

ASSESSOR CHECKLIST: A2LA ENVIRONMENTAL PROGRAM REQUIREMENTS

May 2006

The following pages present the criteria from the “Environmental Program Requirements” in a checklist format. The laboratory’s policies and procedures must meet these requirements. Quality system documentation and supporting records must be available for the assessor’s review.

Laboratory Instructions: If the requirements include the need for a written policy, procedure or arrangement, that requirement statement in this checklist is shaded. *Complete the document reference identifiers in the checklist’s second column (labeled ‘reference’) for each shaded requirement.* The appropriate ‘reference’ can include quality manual, laboratory manual, SOPs, records, etc. references. The references provided shall specify procedure number, page number and section number, where possible. *Completion of this checklist serves to help both the laboratory and the assessor prepare for the assessment and will save a significant amount of assessment time and cost.*

Assessor Instructions: Review the laboratory’s documented quality system to verify compliance with the applicable Environmental Program documentation requirements. Assess to verify that the documented quality system is indeed implemented as described. **Every checklist item shall be accompanied by a tick mark in the yes, no or n/a space.** Record comments related to any requirement in the space provided and sign on the appropriate line on page 2. Assess the laboratory’s technical competence to perform specific tests or specific types of tests. Record comments related to tests on the Test Method Matrix. Additional comments can be noted on the draft scope. All deficiencies must be identified and explained in the assessor deficiency report.

Laboratory Name: _____

City: _____ State: _____

Date: _____

Lab Code: _____

Assessment ID: _____

Certificate #(s): _____

Assessor(s) Name(s): _____

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E. MANAGEMENT REQUIREMENTS					
4.1 Organization					
4E.1.1 The technical director(s) shall certify that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. Such certification shall be documented.					
4E.1.2 The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision to ensure adherence to laboratory procedures and accepted techniques.					
4.2 Quality system					
4E.2.1 The quality manual shall be maintained current under the responsibility of the quality assurance officer.					
4.E.2.2 The Quality Manual shall list on the title page:					
4E.2.2.1 a document title;					
4E.2.2.2 the laboratory's full name and address;					
4E.2.2.3 the name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;					
4E.2.2.4 the name of the quality assurance officer (however named);					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.2.2.5 the identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;					
4E.2.2.6 signed and dated concurrence (with appropriate titles) of all responsible parties including the QA officer(s), technical director(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;					
4E.2.3 The laboratory shall identify the laboratory's approved signatories. (See Section 5.2.1 of ISO/IEC 17025.)					
4E.2.4 The quality manual or related documentation shall contain:					
4E.2.4.1 a list of all test methods under which the laboratory performs its accredited testing;					
4E.2.4.2 reference to the calibration and/or verification test procedures used;					
4E.2.4.3 reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;					
4E.2.4.4 reference to procedures for calibration, verification and maintenance of equipment;					
4E.2.4.5 the laboratory management arrangements for exceptionally permitting deviations from documented policies and procedures or from standard specifications;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.2.4.6 procedures for data review;					
4E.2.4.7 ethics policy statement developed by the laboratory and processes/procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions;					
4E.2.4.8 reference to procedures for reporting analytical results;					
4E.2.4.9 a Table of Contents, and applicable lists of references and glossaries, and appendices;					
4E.2.4.10 the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts.					
4.3 Document control					
4E.3.1 The document control system shall ensure that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force.					
4.4 Review of requests, tenders and contracts					
No additions.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.5 Subcontracting of tests and calibrations					
4E.5.1 Specifically for laboratories pursuing NELAC accreditation; where a laboratory subcontracts any part of the testing covered under NELAP, this work shall be placed with a laboratory accredited under NELAP for the tests to be performed and/or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed. The laboratory performing the subcontracted work shall be indicated in the final report and non-NELAP accredited work shall be clearly identified.					
4.6 Purchasing services and supplies					
No additions.					
4.7 Service to the client					
No additions.					
4.8 Complaints					
No additions.					
4.9 Control of nonconforming testing and/or calibration work					
No additions.					
4.10 Corrective action					
4E.10.1 In addition to providing acceptance criteria and specific protocols for corrective actions in the Method Standard Operating Procedures (see 5E.4.1), the laboratory shall implement general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred. These procedures shall include but are not limited to the following:					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.10.1.1 identify the individual(s) responsible for assessing each QC data type;					
4E.10.1.2 identify the individual(s) responsible for initiating and/or recommending corrective actions;					
4E.10.1.3 define how the analyst shall treat a data set if the associated QC measurements are unacceptable;					
4E.10.1.4 specify how out-of-control situations and subsequent corrective actions are to be documented;					
4E.10.1.5 specify procedures for management (including the QA officer) to review corrective action reports.					
4E.10.2 To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifier(s).					
4.11 Preventive action					
No additions.					
4.12 Control of records					
4E.12.1 The laboratory shall retain all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of five years from generation of the last entry in the records.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.12.2 There are two levels of sample handling: 1) sample tracking and 2) legal chain of custody protocols, which are used for evidentiary or legal purposes. All essential requirements for records of sample tracking (e.g., chain of custody form) are outlined in this section and Section 5E.8. If a client specifies that a sample will be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory will carry out legal chain of custody (e.g. ASTM D 4840-95 and Manual for the Certification of Laboratories Analyzing Drinking Water, March 1997, Appendix A).					
4E.12.3 The record keeping system must allow historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.					
4E.12.4 All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification shall be documented.					
4E.12.5 The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files.					
4E.12.6 All changes to records shall be signed or initialed by responsible staff. The reason for the signature or initials shall be clearly indicated in the records such as “sampled by,” “prepared by,” or “reviewed by.”					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.12.7 All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.					
4E.12.8 Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction. These criteria also shall apply to electronically maintained records.					
4E.12.9 Records, which are stored only on electronic media, must be supported by the hardware and software necessary for their retrieval. Records that are stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.					
4E.12.10 The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.					
4E.12.11 Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.					

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		Compliance			Comments
		Y	N	NA	
4E.12.12 The laboratory shall 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. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed.					
4E.12.13 A record of all procedures to which a sample is subjected while in the possession of the laboratory shall be maintained. These shall include but are not limited to all records pertaining to:					
4E.12.13.1 Sample preservation including appropriateness of sample container and compliance with holding time requirement;					
4E.12.13.2 Sample identification, receipt, acceptance or rejection and log-in;					
4E.12.13.3 Sample storage and tracking including shipping receipts, sample transmittal forms, (chain of custody form).					
4E.12.14 In addition to documenting all the above-mentioned activities, the following shall be retained:					
4E.12.14.1 All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.12.14.2 A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;					
4E.12.14.3 Archived standard operating procedures;					
4E.12.14.4 Correspondence relating to laboratory activities for a specific project;					
4E.12.14.5 All corrective action reports, audits and audit responses;					
4E.12.14.6 Proficiency test results and raw data; and,					
4E.12.14.7 Results of data review, verification, and cross-checking procedures.					
4E.12.15 The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall include:					
4E.12.15.1 Laboratory sample ID code;					
4E.12.15.2 Date of analysis and time of analysis is required if the holding time is 72 hours or less or when time critical steps are included in the analysis, e.g., extractions, and incubations;					
4E.12.15.3 Instrumentation identification and instrument operating conditions/parameters (or reference to such data);					
4E.12.15.4 Analysis type;					

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		Compliance			Comments
		Y	N	NA	
4E.12.15.5 All manual calculations, e.g., manual integrations;					
4E.12.15.6 Analyst's or operator's initials/signature;					
4E.12.15.7 Sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;					
4E.12.15.8 Sample analysis;					
4E.12.15.9 Standard and reagent origin, receipt, preparation, and use;					
4E.12.15.10 Calibration criteria, frequency and acceptance criteria;					
4E.12.15.11 Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;					
4E.12.15.12 Quality control protocols and assessment;					
4E.12.15.13 Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;					
4E.12.15.14 Method performance criteria including expected quality control requirements.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4E.12.16 The laboratory shall maintain a log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.					
4.13 Internal audits					
4E.13.1 Internal audits shall be conducted annually.					
4E.13.2 Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.					
4.14 Management review					
4E.14.1 Management reviews shall be conducted at least annually.					
5 Technical requirements					
5.1 General					
No additions.					
5E.2 Personnel					
5E.2.1 <u>Quality assurance officer</u> : The quality assurance officer (and/or his/her designees) shall:					
5E.2.1.1 serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;					
5E.2.1.2 have functions independent from laboratory operations for which they have quality assurance oversight;					
5E.2.1.3 be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
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		Y	N	NA	
5E.2.1.4 have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under these requirements and, if applicable, NELAC;					
5E.2.1.5 have a general knowledge of the analytical test methods for which data review is performed;					
5E.2.1.6 arrange for or conduct internal audits as per 4.13 annually;					
5E.2.1.7 notify laboratory management of deficiencies or departures in the quality system and monitor corrective action;					
5E.2.2 <u>Technical director</u> : The technical director(s) means a full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of testing and reporting of results. The title of such person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager;					
5E.2.2.1 A laboratory may appoint one or more technical directors for the appropriate fields of testing for which they are seeking accreditation.					
5E.2.2.2 For laboratories pursuing NELAC Accreditation, the technical director's name must appear in the national database.					

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		Compliance			Comments
		Y	N	NA	
5E.2.2.3 The technical director's duties shall include, but not be limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.					
5E.2.2.4 An individual shall not be the technical director(s) of more than one accredited environmental laboratory without authorization from the primary Accrediting Authority. Circumstances to be considered in the decision to grant such authorization shall include, but not be limited to, the extent to which operating hours of the laboratories to be directed overlap, adequacy of supervision in each laboratory, and the availability of environmental laboratory services in the area served.					
5E.2.2.5 The technical director(s) who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical director(s) to temporarily perform this function. If this absence exceeds 65 consecutive calendar days, the primary accrediting authority shall be notified in writing.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.2.2.6 Qualifications of the technical director(s):					
5E.2.2.6.1 Any technical director of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelors degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience					
5E.2.2.6.2 Any technical director of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two years of equivalent and successful college education, with a minimum of 16 college semester credit hours in chemistry. In addition, such a person shall have at least two years of experience performing such analysis					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>5E.2.2.6.3 Any technical director of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelors degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of 16 college semester credit hours in general microbiology and biology and at least two years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience. A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four college semester credit hours in general microbiology may be the technical director(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform and standard plate count. Two years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one year of experience in environmental analysis.</p>					
<p>5E.2.2.6.4 Any technical director of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor's degree in chemistry, physics or engineering with 24 college semester credit hours of chemistry with two or more years of experience in the radiological analysis of environmental samples. A masters or doctoral degree in one of the above disciplines may be substituted for one year experience.</p>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.2.2.6.5 The technical director(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:					
5E.2.2.6.5.1 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 year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.					
5E.2.2.6.5.2 For procedures requiring the use of a polarized light microscope, an associate's degree or two 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.					
5E.2.2.6.5.3 For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in the use of the instrument.					
5E.2.2.6.6 Any technical director of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate's degree or two years of college and one year of experience in radiation measurements, including at least one year of experience in the measurement of radon and/or radon progeny.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E2.3 Notwithstanding any other provision of these requirements, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements serving as the director of the accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility system. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit, and when the facility's laboratory is analyzing water treatment/sewage treatment samples collected within the state where the laboratory is situated, the scope of accreditation shall be determined by the accrediting authority.					
5E2.4 Notwithstanding any other provision of these requirements, a full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the director of an accredited laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit. Such accreditation for an industrial waste treatment facility shall be limited to laboratories analyzing industrial waste treatment samples collected within the state where the laboratory is situated, and the scope of accreditation shall be determined by the state accrediting authority.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.2.5 The laboratory management shall be responsible for:					
5E.2.5.1 Documenting all analytical and operational activities of the laboratory;					
5E.2.5.2 Supervising all personnel employed by the laboratory;					
5E.2.5.3 Ensuring that all sample acceptance criteria (Section 5.11) are verified and that samples are logged into the sample tracking system and properly labeled and stored;					
5E.2.5.4 Documenting the quality of all data reported by the laboratory; and					
5E.2.5.5 Developing a proactive program for prevention and detection of improper, unethical or illegal actions. Components of this program could include: internal proficiency testing (single and double blind); post-analysis, electronic data and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instrument manipulation practices.					
5E.2.5.6 Defining the minimal level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance, colony counting, aseptic or quantitative techniques shall be considered;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>5E.2.5.7 Ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented. (See Appendix C of Environmental Program Requirements);</p> <p><i>Note: In laboratories with specialized “work cells” (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.</i></p>					
<p>5E.2.5.8 Ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:</p>					
<p>5E.2.5.8.1 Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities.</p>					
<p>5E.2.5.8.2 Training courses or workshops on specific equipment, analytical techniques or laboratory procedures shall all be documented.</p>					
<p>5E.2.5.8.3 Training courses in ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions. Evidence must also be on file which demonstrates that each employee has read, acknowledged and understood their personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.</p>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.2.6 Analyst training shall be considered up to date if an employee training file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure as defined by the laboratory document control system) and documentation of continued proficiency by at least one of the following once per year:					
5E.2.6.1 Acceptable performance of a blind sample (single blind to the analyst);					
5E.2.6.2 Another demonstration of capability;					
5E.2.6.3 Successful analysis of a blind performance sample on a similar test method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5035/8260) would only require documentation for one of the test methods;					
5E.2.6.4 At least four consecutive laboratory control samples with acceptable levels of precision and accuracy;					
5E.2.6.5 If 5E2.6.1-4 cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.					
5E.2.7 Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.3 Accommodation and environmental conditions					
5E3.1 Work spaces must be available to ensure an unencumbered work area. Work areas include:					
5E3.1.1 access and entryways to the laboratory;					
5E3.1.2 sample receipt area(s);					
5E3.1.3 sample storage area(s);					
5E3.1.4 chemical and waste storage area(s); and,					
5E3.1.5 data handling and storage area(s).					
5.4 Test and calibration methods and method validation					
5E.4.1 Laboratories shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.					
5E.4.1.1 These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents.					
5E.4.1.2 The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the methods manual (see 5E.4.2).					
5E.4.1.3 The laboratory shall also establish Standard Operating Procedures:					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.4.1.3.1 to ensure that reported data are free from transcription and calculation errors;					
5E.4.1.3.2 to ensure that all quality control measures are reviewed, and evaluated before data are reported;					
5E.4.1.3.3 addressing manual calculations including manual integrations.					
5E.4.1.4 Copies of all SOPs shall be accessible to all personnel.					
5E.4.1.5 The SOPs shall be organized.					
5E.4.1.6 Each SOP shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.					
5E.4.2 The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method. This manual may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described.					
5E.4.3 Each test method shall include or reference where applicable:					
5E.4.3.1 identification of the test method;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.4.3.2 applicable matrix or matrices;					
5E.4.3.3 detection limit;					
5E.4.3.4 scope and application, including components to be analyzed;					
5E.4.3.5 summary of the test method;					
5E.4.3.6 definitions;					
5E.4.3.7 interferences;					
5E.4.3.8 safety;					
5E.4.3.9 equipment and supplies;					
5E.4.3.10 reagents and standards;					
5E.4.3.11 sample collection, preservation, shipment and storage;					
5E.4.3.12 quality control;					
5E.4.3.13 calibration and standardization;					
5E.4.3.14 procedure;					
5E.4.3.15 calculations;					
5E.4.3.16 method performance;					
5E.4.3.17 pollution prevention;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.4.3.18 data assessment and acceptance criteria for quality control measures;					
5E.4.3.19 corrective actions for out-of-control data;					
5E.4.3.20 contingencies for handling out-of-control or unacceptable data;					
5E.4.3.21 waste management;					
5E.4.3.22 references;					
5E.4.3.23 any tables, diagrams, flowcharts and validation data.					
5E.4.4 When the use of reference test methods for a sample analysis are mandated or requested, only those methods shall be used.					
5E.4.5 Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see 5E.4.2 and Appendix C), and be available to the client and other recipients of the relevant reports.					
5E.4.6 Prior to acceptance and institution of any test method, satisfactory demonstration of method capability is required. (See Appendix C and 5E.2.5.7.) Thereafter, continuing demonstration of method performance, as per the quality control requirements in Appendix D (such as laboratory control samples) is required.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.4.7 In cases where a laboratory analyzes samples using a test method that has been in use by the laboratory before July 1999, and there have been no significant changes in instrument type, personnel or test method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency shall be acceptable. The laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.					
5E.4.8 In all cases, the appropriate forms such as the Certification Statement (Appendix C) must be completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement must be retained by the laboratory. (See Appendix C for Certification Statement.)					
5E.4.9 A demonstration of capability must be completed each time there is a change in instrument type, personnel, or test method.					
5E.4.10 In laboratories with a specialized "work cell(s)" (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit must meet the above criteria and this demonstration of capability must be fully documented.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.4.11 When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analyst(s) in that area of the workcell where they are employed. This new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples). Such performance must be documented and the four preparation batches following the change in personnel must not result in the failure of any batch acceptance criteria, e.g., method blank and laboratory control sample, or the demonstration of capability must be repeated. In addition, if the entire work cell is changed/replaced, the work cell must perform the demonstration of capability (Appendix C).					
5E.4.12 When a work cell(s) is employed the performance of the group must be linked to the training record of the individual members of the work cell.					
5.5 Equipment					
5E.5.1 In addition to the requirements in 5.5.5 of ISO/IEC 17025, records of each major item of equipment and all reference standards significant to the tests performed shall also include:					
5E.5.1.1 documentation on reference standards verifications;					
5E.5.1.2 date received and date placed in service (if available);					
5E.5.1.3 if available, condition when received (e.g. new, used, reconditioned);					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.6 Measurement traceability					
5E.6.1 Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and (2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification.					
5E.6.2 <u>Support Equipment</u> : These requirements apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.					
5E.6.2.1 All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities including service calls, shall be kept.					
5E.6.2.2 All support equipment shall be calibrated or verified at least annually, using traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used or:					
5E.6.2.2.1 The equipment shall be removed from service until repaired; or					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.6.2.2.2 The laboratory shall maintain records of established correction factors to correct all measurements.					
5E.6.2.3 Raw data records shall be retained to document equipment performance.					
5E.6.2.4 Prior to use on each working day, balances, ovens, refrigerators, freezers, and water baths shall be checked in the expected use range, with traceable references where available. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.					
5E.6.2.5 Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the laboratory.					
5E.6.2.6 For chemical tests the temperature, cycle time, and pressure of each run of autoclaves must be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.					
5E.6.2.7 For biological tests that employ autoclave sterilization see section D.3.8.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>5E.6.3 <u>Instrument Calibration</u>: These requirements specify the essential elements that shall define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data must be of known quality and be appropriate for a given regulation or decision. These requirements do not specify detailed procedural steps (“how to”) for calibration, but establish the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.</p> <p>Note: In the following sections, initial instrument calibration is directly used for quantitation and continuing instrument calibration verification is used to confirm the continued validity of the initial calibration.</p>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.6.3.1 <u>Initial Instrument Calibration</u> : The following items are essential elements of initial instrument calibration:					
5E.6.3.1.1 The details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics must be included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, then the referenced material must be retained by the laboratory and be available for review.					
5E.6.3.1.2 Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test 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.					
5E.6.3.1.3 Sample results must be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification.					
5E.6.3.1.4 All initial instrument calibrations must be 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 . Traceability shall be to a national standard, when available.					
5E.6.3.1.5 Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient or relative percent difference. The criteria used must be appropriate to the calibration technique employed.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.6.3.1.6 Results of samples not bracketed by initial instrument calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the detection limit.					
5E.6.3.1.7 If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.					
5E.6.3.1.8 Calibration standards must include concentrations at or below the regulatory limit/decision level, if these limits/levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits (See D.1.4 Detection Limits)					
5E.6.3.1.9 If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.6.3.2 Continuing Instrument Calibration Verification: When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument calibration verification:					
5E.6.3.2.1 The details of the continuing instrument calibration procedure, calculations and associated statistics must be included or referenced in the test method SOP.					
5E.6.3.2.2 A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing instrument calibration verification must be analyzed per analytical batch.					
5E.6.3.2.3 Sufficient raw data records must be retained to permit reconstruction of the continuing instrument calibration verification, e.g., test 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. Continuing calibration verification records must explicitly connect the continuing verification data to the initial instrument calibration.					
5E.6.3.2.4 Criteria for the acceptance of a continuing instrument calibration verification must be established, e.g., relative percent difference.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.6.3.2.5 If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration must be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified. However, sample data associated with an unacceptable calibration verification may be reported as qualified data under the following special conditions:					
5E.6.3.2.5.1 When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.					
5E.6.3.2.5.2 When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.6.4 The laboratory shall retain records for all standards, reagents and media including:					
5E.6.4.1 the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied)					
5E.6.4.2 the date of receipt;					
5E.6.4.3 recommended storage conditions;					
5E.6.4.4 an expiration date after which the material shall not be used unless its reliability is verified by the laboratory.					
5E.6.5 Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date.					
5E.6.6 Records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.					
5E.6.7 All containers of prepared reagents and standards must bear a unique identifier and expiration date and be linked to the documentation requirements in 5E.6.3 above.					
<u>Note:</u> Labels may serve as records; however, they shall be retained for an appropriate amount of time as required.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.7 Sampling					
5E.7.1 Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.					
5.8 Handling of test and calibration items					
5E.8.1 The documented system for uniquely identifying the items to be tested shall include identification for all samples, subsamples and subsequent extracts and/or digestates.					
5E.8.2 The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample. This laboratory code shall maintain an unequivocal link with the unique field ID code assigned each container.					
5E.8.3 The laboratory ID code shall be placed on the sample container as a durable label.					
5E.8.4 The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration. In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.					
5E.8.5 The laboratory must have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.8.6 Data from any samples which do not meet the following criteria must be flagged in an unambiguous manner clearly defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to, the following areas of concern:					
5.E.8.6.1 Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;					
5E8.6.2 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;					
5E.8.6.3 Use of appropriate sample containers;					
5E.8.6.4 Adherence to specified holding times;					
5E.8.6.5 Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests;					
5E.8.6.6 Procedures to be used when samples show signs of damage, contamination or inadequate preservation.					
5E8.7 Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified in 5E.8.6 above shall be checked.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E8.7.1 All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within 2°C of the required temperature or the method specified range. For samples with a specified temperature of 4°C, samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.					
5E.8.7.2 The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis.					
5E.8.7.3 The results of all checks shall be recorded.					
5E.8.7.4 Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory shall attempt to consult the client for further instruction before proceeding.					
5E8.7.5 The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.					
5E.8.7.6 If the sample does not meet the sample receipt acceptance criteria listed in these requirements, the laboratory shall either:					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.8.7.6.1 Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or					
5E.8.7.6.2 Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.					
5.E.8.7.6.2.1 The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receipt documents.					
5E.8.7.6.2.2 The analysis data shall be appropriately "qualified" on the final report.					
5E.8.7.7 The laboratory shall utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers.					
5E.8.7.7.1 This sample receipt log shall record the following:					
5E.8.7.7.1.1 Client/Project Name,					
5E.8.7.7.1.2 Date and time of laboratory receipt,					
5E.8.7.7.1.3 Unique laboratory ID code (see 5.11.1), and,					
5E.8.7.7.1.4 Signature or initials of the person making the entries.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.8.7.7.2 During the log-in process, the following information must be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample. Note: the placement of the laboratory ID number on the sample container is not considered a permanent record.					
5E.8.7.7.2.1 The field ID code which identifies each container must be linked to the laboratory ID code in the sample receipt log.					
5E.8.7.7.2.2 The date and time of sample collection must be linked to the sample container and to the date and time of receipt in the laboratory.					
5E.8.7.7.2.3 The requested analyses (including applicable approved test method numbers) must be linked to the laboratory ID code.					
5E.8.7.7.2.4 Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.					
5E.8.7.8 All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.					
5E.8.7.9 A complete chain of custody record form, if utilized, shall be maintained.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.8.8 Storage Conditions Samples shall be stored according to the conditions specified by preservation protocols.					
5E.8.8.1 Samples which require thermal preservation shall be stored under refrigeration which is +/-2° of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable.					
5E.8.8.2 Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.					
5E.8.8.3 Sample fractions, extracts, leachates and other sample preparation products shall be stored according to 5E8.8.1 above or according to specifications in the test method.					
5E.8.9 The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.9 Assuring the quality of test and calibration reports					
5E.9.1 Essential Quality Control Procedures: 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., chemical, whole effluent toxicity, microbiological, radiological, air) and are further described in Appendix D. The standards for any given test type shall assure that the applicable principles are addressed:					
5E.9.1.1 All laboratories shall have detailed written protocols in place to monitor the following quality controls:					
5E.9.1.1.1 Positive and negative controls to monitor tests such as blanks, spikes, reference toxicants;					
5E.9.1.1.2 Tests to define the variability and/or repeatability of the laboratory results such as replicates;					
5E.9.1.1.3 Measures to assure the accuracy of the test method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;					
5E.9.1.1.4 Measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability such as linearity;					
5E.9.1.1.5 Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.9.1.1.6 Selection and use of reagents and standards of appropriate quality;					
5E.9.1.1.7 Measures to assure the selectivity of the test for its intended purpose;					
5E.9.1.1.8 Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.					
5E.9.1.2 All quality control measures shall be assessed and evaluated on an on-going basis, and quality control acceptance criteria shall be used to determine the usability of the data. (See Appendix D of the A2LA Environmental Program Requirements.)					
5E.9.1.3 The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist. (See 5E.8.5.)					
5E.9.1.4 The quality control protocols specified by the laboratory's method manual (5E.4.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D, or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed.					
5E.9.2 The essential quality control measures for testing are found in Appendix D of the A2LA Environmental Program Requirements.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.10 Reporting the Results					
5E.10.1 Some regulatory reporting requirements or formats such as monthly operating reports may not require all items listed in Sections 5.10.2-3 or ISO/IEC 17025 or below, however, the laboratory shall provide all the required information to their client for use in preparing such regulatory reports.					
5E.10.2 Except as discussed in 5E.10.1 above, each report to an outside client shall include at least the following information in addition to the items required by Sections 5.10.2-3 or ISO/IEC 17025:					
5E.10.2.1 phone number with name of contact person for questions;					
5E.10.2.2 unique identification of each page, and the total number of pages. This requirement may be presented in several ways:					
5E.10.2.2.1 The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or					
5E.10.2.2.2 Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (example: 3 of 10, or 1 of 20).					
5E.10.2.2.3 Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E.10.2.3 project name if applicable;					
5E.10.2.4 description and unambiguous identification of the tested sample including the client identification code;					
5E.10.2.5 identification of test results derived from any sample that did not meet sample acceptance requirements such as improper container, holding time, or temperature;					
5E.10.2.6 date and time of sample collection, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours;					
5E.10.2.7 identification whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as µg/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;					
5E.10.2.8 at the laboratory's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;					
5E.10.2.9 date the report is issued;					
5E.10.2.10 clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc.;					
5E.10.2.11 clear identification of numerical results with values outside of quantitation limits;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5E10.3 Laboratories that are operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (in-house or captive laboratories) shall have all applicable information specified above readily available for review by the accrediting authority. However, formal reports detailing the information are not required if:					
5E10.3.1 The in-house laboratory is itself responsible for preparing the regulatory reports; or					
5E10.3.2 The laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management must ensure that the appropriate report items are in the report to the regulatory authority if such information is required.					
5E.10.4 The laboratory shall, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, follow documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved.					
5E.10.5 Laboratories accredited to be in compliance with NELAC requirements shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.					