NELAP Quality Systems Checklist
Quality Systems

Date: _____

Auditor: _____

Organization Name: _____

Person(s) Interviewed: _____

Records Reviewed: _____

	Y/N/NA	Reference	Question
Complaints			
135		5.4.8	Does the laboratory have a policy and procedure for the resolution of complaints received from clients or other parties?
136		5.4.8	Does the laboratory maintain records of all such complaints and of the investigations & actions taken by the laboratory?
Confidential			
26		5.4.1.5.c	Does the laboratory have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?
Corrective Action			
145		5.4.10.1	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?
146		5.4.10.2	Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?
147		5.4.10.3	Where corrective action is needed, does the laboratory identify potential corrective actions?
148		5.4.10.3	Does the laboratory select and implement the action(s) most likely to eliminate the problem and prevent recurrence?
149		5.4.10.3	Are corrective actions made to a degree appropriate to the magnitude and the risk of the problem?
150		5.4.10.3	Does the laboratory document and implement any required changes resulting from corrective action investigations?
151		5.4.10.4	Does the laboratory monitor the results to ensure that the corrective actions taken are effective?
152		5.4.10.5	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 5.4.13 as soon as possible?
153		5.4.10.6.a	In addition to providing acceptance criteria and specific protocols for corrective actions in the Method SOPs (see 5.5.4.1.1), does the laboratory implement general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred?
154		5.4.10.6.a.1-3	Do these corrective action procedures include the following: ___Identify the individual(s) responsible for assessing which QC data type? ___Identify individual(s) responsible for initiating and/or recommending corrective actions? ___Define how the analyst shall treat a data set if the associated QC measurement are unacceptable? ___Specify how out-of-control situations & subsequent corrective actions are to be documented? ___Specify procedures for management & the QA officer to review corrective action reports?
Data Integrity			
22		5.4.1.4.b	Is the laboratory 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?
82		5.4.2.6	Does the laboratory establish and maintain data integrity procedures in the quality manual, defined in detail?

	Y/N/NA	Reference	Question
83		5.4.2.6	Does the data integrity system include: 1) data integrity training 2) signed data integrity documentation for all laboratory employees 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation?
84		5.4.2.6	Are the data integrity procedures & the associated implementation records properly maintained & made available for assessor review?
85		5.4.2.6	Are the data integrity procedures annually reviewed & updated by management?
86		5.4.2.6	Are the data integrity procedures signed & dated by senior management?
87		5.4.2.6.1	Does laboratory management provide a mechanism for confidential reporting of data integrity issues in their laboratory?
88		5.4.2.6.2	In instances of ethical concern, does the mechanism include a process whereby laboratory management are to be informed of the need for any further detailed investigation?
88		5.4.2.6.2	In instances of ethical concern, does the mechanism include a process whereby laboratory management are to be informed of the need for any further detailed investigation?
227		5.4.15	Does the laboratory, as part of their overall internal auditing program, insure that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity?
228		5.4.15	Is discovery of potential issues handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified?
260		5.5.2.7	Is data integrity training provided as a formal part of new employee is it provided on an annual basis for all current employees?
261		5.5.2.7	Are topics covered documented in writing and provided to all trainees?
262		5.5.2.7	Do key topics covered during training include 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?
263		5.5.2.7	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?
264		5.5.2.7	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?
265		5.5.2.7	Do senior managers acknowledge their support of these procedures by: ___Upholding the spirit and intent of the organization's data integrity procedures? ___Effectively implementing the specific requirements of the procedures?
266		5.5.2.7	Are specific examples of breaches of ethical behavior discussed including improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards?
267		5.5.2.7	Does training include discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring and data integrity procedure documentation?
268		5.5.2.7	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?

Demonstration of Capability

246		5.5.2.5	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?
247		5.5.2.5	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?
248		5.5.2.5	Are the records readily available and do they include the date on which authorization and/or competence is confirmed?

	Y/N/NA	Reference	Question
249		5.5.2.5	Do the records include demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.5.4.2.2 for chemical testing?
250		5.5.2.5	Are records on the relevant qualifications, training, skills and experience of the technical personnel maintained by the laboratory?
251		5.5.2.6.a	Does laboratory management define 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?
252		5.5.2.6.b	Does laboratory management ensure that all technical laboratory staff have demonstrated capability in the activities for which they are responsible? Such demonstration shall be documented. (See Appendix C);
253		5.5.2.6.c.1	Does laboratory management maintain documentation 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?
254		5.5.2.6.c.2	Does laboratory management provide for and document training courses or workshops on specific equipment, analytical techniques or laboratory procedures?
255		5.5.2.6.c.3	Does laboratory management ensure that the 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, 5.4.2.3.d) and documentation of continued proficiency by at least one of the following once per year: ___Acceptable performance of a blind sample (single blind to the analyst)? ___An initial measurement system evaluation or another demonstration of capability? ___At least four consecutive laboratory control samples with acceptable levels of precision and accuracy? ___If these cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst?

Document Control

89		5.4.3.1	Does the laboratory have procedures to control all documents that form part of the laboratory's quality system?
90		5.4.3.2.1	Are all documents issued to personnel in the laboratory as part of the quality system reviewed and approved for use by authorized personnel prior to use?
91		5.4.3.2.1	Is there an established master list or equivalent document control procedure identifying the current revision status & distribution of documents in the quality system?
92		5.4.3.2.1	Are the master lists or document control procedures readily available to preclude the use of invalid and/or obsolete documents?
93		5.4.3.2.2.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?
94		5.4.3.2.2.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?
95		5.4.3.2.2.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?
96		5.4.3.2.2.d	Does the document control procedure(s) adopted ensure that obsolete documents retained for either legal or knowledge presentation purposes are suitable marked?
97		5.4.3.2.3	Are quality system documents generated by the laboratory uniquely identified and does such 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)?
98		5.4.3.3.1	Do the designated personnel have access to pertinent background information upon which to base their review and approval?
99		5.4.3.3.1	Are changes to documents reviewed and approved by the same function that performed the original review, unless specifically designated otherwise?
100		5.4.3.3.2	Where practicable, is altered or new text identified in the document or the appropriate attachments?

	Y/N/NA	Reference	Question
101		5.4.3.3.3	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?
102		5.4.3.3.3	Are amendments to documents clearly marked, initialed and dated?
103		5.4.3.3.3	Is a revised document formally re-issued as soon as practicable?
104		5.4.3.3.4	Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?
Facilities			
283		5.5.3.6.a-e	Do work areas provide the following: ___Access and entryways to the laboratory? ___Sample receipt area(s)? ___Sample storage area(s)? ___Chemical and waste storage area(s)? and, ___Data handling and storage area(s)?
Internal Audits			
42		5.4.1.5.i.6	Does the quality manager (and/or his/her designees) arrange for or conduct internal audits as per 5.4.13 annually; and
211		5.4.13.1	Does the laboratory periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard?
212		5.4.13.1	Does the internal audit program address all elements of the quality, including the environmental testing activities?
213		5.4.13.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's environmental test results, does the laboratory take timely corrective action, and notify clients in writing if investigations show that the laboratory results may have been affected?
214		5.4.13.2	Does the laboratory specify in its Quality Manual the time frame for notifying a client of events that cast doubt on the validity of the test results?
215		5.4.13.1	Are such audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited?
216		5.4.13.1	Do personnel not audit their own activities except when it can be demonstrated that an effective audit will be carried out?
217		5.4.13.1	Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management?
218		5.4.13.2	Does the laboratory notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or test certificate or amendment to a report or certificate?
219		5.4.13.3	Is the area of activity audited, the audit findings and corrective actions that arise from them recorded?
220		5.4.13.3	Does the laboratory management ensure that corrective actions are discharged within the appropriate & agreed time frame as indicated in the quality manual and/or SOP's?
221		5.4.13.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?
227		5.4.15	Does the laboratory, as part of their overall internal auditing program, insure that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity?
228		5.4.15	Is discovery of potential issues handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified?
229		5.4.15	Is all documentation of these investigation and actions taken maintained for at least five years?
230		5.4.15	Does documentation of the investigations include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients?

	Y/N/NA	Reference	Question
231		5.4.15	Are all investigations that result in finding of inappropriate activity documented?
Management Review			
222		5.4.14.1	In accordance with a predetermined schedule and procedure, does the laboratory's executive management periodically and at least annually conduct a review of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and introduce necessary changes or improvements?
223		5.4.14.1.a-j	Does the management 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 interlaboratory comparisons or proficiency tests? ___Changes in the volume and type of the work? ___Client feedback? ___Complaints? ___Other relevant factors, such as quality control activities, resources and staff training?
224		5.4.14.2	Does management ensure that those actions are carried out within an appropriate and agreed timescale?
225		5.4.14.2	Does the laboratory have a procedure for review by management and does it maintain records of review findings and actions?
226		5.4.14.2	Are findings from management reviews and the actions that arise from them recorded?
Nonconforming Work			
137		5.4.9.1	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?
138		5.4.9.1	Do the policy and procedures 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, as necessary) are defined and taken when nonconforming work is identified?
139		5.4.9.1.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?
140		5.4.9.1.b	Do the policy and procedures for nonconforming work ensure that an evaluation of the significance of the nonconforming work is made?
141		5.4.9.1.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?
142		5.4.9.1.d	Do the policy and procedures for nonconforming work ensure that where the data quality is or may be impacted, the client is notified and the work may be recalled?
143		5.4.9.1.e	Do the policy and procedures for nonconforming work ensure that the responsibility for authorizing the resumption of work is defined?
144		5.4.9.2	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 5.4.10 promptly followed?
Non-standard Methods			
330		5.5.4.4	Does this agreement include a clear specification of the client's requirements and the purpose of the environmental test?
Organization			
1		5.0	Does the laboratory have all items identified in NELAC Chapter 5 Quality Systems available for on-site inspection or data audit?
17		5.4.1.1	Is the laboratory, or organization of which it is part, an entity that can be held legally responsible?

	Y/N/NA	Reference	Question
18		5.4.1.2	Does the laboratory carry out its environmental testing activities in such a way as to meet the requirements of the NELAC Standard and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition?
19		5.4.1.3	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?
20		5.4.1.4	If the laboratory is part of an organization performing activities other than environmental testing, are the responsibilities of key personnel in the organization defined in order to identify potential conflicts of interest?
21		5.4.1.4.a	Where a laboratory is part of a larger organization, are the organizational arrangements 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 Standard?
22		5.4.1.4.b	Is the laboratory 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?
23		5.4.1.4.b	Does the laboratory not engage in any activities that may endanger the trust in its independence of judgment & integrity in relation to its environmental testing activities?
24		5.4.1.5.a	Does the laboratory managerial and technical personnel have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from procedures for performing environmental tests, and to initiate actions to prevent or minimize such departures?
25		5.4.1.5.b	Does the laboratory have processes to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?
26		5.4.1.5.c	Does the laboratory have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?
27		5.4.1.5.d	Does the laboratory avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?
28		5.4.1.5.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?
29		5.4.1.5.f	Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the environmental tests and/or calibrations?
30		5.4.1.5.f	Does documentation include a clear description of the lines of responsibility in the laboratory and are proportioned such that adequate supervision is ensured?
31		5.4.1.5.g	Does the laboratory provide adequate supervision of environmental testing staff, including trainees, by persons familiar with methods and procedures, purpose of each environmental test, and with the assessment of the environmental test results?
32		5.4.1.5.h	Does the technical management, which has overall responsibility for the technical operations and the provision of the resources needed, ensure the required quality of laboratory operations?
Personnel			
29		5.4.1.5.f	Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the environmental tests and/or calibrations?
30		5.4.1.5.f	Does documentation include a clear description of the lines of responsibility in the laboratory and are proportioned such that adequate supervision is ensured?
33		5.4.1.5.h	Does the technical director(s), however named, certify that personnel with appropriate education and/or technical background perform all tests for which the laboratory is accredited?
34		5.4.1.5.h	Is the personnel education and technical background documented?
44		5.4.1.5.j	Does the laboratory appoint deputies for key managerial personnel including the technical director(s) and/or quality manager?
234		5.5.2.1	Does laboratory management ensure the competence of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports?

	Y/N/NA	Reference	Question
240		5.5.2.2	Does the management formulate goals with respect to the education, training and skills of the laboratory personnel?
241		5.5.2.2	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?
242		5.5.2.2	Is the training program relevant to the present and anticipated tasks of the laboratory?
243		5.5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory?
244		5.5.2.3	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?
245		5.5.2.4	Does the laboratory maintain current job descriptions for all personnel who manage, perform, or verify work affecting the quality of the environmental tests?
Preventative Actions			
157		5.4.11.1	Are needed improvements and potential sources of nonconformance, either technical or concerning the quality system, identified?
158		5.4.11.1	If preventative action is required, are action plans developed, implemented, & monitored to reduce the occurrence of nonconformances & to take advantage of opportunities for improvement?
159		5.4.11.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?
Proficiency Testing			
3		2.5	Do the laboratory's management and all analysts ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis as evidenced by the following points? NOTE: The AA must make a documented determination when exceptions to any of these requirements are applicable on the basis of the laboratory's routine environmental sample composition and SOPs. PT samples are entered into Lab's sample receipt log (Sample tracking may be initiated by laboratory personnel).
12		2.5.1.a	Does the laboratory not send any PT sample, or portion of a PT sample, to another laboratory for any analysis for which the laboratory seeks accreditation or is accredited?
13		2.5.1.b	Does the laboratory not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited?
14		2.5.1.c	Does the laboratory management and staff not communicate with any individual at another laboratory (including intralaboratory communication) concerning PT sample?
16		2.5.2	Does the laboratory maintain copies of all written, printed and electronic records resulting from the analysis of any PT sample for 5 years or for as long as is required by the applicable regulatory program, whichever is greater?
45		5.4.1.5.k	For purposes of qualifying for and maintaining accreditation, does each laboratory participate in a proficiency test program as outlined in Chapter 2?
Purchasing (Services & Supplies)			
49		5.4.2.2	Are the laboratory's quality system policy and objectives defined in a quality manual?
125		5.4.6.1	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?
126		5.4.6.1	Do procedures exist for the purchase, reception, & storage of reagents & consumable materials relevant for the environmental tests?
127		5.4.6.2	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?

	Y/N/NA	Reference	Question
128		5.4.6.2	Does the laboratory ensure that supplies & services comply with specified requirements?
129		5.4.6.2	Does the laboratory maintain records of actions taken to check compliance with these requirements?
130		5.4.6.3	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered?
131		5.4.6.3	Are these purchasing documents reviewed & approved for technical content prior to release?
132		5.4.6.4	Does the laboratory maintain records of these evaluations and list those (suppliers) approved?
133		5.4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies and services which affect the quality of environmental testing?
QC			
156		5.4.10.6.b	Does the laboratory report samples with the appropriate laboratory defined data qualifier(s) when a quality control measure associated with that sample analysis was found to be out of control and the data is to be reported?
485		5.5.9.1	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?
487		5.5.9.2.a.1	Does the laboratory have detailed written protocols in place to monitor positive and negative controls to monitor tests such as blanks, spikes, reference toxicants?
488		5.5.9.2.a.2	Does the laboratory have detailed written protocols in place to monitor tests to define the variability and/or repeatability of the laboratory results such as replicates?
489		5.5.9.2.a.3	Does the laboratory have detailed written protocols in place to monitor 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?
490		5.5.9.2.a.4	Does the laboratory have detailed written protocols in place to monitor measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability such as linearity?
491		5.5.9.2.a.5	Does the laboratory have detailed written protocols in place to monitor selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses?
492		5.5.9.2.a.6	Does the laboratory have detailed written protocols in place to monitor selection and use of reagents and standards of appropriate quality?
493		5.5.9.2.a.7	Does the laboratory have detailed written protocols in place to monitor measures to assure the selectivity of the test for its intended purpose
494		5.5.9.2.a.8	Does the laboratory have detailed written protocols in place to monitor 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?
496		5.5.9.2.b	Are all quality control measures assessed and evaluated on an on-going basis?
500		5.5.9.2.d	When it is not apparent which is more stringent is the QC in the mandated method or regulations followed?
559		Appendix D	Are quality control acceptance criteria used to determine the validity of the data?
Quality Manager			
36		5.4.1.5.i	Is a member of staff appointed as quality manager (however named) who, irrespective of other duties and responsibilities appointed to have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times and have direct access to the highest level of management at which decisions are made on laboratory policy or resources?
37		5.4.1.5.i.1	Does the quality manager (and/or his/her designees) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;

	Y/N/NA	Reference	Question
38		5.4.1.5.i.2	Does the quality manager (and/or his/her designees) have functions independent from laboratory operations for which they can have quality assurance oversight;
39		5.4.1.5.i.3	Does the quality manager (and/or his/her designees) able to evaluate data objectively and perform assessments with outside (e.g., managerial) influence;
40		5.4.1.5.i.4	Does the quality manager (and/or his/her designees) have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC;
41		5.4.1.5.i.5	Does the quality manager (and/or his/her designees) have a general knowledge of the analytical test methods for which data review is performed;
42		5.4.1.5.i.6	Does the quality manager (and/or his/her designees) arrange for or conduct internal audits as per 5.4.13 annually; and
43		5.4.1.5.i.7	Does the quality manager (and/or his/her designees) notify laboratory management of deficiencies in the quality system and monitor corrective action.
Quality Manual			
49		5.4.2.2	Are the laboratory's quality system policy and objectives defined in a quality manual?
56		5.4.2.3	Does the quality manual, and related quality documentation, state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard?
57		5.4.2.3	When the laboratory's quality manual does not contain the necessary requirements, are these requirements addressed elsewhere in separate SOP's or policy documents?
58		5.4.2.3	Does the quality manual list on the title page: ___ Document title? ___The laboratory's full name and address? ___The name, address (if different from above), and telephone number of individual(s) responsible for the laboratory? ___The name of the quality manager (however named); the identification of all major organizational units which are to be covered by this quality manual and the effective date of the version?
59		5.4.2.3	Does the quality manual include or make reference to the supporting procedures including technical procedures and does it outline the structure of the documentation used in the quality system?
60		5.4.2.3.a-c	Does the quality manual and related quality documentation include or reference: ___A quality policy statement, including objectives and commitments, by top management (see 5.4.2.2)? ___The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts? ___The relationship between management, technical operations, support services and the quality system?
61		5.4.2.3.d	Does the quality manual and related quality documentation include or reference procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a document control system which ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force?
62		5.4.2.3.e	Does the quality manual and related quality documentation include or reference job descriptions of key staff and reference to the job descriptions of other staff?
63		5.4.2.3.f	Does the quality manual and related quality documentation include identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed and dated concurrence, (with appropriate title(s) of all responsible parties including the quality manager(s), technical director(s), and the agent who is in charge of all laboratory activities such as the laboratory director or laboratory manager?
64		5.4.2.3.g	Does the quality manual and related quality documentation include or reference the laboratory's procedures for achieving traceability of measurements?
65		5.4.2.3.h	Does the quality manual and related quality documentation include or reference a list of all test methods under which the laboratory performs its accredited testing?
66		5.4.2.3.i	Does the quality manual and related quality documentation include or reference mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

	Y/N/NA	Reference	Question
67		5.4.2.3.j	Does the quality manual and related quality documentation include reference to calibration and/or verification test procedure used?
68		5.4.2.3.k	Does the quality manual and related quality documentation include or reference procedures for handling submitted samples?
69		5.4.2.3.l	Does the quality manual and related quality documentation include or reference the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests?
70		5.4.2.3.m	Does the quality manual and related quality documentation include or make reference to calibration and/or verification test procedure used?
71		5.4.2.3.n	Does the quality manual and related quality documentation include or make reference to verification practices which may include interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes?
72		5.4.2.3.o	Does the quality manual and related quality documentation include or reference procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur?
73		5.4.2.3.p	Does the quality manual and related quality documentation include or reference the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications?
74		5.4.2.3.q	Does the quality manual and related quality documentation include or reference procedures for dealing with complaints?
75		5.4.2.3.r	Does the quality manual and related quality documentation include or reference procedures for protecting confidentiality (including national security concerns), and proprietary rights?
76		5.4.2.3.s	Does the quality manual and related quality documentation include or reference procedures for audits and data review?
77		5.4.2.3.t	Does the quality manual and related quality documentation include or reference processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training?
78		5.4.2.3.u	Does the quality manual and related quality documentation include or make reference to procedures for reporting analytical results?
79		5.4.2.3.v	Does the quality manual and related quality documentation include a Table of Contents, and applicable lists of references and glossaries, and appendices?
80		5.4.2.4	Does the quality manual define the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this Standard?
81		5.4.2.5	Does the quality manager maintain the current quality manual?
Quality Policy			
50		5.4.2.2	Are the overall objectives documented in a quality policy statement, issued under the authority of the chief executive?
51		5.4.2.2.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; The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.
52		5.4.2.2.b	Does the quality policy include the management's statement of the laboratory's standard of service;
53		5.4.2.2.c	Does the quality policy include the objectives of the quality system; The laboratory management shall ensure that these policies and objectives are documented in a quality manual?
54		5.4.2.2.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; and
55		5.4.2.2.e	Does the quality policy include the laboratory management's commitment to compliance with this Standard?
Quality System			
46		5.4.2.1	Has the laboratory established, implemented, & maintained a quality system, based on the required elements for NELAC Chapter 5, that is appropriate to the type, range, & volume of environmental testing activities it undertakes?
47		5.4.2.1	Does the laboratory document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the environmental test results?

	Y/N/NA	Reference	Question
48		5.4.2.1	Is the quality system documentation communicated to, understood by, available to, & implemented by the appropriate personnel?
Records			
160		5.4.12	Does the laboratory retain all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of five years?
161		5.4.12	Does the laboratory maintain a record system to suit its particular circumstances and comply with any applicable regulations?
162		5.4.12	Does the record system produce unequivocal, accurate records which document all laboratory activities?
163		5.4.12	If the laboratory's clients specify that a sample will be used for evidentiary purposes, does the laboratory have a written SOP for how it will carry out legal chain of custody (for example, ASTM D 4840- 95 and Manual for the Certification of Laboratories Analyzing Drinking Water, March 1997, Appendix A)?
164		5.4.12.1.1	Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records?
165		5.4.12.1.1	Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions? (Records may be in any media, such as hard copy or electronic media).
166		5.4.12.1.2	Are all records legible?
167		5.4.12.1.2	Are all records retained in such a way that they are readily retrievable?
168		5.4.12.1.2	Are all records stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?
169		5.4.12.1.2	Has retention times of records been established?
170		5.4.12.1.3	Are all records held secure and in confidence?
172		5.4.12.1.5	Does the record keeping system allow historical reconstruction of all laboratory activities that produced the analytical data?
174		5.4.12.1.5.a	Do the records include the identity of personnel involved in sampling, sample receipt, preparation, or testing?
175		5.4.12.1.5.b	Is all information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification documented?
176		5.4.12.1.5.c	Does the record keeping system facilitate the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files?
177		5.4.12.1.5.d	Are all changes to records signed or initialed by responsible staff?
178		5.4.12.1.5.d	Is the reason for the signature or initials clearly indicated in the records such as "sampled by," "prepared by," or "reviewed by"?
180		5.4.12.1.5.f	Are entries in records changed so as not to be obliterated by methods such as erasures, overwritten files or markings?
181		5.4.12.1.5.f	Are all corrections to record-keeping errors made by one line marked through the error?
183		5.4.12.1.5.f	Does the individual making the correction sign (or initial) and date the correction?
194		5.4.12.2.4.a	Are all records (including those pertaining to test equipment), certificates and reports safely stored, held secure and in confidence to the client?
195		5.4.12.2.4.a	Are all NELAP-related records available to the accrediting authority?
196		5.4.12.2.4.b	Are all records, including those specified in 5.4.12.2.5 retained for a minimum of five years from generation of the last entry in the records?
197		5.4.12.2.4.b	Is all information necessary for the historical reconstruction of data maintained by the laboratory?
200		5.4.12.2.4.d	Has the laboratory established a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting?

	Y/N/NA	Reference	Question
201		5.4.12.2.4.e	Is access to archived information documented with an access log?
202		5.4.12.2.4.e	Are records protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources?
203		5.4.12.2.4.f	Does the laboratory have a plan to ensure that the records are maintained or transferred according to the clients' instructions (see 4.1.8.e) in the event that a laboratory transfers ownership or goes out of business? (In cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed.)
204		5.4.12.2.5.1.a	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to sample preservation including appropriateness of sample container and compliance with holding time requirement?
205		5.4.12.2.5.1.b	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to sample identification, receipt, acceptance or rejection and log-in?
206		5.4.12.2.5.1.c	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to sample storage and tracking including shipping receipts, sample transmittal forms, (chain of custody form);
207		5.4.12.2.5.1.d	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to the receipt and retention of samples, including all provisions necessary to protect the integrity of samples?
208		5.4.12.2.5.2.a-h	In addition to documenting all the above-mentioned activities, are the following retained: ___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); ___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? ___Copies of final reports? ___Archived SOPs? ___Correspondence relating to laboratory activities for a specific project? ___All corrective action reports, audits and audit responses? ___Proficiency test results and raw data? and, ___Results of data review, verification, and cross-checking procedures?
210		5.4.12.2.5.4.a-c	Are the following administrative records maintained; Personnel qualifications, experience and training records and Records of demonstration of capability for each analyst and A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record?
Records-Electronic			
171		5.4.12.1.4	Does the laboratory have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of records stored electronically?
182		5.4.12.1.5.f	Is the individual making the change to electronically maintained records identified?
182		5.4.12.1.5.f	Is the individual making the change to electronically maintained records identified?
184		5.4.12.1.5.f	Are entries to electronically maintained records changed so as to not erase or overwrite the files?
184		5.4.12.1.5.f	Are entries to electronically maintained records changed so as to not erase or overwrite the files?
184		5.4.12.1.5.f	Are entries to electronically maintained records changed so as to not erase or overwrite the files?
198		5.4.12.2.4.b	Are records which are stored only on electronic media supported by the hardware and software necessary for their retrieval?
Reporting/Reports			
259		5.5.2.6.g	Does laboratory management document the quality of all data reported?
501		5.5.10.1	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?
502		5.5.10.1	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?

	Y/N/NA	Reference	Question
503		5.5.10.1	Is any information listed in 5.5.10.2 to 5.5.10.4 which is not reported to the client readily available in the laboratory which carried out the environmental tests results?
504		5.5.10.1	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?
505		5.5.10.1	Are the results reported in a test report that includes all the information requested by the client and necessary for the interpretation of the environmental test results, and all information required by the method used?
506		5.5.10.1	Does the laboratory, if it is operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (in-house or captive laboratories) have all applicable information specified in 5.5.10.2.a-m readily available for review by the accrediting authority?
507		5.5.10.1	Does the facility management ensure that the appropriate report items are in the report to the regulatory authority if such information is required?
508		5.5.10.2.a-e	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? ___A title (e.g. "Test Report," "Certificate of Results," or "Laboratory Results")? ___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? ___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? ___The name an address of the client and project name on the test reports? ___Identification of the method used?
509		5.5.10.2.f	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? A description of, and unambiguous identification of the sample(s), including the client identification code?
510		5.5.10.2.g	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? The date of receipt of the sample(s) where this is critical to the validity and application of the results, date and time of sample collection, the date(s) of performance of the environmental test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours?
511		5.5.10.2.h	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? 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?
512		5.5.10.2.i	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? The environmental test results with, where appropriate, the units of measurement, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting until such as ug/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;
513		5.5.10.2.j	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? The name(s), function(s) and signatures or equivalent electronic identification of person(s) authorizing the test report, and date of issue?
514		5.5.10.2.k	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? A statement to the effect that the results relate only to the samples?

	Y/N/NA	Reference	Question
515		5.5.10.2.l	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory?
516		5.5.10.2.m	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? Laboratories accredited to be in compliance with these standards shall certify that the test results meet all requirements of NELAC or provides reasons and/or justification if they do not?
517		5.5.10.3.1.a-f	Where it is necessary for the interpretation of the test results, does the test report also include the following: ___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? ___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? ___Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed when a client's instruction so requires? ___Where appropriate and needed, opinions and interpretations? ___Additional information which may be required by specific methods, clients or groups of clients? ___Qualification of numerical results with values outside of the working limits?
518		5.5.10.3.2.a-f	Do test reports containing the results of sampling include the following, where necessary for the interpretation of test results: ___The date of sampling? ___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); ___The location of sampling, including any diagrams, sketches or photographs? ___A reference to the sampling plan and procedures used? ___Details of any environmental conditions during sampling that may affect the interpretation of the test results? ___Any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned?
519		5.5.10.4	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made?
520		5.5.10.4	Are opinions and interpretations clearly marked as such in a test report?
521		5.5.10.5	Does the subcontractor report the results either in writing or electronically?
522		5.5.10.5	Does the laboratory make a copy of the subcontractor's report available to the client when requested by the client?
523		5.5.10.5	When the test report contains results of tests performed by subcontractors, are these results clearly identified by subcontractor name or applicable accreditation number?
524		5.5.10.6	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
525		5.5.10.7	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?
526		5.5.10.8	Are material amendments to a test report after issue made only in the form of a further document, or data transfer, which includes the statement "Supplement to Test Report, serial number ... [or as otherwise identified]", or an equivalent form of wording?
527		5.5.10.8	Do such test report amendments meet all the requirements of this Standard?
528		5.5.10.8	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?

Requests, Tenders, & Contracts

105		5.4.4.1	Has the laboratory established and maintained procedures for the review of requests, tenders and contracts?

	Y/N/NA	Reference	Question
106		5.4.4.1.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?
107		5.4.4.1.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?
108		5.4.4.1.b	Is the current accreditation status of the laboratory reviewed?
109		5.4.4.1.b	Does the laboratory inform the client of the results of the capability review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work?
110		5.4.4.1.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?
111		5.4.4.1	Are any differences between the request or tender & the contract resolved before any work commences?
112		5.4.4.2	Are records of reviews, including any significant changes maintained? 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.
113		5.4.4.2	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? 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.
114		5.4.4.3	Does the review cover any work that is subcontracted by the laboratory?
115		5.4.4.4	Is the client informed of any deviation from the contract?
116		5.4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated?
117		5.4.4.5	Are any contract amendments communicated to all affected personnel?
118		5.4.4.5	If a contract needs to be amended after work has commenced, does the laboratory report any suspensions, revocations, or voluntary withdrawals of accreditation to the client?
308		5.5.4.2.1.c	Is the client informed as to the method chosen?
309		5.5.4.2.1.d	Does the laboratory inform the client when the method proposed by the client is considered to be inappropriate or out of date?

Sample Receiving

258		5.5.2.6.f	Does laboratory management ensure that all sample acceptance criteria (Section 5.5.8) are verified and that samples are logged into the sample tracking system and properly labeled and stored?
440		5.5.8.1	Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of samples, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the client? ___Handling? ___Protection? ___Storage? ___Retention and/or disposal of samples, including all provisions necessary to protect the integrity of the sample?
444		5.5.8.2	Does the sample identification system, if appropriate, accommodate a sub-division of groups of samples and the transfer of samples within and from the laboratory?

	Y/N/NA	Reference	Question
445		5.5.8.2.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?
447		5.5.8.2.a	Does the laboratory assign a unique identification (ID) code to each sample container received in the laboratory? Note: 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?
448		5.5.8.2.b	Does the laboratory sample code maintain an unequivocal link with the unique field ID code assigned each container?
450		5.5.8.2.d	Is the laboratory ID code entered into the laboratory records and is it the link that associates the sample with related laboratory activities such as sample preparation?
451		5.5.8.3	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?
452		5.5.8.3	Does the laboratory consult with the client for further instruction when there is doubt as to the suitability of a sample for environmental test, or when a sample does not conform to the description provided, or the environmental test or calibration required is not specified in sufficient detail?
453		5.5.8.3	Are such discussions with the client (on suitability of the sample for testing) recorded?
454		5.5.8.3.1.a.1	Are all samples which require thermal preservation accepted only if the arrival temperature is either within 2°C of the required temperature or the method specified range or 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? Note: Samples that are hand delivered to the laboratory on the same day that they are collected 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.
456		5.5.8.3.1.a.3.i-iii	When the following conditions are not met, does the laboratory perform a chlorine residual check on microbiological samples from chlorinated water systems: ___Sufficient sodium thiosulfate is added to each container to neutralize at minimum 5 mg/l of chlorine for drinking water and 15mg/l of chlorine for wastewater samples ___One container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15mg/l chlorine as appropriate and the check is documented ___Chlorine residual is checked in the field and actual concentration is documented with sample submission?
458		5.5.8.3.1.c.1-2	If the sample does not meet the sample receipt acceptance criteria, does the laboratory either: ___Retain correspondence and/or records of conversations concerning the final disposition of rejected samples or ___Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria by noting the condition of these samples on the chain of custody or transmittal form and laboratory receipt documents or adding a qualifier to the analysis data on the final report?
459		5.5.8.3.1.d	Does the laboratory utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers?
460		5.5.8.3.1.d.1.i-iv	Is the sample receipt log used to record the following: ___Client/project name? ___Date and time of laboratory receipt? ___Unique laboratory ID code? ___Signature or initials of the person making the entries? Note: The placement of the laboratory ID number on the sample container is not considered a permanent record. (5.5.8.3.1.d.2)
461		5.5.8.3.1.d.2	During the log-in process, is sample collection information unequivocally linked to the log record or included as a part of the log?
462		5.5.8.3.1.d.2	If sample collection information is recorded/documented elsewhere, are the records a part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample?
463		5.5.8.3.1.d.2.i	Is the field ID code which identifies each container linked to the laboratory ID code in the sample receipt log?
464		5.5.8.3.1.d.2.ii	Are the date and time of sample collection linked to the sample container and to the date and time receipt in the laboratory
465		5.5.8.3.1.d.2.iii	Is the requested analyses (including applicable approved test method numbers) linked to the laboratory ID code?

	Y/N/NA	Reference	Question
466		5.5.8.3.1.d.2.iv	Are any comments resulting from inspection for sample rejection linked to the laboratory ID code?
467		5.5.8.3.1.e	Is all documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter retained?
468		5.5.8.3.1.f	If chain of custody procedures are used, is a complete chain of custody record form maintained?
469		5.5.8.3.2	Does the laboratory have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected?
470		5.5.8.3.2	Is this sample acceptance policy available to sample collection personnel?
471		5.5.8.3.2	Are data from any samples which does not meet the sample acceptance criteria flagged in an unambiguous manner clearly defining the nature and substance of the variation?
472		5.5.8.3.2	Does this sample policy at least include: ___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 and ___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 and ___Use of appropriate sample containers and ___Adherence to specified holding times and ___Adequate sample volume to perform the necessary tests and ___Procedures to be used when samples show signs of damage, contamination or inadequate preservation?
Samples			
430		5.5.7.1	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?
431		5.5.7.1	Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken?
432		5.5.7.1	Are sampling plans, whenever reasonable, based on appropriate statistical methods?
433		5.5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the environmental test and calibration results?
435		5.5.7.2	Are client required deviations, additions or exclusions from the documented sampling procedure, recorded in detail with the appropriate sampling data?
436		5.5.7.2	Are client required deviations included in all documents containing environmental test results?
437		5.5.7.2	Are any required deviations, additions, or exclusions (to sampling plans) communicated to the appropriate personnel?
438		5.5.7.3	Do the records include: ___The sampling procedure used? ___The identification of the sampler? ___The environmental conditions (if relevant)? Diagrams or other equivalent means to identify the sampling location (as necessary)? ___The statistics the sampling procedures are based upon; (if appropriate)?
439		5.5.7.3	Does the laboratory have procedures for recording data and operations relevant to sampling that forms part of the environmental testing that is undertaken?
483		5.5.8.4.b.1	Does the laboratory have SOPs for the disposal of samples, digestates, Leachates and extracts or other sample preparation products?
SOP			
256		5.5.2.6.d	Does laboratory management document all analytical and operational activities of the laboratory?
284		5.5.4.1	Does the laboratory use appropriate methods and procedures for all environmental tests and/or calibrations within its scope?
286		5.5.4.1	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?

	Y/N/NA	Reference	Question
287		5.5.4.1	Do deviations from environmental test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client?
288		5.5.4.1.1	Does the laboratory maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods?
289		5.5.4.1.1.b	If the test methods are copies of published methods are any changes or selected options in the methods are documented and included in the methods manual?
290		5.5.4.1.1.c	Are copies of all SOPs accessible to all personnel?
291		5.5.4.1.1.d	Are the SOPs organized?
292		5.5.4.1.1.e	Does each SOP clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority?
Subcontracting			
119		5.4.5.1	Does the laboratory submit any subcontract work for testing covered under NELAP only to a laboratory accredited under NELAP for the tests to be performed or one that meets applicable statutory & regulatory requirements for performing the tests & submitting the results of tests performed.
120		5.4.5.1	When a laboratory subcontracts work, does the laboratory clearly identify in final reports non-NELAP accredited work?
121		5.4.5.1	Is the laboratory performing the subcontracted work indicated in the final report and non-NELAP accredited work clearly identified?
122		5.4.5.2	Does the laboratory advise the client of the subcontracting arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing?
123		5.4.5.3	Is the laboratory responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used?
124		5.4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for environmental tests and maintain a record of the evidence of compliance with 5.4.5.1?
Supervision			
31		5.4.1.5.g	Does the laboratory provide adequate supervision of environmental testing staff, including trainees, by persons familiar with methods and procedures, purpose of each environmental test, and with the assessment of the environmental test results?
257		5.5.2.6.e	Does laboratory management supervise all personnel employed by the laboratory?
Technical Director			
35		5.4.1.5.h	Do the technical director(s) meet the requirements specified in the Accreditation Process? (see 4.1.1.1)
Traceability			
412		5.5.6.2.2	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?
413		5.5.6.3.1	Does the laboratory have a program and procedure for the calibration of its reference standards?
415		5.5.6.3.1	Are reference standards calibrated before and after any adjustment?
Training			
40		5.4.1.5.i.4	Does the quality manager (and/or his/her designees) have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC;
41		5.4.1.5.i.5	Does the quality manager (and/or his/her designees) have a general knowledge of the analytical test methods for which data review is performed;
48		5.4.2.1	Is the quality system documentation communicated to, understood by, available to, & implemented by the appropriate personnel?

Y/N/NA	Reference	Question

Additional Comments: