of the net counting rate of the sample)? (The SDWA detection limit equivalent to the concentration at which the relative standard deviation of the measurement due to counting statistics is 1/1.96.)				
	Evaluation of Precision and Bias				
1.5.3	**Reference Methods**				
1.5.3	a) Has the laboratory evaluated the precision and bias of a reference method for each analyte of concern for each quality system matrix according to Section 1.6 of Volume 1, Module 6 or alternate documented procedure if the analyte cannot be spiked into the sample matrix and QC samples are not commercially available?				
1.5.3	**Non-Reference Methods**				
1.5.3	b) For laboratory-developed methods or non-reference methods that were not in use by the laboratory before July 2003, did the laboratory have a documented procedure to evaluate precision and bias?				
1.5.3	Did the laboratory also compare results of the precision and bias measurements with criteria established by the client, given in the reference method, or established by the laboratory?				

Section Reference	Question	Yes	No	NA	Comments
1.5.3	c) Did the laboratory evaluate precision and bias in the relevant quality system matrices and process the samples through the entire measurement system for each analyte of interest? (An example of a systematic approach to evaluate precision and bias could be the following: Analyze QC samples in triplicate containing the analytes of concern at or near the MDA, at a level near ten (10) times the MDA, and at a mid-range concentration. Process these samples on different days as three (3) sets of samples through the entire measurement system for each analyte of interest. Each day one QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three (3) days. For each analyte, calculate the mean recovery for each day, for each level over days, and for all nine (9) samples. Calculate the relative standard deviation for each of the separate means obtained.)				
	Measurement Uncertainty				
1.5.4	Does all radiochemical measurements provide the uncertainty of each quantitative measurement result?				
1.5.4	Are each result reported with the associated measurement uncertainty as a combined standard uncertainty?				
1.5.4	Is the SOP for determining the measurement uncertainty consistent with mandated method and regulation?				
1.5.4	For Combined Standard Uncertainty are all measurement uncertainties propagated and reported with each result?				
1.5.4	Is the formula for calculating the Combined Standard Uncertainty (CSU) of a result documented in the appropriate SOP?				
1.5.4	Does the CSU include both systematic and random error?				
1.5.4	Is the CSU always 1 sigma?				
1.5.4	Are results reported at the 95% confidence level,which is 1.96-sigma (often abbreviated as 2-sigma)?				

Section Reference	Question	Yes	No	NA	Comments
1.5.4	Is the uncertainty of a count estimated as the square root of counts except when there are zero (0) counts? (In the case of zero (0) counts, the uncertainty of the count is assumed to be the square root of one count.) For counting methodologies where very low counts are possible, the MARLAP 19.57 equation may be used with acceptance by the client.				
1.5.4	Do Systematic Errors include the following:				
1.5.4	a) The errors from all measurement devices, such as, but not limited to pipettes and balances.?				
1.5.4	b) The uncertainty of known values of tracer solutions, calibration uncertainties, etc?				
1.5.4	Do Random Errors include the total random counting error associated with each sample and appropriately propagated when more than one variable is used to determine the result?				
1.5.4	Are the results of the precision evaluation in Section 1.5.3 compared to the uncertainty estimates as a check on the validity of the uncertainty evaluation procedures?				
1.5.4	Does the experimentally observed precision at each testing level statistically greater than the maximum combined standard uncertainty of the measurement results at that level, although it may be somewhat less?				
1.5.4	Is the combined standard uncertainty, when used, the uncertainty of a measured value expressed as an estimated standard deviation?				
1.5.4	Is it calculated by combining the standard uncertainties of the input estimates?				
	Evaluation of Selectivity				
1.5.5	Does the laboratory evaluate selectivity, if applicable, by following the checks established within the method?				
	Demonstration of Capability (DOC)				
1.6	**General**				

Section Reference	Question	Yes	No	NA	Comments
1.6.1	Prior to acceptance and institution of any method for data reporting has the laboratory ensured that a satisfactory initial DOC has been completed? (see Section 1.6.2).				
1.6.1	Upon implementation of a method has the laboratory ensured that ongoing DOC (see Section 1.6.3) has been conducted, as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) ?				
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 has been no significant changes in instrument type, personnel or method, is the ongoing DOC acceptable as an initial DOC?				
1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required? (For the initial DOC, appropriate records as discussed in Section 1.6.2 shall be completed.)				
1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
1.6.1	Are all demonstrations documented?				
1.6.1	Are all data applicable to the demonstration retained and readily available at the laboratory?				
	Initial DOC				
1.6.2	Is an initial DOC made prior to using any method, and at any time that there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
1.6.2	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
1.6.2.1	a) analyst(s) involved in preparation and/or analysis?				
1.6.2.1	b) matrix?				
1.6.2.1	c) analyte(s), class of analyte(s), or measured parameter(s)?				
1.6.2.1	d) identification of method(s) performed?				

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

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

Section Reference	Question	Yes	No	NA	Comments
1.6.3.2	a) acceptable performance of a blind sample (single blind to the analyst); Note: Successful analysis of a blind performance sample on a similar method using the same technology?				
1.6.3.2	b) another initial DOC?				
1.6.3.2	c) at least four (4) consecutive laboratory control samples with acceptable levels of precision; The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis;The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCS for each method for each analyst each year?				
1.6.3.2	d) document a process of analyst review using QC samples;QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary?				
1.6.3.2	e) analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) if a) through d) are not technically feasible?				
	Technical Requirements				
1.7.1	**Instrument Calibration**				
1.7.1	**a) Initial Calibration**				
1.7.1	a) Does the laboratory have a laboratory method SOP for the frequency of calibration if not specified in the method?				
1.7.1	a) Is a specific frequency (e.g., annually) or calibrations based on observations from the associated control or tolerance chart, specified in the laboratory method SOP?				
1.7.1	a) Additionally, does the laboratory contain the following in their calibration procedure:				
1.7.1	a) i. details of the initial instrument calibration procedures including calculations, acceptance criteria and associated statistics?				
1.7.1	a) i. When initial instrument calibration procedures are referenced in the method, is the referenced material retained by the laboratory and available for review?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	a) ii. sufficient raw data records retained to permit reconstruction of the initial instrument calibration (e.g., calibration date, method, instrument, analysis date, each analyte name, analyst's initials or signature; activity and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to activity or concentration)?				
1.7.1	a) iii. Sample results are quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program				
1.7.1	a) iv. initial instrument calibrations verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots?				
1.7.1	a) iv. traceability to a national standard, when commercially available?				
1.7.1	a) v. criteria for the acceptance of an initial instrument calibration established (e.g., correlation coefficient or relative percent difference) appropriate to the calibration technique employed?				
1.7.1	a) vi. corrective action and evidence of reanalysis of samples for when instrument calibration results are outside the established acceptance criteria. If re- analysis of the samples is not possible, is data associated with an unacceptable initial instrument calibration reported with appropriate data qualifiers?				
1.7.1	a) vii.If a reference or mandated method does not specify the number of calibration standards, a written procedure for determining the number of points for establishing the initial instrument calibration?				
1.7.1	a) viii. Detection efficiency is determined with sources tracable to NIST or accepted international standards, or with sources prepared from NIST/international traceable standards?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	a) viii.When sources used for determinations for detection efficiency are not prepared from NIST/international traceable standards, they shall be "working reference materials" defined as follows: a reference material with one or more properties sufficiently well established to be used for calibration or assessment of a measurement method. Working reference materials may be prepared by the laboratory for their own use. (See ASTM C1128)				
1.7.1	a) ix. For alpha spec, is a material balance check performed on each source to clearly demostrate accountability of all activity by mass balance?				
1.7.1	a) ix. Is the balance checkperformed on the fraction remianing from the neodymium fluoride precipitation or the electrodeposition plus all rinses from an adequate cleaning of any vessel used in the process?				
1.7.1	a) ix. Is the estimated error in preparing the source propagated into the error of the efficiency determination?				
	b) Instrument Calibration Verification (Performance Checks)				
1.7.1	b) Are performance checks performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly, the detector response has not significantly changed, and therefore the instrument calibration has not changed?				
1.7.1	b) Is the same check source used in the preparation of the tolerance chart or control chart at the time of calibration used in the calibration verification of the instrument (performance checks)?				
1.7.1	b) Are the check sources providing adequate counting statistics for a relatively short count time?				
1.7.1	b) Is the source sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel?				
1.7.1	b) i.For gamma-ray spectroscopy systems, are performance checks for detection efficiency, energy calibration, and peak resolution performed on a day-of-use basis?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	b) If a performance check fails, does the laboratory immediately analyze two additional consecutive performance checks (immediately is defined as starting a consecutive pair within one hour; no samples can be run between the failed performance check and the two additional performance checks). This approach allows for spurious failures of analytes to be reported without reanalysis of samples. Any corrective actions that change the dynamics of the system requires that all samples since the last acceptable performance check be reanalyzed.				
1.7.1	b) Do both of these performance checks meet acceptance criteria in order for the samples to be reported without reanalysis?				
1.7.1	b) If either of these two performance checks fail, are the associated samples cannot be reported and reanalyzed?				
1.7.1	b) If the laboratory cannot immediately analyze two performance checks, perform corrective action(s) and repeat the performance check. Are all associated samples since the last successful performance check reanalyzed?				
1.7.1	b) Does recalibration occur if the above scenario fails. Are all affected samples since the last cceptable performance check reanalyzed?				
1.7.1	b)Flagging of data for a failed performance check is only appropriate when the affected samples cannot be reanalyzed. Does the laboratory notify the client prior to reporting data associated with a failed performance check?				
1.7.1	b) Is the Full-Width-Half-Maximum (FWHM) resolution of the alpha or gamma detector evaluated prior to instrument use and following repair or loss of control (MARLAP 18.5.6.2).Is the measured FWHM resolution trended?				
1.7.1	b) It is important to use calibration or QC sources that will not cause detector contamination from recoil atoms from the source.				
1.7.1	b) i For systems using sample changers and/or long count times that run more than a day, is the energy calibration checked before each analytical batch?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	b) ii. For alpha-particle spectroscopy systems, are the performance check for energy calibration performed on a weekly basis and the performance check for detection efficiency performed on at least a monthly basis?				
1.7.1	b)ii Detector response (counting efficiency) determinations shall be performed when the check source count is outside the acceptable limits of the control chart (reference ANSI N42.23, Annex A5).				
1.7.1	b) iii. For gas-proportional and liquid scintillation counters, is the performance check for detection efficiency performed on a day-of-use basis?(For batches of samples that uninterruptedly count for more than a day, is a performance check may be performed instead at the beginning and end of the batch as long as this time interval is no greater than one week).				
1.7.1	b) iv. For scintillation counters is the calibration verification for detection efficiency performed on a day-of-use basis?				
1.71	b) iv) For radon scintillation detectors, is efficiency verified at least monthly, when the system is in use.				
	c) Background Measurement				
1.7.1	c) Are the background measurements made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required measurement quality objectives? (This background measurement is not the short-term check for contamination that is addressed in 1.7.1 d).				
1.7.1	c)Are these values subtracted from the total measured activity in the determination of the sample activity?				
1.7.1	c) Are Background Subtraction Count (BSC) measurements conducted after calibration and monthly thereafter, and monitored for trends to ensure that a laboratory maintains its capability to meet required project objectives? (Successive long background measurements may be evaluated as background check measurements.)				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	c) (Low levels of contamination not detected in a shorter background counting time may bias the results of sample analyses.) Is the duration of the background check measurement handled in sufficient duration (i.e., at least as long as the sample count time) to quantify contamination that may impact routine sample measurements? (The background check frequency may be extended to accommodate long sample count times.)				
1.7.1	c) Does the laboratory prevent releasing any associated sample results that are conducted less frequently than daily, until a (bracketing) background check is measured and has met all acceptance criteria? (An Instrument Contamination Check (ICC) for alpha spectroscopy can be a shorter measurement that can be performed on a weekly basis, in which case reporting sample results are not contingent on bracketing ICC checks.)				
1.7.1	c) Are background checks collected before and after any counting chamber changes are made (i.e., cleaning, liner replacement, or instrument modification)?				
1.7.1	c) i. For gamma-ray spectroscopy systems are background measurements performed on at least a monthly basis?				
1.7.1	c) ii. For alpha-particle spectroscopy systems, are background measurements performed on at least a monthly basis for each Region on Interest ROI)?				
1.7.1	c) iii. Are gas-proportional counters background measurements performed on at least a weekly basis?				
1.7.1	c) iii. Are gas-proportional counters, long background measurements (to be used for background corrections) performed on a monthly basis, at minimum?				
1.7.1	c) iii. Are backgrounds for gas flow proportional counters rechecked after being subjected to high-activity?				
1.7.1	c) iv. For scintillation counters are background measurements performed each day of use?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	v)Are Background Subtraction Count (BSC) measurements conducted after calibration and monthly thereafter and monitored for trends to ensure that a laboratory maintains its capability to meet required project objectives?				
1.7.1	vi) Successive long background measurements may be evaluated in lieu of shorter background check measurement.				
1.7.1	vii) Low levels of contamination not detected in a shorter background counting time may bias the results of sample analyses. The duration of the background check measurement shall be of sufficient duration (i.e., at least as long as the sample count time) to quantify contamination that may impact routine sample measurements.				
1.7.1	viii) The background check frequency may be extended to accommodate long sample count times.				
1.7.1	ix) If the background check is conducted less frequently than daily, any associated sample results shall not be released for use until a (bracketing) background check is measured and has met all acceptance criteria. An Instrument Contamination Check (ICC) for alpha spectroscopy can be a shorter measurement that can be performed on a weekly basis, in which case reporting sample results is not contingent on bracketing ICC checks.				
1.7.1	x) A background check shall also be collected before and after any counting chamber changes are made (i.e., cleaning, liner replacement, or instrument modification).				
1.7.1	xi) For gamma spectroscopy systems, long background measurements (to be used for background corrections) shall be performed on at least a monthly basis. The duration of the background measurement shall be sufficient to quantify contamination that may affect routine sample measurements (the count time for the background measurement shall be at least as long as the sample count time.)				
1.7.1	xii) For alpha spectroscopy systems, monthly background determinations shall be performed for each Region of Interest (ROI). The duration of the background measurement shall be sufficient to quantify contamination that may affect routine sample measurements				

Section Reference	Question	Yes	No	NA	Comments
1.7.1	xii) Labs must have procedures in place to define high activity and counting procedures to check for gross contamination from high activity samples.				
1.7.1	xiii) For gas-proportional counters, long background measurements (to be used for background corrections) shall be performed on a monthly basis, at minimum (but some clients may specify TNI 1.7.1.c) iii) – weekly).				
1.7.1	xiii) Labs must have procedures in place to define high activity.				
1.7.1	xiv) For scintillation counters, the duration of the background measurement shall be sufficient to quantify contamination that may affect routine sample measurements.				
1.7.1	xiv) The daily instrument check (each day of use) shall include a check with an unquenched, sealed background vial (which should never be used to correct sample results for background measurements, since it is not in the same configuration as samples)				
	d) Instrument Contamination Monitoring				
1.7.1	d) Does the laboratory have a written procedure for monitoring radiation measurement instrumentation for radioactive contamination?				
1.7.1	d)Does the procedure indicate the frequency of the monitoring and indicate criteria, which initiates corrective action?				
	Quality Control for Radiochemistry				
1.7.2	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken as specified in this Section?				
1.7.2	Was this monitoring planned and reviewed?				
1.7.2	Are the failures of any QC sample analysis and the corrective actions taken noted in the laboratory report for the associated samples?				
1.7.2	QC Sample Preparation: Are all samples and QC samples in each prep batch prepared concurrently and in the same manner?				
1.7.2	QC Sample Counting: Are all QC samples counted and analyzed in the same manner as the samples in the prep batch, in the same time frame, and using the same instrument calibration parameters, instrument analysis algorithms, etc.?				
1.7.2	Do all method QC samples follow Appendix B requirement?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2	Note: The “same time frame” implies that where multiple detectors are used and are sufficient to count the entire batch at the same time, with the same count time duration. If the number of detectors is not sufficient to count the entire batch at the same time, then samples shall be counted consecutively on the available detector(s).				
1.7.2	Note: The “same instrument calibration p arameters, instrument analysis algorithms, etc.” implies that these parameters for a given instrument shall not be changed for the samples in that batch, counting shall be at the same time, with the same count time duration. It is understood that for multiple detectors, the parameters may not be identical.				
	Negative Control – Method Performance: Method Blank				
1.7.2.1	a) Is the method blank used to assess the preparation batch for possible contamination during the preparation and processing steps or for other low-level bias?				
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?				
1.7.2.1	a)Are the procedures in place to determine if a method blank result is significantly different from zero?				
1.7.2.1	a)Are any affected samples associated with a failed method blank reprocessed for analysis or the results reported with appropriate data- qualifying codes?				
1.7.2.1	b) Is the method blank analyzed at a minimum of one (1) per preparation batch, with a maximum of twenty (20) field samples, for all radiochemical methods except gross alpha/beta in solid matrices and gamma-ray spectrometry?				
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 as free of the analytes of interest as possible?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.1	c) Does the laboratory prevent subtraction of the method blank result from the sample results in the associated preparation or analytical batch unless permitted by method or program? (This requirement does not preclude corrections for background radiation (e.g., instrument background, analyte in the tracer or carrier, reagent impurities, peak overlap, etc.) to all analyzed samples, both program/project submitted and internal quality control samples.)				
1.7.2.1	c) Does the laboratory prevent corrections from depending on the result of the method blank analysis, whose purpose is to check for uncorrected contamination or other low-level bias?				
1.7.2.1	c) Is the method blank sample prepared with aliquot size similar to that of the routine samples for analysis?				
1.7.2.1	d) Are batch blanks counted for a sufficient time to meet the required detection limit, except in the case where the achieved MDA is calculated from the standard deviation of a blank population?				
1.7.2.1	d) In this case where the achieved MDA is calculated from the standard deviation of a blank population, are the batch blanks counted for the same count time as the samples?				
1.7.2.1	e) Is the batch blank matrix the same as the samples, as can be reasonably achieved, and shall be documented in the Case narrative?				
	f) Blank Acceptance Criteria				
1.7.2.1	f) i Does the laboratory ensure that a method blank is prepared and analyzed per preparatory batch?				
1.7.2.1	f) ii Is the blank acceptance criteria: |ZBlank |≤ 3 (MARLAP 18.4.1) or a Method Blank in-house control limits of ±3 σ of the mean?				
1.7.2.1	f) iii Is the Batch Blank MDA less than the Reporting Limit?				
1.7.2.1	f) If the above criteria has not been met has the laboratory taken corrective actions (e.g., recount, interferent cleanup, as appropriate), unless all sample results are greater than five times the blank activity?				
1.7.2.1	f) If the criteria is still not met has the samples been reanalyzed?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.1	g) For batch blank matrices has the laboratory used the following for all radiochemistry analyses:				
1.7.2.1	g) i)Distilled or deionized water, radon free?				
1.7.2.1	g) ii)Characterized solid material representative of the sample matrix?				
1.7.2.1	g) iii) Filters, physically and chemically identical filter media, analyte free (if supplied to the laboratory by customer)?				
	Positive Control – Method Performance: Laboratory Control Sample (LCS)				
1.7.2.2	a) Is the LCS used to evaluate the performance of the total analytical system, including all preparation and analysis steps?				
1.7.2.2	Are the results of the LCS are compared to established criteria and, if found to be outside of these criteria may indicate that the analytical system is “out of control?				
1.7.2.2	Are any affected samples associated with an out-of-control LCS reprocessed for reanalysis or the results reported with appropriate data qualifying codes?				
1.7.2.2	b) Is the LCS analyzed at a minimum of one per preparation batch? (Exceptions would be for those analytes for which no spiking solutions are available.)				
1.7.2.2	c) Is the LCS a quality system matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes? (The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.				
1.7.2.2	d) Alternatively does the LCS consist of a medium containing known and verified concentrations of analytes or as Certified Reference Material (CRM)?				
1.7.2.2	d) Are the components to be spiked as specified by the mandated method or regulation or as requested by the client?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.2	e) Are the laboratory control samples: (1) at least ten (10) times the MDA, and (2) at a level comparable to that of routine samples when such information is available if the sample activities are expected to exceed ten times the MDA?				
1.7.2.2	f) Are the laboratory standards used to prepare the laboratory control sample from a source independent of the laboratory standards used for instrument calibration?				
1.7.2.2	f) Do they meet the requirements for reference standards provided in Section 1.7.5.2.c)?				
1.7.2.2	g) Where a radiochemical method, other than gamma-ray spectroscopy, has more than one reportable analyte isotope (e.g. plutonium, 238Pu and 239Pu, using alpha-particle spectrometry), only one of the analyte isotopes need be included in the laboratory control sample at the indicated activity level. Where more than one analyte is detectable, has each been assessed against the specified acceptance criteria?				
1.7.2.2	h) Where gamma-ray spectrometry is used to identify and quantify more than one analyte, does the laboratory control sample shall contain gamma-emitting radionuclides that represent the low (e.g., 241Am), medium (e.g., 137Cs) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra? (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.)				
1.7.2.2	i) Are the laboratory control samples prepared with similar aliquot size to that of the routine samples for analyses?				
1.7.2.2	j) Is the LCS counted for a sufficient time to quantify the activity level of the LCS?				
1.7.2.2	k) Is the LCS matrix the same as the samples, or as close as can be reasonably achieved?				
1.7.2.2	k) Is the matrix documented in the Case narrative?				
1.7.2.2	l) Has the laboratory met the LCS Acceptance Criteria as listed below:				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.2	l) $\|Z_{LCS}\| \leq 3$ (MARLAP 18.4.3) or use in-house control limits of LCS ± 3 σ of the mean. In-house control limits may not fall more than 25% from the known LCS value?				
1.7.2.2	m) LCS Selection and Level: Does the LCS contain at least one analyte reported for samples by that analytical method (separation chemistry and decay mechanism) and should be at least five times, but not greater than 20 times, the RL with the following exceptions				
1.7.2.2	m) i) Some programs may require, following TNI, at least 10 times the MDA and at a level compatible with routine samples.				
1.7.2.2	m) ii) For RLs of low activity, the analyte shall be at a level where the random counting error does not exceed 10% in the counting time required to attain the RL.				
1.7.2.2	m) iii) Analytes for gamma spectroscopy need not be the same as the sample analyte but should fall in the approximate energy region of the spectrum (i.e., low, mid-range, and high energy) of the reported analytes.				
1.7.2.2	m) iv) For gross alpha and/or gross beta analysis, the analytes in the LCS shall be the same analytes used for the calibration curve.				
1.7.2.2	m) v) If a laboratory standard containing the reported analyte is not available, an LCS analyte having similar separation chemistry, energy and decay mechanisms shall be used unless otherwise agreed to by the client.				
1.7.2.2	n) Is the LCS traceable to the NIST or accepted international standard, or a working reference material as described in1.7.1 a) viii)? (it may be used repeatedly for different analytical batches as long as it is appropriate for the matrix and geometry of the batch)				
	Sample-Specific Controls				
1.7.2.3	Does the laboratory document procedures for determining the effect of the sample matrix on method performance?				
1.7.2.3	Do these procedures relate to the analyses of quality system matrix specific quality control (QC) samples and are designed as data quality indicators for a specific sample using the designated method?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.3	(Examples of matrix-specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); and replicates.) Does the laboratory 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, evaluating and reporting results based on performance of the QC samples?				
1.7.2.3	**a) Matrix Spike**				
1.7.2.3	a) i) Are the results of the matrix spike analysis one of the quality control measures used to assess the batch?				
1.7.2.3	a)ii) Does the laboratory determine the frequency of the analysis of matrix spikes as specified by the method or as part of the contract review process?				
1.7.2.3	a)iii) Are the components to be spiked as specified by the mandated method, including permit specified analytes, as specified by regulation or client requested analytes?				
1.7.2.3	a)iv) Is the lack of sufficient sample aliquot size to perform a matrix spike noted in the laboratory report?				
1.7.2.3	a) v) Is the activity of the matrix spike analytes(s) be greater than five times the MDA?				
1.7.2.3	a) vi) Are laboratory standards used to prepare the matrix spike from a source independent of the laboratory standards used for instrument calibration?				
1.7.2.3	a) vii) Is the matrix spike prepared by adding a known activity of target analyte after sub-sampling if required but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.)?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.3	a) vii) Where a radiochemical method, other than gamma-ray spectroscopy, has more than one reportable analyte isotope (e.g. plutonium, 238Pu and 239Pu, using alpha-particle spectrometry), only one of the analyte isotopes need be included in the matrix spike sample at the indicated activity level. Where more than one analyte is detectable, is each assessed against the specified acceptance criteria?				
1.7.2.3	a) viii) Are matrix spikes added as early in the sample preparation steps as practicable?				
1.7.2.3	a) ix) Note-Matrix spikes are not required for radiochemical analyses if an isotopic tracer or chemical carrier is used in the analysis to determine chemical recovery (yield) for the chemical separation and sample mounting procedures. Matrix spikes are not required for gross alpha, gross beta, gamma, or non-aqueous tritium analysis.				
1.7.2.3	a) x) Are matrix spikes ran on a separate sample aliquot using the same analyte as that being analyzed whenever possible?				
1.7.2.3	a) xi) Acceptance Criteria: Matrix spike recoveries shall be evaluated using the following criteria: If the activity of the sample is less than 5 times the spiking level, matrix spike recoveries shall be within the control limits of 60 - 140%, or as specified by the client. If the activity of the sample is greater than 5 times the spiking level, |ZMS | ≤ 3 shall be used (MARLAP 18.4.3).				
1.7.2.3	a) xii) Matrix Spike Selection and Level: Is the matrix spike added at a concentration of at least five, but not greater than 20 times the RL? (For samples having known significant activity of the targeted radionuclides, more than 20 times the RL may be added to minimize the effect of the sample activity on determination of spike recoveries.) Some programs may require, following TNI, at least 5 times the MDA.				
1.7.2.3	a) xiii) Counting: Is the matrix spike counted for a sufficient time to meet the required detection limit?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.3	a) xiii) Where the original (unspiked) sample contains significantly elevated activity, is the matrix spike counted for a duration equal to that of the associated original sample?				
	Replicates / Matrix Spike Duplicates / Laboratory Control Sample Duplicates				
1.7.2.3	b) i. Replicates 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. Replicates provide the most useful measure of precision when target analytes are found in the sample chosen for replication.				
1.7.2.3	b) ii. Is the frequency of the analysis of matrix replicates and duplicates as specified by the method or determined as part of the contract review process?				
1.7.2.3	b) iii. Are replicates performed on replicate aliquots of actual samples?				
1.7.2.3	iii) The purpose of the Duplicate sample analysis is to assess laboratory precision by providing information on the laboratory's reproducibility and the homogeneity of the sample.				
1.7.2.3	iv) The Duplicate activity shall not be averaged with the corresponding sample activity when reporting results.				
1.7.2.3	v) Are samples identified as Field Blanks not used for Duplicate sample analysis?				
1.7.2.3	vi) Is at least one Duplicate sample prepared and analyzed with every Analytical Batch of samples.				
1.7.2.3	vii) Is the Duplicate counted for the same duration to meet the required detection limit?				
1.7.2.3	viii) When the sample does not contain significantly elevated activity, are QC samples counted for a duration equal to that of the associated original sample?				
1.7.2.3	b) ix) Evaluation Criteria: Does the laboratory evaluate duplicates using the following three possible criteria:				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.3	b) ix) -|ZDup | ≤ 3 (MARLAP 18.4.1) if using MARLAP; or the duplicate error ratio (DER) between the sample and the duplicate is <3; or the relative percent difference (RPD) is <25%.				
1.7.2.3	b) ix)-When the MARLAP, DER or the RPD criteria pass, then the Duplicate is acceptable.				
1.7.2.3	b) x) Duplicates that do not meet the above requirements due to difficulty in subsampling shall be described in the case narrative.				
	c) Tracer				
1.7.2.3	c) For those methods that employ a tracer for yield determination, does each sample result have an associated tracer yield calculated and reported?				
1.7.2.3	c) Is the tracer added to the sample after subsampling, if required, but before any chemical treatment (e.g., chemical digestion, dissolution, separation, etc.) unless otherwise specified by the method?				
1.7.2.3	c) When the specified tracer yield acceptance criteria are not met, has the specified corrective action and contingencies followed by the laboratory?				
1.7.2.3	c) Has the occurrence of a failed tracer yield and the actions taken shall be noted in the laboratory report to the client?				
1.7.2.3	c) When tracers are used, is each sample (including any batch associated QC samples) also spiked with the same materials and individual sample yields determined?				
1.7.2.3	c) Is the tracer added to the sample at the very beginning of the sample preparation?				
1.7.2.3	c) For solid samples, is the tracer added after grinding, sieving, etc., but prior to any muffling or dissolution of the sample?				
1.7.2.3	c) i. Does the chemical yield for each sample determined using an indirect yield measurement method that falls within the range 30% - 110% or as specified by the client?				
1.7.2.3	c) i. Is the technique used for the indirect yield measurement sufficient to maintain relative uncertainties associated with the yield correction below 10% at the 2-sigma level?				

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

Section Reference	Question	Yes	No	NA	Comments
1.7.2.3	d) When carriers are used, does the laboratory ensure that each sample (including any batch associated QC samples) is also spiked with the same materials and individual sample yields determined?				
1.7.2.3	d) Is the carrier added to the sample at the very beginning of the sample preparation?				
1.7.2.3	d) For solid samples, is the carrier added after grinding, sieving, etc., but prior to any muffling or dissolution of the sample?				
1.7.2.3	d) i. Requirements for indirect yield measurements: Does the chemical yield for each sample determined using an indirect yield measurement method that falls within the range 30% - 110% or as specified by the client?				
1.7.2.3	d) Is the technique used for the indirect yield measurement sufficient to maintain relative uncertainties associated with the yield correction below 10% at the 2-sigma level?				
1.7.2.3	d) ii. Does the laboratory have sample results below 30% that are considered quantitative and acceptable based on the criteria listed below:				
1.7.2.3	ii) a. The relative uncertainty associated with the yield correction is less than 10% (2-sigma)?				
1.7.2.3	ii)b. Spectral resolution requirements are met and there are no indications of spectral interferences?				
1.7.2.3	ii)c. Detection limit requirements are met?				
1.7.2.3	d)iii. Reporting yield measurement uncertainties: Are the uncertainties associated with chemical yield corrections incorporated into the CSU of the associated sample results?				
	1.7.2.4 Data Reduction				
1.7.2.4	a) Are the procedures for data reduction, such as use of linear regression documented?				
1.7.2.4	b) Measurement Uncertainties. Is each result reported with its measurement uncertainty?				
1.7.2.4	b) At a minimum does the report:				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.4	b) i) indicate whether the uncertainty is the combined standard uncertainty ("one sigma")? Or				
1.7.2.4	b) i) an expanded uncertainty?				
1.7.2.4	b) ii) for expanded uncertainties, indicate the coverage factor (k) and optionally the approximate level of confidence?				
1.7.2.4	c) Are the procedures for determining the measurement uncertainty documented consistent with the ISO Guide 98: 1995, Guide to the Expression of Uncertainty in Measurement (GUM) and with the recommendations of Chapter 19 of the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP) Volume I (EPA 402-B-04- 001A), Volume II (EPA 402-B-04-001B), Volume III (EPA 402-B-04-001C), July 2004?				
1.7.2.4	d) Negative Numbers: Are negative activities reported as such?				
1.7.2.4	d) If the sum of the activity and the measurement uncertainty at ± 3 sigma is a negative number, is the cause investigated and evaluated to determine if it is systematic or random error?				
1.7.2.4	d) If the cause is systematic, has it been corrected?				
1.7.2.4	d) If the cause is random, was it documented in the case narrative?				
1.7.2.4	d) (Recurrent problems with significant negative results suggest that the background subtraction and/or blank subtraction, if applicable, are in error or that the estimate of error is low.)				
1.7.2.4	d) Has the laboratory investigated such problems and provided documentation of the resolution in the case narrative?				
	Reagent Quality, Water Quality, and Checks				
1.7.2.5	a) In methods where the purity of reagents is not specified, are reagents analytical reagent grade or better?				
1.7.2.5	a) Does the laboratory prevent from using reagents of lesser purity than those specified by the method?				
1.7.2.5	a) Are the labels on the container checked to verify that the purity of the reagents meets the requirements of the particular method?				
1.7.2.5	a) Is such information made available?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.5	b) Are the quality of water sources monitored and documented and meet method specified requirements?				
1.7.2.5	c) Does the quality control program establish and maintain provisions for radionuclide standards?				
1.7.2.5	c) i) Are reference standards that are used in a radiochemical laboratory obtained from NIST or suppliers who participate in supplying NIST standards or NIST traceable radionuclides?				
1.7.2.5	c) i) Are reference standards purchased outside the United States traceable back to each country's national standards laboratory?				
1.7.2.5	c) i) Do commercial suppliers of reference standards shall conform to ANSI N42.22 to assure the quality of their products?				
1.7.2.5	c) ii) Are reference standards accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates?				
1.7.2.5	c) iii) Has the laboratory should consulted with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value?				
1.7.2.5	c) iii) Does laboratory use only the decay-corrected certified value?				
1.7.2.5	c) iii) Does the laboratory have a written procedure for handling, storing, and establishing expiration dates for reference standards?				
1.7.2.5	d) Does the laboratory ensure that water purity is at least distilled or deionized water?				
1.7.2.5	e) Are standards verified prior to initial use?				
1.7.2.5	e) i) Are preparations of standards solutions used for a period of time exceeding one year verified annually, at a minimum, and documented in a logbook?				
1.7.2.5	e) ii) Are at least three verification measurements of a standard used to determine the mean value and standard deviation of the verification results?				
1.7.2.5	e) iii)Is the mean value shall be within 5% of the decay corrected certified value?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.5	e) vi) Is the 2-sigma value used for the 95% confidence interval of the mean not exceed 10% of the mean value of the three verification measurements.				
1.7.2.5	e) v) Does the laboratory ensure If all criteria is met, that the certified value is used?				
1.7.2.5	f) Are corrections for radioactive decay and/or ingrowth of progeny performed for radionuclide standards?				
	Selectivity				
1.7.2.6	Does the laboratory evaluate selectivity by following the checks established within the method?				
	Constant and Consistent Test Conditions				
1.7.2.7	a) Does the laboratory assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used?				
1.7.2.7	b) Glassware Cleaning- Is glassware cleaned to meet the sensitivity requirements of the method?				
1.7.2.7	b) Does the laboratory ensure that any cleaning and storage procedures that are not specified by the method are documented in laboratory records and SOPs? (Note that some applications may require single-use glassware).				
1.7.2.7	c) Radiological Control Program- Does the laboratory maintain a radiological control program that addresses analytical radiological control?				
1.7.2.7	c) Does the program address the procedures for segregating samples with potentially widely varying levels of radioactivity?				
1.7.2.7	c) Does the radiological control program explicitly define how low-level and high-level samples will be identified, segregated and processed in order to prevent sample cross-contamination?				
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?				
1.7.2.7	d) Are background contamination monitoring samples analyzed at a sufficiently low level of detection to confirm that no impacts to client samples have occurred due to cross-contamination?				

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

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

Section Reference	Question	Yes	No	NA	Comments
1.7.3.3	a) ii) Are the results are compared to the acceptance criteria as published in the mandated method?				
1.7.3.3	a) ii) Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
1.7.3.3	a) ii) For matrix spike results outside established criteria, is corrective action documented or the data reported with appropriate data qualifying codes?				
1.7.3.3	a) iii) Is the occurrence of a failed matrix spike and any associated actions noted in the laboratory report to the client?				
	b) Replicates				
1.7.3.3	b) i) Are the results from replicates primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., normalized differences)?				
1.7.3.3	b) ii) Does the laboratory document the calculation for relative percent difference or other statistical treatments?				
1.7.3.3	b) iii) Are the results compared to the acceptance criteria as published in the mandated method?				
1.7.3.3	b) iii) Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits?				
1.7.3.3	b) iii) For replicate results outside established criteria, is corrective action documented or the data reported with appropriate data qualifying codes?				
1.7.3.3	b) iv) Is the occurrence of a failed replicate and any associated actions shall be noted in the laboratory report to the client?				
	Sample Handling				
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℃ of the required temperature or the method specified range?				
1.7.4	a) For samples with a specified temperature of 4℃, samples with a temperature ranging from just above the freezing temperature of water to 6℃ are they considered acceptable?				

Section Reference	Question	Yes	No	NA	Comments
1.7.4	a) i) Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.4.a. In these cases, are the samples are considered acceptable if the samples were received on ice?				
1.7.4	a) ii) If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection. Does the laboratory adhere to the above requirement?				
1.7.4	b) Does the laboratory implement procedures for checking chemical preservation using readily available techniques, such as pH or chlorine, prior to or during sample preparation or analysis?				
	Method Specific Directions				
	Isotopic Determinations by Alpha Spectrometry				
1.8.1	a) Tracer: Are they used for isotope specific analysis by alpha spectrometry?				
1.8.1	a) Does Initial sample preparation include treatment to ensure that tracer and analyte will undergo similar reactions during processing?				
1.8.1	a) Are all tracers of the same element or of an element with the same chemistry for the separation?				
1.8.1	a) If a significant contribution is found, is the method for correction site accepted prior to use?				
1.8.1	b) Background Correction: Are the gross counts in each target analyte and tracer ROI corrected for the particular detector's background contribution in those same ROIs?				
1.8.1	c) Blank Correction: Does the laboratory ensure that blank corrections are not performed, except except where required by client and fully documented in the Case Narrative.?				
1.8.1	d) Conditions Requiring Reanalysis: Does the laboratory ensure reanalysis is completed for the following criteria?				

Section Reference	Question	Yes	No	NA	Comments
1.8.1	d) i) Sample- and Analyte-Specific Conditions: Any one of the following are additional conditions that require reanalysis for a particular sample and analyte if sufficient sample quantity remains:				
1.8.1	d) i) a. If the tracer recovery for the sample does not fall within 30% - 110%, reanalysis is required, beginning with preparation but see 1.7.2.3 c) i) through iii))?				
1.8.1	d) i) b. If the FWHM for the tracer peak exceeds 100 keV and/or the peak energy does not fall within ± 50 keV of the known peak energy, reanalysis is required?				
1.8.1	d) i) c. If the target analyte and tracer peaks are not resolved because the target analyte activity is significantly larger than the tracer activity, the sample shall be reanalyzed with a smaller aliquot such that resolution of tracer and analyte peaks is accomplished?				
1.8.1	d) i) d. If the sample analyte spectrum contains significant interferences with the analyte and/or tracer ROIs, reanalysis is required?				
1.8.1	d) ii) Analytical Batch Conditions: If the tracer chemical recovery for the Batch Blank does not fall within 30% - 110%, reanalysis of the entire Analytical Batch, beginning with the preparation, is required if sufficient sample is available?				
1.8.1	e) Instrument Calibration: Does the calibration of each alpha spectrometry detector used to produce data include channel vs. energy calibration, detector response,efficiency determination and background determination for each ROI.?				
1.8.1	f) Efficiency determination and background determination for each ROI. Are alpha spectrum regions of interest selected with consistency from analyte to analyte?				
	g) Energy Calibration:				
1.8.1	g) i) Is energy calibration for each detector shall performed?				
1.8.1	g) i) Does the curve fit for Energy (Y-axis) versus Channel (X-axis) and the equation with the slope?				
1.8.1	g) ii) Is the slope of the equation <15 keV/channel?				

Section Reference	Question	Yes	No	NA	Comments
1.8.1	g) iii) Is the energy calibration performed using at least three isotopes within the energy range of 3 to 6 MeV?				
1.8.1	g) iv) Are the final peak energy positions of all observed isotopes within ±40 keV of the expected peak energy?				
	h) Background Requirements:				
1.8.1	h) i) Are the background total counts (or counts per unit time) for each target analyte and tracer isotope ROI analyzed on each detector and documented?				
1.8.1	h) ii) Is the background for each ROI sufficiently low to ensure that required detection limits are met?				
1.8.1	h) iii) Are the limits of acceptability for each background ROI documented? Are these set such that RLs can be obtained for backgrounds at the limit of acceptability?				
1.8.1	h) iv) Are background count times equal to or longer than sample count times?				
	i) Detector Response Determination Requirements				
1.8.1	i) Typically, when a tracer is used for the analysis, detector response (detector efficiency) is not used directly in calculation of final results. Is the detector response used to calculate the estimated yields for evaluation of method performance?				
1.8.1	i) i) Do the response (efficiency) counts for the ROI background corrected using the same ROI for the background unless the background is less than 0.5% of the total counts in the ROI?				
1.8.1	i) ii) Is the response (efficiency) determined on at least 3,000 net counts in the ROI (after background correction)?				
1.8.1	i) iii) Are check source counts to verify detector response (efficiency) determined on at least 2,000 counts?				
1.8.1	i) iv) Are detector response and detector response error documented?				
1.8.1	i) v) Are detector response check as determined by the check source and/or pulsar count and the associated error and limits of acceptability for the check source result documented?				
	j) Spectrum Assessment:				

Section Reference	Question	Yes	No	NA	Comments
1.8.1	j) i) Are ROIs clearly indicated either graphically or in tabular form on alpha printouts.				
1.8.1	j) i) Are spectra with ROIs saved and made available for review upon request?				
1.8.1	j) ii) Is the FWHM resolution for each sample and QC sample tracer peak ≤100 keV?				
1.8.1	j) iii) Is the tracer peak energy for each sample and QC sample within ±50 keV of the expected energy?				
1.8.1	j) iv) Does each sample and QC sample spectrum assessed for:				
1.8.1	correctly chosen ROIs?				
1.8.1	acceptable spectral resolution?				
1.8.1	acceptable energy calibration?				
1.8.1	and interferences with the analyte and tracer ROIs?				
1.8.1	j) v) Are any manual integration or adjustment of ROIs fully discussed in the Case Narrative?				
	Radon Scintillation (Lucas Cell)				
1.8.2	a) Do procedures for sample analyses by Lucas Cell incorporate and adhere to ASTM D3454 (current version), Standard Test Method for Radium-226 in Water?				
1.8.2	a) SOPs for sample analyses by Lucas Cell shall incorporate and adhere to EPA Method 903.1 (current version), Radium-226 in Drinking Water Radon Emanation Technique. Performance shall be in accordance with the standard unless otherwise defined in this document or as documented by the laboratory and accepted by clients. Reference is to the current version of the method.				
1.8.2	When references are updated, is an implementation schedule determined by the lab?				
1.8.2	b) Does the laboratory ensure that the operating voltage plateau for the detector does not exceed a slope of 2%/100V?				
1.8.2	c) Are new lucas cells calibrated every month for the first six months of use and then annually after the initial six months of use?				

Section Reference	Question	Yes	No	NA	Comments
1.8.2	d) Are background measurements for quantitation in each cell carried out prior to each sample measurement using the same cell/detector combination used for establishing the calibration factors.?				
1.8.2	e) Is the bubbler used for radium-226 standardizationnot used for sample analysis?				
	Liquid Scintillation Counting				
1.8.3	a) Tritium in Water: Are water samples for tritium analysis and all associated QC samples distilled prior to analysis unless specified otherwise by the client?				
1.8.3	a) Does the applicable preparation SOP specify the fraction to be collected?				
1.8.3	a) Does the same fraction shall be collected for samples and all associated QC samples?				
1.8.3	b) Counting Vial Preparation: Are samples counted in vials equivalent to or superior to low potassium glass vials or high density polyethylene vials?				
1.8.3	b) Are samples in polyethylene vials counted within a time period not to exceed the manufacturer's specification for the cocktail used in the analysis?				
1.8.3	b) Does analysis documentation contain sufficient information for this to be verified?				
1.8.3	b) Are vials prepared according to manufacturer's specification for the cocktail?				
1.8.3	b) Are the vials "dark adapted" for a minimum of 30 minutes or according to the cocktail manufacturer's specifications before counting?				
1.8.3	b) Are the prepared vials inspected to verify that the sample loaded properly in the cocktail?				
1.8.3	c) Do the Laboratory SOPs for methods using liquid scintillation counting incorporate and adhere to ANSI N42.15-1997 (or latest version), American National Standard Check Sources for and Verification of Liquid Scintillation Systems?				
1.8.3	c) Does the laboratory ensure all references are to the current version?				
1.8.3	c) When references are updated, has the lab determined an implementation schedule?				

Section Reference	Question	Yes	No	NA	Comments
1.8.3	d) Instrument Background: Is the instrument background vial for all tritium matrices prepared with low-tritium or "dead" water unless the laboratory can demonstrate suitably small background or blank effects from other sources of water.				
1.8.3	d) Is the instrument background vial prepared with the same water to cocktail ratio as the samples are prepared?				
1.8.3	d) Is the type of water used to prepare the instrument background vial explicitly noted on the preparation and counting documentation?				
1.8.3	d) Is the instrument background ran with each sample batch?				
1.8.3	d) Unless calculated from a running average of background counts or a background quench curve, is the most recent background count used to calculate sample activities and MDAs?				
1.8.3	d) (This is not a performance check, rather a background subtraction sample in a configuration equivalent to that of associated samples in the batch. It is used to generate the background subtraction data for the batch (using the results associated directly with that batch, results of a rolling mean, or background quench curve). Is the effect of quench on background evaluated and corrected using a background quench curve if it is significant?				
1.8.3	e) For analysis methods using quench curves to determine individual sample detection efficiency or background, are the quench curves shall be generated at least yearly and verified after any instrument maintenance?				
1.8.3	f) If the calibration method is constant quench, is the detection efficiency checked at least weekly when in use or with each counting batch?				
1.8.3	g) Sample-Specific Conditions: The following are conditions that require reanalysis for a particular sample and analyte, beginning with the preparation or recounting, as appropriate.				
1.8.3	g) Does the laboratory ensure the following criteria is met?				
1.8.3	g) i) If the constant quench method of calibration is used, the quench of each sample analyzed shall fall within +/-5% relative to the average efficiency at that quench level. If this condition is not met, the sample must be reanalyzed beginning with vial preparation.				

Section Reference	Question	Yes	No	NA	Comments
1.8.3	g) ii) If the sample quench does not fall within the range of the quench curve, the samples shall be reanalyzed such that the sample quench is in the range of a quench curve.				
1.8.3	h) Spectrum Assessment: For analytes requiring separations other than distillation:				
1.8.3	h) Does the laboratory ensure the following criteria is met?				
1.8.3	h) i) Sample spectra shall be retained (electronic or hardcopy) for each sample and QC sample including identification of ROIs.				
1.8.3	h) ii) Each sample and QC sample spectrum shall be assessed for correctly chosen ROIs, acceptability of peak shape, and interferences due to non-target analytes or luminescence.				
	Gas Flow Proportional Counting				
1.8.4	a) Planchets: Are they thoroughly cleaned before use to ensure that there are no interfering residues or contamination?				
1.8.4	a) Are all planchets prepared not to exceed sample weights in excess of the calibrated ranges of established self-absorption curves?				
1.8.4	a) Are sample weights documented and stable prior to counting?				
1.8.4	a) Does the laboratory ensure that planchets exhibiting physical characteristics notably different from the self-absorption standards (e.g., evidence of corrosion) are not counted unless remediation efforts such as additional sample preparation and remounting or flaming prove unsuccessful?				
1.8.4	a) Are any non-routine counting situations documented in the case narrative?				
1.8.4	b) Instrument Calibration: Is instrument calibration performed in accordance with the requirements in ANSI N42.25, Calibration and Usage of Alpha/Beta Proportional Counters and where the word “should” is used in ANSI N42.25, calibration shall be performed in accordance with the statement?				
1.8.4	b) Are all references to the current version?				
1.8.4	b) When references change, has the laboratory determined an implementation schedule?				

Section Reference	Question	Yes	No	NA	Comments
1.8.4	c) Calibration Sources and Standards: Is the standard reference material used to prepare sources for determining detector efficiencies and self-absorption curves traceable to NIST or accepted international standards?				
1.8.4	c) Do the calibration sources provide adequate counting statistics over the period for which the source is to be counted?				
1.8.4	c) i) Does the laboratory ensure that, the source is not so radioactive as to cause pulse pileups or dead time that is significantly different from that to be expected from routine analyses?				
1.8.4	c) ii) Are the geometry of the calibration sources used for efficiency and self-absorption/crosstalk curves the same as that of the prepared sample and QC sample planchets.				
1.8.4	c) ii) Is the depth and shape (flat, flanged, ringed, etc.), in addition to the diameter, factors the same for calibration sources as for samples?				
1.8.4	c) iii) Are the sources used for the determination of self-absorption and cross talk should be of similar isotope content to that of the analytical samples? Is Am-241; Po-210; or Th-230 used for alpha and Cs-137 or Sr-90/Y-90 for beta?				
	d) Self-Absorption and Crosstalk Curves:				
1.8.4	d) i) Does the laboratory use self-absorption curves for both alpha and beta counting?				
1.8.4	d) ii) Is a crosstalk curve established for alpha to beta crosstalk versus residue weight?				
1.8.4	d) iii) Beta to alpha crosstalk is not significantly affected by planchet residue weight, and is generally constant over the applicable weight range. Therefore, this crosstalk correction does not require residue weight consideration. Has the laboratory met the above criteria?				
1.8.4	d) iv) Does the data used to generate self-absorption and crosstalk curves consist of at least seven points, well distributed throughout the mass range?				
1.8.4	d) v) Does each alpha and beta calibration standard counted to an accumulation of at least 10,000 counts minimum for the initial calibration and 5,000 counts minimum for the calibration verification?				

Section Reference	Question	Yes	No	NA	Comments
1.8.4	d) vi) Do new cross-talk curves measured prior to initial use, after loss of control, and upon incorporation of new or changed instrument settings. (MARLAP 18.5.6.1)?				
1.8.4	**e) Check Source Requirements**				
1.8.4	e) i) Is alpha and beta response and corresponding crosstalk of each detector used to count analytical samples or QC samples checked daily with separate alpha and beta emitting sources?				
1.8.4	e) i) The only exception to this requirement is when performing analyses with extended count times. In this case, are check source measurements performed between sample sets?				
1.8.4	ii) Following gas bottle changes, are check sources and backgrounds analyzed before samples are counted?				
1.8.4	iii) Is check source data documented and retained?				
	Gamma Spectrometry				
1.8.5	a) Sample Counting Requirements				
1.8.5	a) i) Do SOPs for sample analysis by gamma spectrometry incorporate and adhere to ANSI N42.14-1991 (or latest version), Calibration and Use of Germanium Spectrometers for the Measurement of Gamma Ray Emission Rate of Radionuclides, and/or ANSI N42.12-1994 (or latest version), Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides?				
1.8.5	a) i) Are references to the current version?				
1.8.5	a) i) When references change, has the laboratory determined an implementation schedule?				
1.8.5	a) ii) Do gamma detector systems consist of any detector suitable for measuring the gamma isotopes of interest in the typical energy range of approximately 0.059 to 2 MeV with the capacity to attain specified RLs and to meet bias and precision? (Ge detectors of either intrinsic (pure) germanium or lithium drifted germanium are preferred; however for some specific requirements, another detector type, such as sodium iodide, may be more appropriate.)				

Section Reference	Question	Yes	No	NA	Comments
1.8.5	a) iii) Are detectors calibrated for the specific geometry and matrix considerations used in the sample analysis. The laboratory shall have the capability to seal soil (or other solid matrix) samples in airtight cans or equivalent in order to allow ingrowth of radon for accurate analysis of Ra-226 or its progeny by gamma spectroscopy when requested?(This applies to Ra-226 soil samples only.)				
1.8.5	a) iv) Spectral Data Reference: Is the identification of the reference used for the half-life, abundance, and peak energy of all nuclides documented?				
1.8.5	a) iv) Does the laboratory document, review, and provide configuration control for gamma spectrometry libraries?				
1.8.5	a) iv) Are assumptions made for libraries (i.e., half-lives based on supported/unsupported assumptions, inferential determinations (e.g., Th-234 = U-238 because supported) documented and narrated?				
	b) Efficiency Calibration Requirements:				
1.8.5	b) i) Has Each gamma spectrometry system been efficiently calibrated for the sample geometry and matrix with traceable NIST or accepted international standards or prepared from NIST/international traceable sources?				
1.8.5	b) i) 1) Germanium Detectors: Refer to ANSI N42.14 for guidance on isotope specific efficiency and efficiency as a function of energy calibrations. The efficiency calibration measurements shall be at least six peaks which cover the typical energy range of approximately 0.059 to 2 MeV. At least 10,000 net counts (total counts minus the Compton continuum and ambient background) shall be accumulated in each full-energy gamma-ray peak of interest used for the efficiency equation (ASTM D 3649-98a). Sodium Iodide Detectors: Refer to ANSI N42.12. Efficiencies shall be determined when there is a change in resolution, geometry, or system configuration (ASTM D 3649-98a).				

Section Reference	Question	Yes	No	NA	Comments
1.8.5	b) ii) Current software that does not require a physical calibration standard to obtain efficiencies for various matrices and geometries may be used to count samples where a standard calibration source of known matrix and geometry cannot be specified. This type of calibration technique is preferred for matrices such as waste or debris. When such software is used, the laboratory shall supply detailed information and documentation regarding the selection of parameters used to specify the efficiency calibration and sample models. Each sample selected for analysis using this type of calibration shall have a unique set of model parameters associated with it. When such models are used, the closest model to the actual sample shall be selected. The model selected for each sample shall be presented in the case narrative and shall include a discussion of actual and predicted peak ratios for isotopes with multiple gamma energies present in the sample.				
1.8.5	c) Energy Calibration Requirements: Is each gamma spectrometry system energy calibrated with NIST/international traceable standards or prepared from NIST/international traceable sources?				
1.8.5	c) i) Germanium Detectors: (Refer to ANSI N42.14, Section 5.1 for guidance on calibrating gamma-ray energy as a function of channel number at a fixed gain)				
1.8.5	c) i) Are energy calibration measurements made using at least six peaks which cover the energy range from 0.059 to approximately 2 MeV?				
1.8.5	c) i) Are additional peaks used deemed appropriate by the laboratory?				
1.8.5	c) ii) Does the laboratory ensure that at least 10,000 net counts (total counts minus the Compton continuum and ambient background) are accumulated in each full-energy gamma-ray peak of interest (ASTM D 3649-98a)?				
1.8.5	c) iii) Is energy calibration linear and accurate to 0.5 keV?				
1.8.5	c) iv) Sodium Iodide Detectors: In accordance to: ANSI N42.12, Section 4.3.2.?				
1.8.5	d) Performance Evaluation:				
1.8.5	Germanium Detectors: In accordance to ANSI N42.14, Section 7?				
1.8.5	Sodium Iodide Detectors: In accordance to ANSI N42.12, Section 4.3.5?				

Section Reference	Question	Yes	No	NA	Comments
1.8.5	e) Spectrum Assessment: Is each sample and QC sample spectrum assessed for acceptability of key peak width and shape, and interference due to superimposed peaks or other sources?				
1.8.5	e) Is any major contributor to the spectrum that is an unidentified peak discussed in the case narrative?				
	Conditions Requiring Reanalysis or Recount				
1.8.6	If reanalysis is not possible, has the laboratory ensure to contact the client for specific guidance or requirements?				
	a) General Conditions:				
1.8.6	a) i) If the RLs could not be achieved because of laboratory errors or oversights such as inadequate count times, inadequate aliquot size, inappropriate dilution, low detector efficiencies, high detector backgrounds, etc., then does the laboratory ensure that the sample is reanalyzed under more optimal conditions?				
1.8.6	a) ii) If the RLs could not be achieved because of problems associated with the sample such as inadequate sample provided, elevated radioactivity levels, sample matrix interferences such as high amounts of suspended solids, multiphase liquids, etc., then does the laboratory explain such problems in the Case narrative?				
	b) Sample and Analyte-Specific Conditions:				
1.8.6	b) Does the laboratory ensure that any one of the following are additional conditions that require reanalysis for a particular sample and analyte:				
1.8.6	b) i) If, for any reason, sample or batch QC integrity becomes suspect (e.g., spillage, mis-identification, cross-contamination), all potentially affected samples shall be reanalyzed from a point before that at which the integrity came into question?				
1.8.6	b) i) If new batch QC must be prepared for reanalysis, samples for reanalysis shall be restarted at the normal point of initiation for the batch QC?				
1.8.6	**b) ii) All samples associated with expired standards.**				

Section Reference	Question	Yes	No	NA	Comments
1.8.6	c) Analytical Batch Conditions: Except where noted otherwise, did any one of the following conditions requires reanalysis of the entire analytical batch, beginning with the preparation: batches that failed the Method Blank or LCS criteria?				
1.8.6	d) Conditions Requiring a Re-count: If the RL was not achieved due to inadequate count duration, low detector efficiencies, or high detector backgrounds, has the sample been re-counted under more optimal conditions?				
1.8.6	d) Are the reasons for the re-counts documented in the case narrative?				
1.8.6	**Volume 1 Module 7**				
	Toxicity Testing				
	Method Validation				
1.5	Does the laboratory validate non-refenece methods, laboraotry-designed/developed methods, reference methods used outside their published scope and amplications and modification of reference methods?				
1.5	**Demonstration of Capability (DOC)**				
1.6	Prior to acceptance and institution of any method for data reporting, is a satisfactory initial DOC performed (per Section 1.6.2)?				
1.6.1	Were ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) required?				
1.6.1	Note: In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the on-going DOC is acceptable as an initial DOC.				
1.6.1	Does the laboratory have records on file to demonstrate that an initial DOC is not required?				
1.6.1	Is an initial DOC completed each time there is a change in instrument type, personnel, or method?				
1.6.1	Are all demonstrations documented, and all data applicable to the demonstration retained, and readily available at the laboratory?				
	Initial DOC				

Section Reference	Question	Yes	No	NA	Comments
1.6.2	Is an initial DOC conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period?				
1.6.2	Does the laboratory document each initial DOC in a manner such that the following information is readily available for each affected employee:				
1.6.2.1	a) analyst(s) involved in preparation and/or analysis?				
1.6.2.1	b) matrix?				
1.6.2.1	c) species and endpoint?				
1.6.2.1	d) identification of method(s) performed?				
1.6.2.1	e) identification of laboratory-specific SOP used for analysis, including revision number?				
1.6.2.1	f) date(s) of analysis?				
1.6.2.1	g) summary of analyses, including information outlined in Section 1.6.2.2.c?				
1.6.2.1	If the method or regulation does not specify a DOC, does the laboratory use the procedure stated in section 1.6.3?				
1.6.2.2	Does the laboratory document other approaches to initial DOC, and are they adequate?				
1.6.2.2	Does each analyst meet the quality control requirements as specified in section 1.7.1.2?				
	Ongoing DOC				
1.6.3	Does the laboratory have a documented procedure describing ongoing demonstration of capability?				
1.6.3	Does the analyst(s) demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard?				
1.6.3	Does the laboratory have a documented procedure describing ongoing DOC?				

Section Reference	Question	Yes	No	NA	Comments
1.6.3	Does the ongoing demonstration include performing another initial demonstration of capability as per 1.6.2 or a documented process of analyst review using QC samples can serve as the annual on-going demonstration of capability?				
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?				
	Technical Requirements				
	Quality Control				
1.7.1	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken?				
1.7.1	Does the resulting data recorded in each trend detectable and, where practicable, are the statistical techniques applied to the reviewing of the results?				
1.7.1	Is the monitoring planned and reviewed and does it include, but not be limited to, any of the following:				
1.7.1	a) Is there a regular use of certified reference materials and/or internal quality control using secondary reference materials?				
1.7.1	b) Is the participation in inter-laboratory comparison or proficiency-testing program?				
1.7.1	c) Are the replicate tests using the same or different methods?				
1.7.1	d) Is there retesting of retained samples?				
1.7.1	e) Is ther a correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate)?				
	Essential Quality Control Procedures				
1.7.1.1	Do the general quality control principles apply, where applicable, to the testing laboratory?				
1.7.1.1	Is the manner in which they are implemented dependent on the types of tests performed by the laboratory and are further described in this module?				
1.7.1.1	Are the standards for any given test type assured that the applicable principles are addressed?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.1	a) Does the laboratory have detailed written protocols in place to monitor the following quality controls:				
1.7.1.1	a) i) Does the laboratory have positive and negative controls to monitor tests such as blanks, spikes, reference toxicants?				
1.7.1.1	a) ii)Does the laboratory have tests to define the variability and/or repeatability of the laboratory results such as replicates?				
1.7.1.1	a) iii) Does the laboratory have measures to evaluate method capability, such as percent minimum significant difference (PMSD)?				
1.7.1.1	a) iv) Does the laboratory have a selection of appropriate formulae to reduce raw data to final results such as regression and statistical analyses?				
1.7.1.1	a) v) Does the laboratory have a selection and use of reagents and standards of appropriate quality?				
1.7.1.1	a) vi) Does the laboratory have measures to assure the selectivity of the test for its intended purpose?				
1.7.1.1	a) vii) Does the laboratory have measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method such as temperature, humidity, light or specific equipment conditions?				
1.7.1.1	b) Are all quality control measures assessed and evaluated on an ongoing basis, and quality control acceptance criteria used to determine the usability of the data?				
1.7.1.1	c) Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?				
1.7.1.1	d) Is the quality control protocols specified by the laboratory's method manual followed?				
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?				
1.7.1.1	d) When it is not apparent which is more stringent does the laboratory have the QC in the regulations to be followed?				
	Positive and Negative Controls				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.2	a) Does the laboratory have reference toxicant tests to demonstrate a laboratory's ability to obtain consistent results with the method and evaluate the overall health and sensitivity of test organisms over time?				
1.7.1.2	a) i) Does the laboratory demonstrate its ability to obtain consistent results with standard reference toxicants (SRT)?				
1.7.1.2	a) ii) Does ongoing laboratory performance demonstrate 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)?				
1.7.1.2	a) 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)?				
1.7.1.2	a) iii)For methods conducted at a frequency of monthly or greater, are SRT tests conducted monthly?				
1.7.1.2	a) iii) For methods and species commonly used in the laboratory, but tested at a frequency of less than monthly, are SRT tests conducted concurrently with the environmental test?				
1.7.1.2	a) iii) If the test organisms are obtained from an outside source, does the sensitivity of each batch of organisms received from a supplier determined via a concurrent SRT test unless the supplier can provide control chart data for the last five SRT tests using the same SRT and test conditions?				
1.7.1.2	a) iii) Is the supplied SRT data not older than six (6) months?				
1.7.1.2	a) iv) If the regulation identifies a reference toxicant or dilution series for a particular test, does the laboratory follow the specified requirements?				
1.7.1.2	a) iv) Do all reference toxicant tests conducted for a given method and species used in the same reference toxicant, test concentrations, dilution water and data analysis methods?				
1.7.1.2	a) iv) Is a dilution factor of 0.5x or greater used for both acute and chronic tests?				
1.7.1.2	a) v) Are the reference toxicant tests conducted following the procedures required in the method?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.2	b) i) Are the standards for the use, type and frequency of testing of negative controls specified by the methods and by permit or regulation and followed?				
1.7.1.2	b) i)Is the negative control included with each test to evaluate test performance and the health and sensitivity of the specific batch of organisms?				
1.7.1.2	b) 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?				
	Variability and/or Reproducibility				
1.7.1.3	Is the intra-laboratory precision determined on an ongoing basis through the use of further reference toxicant tests and related control charts as described above?				
	Test Sensitivity				
1.7.1.4	a) Is the PMSD calculated according to the formula specified by the method and reported with the test results?				
1.7.1.4	b) For Point estimates: (LCp, ICp, or ECp), are confidence intervals reported as a measure of the precision around the point estimate value, when the calculation is possible?				
	Selection and Use of Reagents and Standards				
1.7.1.5	a) Is the grade of all reagents used in toxicity tests specified in the method except the reference standard?				
1.7.1.5	a) Are all reference standards prepared from chemicals that are analytical reagent grade or better?				
1.7.1.5	a) Is the preparation of all standards and reference toxicants documented?				
1.7.1.5	b) Are all standards and reagents associated with chemical measurements, such as dissolved oxygen, pH or specific conductance, comply with the Chemistry Module?				
1.7.1.5	c) Is only reagent-grade water collected from distillation or de-ionization units used to prepare reagents?				
	Constant and Consistent Test Conditions				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.6	a) If closed refrigerator-sized incubators are used, does the laboratory have culturing and testing of organisms separated to avoid cross-contamination?				
1.7.1.6	b) Does the laboratory have space adequate for the types and numbers of tests performed?				
1.7.1.6	b) Does the building provide adequate cooling, heating and illumination for conducting testing and culturing; hot and cold running water available for cleaning equipment?				
1.7.1.6	c) Is air used for aeration of test solutions, dilution waters and cultures free of oil and fumes?				
1.7.1.6	d) Does the laboratory or a contracted outside expert positively identify test organisms to species on an annual basis?				
1.7.1.6	d) Is the taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) kept on file at the laboratory?				
1.7.1.6	d) When organisms are obtained from an outside source the supplier provide this same information.				
1.7.1.6	e) Is the equipment used for routine support measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, ammonia and weight calibrated, and/or standardized per manufacturer's instructions?				
1.7.1.6	e) Are all measurements and calibrations documented?				
1.7.1.6	f) Is test temperature maintained as specified for the method?				
1.7.1.6	f) Is the temperature control equipment adequate to maintain the required test temperature(s)?				
1.7.1.6	f) Is the average daily temperature of the test solutions maintained within method specified range?				
1.7.1.6	f)Is the minimum frequency of measurement once per twenty-four (24) hour period?				
1.7.1.6	f). Is the test temperature for continuous-flow toxicity tests recorded and monitored continuously?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.6	f) Does the laboratory use electronic data loggers and is temperature monitored at a frequency sufficient to capture temporal variations of the environmental control system?				
1.7.1.6	g) Does the laboratory have reagent grade water, prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration that meets the method specified requirements?				
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?				
1.7.1.6	h) Does the laboratory have water used for culturing and testing analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock that can be identified?				
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?				
1.7.1.6	i) Does the laboratory have written procedures for the evaluation of food acceptance?				
1.7.1.6	j) Does the laboratory have a subset of organisms used in bioaccumulation tests analyzed at the start of the test (baseline) for the target compounds to be measured in the bioaccumulation tests?				
1.7.1.6	k) Are the test chamber sizes and test solution volumes as specified in the method, and are the test chambers used identical?				
1.7.1.6	l) Are test organisms fed the quantity and type food or nutrients specified in the method, and are they fed at the intervals specified in the methods?				
1.7.1.6	m) Are all organisms in a test from the same source and lot, where available, are certified seeds used for soil tests?				

Section Reference	Question	Yes	No	NA	Comments
1.7.1.6	n) Are all organisms used in tests, or used as brood stock to produce neonate test organisms (for example cladocerans and larval fish), appear healthy, show no signs of stress or disease and do they exhibit acceptable survival (90% or greater) during the twenty-four (24) hour period immediately preceding use in tests?				
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?				
1.7.1.6	o) Do materials reduced or added to sample toxicity?				
1.7.1.6	o) Are appropriate materials used for toxicity testing and culturing as described in the methods?				
1.7.1.6	p) Is the light intensity maintained as specified in the methods?				
1.7.1.6	p) Are the measurements made and recorded on a yearly basis?				
1.7.1.6	p) Are photoperiod records maintained as specified in the methods and documented at least quarterly?				
1.7.1.6	p) For algal and plant tests, is the light intensity measured and recorded at the start of each test?				
1.7.1.6	q) Are the health and culturing conditions of all organisms used for testing documented by the laboratory?				
1.7.1.6	q)Does the documentation include culture conditions (e.g. salinity, hardness, temperature, pH) and observations of any stress, disease or mortality?				
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?				
1.7.1.6	q) Do the observation records adequately address the twenty-four (24) hour time period referenced in item 1.7.1.6 n) above?				
1.7.1.6	q) Does the laboratory record each of these observations and water quality parameters upon the arrival of the organisms at the laboratory?				
1.7.1.6	r) Are the age and the age ranges of the test organisms as specified in the method?				

Section Reference	Question	Yes	No	NA	Comments
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?				
1.7.1.6	s) Does the maximum holding time of effluents (elapsed time from sample collection to first use in a test) not exceeding thirty-six (36) hours?				
1.7.1.6	s) Are samples used for renewal up to seventy two (72) hours after first use except as prescribed by the method and is it approved by the regulatory agency having authority for program oversight?				
1.7.1.6	t) Do all tests have at least the minimum number of replicates per treatment as prescribed by the method?				
1.7.1.6	u) Does the controlled populations of Ceriodaphnia in chronic effluent or receiving water tests contain no more than 20% males?				
1.7.1.6	v) Is the culturing of C. dubia adequate such that blocking by parentage can be established?				
1.7.1.6	w) Is the dissolved oxygen and pH in aquatic tests within acceptable range at test initiation?				
1.7.1.6	w) Is the minimal aeration provided to the tests if acceptable dissolved oxygen concentrations cannot be otherwise maintained?				
1.7.1.6	x) Are the test soils or sediments within the geochemical tolerance range of the test organism?				
1.7.1.6	y) Does the laboratory have individual tests conditionally acceptable if temperature, dissolved oxygen, pH and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests (see test conditions and test acceptability criteria specified for each method)?				
1.7.1.6	y) Does the acceptability of the test depend on the experience and professional judgment of the technical director and the permitting authority?				
	Data Acceptance/Rejection Criteria				
	Positive Controls				
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?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.1	Does the laboratory evaluate precision (i.e. coefficient of variation, CV) for these tests against method specific or laboratory-derived criteria to determine validity of the testing result?				
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)?				
1.7.2.1	For endpoints from hypothesis tests (NOEC, NOAEC) are the values plotted directly, and the control limits consist of one concentration interval above and below the concentration representing the central tendency (i.e. the mode)?				
1.7.2.1	For endpoints that are point estimates does the laboratory have the cumulative mean CV is calculated?				
1.7.2.1	For endpoints from hypothesis tests, is the PMSD calculated?				
1.7.2.1	Are these values maintained on control charts?				
1.7.2.1	Note: Control chart limits are expected to be exceeded occasionally regardless of how well a laboratory performs.				
1.7.2.1	Does the laboratory have acceptance/rejection policies, consistent with the methods, for SRT data which considers source of test organisms, the direction of the deviation, test dilution factor, test sensitivity (for hypothesis test values), testing frequency, out-of-control test frequency, relative width of acceptance limits, inter-test CV, and degree of difference between test results and acceptance limits?				
1.7.2.1	Is the intra-laboratory precision determined on an ongoing basis through the use of control charts?				
1.7.2.1	i. 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?				
	Negative Controls				
1.7.2.2	Does the laboratory have the test acceptability criteria specified in the method achieved for both the reference toxicant and the effluent or environmental sample toxicity test?				

Section Reference	Question	Yes	No	NA	Comments
1.7.2.2	Does the laboratory have the criteria calculated and does it meet the method specified requirements for performing toxicity tests?				
	Selection of Appropriate Statistical Analysis Methods				
1.7.2.3	a) Are the methods of data analysis and reporting as specified by language in the regulation, permit, or the method followed as required?				
1.7.2.3	b) Is the toxicity data plotted on semi-logarithmic graph paper, relating time, mortality, and effluent concentration to verify computational results?				
	Sample Handling				
1.7.3	Are all samples chilled to 0-6℃ during or immediately after collection except as prescribed by the method and approved by the regulatory agency having authority for program oversight?				