NYSDOH ELAP Quality Systems Checklist

This checklist incorporates references to both 'The NELAC Institute' 2003 and 2009 Standards, **where applicable**.

Directions: Place a mark (e.g., /, √ or X) in the appropriate column (Yes (Y), No (N), or Not Applicable (N/A)). If it is an observation on areas for possible improvement, place a "S" for suggestion under the "N" column. In database, use code "SGST."

Lab ID: _____ Assessment ID: _____

Lab Name: _____

If the information on the "Lab Pre-Assessment Report" is NOT accurate, note the changes that need to be made below. In addition, the lab will need to formally request the change using Application Form 107.

Address (Mailing): _____

Address (Physical Location): _____

Telephone: _____ E-mail: _____

Personnel Interviewed:

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

_____ _____ _____

At the time of the assessment, a question marked 'yes' indicates that no evidence of a deficiency was observed.

Assessment Date(s):_____ Assessor (Signature): _____

Areas Assessed (Check only the applicable areas. Specific methods and data reviewed are to be listed/noted on the checklists.):

___ Quality System ___ Organic Chemistry ___ Inorganic/Wet Chemistry ___ Radon ___ Radiochemistry ___ Asbestos/Fibers
___ Microbiology ___ ADS ___ Critical Agents

If method specific checklist(s) was(were) used, indicate its(their) title(s) and revision number(s) (e.g., Radon CRM, PCM, BOD/CBOD).

_____

If this was a team assessment and you were the Lead Assessor, indicate the name(s) of your team member(s):

_____ _____ _____

_____ _____ _____

If this was a team assessment, indicate the Lead Assessor's name. _____

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Relevant Aspect of Standards - INTRODUCTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
1. INTRODUCTION						
A. Are all items identified in quality system section of this standard available for on-site inspection or data audit?	5.0 [M2, 1.1]				**501+**	
B. If the lab is operated by the government, does the lab perform commercial testing? Per Subpart 55-3.1 (f), a governmental laboratory is defined as any laboratory operated by the federal government, a State agency, or an authority, county, city, town, village, water district, sewer district or other political subdivision of the State.	ELAP 55-3.1 and 3.3				**NA**	**For internal use**
C. Does the laboratory operate mobile facilities? Per Subpart 55-2.1 (c), mobile laboratory means a separate, self-contained mobile facility for the examination of environmental samples or specimens as described in subdivision (a) of this section. A mobile laboratory shall have a fixed address, provided to the department with each application for approval, to which proficiency test samples and other correspondence may be sent, and shall be managed by a responsible person authorized to receive service of process.	ELAP 55-2.1				**NA**	**For internal use**
LABORATORY CONDUCT DURING PROFICIENCY TESTING (PT) and PT FREQUENCY						
D. 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? a.) ___ Does the laboratory not send any PT sample, or portion of a PT sample, to another laboratory for any analysis for which it seeks accreditation, or is accredited, 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, c.) ___ Does the laboratory management & staff not communicate with any individual at another laboratory (including intralaboratory communication) concerning the PT sample, d.) ___ Does the laboratory management & staff not attempt to obtain the assigned value of any PT sample from the PT Provider, and e.) ___ Does the laboratory maintain copies of all written, printed, & 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? Note: These records include bench sheets, instrument strip charts or printouts, data calculations, data reports, & PT study report forms used by the laboratory to record PT results.	2.5, 2.5.1, and 2.5.2 [M1, 5.1.1; M1, 5.1.2 (a) – (d); and M1, 5.3.1]				**502+** **502a+** **502b+** **502c+** **502d+** **502e+**	
E. Does the laboratory perform proficiency testing **two times per year per analyte per matrix** per program from a NELAC approved provider?	5.4.1.5.k, D.1.3c, D.3.3.b [M1, 4.1.1,				**5434**	

Relevant Aspect of Standards - INTRODUCTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	4.2.1(a)]					
F. Does the laboratory satisfactorily analyze **at least one proficiency test sample per analyte per year** for **each** accredited **Potable Water** method? Refer to 40 CFR 141.23(k)(3)(i), 141.24(h)(17)(i)(A), and 141.89(a)(1)(i),	EPA SDWA				**507+**	
USE OF NELAP ACCREDITATION AND CHANGES TO CERTIFICATIONS						
G. Does the laboratory **post or display** their most recent NELAP accreditation certificate or its NELAP-accredited fields of testing in a **prominent place** in the laboratory facility?	6.8.a.1				**503**	
H. Does the laboratory make **accurate statements** concerning its NELAP accreditation fields of testing and NELAP accreditation status?	4.6.1 6.8.a.2 [M2, 5.10.11(c)]				**504**	
I. Does the laboratory accompany the accrediting authority's name and/or the NELAC/NELAP logo with **at least the phrase "NELAP accredited" and its accreditation number** when the accrediting authority's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials?	6.8.a.3				**505**	
J. Does the laboratory use its NELAP certificate, NELAP accreditation status and/or NELAC/NELAP logo in such a manner so as **not to imply endorsement** by the accrediting authority?	4.6.1 6.8.a.4				**506**	
K. If, during the on-site assessment, the laboratory indicates **withdrawal for a portion of the approved scope** is desired, has a formal request been made to the ELAP Office? (Lab will need to submit appropriate application form (i.e., 108, 109, 1977, 1978, or 1977CA).)	ELAP Forms				**508**	
L. If, during the on-site assessment, the laboratory indicates **additions be made to its scope**, has a formal request been made to the ELAP Office? (Lab will need to submit appropriate application form (i.e., 108, 109, 1977, 1978, or 1977CA).)	ELAP Forms				**508a**	
2. LABORATORY MANAGEMENT ORGANIZATION						
A. Is the laboratory, or the organization of which it is part, an entity that can be **held legally responsible**?	5.4.1.1 [M2, 4.1.1]	**X**			**542a+**	**This is confirmed by the ELAP Office upon application review (initial and renewal).**
B. Does the laboratory accept responsibility to carry out its environmental testing activities in such a way as to meet the requirements of this standard and to satisfy the needs of the client, the regulatory authorities, or organizations providing recognition?	5.4.1.2 [M2, 4.1.2]				**5412**	
C. Does the laboratory management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities?	5.4.1.3 [M2, 4.1.3]				**542**	
D. Does the laboratory have managerial staff **with the authority and resources** needed to carry	5.4.1.5.a				**543**	

Relevant Aspect of Standards - INTRODUCTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
out their duties (e.g., identify departures from the quality system, or from the procedures for performing environmental tests and initiate actions to prevent such departures from the quality system)?	[M2, 4.1.5 (a)]					
E. Does the laboratory have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity?	5.4.1.5.d [M2, 4.1.5 (d)]				**543a**	
F. Is the laboratory able to demonstrate that it is **impartial** and that it has personnel that are **free from undue commercial, financial, or other pressures** which might influence technical judgment or adversely affect the quality of their work?	5.4.1.5.b [M2,4.1.4 note 2; 4.1.5(b)]				**544**	
G. Does the laboratory not engage in any activities that may **endanger the trust in its independence of judgment and integrity** in relation to its environmental testing activities?	5.4.1.4.b [M2,4.1.4 note 2]				**545**	
H. If the laboratory is part of an organization performing activities other than environmental testing, are the responsibilities of key personnel in the organization (having an involvement or influence on the environmental testing activities of the laboratory) **defined in order to identify potential conflicts of interest**?	5.4.1.4 [M2,4.1.4]				**5414**	
I. Where a laboratory is part of a larger organization, are the organizational arrangements such that departments having conflicting interests (e.g., production, financing or commercial marketing) do not adversely influence the laboratory's compliance with the requirements of this standard?	5.4.1.4.a M2,4.1.4 note 1]				**5414a**	
J. Does the laboratory specify the responsibility, authority, and interrelationships of all personnel who manage, perform or verify work affecting the quality of tests and/or calibration?	5.4.1.5.f [M2, 4.1.5(f)]				**546**	
K. Does the documentation include a **clear description of the lines of responsibility** in the laboratory and is it proportioned such that adequate supervision is ensured?	5.4.1.5.f [M2, 4.1.5(f)]				**546a**	
L. Does the laboratory **provide adequate supervision** of testing and calibration staff, including trainees, by persons familiar with methods and procedures, the objective of each test or calibration, and the assessment of the results? Note: Refer to deficiencies in section 17 'Personnel', too.	5.4.1.5.g [M2, 4.1.5(g)]				**547**	
M. Does the laboratory have **documented certifications** that personnel with **appropriate educational and/or technical backgrounds** perform all tests for which the laboratory is accredited? Note: Refer to deficiencies in section 17 'Personnel', too.	5.4.1.5.h [M2, 5.2.1, 5.2.5]				**549**	
N. Does the laboratory have technical management who have **overall responsibility** for the	5.4.1.5.h				**5410**	

Relevant Aspect of Standards - INTRODUCTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
technical operations and the provision of resources needed to ensure the quality of laboratory operations?	[M2, 4.1.5(g)]					
O. Does the **technical director(s)** meet the personnel qualifications in the NELAC Standard? Note: ALL CASES – full-time member of the laboratory staff who exercises actual day-to-day supervision of laboratory operations & reporting of results, monitors standards of QA/QC performance, and monitors the validity of analyses performed & data generated in the laboratory to assure reliable data	5.4.1.5.h [M2, 5.2.6.1]	**For internal use**				**ELAP's Technical Staff reviews personnel applications upon receipt. Refer to pre-assessment reports for competencies. These are also reviewed during the review of the assessment package.**
P. Does the laboratory appoint a **QA officer** (however named) (and/or his/her designee(s)) who has defined responsibility and authority for ensuring that the quality system is implemented and followed at all times?	5.4.1.5.i [M2, 4.1.7.1]				**5420**	
Q. Does the **QA officer** (and/or his/her designee(s)) have direct access to the technical directors and to the highest level of management where decisions are made on laboratory policy and resources? Note: Where staffing is limited, the quality manager may also be the technical director or deputy technical director.	5.4.1.5.i [M2, 4.1.7.1]				**5421**	
R. Does the **QA officer** (and/or his/her designee(s)) serve as the focal point for QA/QC?	5.4.1.5.i.1 [M2, 4.1.7.1(a)]				**5422**	
S. Does the **QA officer** (and/or his/her designee(s)) take responsibility for the oversight and/or review of quality control data?	5.4.1.5.i.1 [M2, 4.1.7.1(a)]				**5423**	
T. Does the **QA officer** (and/or his/her designee(s)) have **functions independent** from laboratory operations for which they have QA oversight?	5.4.1.5.i.2 [M2, 4.1.7.1(b)]				**5424**	
U. Does the **QA officer** (and/or his/her designee(s)) evaluate data objectively and perform assessments without outside (e.g., managerial) influence?	5.4.1.5.i.3 [M2, 4.1.7.1(c)]				**5425**	
V. Does the **QA officer** (and/or his/her designee(s)) have documented training and/or experience in QA/QC procedures?	5.4.1.5.i.4 [M2, 4.1.7.1(d)]				**5426**	
W. Is the **QA officer** (and/or his/her designee(s)) knowledgeable in the quality system as defined in this Standard?	5.4.1.5.i.4 [M2, 4.1.7.1(d)]				**5427**	
X. Does the **QA officer** (and/or his/her designee(s)) have general knowledge of the analytical test	5.4.1.5.i.5				**5428**	

Relevant Aspect of Standards - INTRODUCTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
methods for which data review is being performed?	[M2, 4.1.7.1(e)]					
Y. Does the **QA officer** (and/or his/her designee(s)): a.) ___ arrange for or conduct **internal audits** on the entire technical operation annually, and b.) ___ notify laboratory management of deficiencies in the quality system and **monitor corrective actions** in a timely manner? Note: The QA officer needs to take responsibility to plan & organize internal audits as required by management & schedule. Refer to Section 14 'Internal Audits'.	5.4.1.5.i.6 5.4.1.5.i.7 5.4.13.1 [M2, 4.1.7.1(f)-(h); M2, 4.14.1; M2, 4.14.2]				**5429+**	
Z. Does the **QA officer** (and/or his/her designee(s)) keep the quality manual current?	5.4.2.5 [M2, 4.2.8.2]				**5431**	
AA. Does the laboratory **nominate deputies in the case of absence** of the technical director or QA officer?	5.4.1.5.j [M2, 4.1.5(j)]				**5432**	
BB. Has ELAP been notified in writing 1) **within 30 days** of a change in Technical Director or 2) **within 65 days** of a temporary leave of the Technical Director?	ELAP 55-2.6.c.1 and 55-2.10.d				**5435+**	
CC. Has ELAP been notified in writing about any **changes in key staff** (i.e., Owner, Technical Director, Lead Technical Director, QAO, ADS Operator, and Critical Agents Analyst)?	ELAP 55-2.6, 55.2-10, 55-2.11, 55-2.13, and 55-2.14				**5436+**	**Lab needs to have submitted application form 107.**

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
3. LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES						
A. Does the laboratory establish, implement, and maintain a **documented quality system** appropriate to the type, range and volume of environmental testing activities it undertakes?	5.4.2.1 [M2,4.2.1]				**551+**	
B. Does the **quality manual and related quality documentation** state the laboratory's policies and procedures established in order to meet the requirements of this Standard?	5.4.2.1 5.4.2.3 [M2,				**552**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
Note: When the laboratory quality manual contains the necessary requirements, a separate SOP or policy is not required. The laboratory's policies, programs, procedures, & instructions need to be documented to the extent necessary to assure the quality of test results.	4.2.1;M2, 4.2.8.3(h); M2, 4.2.5]					
C. Is the quality documentation **available to, understood by, and implemented by all** laboratory personnel?	5.4.2.1 [M2, 4.2.1]				**553**	
D. Is the laboratory's **quality system policies and objectives defined** in a quality manual (however named)? Note: NELAC 5.4.2.2.c requires the lab management to ensure that these policies & objectives are documented in a quality manual.	5.4.2.2 5.4.2.3.a [M2, 4.2.8.3(h); M2, 4.2.2]				**5422a**	
E. Does the **quality manual title page** list the following: a.) ___ Document title; b.) ___ Laboratory's full name and address; c.) ___ The name, signature, title, address (if different from above), and telephone number of individual(s) responsible for the laboratory; d.) ___ The name and signature of the quality assurance officer (however named); e.) ___ The identification of all major organizational units covered by this quality manual; and f.) ___ Effective date of the version? Note: NELAC 5.4.2.3.f requires identification of the laboratory's approved signatories. The title page must have signed and dated concurrence (with appropriate titles) of all responsible parties.	5.4.2.3 5.4.2.3.f [M2, 4.2.8.3(a-d,f)]				**554a** **554b** **554c** **554d** **554e** **554f**	**Please list the effective date & version number of quality manual reviewed:** **Date:** _____ **Revision/Version No.:** _____
F. Does the quality manual and related quality documentation include a **quality policy statement** with at least the following: a.) ___ laboratory management's commitment to good professional practice and to the quality of its environmental testing in servicing its clients; b.) __ management's statement of the laboratory's standard of service; c.) __ objectives of the quality system; d.) __ a requirement that all personnel familiarize themselves with the quality documentation and implement the policies and procedures in their work; and e.) __ the laboratory management's commitment to compliance with this Standard? Note: NELAC 5.4.2.2.a) requires that the laboratory define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.	5.4.2.2 a-e 5.4.2.3.a [M2, 4.2.2(a), (b), (g), (d), and (e)]				**555a** **555b** **555c** **555d** **555e**	
G. Does the **quality manual and related quality documentation** include the following: a.) ___ **table of contents**, applicable lists of references and glossaries, and appendices;	5.4.2.3.v [M2, 4.2.8.3(i)]				**5522**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
b.) ___ the organization and management structure of the laboratory, its place in any parent organization, and relevant **organizational charts**;	5.4.2.3.b 5.4.2.4 5.4.1.5.e [M2, 4.1.5(e); M2, 4.2.6; M2, 4.2.8.4(e)]				**556**	
c.) ___ an outline of the structure of the **documentation used** in the quality system;	5.4.2.3 [M2, 4.2.5]				**5423b**	
d.) ___ reference to the **supporting procedures** including technical procedures;	5.4.2.3 [M2, 4.2.5]				**5423a**	
e.) ___ procedures to ensure that all records required under this Standard are **retained**; Note: A minimum of 5 years is the retention for quality related documentation.	5.4.2.3.d [M2, 4.2.8.4.(f)]				**557**	
f.) ___ the **relationship between** management, technical operations, support services, and the quality system;	5.4.1.5.e 5.4.2.3.c [M2, 4.1.5(e)]				**557a**	
g.) ___ procedures for **control and maintenance of documentation** through a document control system which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was enforced;	5.4.2.3.d [M2, 4.2.8.4(f)]				**558**	
h.) ___ job **descriptions of key staff** and reference to the job descriptions of other staff;	5.4.2.3.e [M2, 4.2.8.4(g)]				**5423e**	
i.) ___ procedures for achieving traceability of measurements;	5.4.2.3.g [M2, 4.2.8.4(h)]				**559**	
j.) ___ **list of all methods** under which the laboratory performs its accredited testing;	5.4.2.3.h [M2, 4.2.8.4(i)]				**5510**	
k.) ___ mechanisms for ensuring that the laboratory **reviews all new work** to ensure that it has the appropriate facilities and resources before commencing such work;	5.4.2.3.i [M2, 4.2.8.4(j)]				**5511**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
l.) ___ reference to **the calibration and/or verification test procedures** used;	5.4.2.3.j [M2, 4.2.8.4(i)]				**5512**	
m.) ___ procedures for **handling submitted samples**;	5.4.2.3.k [M2, 4.2.8.4(k)]				**5513**	
n.) ___ reference the **major equipment and reference measurement standards used** as well as the facilities and services used by the laboratory in conducting tests;	5.4.2.3.l [M2, 4.2.8.4(b)]				**5514**	
o.) ___ reference to procedures for calibration, verification and maintenance of equipment;	5.4.2.3.m [M2, 4.2.8.4(a)]				**5515**	
p.) ___ reference to verification practices including inter-laboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes;	5.4.2.3.n [M2, 5.9.1(b)]				**5516**	
q.) ___ procedures to be followed **for feedback and corrective action for failed quality control samples**, or when departures from documented policies, procedures, or this Standard occur;	5.4.2.3.o [M2, 4.2.8.4(l)]				**5517**	
r.) ___ management arrangements for exceptionally permitting departures from standard operating procedures, policies or standard specifications;	5.4.2.3.p [M2, 4.2.8.4(m)]				**5517A**	
s.) ___ procedures for dealing with **complaints**; Note: This refers to resolution of complaints received from clients or other parties about laboratory activities.	5.4.2.3.q [M2, 4.2.8.4(n]				**5518**	
t.) ___ processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training;	5.4.2.3.t [M2, 4.2.8.4(q)]				**5519**	
u.) ___ documented policies and procedures to ensure the **protection of clients' confidential information** and proprietary rights; Note: This includes procedures for protecting the electronic storage and transmission of results.	5.4.1.5.c 5.4.2.3.r [M2, 4.1.5(c); M2, 4.2.8.4(o)]				**5433A**	
v.) ___ procedures for **audits and data review**; and	5.4.2.3.s [M2,				**5430**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	4.2.8.4(p)]					
w.) ___ reference to procedures for reporting analytical results?	5.4.2.3.u [M2, 4.2.8.4(d)]				**5521**	
DATA INTEGRITY PROCEDURES						
H. Does the quality manual define in detail the **data integrity procedures**, including: a.)__ data integrity training, b.)__ signed data integrity documentation for all laboratory employees, c.)__ in-depth periodic monitoring of data integrity, and d.)__ data integrity procedure documentation(subject to document control procedure)?	5.4.2.6 [M2, 4.2.8.1; M2, 5.2.7]				**5520**	
I. Does laboratory management provide a mechanism for confidential reporting of data integrity issues within the laboratory? Note: A primary element of this mechanism is to assure confidentiality & a receptive environment in which all employees may privately discuss ethical issues or reports items of ethical concern.	5.4.2.6.1 [M2, 4.2.8.1(a)]				**54231**	
J. In instances of ethical concern, does the mechanism include a process whereby laboratory management are to be informed of any further detailed investigation?	5.4.2.6.2 [M2, 4.2.8.1(b)]				**54232**	
K. Are the data integrity procedures signed and dated by senior management?	5.4.2.6 [M2, 4.2.8.1]				**54155**	
L. Are the data integrity procedures annually reviewed and updated by management?	5.4.2.6 [M2, 4.2.8.1]				**54157**	
M. Are these procedures and the associated implementation records properly maintained and made available for assessor review?	5.4.2.6 [M2, 4.2.8.1]				**54156**	
N. Are reviews conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity?	5.4.15 [M2, 4.16]				**54151**	
O. Are 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?	5.4.15 [M2, 4.16]				**54152**	
P. Are all investigations that result in findings of inappropriate activity documented including any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients?	5.4.15 [M2, 4.16]				**54153+**	
Q. Is documentation of data integrity investigations and actions taken maintained for five years?	5.4.15				**54154**	
R. Do senior managers acknowledge their support of these procedures by	5.5.2.7				**54158**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
1)___ Upholding the spirit and intent of the organizations data integrity procedures, and 2)___ Effectively implementing the specific requirements of the procedures?	[M2, 5.2.7]					

4. DOCUMENT CONTROL						
A. Does the laboratory establish and maintain procedures to control **all documents** that form part of its quality system, whether internally generated or from external sources? Note: Documents can be internally generated from external sources & can include policy statements, procedures, tables, charts, textbooks, posters, memoranda, plans, software, etc. These documents may be available as hardcopy or electronic media and can be digital, analog, photographic, or written.	5.4.3.1 [M2, 4.3.1]				**5431a**	
B. 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 issue?	5.4.3.2.1 [M2, 4.3.2.1]				**54321**	
C. Does the laboratory have a **master list** or equivalent document control procedure which identifies the current version status and distribution of documents? Note: The list shall be readily available to preclude the use of invalid and/or obsolete documents.	5.4.3.2.1 [M2, 4.3.2.1]				**54321a**	
D. Does the adopted document control procedure ensure that a.)__ authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the lab are performed, b.)__ documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with appropriate requirements, c.)__ invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use, and d.)__ obsolete documents retained for either legal or knowledge preservation purposes are suitability marked?	5.4.3.2.2 5.4.3.2.2.a 5.4.3.2.2.b 5.4.3.2.2.c 5.4.3.2.2.d [M2, 4.3.2.2(a-d)]				**54322a** **54322b** **54322c** **54322d**	
E. Are quality system documents generated by the laboratory uniquely identified by including: a.)___ date of issue and/or revision identification, b.)___ page numbering, c.)___ the total number of pages or mark to signify the end of the document, and d.)___ issuing authority(ies)?	5.4.3.2.3 [M2, 4.3.2.3]				**54323**	
F. Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise?	5.4.3.3.1 [M2, 4.3.3.1]				**54331**	

G. Do the designated personnel have access to pertinent background information upon which to base their review and approval?	5.4.3.3.1 [M2, 4.3.3.1]				**54331a**	
H. Where practicable, is the altered or new text identified in the document or the appropriate attachments?	5.4.3.3.2 [M2, 4.3.3.2]				**54332**	
I. Does the laboratory define the procedures and authorities if its document control system allows for amendment of documents by hand pending re-issue?	5.4.3.3.3 [M2, 4.3.3.3]				**54333**	
J. Are such amendments clearly marked, initialed, and dated?	5.4.3.3.3 [M2, 4.3.3.3]				**54333b**	
K. In the case of hand amendments, is a revised document formally re-issued as soon as practicable?	5.4.3.3.3 [M2, 4.3.3.3]				**54333c**	
L. Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?	5.4.3.3.4 [M2, 4.3.3.4]				**54334**	

Relevant Aspect of Standards – REVIEW OF REQUESTS, TENDERS AND CONTRACTS	**2003 NELAC [2009 TNI]**	**Y**	**N**	**N/A**	**Codes**	**Comments**
5. REVIEW OF REQUESTS, TENDERS AND CONTRACTS						
A. Does the lab establish and maintain procedures for review of requests, tenders and contracts?	5.4.4.1 [M2, 4.4.1]				**5441**	
B. Do the policies and procedures for reviews leading to a contract for environmental testing ensure that a.)__ the requirements, including the methods to be used, are adequately defined, documented and understood, b.)__ the laboratory has the capability and resources to meet the requirements, and c.)__ the appropriate environmental test method is selected and capable of meeting clients requirements?	5.4.4.1 5.4.4.1.a 5.4.4.1.b 5.4.4.1.c [M2, 4.4.1(a-c)]				**5541a** **5541b** **5541c**	
C. Does the laboratory inform the client of the results of the review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the clients work?	5.4.4.1.b [M2, 4.1.1]				**5541b1**	
D. Does the review of capability establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the environmental tests in question?	5.4.4.1.b [M2, 4.1.1]				**5541b2**	

Relevant Aspect of Standards – REVIEW OF REQUESTS, TENDERS AND CONTRACTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
E. Are any differences between the request or tender and the contract resolved before any work commences? Note: The contract shall be acceptable to both the laboratory and the client. A contract may be any oral or written agreement to provide the client with environmental testing services.	5.4.4.1 [M2, 4.1.1]				**54411**	
F. Does the laboratory maintain records of reviews, including any significant changes?	5.4.4.2 [M2, 4.4.2]				**5442**	
G. Does the laboratory maintain records 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?	5.4.4.2 [M2, 4.4.2]				**55421**	
H. Are review records adequate for the complexity of the review such that a.)__ for review of routine or other simple tasks, the date and initials of the person in the lab responsible for carrying out the contracted work are considered adequate; b.)__ for repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the client, provided that the client's requirements do not change; and c.)__ for new, complex or advanced environmental testing a more comprehensive record should be maintained?	5.4.4.2 [M2, 4.4.2]				**54422**	
I. Does the review cover any work that is subcontracted by the laboratory?	5.4.4.3 [M2, 4.4.3]				**5443**	
J. Is the client informed of any deviation from the contract?	5.4.4.4 [M2, 4.4.4]				**5444**	
K. If a contract needs to be amended after work has commenced, is the same contract review process repeated and any amendments communicated to all affected personnel?	5.4.4.5 [M2, 4.4.5]				**5445**	
L. Does the laboratory report any suspension of accreditation, revocation or accreditation, or voluntary withdrawal of accreditation to the client?	5.4.4.5				**54451+**	

Relevant Aspect of Standards - SUBCONTRACTING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
6. SUBCONTRACTING						
A. Does the laboratory have records to indicate that it advise the client in writing of its intention to sub-contract any portion of the testing to another party? Note: When possible, approval of client needs to be gained, preferably in writing.	5.4.5.2 [M2, 4.5.2]				**5141**	
B. Where a laboratory sub-contracts any part of the testing covered under NELAP, do records indicate that this work is placed with a laboratory accredited under NELAP for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for	5.4.5.1 5.4.5.4 [M2, 4.5.1;				**5142**	

Relevant Aspect of Standards - SUBCONTRACTING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
performing the tests and submitting results of tests performed?	M2, 4.5.5]					
C. Is non-NELAC work performed by a subcontracted laboratory clearly identified in the laboratory report? Note: The laboratory must indicate in final reports the laboratory performing subcontracted work. Refer to deficiency in section 25 'Reports' (i.e., 5138 and/or 5134f).	5.4.5.1 [M2, 5.10.3; M2, 5.10.11(c); M2]				**5143**	
D. Does the lab accept responsibility for subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor to be used?	5.4.5.3 [M2, 4.5.3]				**5453**	
E. Does the lab maintain a **register of all subcontractors** that it uses for environmental tests and a record of the evidence (certificates of approval)? Note: The certificates on record need to be current.	5.4.5.4 [M2, 4.5.4]				**5454**	

Relevant Aspect of Standards – PURCHASING SERVICES AND SUPPLIES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
7. PURCHASING SERVICES AND SUPPLIES						
A. Do documented policies and procedures exist for the selection and purchasing of services and supplies used that effect the quality of environmental testing operations of the laboratory?	5.4.6.1 [M2, 4.6.1]				**5461**	
B. Do documented procedures exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory?	5.4.6.1 [M2, 4.6.1]				**51024**	
C. Does the laboratory ensure that purchased supplies, reagents, and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned?	5.4.6.2 [M2, 4.6.2]				**5153**	
D. Do the services and supplies used comply with specified requirements?	5.4.6.2 [M2, 4.6.2]				**5462a**	
E. Are records maintained of actions taken to check compliance?	5.4.6.2 [M2, 5.4.6.2.]				**5462**	
F. Are purchasing documents, containing data describing the services and supplies ordered, reviewed and approved for technical content prior to release?	5.4.6.3 [M2, 4.6.3]				**5463**	
G. Does the laboratory evaluate suppliers of critical consumables, supplies and services which affect the quality of environmental testing?	5.4.6.4 [M2, 4.6.4]				**5464a**	

Relevant Aspect of Standards – PURCHASING SERVICES AND SUPPLIES	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
H. Does the laboratory maintain records of evaluations of all suppliers from whom it obtains support services or supplies required for tests and list those approved?	5.4.6.4 [M2, 4.6.4]				**5464**	

Relevant Aspect of Standards – SERVICE TO THE CLIENT	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
8. SERVICE TO THE CLIENT						
A. Does the lab afford clients or their representatives cooperation to clarify the client's request and to monitor the lab's performance in relation to the work performed, provided that the lab ensures confidentiality to other clients?	5.4.7 [M2, 4.7.1]				**547A**	
B. Does the laboratory seek feedback, both positive and negative, from its customers?	[M2, 4.7.2]			**X**	**547B**	**Until 2009 TNI is implemented.**
C. Does the laboratory use and analyze the customer feedback to improve the management system, testing and calibration activities, and customer service?	[M2, 4.7.2]			**X**	**547C**	**Until 2009 TNI is implemented.**
D. Does the laboratory have documented policies and procedures for the resolution of complaints received from clients or other parties?	5.4.8 [M2, 4.8]				**547D**	
E. Are records maintained of actions taken to check compliance?	5.4.8 [M2, 4.8]				**547E**	

Relevant Aspect of Standards - COMPLAINTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
9. COMPLAINTS						
A. Are records of the complaints and subsequent actions maintained?	5.4.8 [M2, 4.8]				**5163**	

Relevant Aspect of Standards – CONTROL OF NONCONFORMING WORK	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
10. CONTROL OF NONCONFORMING WORK						
A. Does the laboratory have a policy and procedures that are implemented when any aspect of its environmental testing work, or the result of this work, do not conform to its own procedures or agreed requirements of the client?	5.4.9.1 [M2, 4.9.1]				**5491**	
B. Do the policy and procedures ensure that a.)__ the responsibilities and authorities for the management of nonconforming work are designated and actions are defined and taken when nonconforming work is identified;	5.4.9.1a-e [M2, 4.9.1(a-e)]				**5491a**	

Relevant Aspect of Standards – CONTROL OF NONCONFORMING WORK	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
b.)__ an evaluation of the nonconforming work is made; c.)__ corrective actions are taken immediately, together with any decision about the acceptability of nonconforming work; d.)__ where necessary, the client is notified and work is recalled; and e.)__ the responsibility for authorizing the resumption of work is defined?					**5491b** **5491c** **5491d** **5491e**	
C. Does the laboratory implement corrective action procedures when 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?	5.4.9.2 [M2, 4.9.2]				**5492**	

Relevant Aspect of Standards – CORRECTIVE ACTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
11. CORRECTIVE ACTION						
A. Has the laboratory established a corrective action policy and procedure?	5.4.10.1 [M2, 4.11.1]				**54101**	
B. Does the laboratory designate appropriate authorities for implementing corrective action when nonconforming work or departures from policies and procedures in the quality system or technical operations have been identified?	5.4.10.1 [M2, 4.11.1]				**54101a**	
C. Does the corrective action procedure start with an **investigation of root cause(s)** of the problem?	5.4.10.2 [M2, 4.11.2]				**54102**	
D. Does the laboratory identify potential corrective actions and select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?	5.4.10.3 [M2, 4.11.3]				**54103**	
E. Are corrective actions appropriate in degree to the magnitude and risk of the problem?	5.4.10.3 [M2, 4.11.3]				**54103a**	
F. Does the laboratory document and implement any required changes resulting from corrective action investigations?	5.4.10.3 [M2, 4.11.3]				**54103b**	
G. Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?	5.4.10.4 [M2, 4.11.4]				**54104**	
H. Does the laboratory ensure that appropriate areas of activity, identified or doubted as nonconforming or departure from policies and procedures, are promptly audited?	5.4.10.5 [M2, 4.11.5]				**54105**	
I. Does the laboratory implement general procedures to be followed when there are departures from documented policies, procedures, and QC have occurred?	5.4.10.6 [M2, 4.11.6]				**5532+**	
J. Do the procedures to be followed when there is a departure from documented policies, procedures, and QC: a.) __ Identify the individuals responsible for assessing each QC data type;	5.4.10.6 [M2, 4.11.6]				**5533a**	

Relevant Aspect of Standards – CORRECTIVE ACTION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
b.) __ Identify the individuals responsible for initiating and/or recommending corrective actions; c.) __ Define how the analyst should treat the data set if the associated QC measurements are unacceptable; d.) __ Specify how out-of-control situations and subsequent corrective actions are to be documented; and e.) __ Specify procedures for management (including the QA officer) to review corrective action reports?	5.4.10.6.a.1 [M2, 4.11.6(a)] 5.4.10.6.a.2 [M2, 4.11.6(b)] 5.4.10.6.a.3 5.4.10.6.a.4 5.4.10.6.a.5				**5533b** **5533c** **5533d** **5533e**	
K. If a QC measure is out of control and the data is to be reported, are **data qualifiers** reported with samples associated with failed QC measures? Note: The laboratory must indicate in final reports any deviations that may have affected the quality of the work. Refer to deficiency in "REPORTS" section of checklist (e.g., 5133l).	5.4.10.6.b [M2, 5.10.3.1(b)]				**5534+**	
L. To the extent possible, are samples reported only if all quality control measures are acceptable?	5.4.10.6.b				**5535A**	

Relevant Aspect of Standards – PREVENTIVE ACTION AND IMPROVEMENT	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
12. PREVENTIVE ACTION AND IMPROVEMENT						
A. Does the laboratory have a pro-active process to identify opportunities for improvement?	5.4.11				**5411A**	
B. Are needed improvements and potential sources of non-conformances, either technical or concerning the quality system, identified?	5.4.11.1 [M2, 4.12.1]				**54111**	
C. Does the laboratory develop, implement and monitor action plans where preventive action is required?	5.4.11.1 [M2, 4.12.1]				**54111a**	
D. Do procedures for preventive action include the initiation of such actions and application of controls to ensure that they are effective?	5.4.11.2 [M2, 4.12.2]				**54112**	
E. Does the laboratory continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit responses, analysis of data, corrective and	[M2, 4.10]			**X**	**54112a**	**Until 2009 TNI is implemented.**

Relevant Aspect of Standards – PREVENTIVE ACTION AND IMPROVEMENT	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
preventive actions, and management reviews?						

Relevant Aspect of Standards – CONTROL OF RECORDS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
13. CONTROL OF RECORDS						
A. Does the laboratory maintain a record system to suit its particular circumstances and comply with any applicable regulations? Note: Records may be in any media such as hardcopy or electronic media.	5.4.12 [M2, 4.13.1.1]				**5121**	
B. Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records?	5.4.12.1.1 [M2, 4.13.1.1]				**541211**	
C. Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?	5.4.12.1.1 [M2, 4.13.1.1]				**541211a**	
D. Does the system produce unequivocal, accurate records, which document all laboratory activities?	5.4.12 [M2, 4.13.3(a)]				**5122**	
E. Does the laboratory retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for a **minimum of five years**? a.) __ Are records related to Potable Water chemical analyses retained for a minimum of ten years (twelve years for Pb and Cu)? Note: The applicable NYS and federal regulations are as follows: NYS Part 55-2.4 (a) (3), 55-2.13 (d) (3) & (7), 5-1.49 (f), and 5-1.72 (d); and 40 CFR 141.33.	5.4.12 [M2, 4.13.3(a)] 5.4.12.2.4.b [M2, 4.13.3(b)]				**5123** **5123a**	
F. Has the laboratory **established retention times of records**?	5.4.12.1.2 [M2, 4.13.1.2]				**5123b**	
G. Are all records (including the hardware and software necessary for the historical reconstruction of electronic data) that are pertinent to a specified project **retained for a minimum of five years** from last entry unless otherwise designated for a longer period of time in another regulation?	5.4.12.2.4.b [M2, 4.13.3(b)]				**51215**	
H. Are all records, certificates and reports held secure and in confidence to the client?	5.4.12.1.3 [M2,				**51213**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	4.13.1.3] 5.4.12.2.4(a) [M2, 4.13.1.3]					
I. Are NELAP related records available to the accrediting authority?	5.4.12.2.4. a [M2, 4.13.3(c)]				**51214**	
J. Are all records legible?	5.4.12.1.2 [M2, 4.13.1.2]				**541212**	
K. Does the record keeping system allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data?	5.4.12.1.5 [M2, 4.13.3] 5.4.12.2.4. b [M2, 4.13.3(f)]				**5124**	
L. Does the laboratory have a written SOP for how the laboratory will carry out legal chain of custody if the client specifies that a sample will be used for evidentiary purposes?	5.4.12 [M2, 5.8.8]				**5124a**	
M. Does the laboratory have procedures to prevent unauthorized access to or amendment of records stored electronically?	5.4.12.1.4 [M2, 4.13.1.4]				**541214**	
N. Do records that are stored or generated by computers or personal computers (PCS) have hard copy or write-protected backup copies?	5.4.12.1.4 5.4.12.2.4.c [M2, 4.13.1.4]				**51216**	
O. Is the history of the sample readily understood through the documentation including inter-laboratory transfers of samples and/or extracts?	5.4.12.1.5 [M2, 4.13.3(a)]				**5125**	
P. Do the records include the identity of personnel involved in sampling, preparation, calibration or testing?	5.4.12.1.5. a [M2, 4.13.2.1]				**5126**	
Q. Is all information relating to the laboratory facilities, equipment, analytical methods, and	5.4.12.1.5.				**5127**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
related laboratory activities, such as sample receipt, sample preparation, or data verification documented?	b [M2, 4.13.3(a)]					
R. Does the record keeping system facilitate the retrieval of all working files and archived records for inspection and verification purposes? Note: The laboratory needs to have the supportive hardware & software necessary for data retrieval. Also, the records are to be readily retrievable in laboratory to provide suitable environment to prevent damage or deterioration. Refer to deficiency 51219 in this section.	5.4.12.1.5.c [M2, 4.13.1.2] 5.4.12.2.4. b [M2, 4.13.3(d)]				**5128**	
S. Are all changes to records entries signed or initialed by responsible staff with the reason for the signature or initial clearly indicated in the records? Note: Examples of change records are as follows: "sampled by", "prepared by", reviewed by")	5.4.12.1.5. d [M2, 4.13.2.3]				**5129**	
T. Are all generated data, except those that are generated by automated data collection systems, recorded directly, promptly and legibly in permanent ink?	5.4.12.1.5. e [M2, 4.13.3(g)]				**51210**	
U. Are entries to electronically maintained records changed so as to not erase or overwrite the files?	5.4.12.1.5.f [M2, 4.13.2.3]				**541215f**	
V. Is the individual making the change to electronically maintained records identified?	5.4.12.1.5.f [M2, 4.13.2.3]				**51215fa**	
X. Are entries in records not obliterated by methods such as erasures, overwritten files or markings?	5.4.12.1.5.f [M2, 4.13.2.3]				**51211**	
Y. Are all corrections to record-keeping errors made by one line marked through the error and the individual making the correction signing (or initialing) and dating the correction? Note: When mistakes occur in the records, each mistake is crossed out, not erased/deleted or made illegible, with correct value entered alongside.	5.4.12.1.5.f [M2, 4.13.2.3] 5.4.12.2.3 [M2, 4.13.3(g)(i)]				**51212**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
Z. Do the records for each environmental test contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original? a.) __ Does the laboratory retain records of original observations, derived data, & sufficient information to establish an audit trail, calibration records, staff records, & copy of each test report issued for a defined period? b.) __ Do the records include identity of personnel responsible for the sampling, performance of environmental test, and checking of results? Note: Refer to deficiency 51223f for analyst identification and 51222h for data review & cross-checking in this section.	5.4.12.2.1 [M2, 4.13.2.1]				**541221** **541221a** **541221b**	
AA. Are observations, data and calculations recorded at the time they are made?	5.4.12.2.2 [M2, 4.13.2.2]				**541222**	
BB. Are observations, data and calculations identifiable to the specific task?	5.4.12.2.2 [M2, 4.13.2.2]				**541222a**	
CC. In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data?	5.4.12.2.3 [M2, 4.13.2.3]				**541223**	
DD. When corrections are made due to reasons other than transcription errors, does the laboratory document the reason for the correction?	5.4.12.2.3 [M2, 4.13.3(g)]				**541223a**	
EE. Does the laboratory have a **record management system** for control of laboratory notebooks; instrument logbooks; standards logbooks; and records for data reduction, validation storage and reporting?	5.4.12.2.4.d [M2, 4.13.1]				**51217**	
FF. Is access to **archived information** documented with an access log?	5.4.12.2.4.e [M2, 4.13.3(e)]				**51218**	
GG. Is **archived information** protected against fire, theft, loss, environmental deterioration, and vermin and, in the case of electronic records, electronic or magnetic sources?	5.4.12.2.4.e [M2, 4.13.1.2]				**51219**	
HH. Does the laboratory have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory **transfers ownership or goes**	5.4.12.2.4.f [M2,				**51220**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
out of business?	4.13.3(h)]					
II. Does the laboratory retain records of the following procedures to which a sample is subjected while it is in the lab's possession: a.) __ Sample preservation, appropriateness of sample container, & compliance with holding time requirements, b.) __ Sample identification, receipt, acceptance or rejection, & log-in, c.) __ Sample storage & tracking including shipping receipts, transmittal forms, and chain-of-custody forms, d.) __ Documented procedures for receipt, retention, or safe disposal of test items that includes all provisions necessary to protect the integrity of the laboratory?	5.4.12.2.5.1.a 5.4.12.2.5.1.b 5.4.12.2.5.1.c 5.4.12.2.5.1.d [M2, 4.13.3(a)]				**51221a** **51221b** **51221c** **51221d**	
JJ. Does the laboratory retain a.) __ All original raw data, whether hard copy or electronic, for calibrations, sample analyses, & quality control measures, b.) __ A written description or reference to the specific test method used, c.) __ Copies of final reports, d.) __ Archived standard operating procedures, e.) __ Correspondence relating to its activities for a specific project, f.) __ All corrective action reports, audits, & audit response, g.) __ Proficiency test results & raw data, and h.) __ Records of data review, verification, & cross checking procedures? Note: Raw data includes analyst work sheets and data output records (chromatograms, strip charts, & other instrument readouts). With respect to written description or reference to the specific test method used, it includes a description of specific computational steps used to translate parametric observations into reportable analytical values.	5.4.12.2.5.2.a-h [M2, 4.13.2.1]				**51222a+** **51222b** **51222c** **51222d** **51222e** **51222f** **51222g+** **51222h**	
KK. Do strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include: a.) __ Laboratory sample ID code, b.) __ Date of analysis and time of analysis if the hold time is 72 hours or less or when time critical steps are included in the analysis (e.g., extractions and incubations), c.) __ Instrumentation identification and instrument operating conditions/parameters (or reference to such data), d.) __ Analysis type (method or technique) e.) __ All calculations (e.g., automated and manual integrations), f.) __ Analyst's or operator's initials/signature,	5.4.12.2.5.3.a-n [M2, 4.13.3(f)(ii – xvi)]				**51223a** **51223b** **51223c** **51223d** **51223e** **51223f**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
g.) __ Sample preparation (including cleanup & separation protocols, incubation periods or subcultures, ID codes, volumes, weights, instrument printouts, meter readings, calculations, & reagents used), h.) __ Sample analysis (test results), i.) __ Standard & reagent origin, receipt, preparation, & use, j.) __ Calibration criteria, frequency, & acceptance criteria, k.) __ Data & statistical calculations, review, confirmation, interpretation, assessment, & reporting conventions, l.) __ Quality control protocols & assessment, m.) __ Electronic data security, software documentation, software & hardware audits, backups of automated data entries, records of any changes to automated data entries, and n.) __ Method performance criteria including expected quality control requirements?					**51223g** **51223h** **51223i** **51223j** **51223k** **51223l** **51223m** **51223n**	
LL. Are the following **administrative records** maintained: a.) __ Personnel qualifications, experience and training records, b.) __ Initial and continuing demonstration of proficiency for each analyst, and c.) __ A **log of names, initials and signatures** for all individuals who are responsible for signing or initialing any laboratory record?	5.4.12.2.5.4.a 5.4.12.2.5.4.b [M2, 4.13.3(f)(xviii)] 5.4.12.2.5.4.c [M2, 4.13.3(f)(xix)]				**51224a** **51224b** **51224c**	

Relevant Aspect of Standards – INTERNAL AUDITS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
14. INTERNAL AUDITS						
A. Does the laboratory conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this standard with a predetermined schedule and procedure, and **at least annually**? Note: Refer to deficiency 5429 in section 2 'Laboratory Management Organization', too.	5.4.13.1 [M2, 4.14.1; M2, 4.14.5(c)]				**54131**	
B. Does the internal audit program address all elements of the quality system, **including testing**	5.4.13.1				**54131a**	

Relevant Aspect of Standards – INTERNAL AUDITS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
activities?	[M2, 4.14.1]					
C. Do personnel audit their own activities only when it can be demonstrated that an effective audit will be carried out?	5.4.13.1 [M2, 4.14.1]				**54131b**	
D. Is the internal audit conducted by personnel trained and qualified as auditors who, wherever possible, are independent of the activities being audited (e.g., QA Officer)?	5.4.13.1 [M2, 4.14.1]				**5523**	
E. Is **immediate corrective action** taken when audit findings cast doubt on the correctness or validity of the calibrations or test results?	5.4.13.2 [M2, 4.14]				**5524**	
F. Are **clients notified immediately**, in writing, when their work is affected by the findings from an internal audit?	5.4.13.2 [M2, 4.14.2]				**5525**	
G. Does the laboratory have a policy in its Quality Manual that **specifies the time frame** for notifying a client of events that cast doubt on the validity of the results?	5.4.13.2 [M2, 4.14.5(a)]				**5525a**	
H. Are all audits and review findings and any corrective actions that arise from them recorded?	5.4.13.3 [M2, 4.14.3]				**5529+**	
I. Does the laboratory management ensure that corrective actions arising from **internal audits and management reviews** are discharged within the agreed time frame as indicated in the quality manual and/or SOPs?	5.4.13.3 [M2, 4.14.5(b)] 5.4.14.2 [M2, 4.15.2]				**5530**	
J. Is the implementation and effectiveness of the corrective action taken verified and recorded from follow-up audit activities?	5.4.13.4 [M2, 4.14.4]				**54134**	

Relevant Aspect of Standards – MANAGERIAL REVIEWS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
15. MANAGERIAL REVIEWS						
A. Does the laboratory have a procedure for the **annual** management review of the quality system and does it maintain records of review findings and actions?	5.4.14.2 [M2, 4.15.2]				**5526**	
B. Is an **annual** review of the quality system completed by management to evaluate its continuing suitability and effectiveness and make any necessary changes or improvements?	5.4.14.1 [M2, 4.15.1; M2, 4.15.3]				**5527+**	
C. Does the **annual** review take into account a.) __ the suitability of policies and procedures; b.) __ reports from managerial and supervisorial personnel; c.) __ the outcome of recent internal audits;	5.4.14.1 a-j [M2, 4.15.1]				**5528a** **5528b** **5528c**	

Relevant Aspect of Standards – MANAGERIAL REVIEWS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
d.) __ corrective and preventive actions; e.) __ assessment by external bodies ; f.) __ the results of interlaboratory comparisons or proficiency tests; g.) __ any changes in the volume and type of work undertaken; h.) __ feedback from clients; i.) __ complaints; and j.) __ other relevant factors, such as quality control activities, resources and staff training?					**5528d** **5528e** **5528f** **5528g** **5528h** **5528i** **5528j**	

Relevant Aspect of Standards – LABORATORY TECHNICAL REQUIREMENTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
16. LABORATORY TECHNICAL REQUIREMENTS						
A. Does the laboratory take into account all factors in developing environmental tests & procedures (i.e., human factors, environmental test methods & method validation, equipment, measurement traceability, sampling, and handling of samples)?	5.5.1.2 [M2, 5.1.1; M2, 5.1.2]				**5526a**	
B. Does the laboratory take into account all factors (listed above) in the training & qualification of personnel?	5.5.1.2 [M2, 5.1.2]				**5526b**	
C. Does the laboratory take into account all factors (listed above) in the selection & calibration of the equipment it uses?	5.5.1.2 [M2, 5.1.2]				**5526c**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY TRAINING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
17. PERSONNEL, INCLUDING DATA INTEGRITY TRAINING						
A. Does the laboratory maintain records to indicate that it has **sufficient personnel**, having the **necessary** education, training, technical knowledge and experience for their assigned functions? Note: Refer to deficiencies 547 and 549 in section 2 'Laboratory Management Organization', too.	5.5.2.1 [M2, 4.1.5(a)]				**561**	
B. Does the laboratory management **ensure the competence** of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports?	5.5.2.1 [M2, 5.2.1]				**561a**	
C. Are personnel responsible for **complying with all quality assurance/quality control requirements** that pertain to their organizational/technical function?	5.5.2.1 [M2, 4.2.2(d)]				**562**	
D. Does each technical staff member have a **combination of experience and education** to adequately demonstrate a.) __ a specific knowledge of their particular function; and	5.5.2.1 [M2, 5.2.1]				**563**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY TRAINING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
b.) __ a general knowledge of laboratory operations, analytical methods, QA/QC procedures and records management? Note: Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience, and/or demonstrated skills.						
E. Does laboratory management ensure that staff who are undergoing training are provided with **appropriate supervision**?	5.5.2.1 [M2, 5.2.1]				**5521a**	
F. Does laboratory management **formulate goals** with respect to the education, training and skills for laboratory personnel?	5.5.2.2 [M2, 5.2.2]				**5521b**	
G. Does the laboratory have a policy and procedures for **identifying training needs** and **providing training** of personnel?	5.5.2.2 [M2, 5.2.2]				**5521c**	
H. Is the training program **relevant to the present and anticipated tasks** of the laboratory?	5.5.2.2 [M2, 5.2.2]				**5522a**	
I. If the laboratory uses personnel under contract to the laboratory or if additional technical and key support personnel are used, does the laboratory **ensure that such personnel are supervised and competent** and that they work in accordance with the laboratory's quality system?	5.5.2.3 [M2, 5.2.3]				**5523a**	
J. Does the laboratory **maintain current job descriptions** for all personnel who manage, perform, or verify work affecting the quality of testing?	5.5.2.4 [M2, 5.2.4]				**5524a**	
K. Does laboratory management authorize specific personnel to a.) __ perform particular types of sampling, b.) __ environmental test and/or calibration, c.) __ issue reports, d.) __ give opinions and interpretations, and e.) __ operate particular types of equipment?	5.5.2.5 [M2, 5.2.5]				**55251** **55252** **55253** **55254** **55255**	
L. Does the laboratory maintain **records**, **with dates**, of the relevant authorizations, competence, educational and professional qualifications, training, skills, and experience for all technical and contracted personnel? Note: The records shall also include demonstrated proficiency for each laboratory test method.	5.5.2.5 [M2, 5.2.5]				**5525b**	
M. Is there a defined **minimum level of qualification**, experience, and skills (including basic lab skills such as using a balance, colony counting, aseptic or quantitative techniques) necessary for all positions in the lab?	5.5.2.6.a [M2, 5.2.4]				**564**	
N. Does the laboratory management maintain records to ensure that all technical laboratory staff have **demonstrated and documented initial and ongoing proficiency** in the activities for which they are responsible? Note: M2, 5.2 does not require the use of the "Demonstration of Capability, Certification	5.5.2.6.b C.1 & C.2				**565**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY TRAINING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
Statement" included in NELAC 2003, Appendix C.1. Another documented statement is acceptable.						
O. Does laboratory management ensure that **training records are kept up-to-date** for all technical staff that include: a.) __ Evidence that the employee has read, understands, and is using the **latest version** of the lab's in-house quality documentation, which relates to his/her job responsibilities; b.) __ **Training courses or workshops** on specific equipment, analytical techniques, or lab procedures; c.) __ **Annual** training course in data integrity procedures including the potential punishments & penalties for violations; Note: The training is to be a formal part of new employee orientation and annually thereafter. d.) __ **Annual** signature for each employee demonstrating they have read; acknowledge, and understand their personal & legal data integrity responsibilities including potential punishments & penalties for violations; and e.) __ Documentation certifying that the employee has read, understands, and agrees to use the **latest version** of a test method used? Note: The most recent version is the approved method or SOP defined by the laboratory's document control system.	5.5.2.6.c 5.5.2.6.c.1 [M2, 5.2.5] 5.5.2.6.c.2 [M2, 5.2.2] 5.5.2.7 [M2, 5.2.7] 5.5.2.7 [M2, 5.2.7] 5.5.2.6.c.3 [M2, 5.2.5]				**566a** **566b** **566c** **566d** **566e**	
P. Does laboratory management ensure that the training records of each of the technical staff is updated by including **documentation of continuing proficiency** by at least one of the following? a.) __ Acceptable performance of a blind sample; b.) __ Another demonstration of capability; c.) __ Successful analysis of a blind performance sample on a similar test method using the same technology; a d.) __ Analysis of at least 4 consecutive lab control samples with acceptable levels of precision and accuracy; or e.) __ If one of the above can not be performed, the analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable results. Note: M2, 5.2 does not incorporate these examples.	5.5.2.6.c.3.i -v C.1 & C.2				**567**	
Q. Does the laboratory **document all analytical and operational activities** of the laboratory?	5.5.2.6.d [M2, 4.13.2]				**568**	
R. Does the laboratory management ensure **supervision of all personnel** employed by the laboratory?	5.5.2.6.e [M2, 4.1.5(a)]				**5526e**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY TRAINING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
S. Does the laboratory management ensure **all sample acceptance criteria are verified** and that samples are logged into the sample tracking system and properly labeled and stored?	5.5.2.6.f				**569**	
T. Does the laboratory management **ensure the quality of all data** reported by the laboratory?	5.5.2.6.g				**5610**	
U. Does **data integrity training** include: a.) __ topics covered shall be documented in writing and provided to all trainees, b.) __ organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, c.) __ how and when to report data integrity issues, d.) __ record keeping, e.) __ employees are required to understand that any infractions of lab data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, or civil/criminal prosecution, f.) __ specific examples of breaches of ethical behavior, g.) __ discussion regarding all data integrity(DI) procedures, DI training, in-depth data monitoring, and DI procedure documentation, and h.) __ requirement for emphasis on the importance or proper written narration on the part of the analyst with respect the those cases where analytical data may be useful, but are in some way partially deficient? Note 1: Specific examples are improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards. Note 2: The data integrity training and annual refresher training needs to be documented demonstrating that all staff have participated and understood their obligations by signing an attendance sheet or other forms of documentation. Note 3: The deficiencies related to data integrity procedures are located in section 3 'LABORATORY QUALITY SYSTEM, INCLUDING DATA INTEGRITY PROCEDURES'.	5.5.2.7 [M2, 5.2.7]				**5527a** **5527b** **5527c** **5527d** **5527e** **5527f** **5527g** **5527h**	

Relevant Aspect of Standards – PHYSCIAL FACILITIES (ACCOMMODATION & ENVIRONMENTAL CONDITIONS)	2003 NELAC [2009 TNI]]	Y	N	N/A	Codes	Comments
18. PHYSICAL FACILITIES (ACCOMMODATION & ENVIRONMENTAL CONDITIONS)						
A. Do the laboratory accommodations, test areas, energy sources, lighting, and environmental conditions **facilitate proper performance of tests**? Note: This also includes heating and ventilation.	5.5.3.1 [M2, 5.3.1]				**571**	
B. Is the environment in which these activities take place such that the results are not invalidated or the required accuracy of measurement is not adversely affected?	5.5.3.1 [M2, 5.3.1]				**572**	

Relevant Aspect of Standards – PHYSCIAL FACILITIES (ACCOMMODATION & ENVIRONMENTAL CONDITIONS)	2003 NELAC [2009 TNI]]	Y	N	N/A	Codes	Comments
C. Are the technical requirements for accommodation and environmental conditions that can affect the results of tests documented?	5.5.3.1 [M2, 5.3.1]				**55311**	
D. Does the environment provided for the **effective monitoring, control and recording** of environmental conditions, as appropriate (such as biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound & vibration levels)?	5.5.3.2 [M2, 5.3.2]				**573**	
E. In instances where monitoring or control of any of the above mentioned items are specified in a test method or by regulation, does the laboratory meet and document adherence to the laboratory facility requirements?	5.1.5 5.5.3.2				**574**	
F. Are tests stopped when the environmental conditions jeopardize the results?	5.5.3.2 [M2, 5.3.2]				**55321**	
G. Is there **effective separation between neighboring areas** when the activities therein are incompatible (including culture handling or incubation areas and volatile organic chemicals handling areas)?	5.5.3.3 [M2, 5.3.3]				**575**	
H. Are measures taken to **prevent cross contamination**?	5.5.3.3 [M2, 5.3.3]				**55331**	
I. Is access to and use of neighboring areas where activities are incompatible defined and controlled?	5.5.3.4 [M2, 5.3.4]				**576**	
J. Are adequate measures taken to ensure **good housekeeping** and to ensure that any contamination does not adversely affect data quality?	5.5.3.5 [M2, 5.3.5]				**577**	
K. Are special procedures prepared when necessary?	5.5.3.5 [M2, 5.3.5]				**578**	

L. Are work spaces made available to ensure an **unencumbered work area**? Work areas include:
a.) __ Access and entryways to the laboratory;
b.) __ Sample receipt area(s);
c.) __ Sample storage area(s);
d.) __ Chemical and waste storage area(s); and
e.) __ Data handling and storage area(s).
	5.5.3.6.a-e				**579**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
19. ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION						
A. Does the laboratory use **appropriate methods and procedures** for all test methods and laboratory activities within its scope?	5.5.4.1 [M2, 5.4.1]				**5101**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
Note: It includes sample collection, sample handling, transport & storage, sample preparation, sample analysis, estimations of uncertainty, & statistical techniques.						
B. Does the laboratory document instructions a.) __ on the use and operation of all relevant equipment and b.) __ on the handling and preparation of samples, where the absence of such instructions could jeopardize the calibrations or tests?	5.5.4.1 [M2, 5.4.1]				**5102a** **5102b**	
C. Are all instructions, standards, manuals and reference data relevant to the work of the laboratory **maintained up-to-date and readily available** to the staff?	5.5.4.1 [M2, 5.4.1]				**5103**	
D. Do **deviations from test methods** occur only if the deviation has been documented, technically justified, authorized, and accepted by the client?	5.5.4.1 [M2, 5.4.1]				**554111**	
E. Does the laboratory **maintain SOPs** that accurately reflect all phase of laboratory activities and test methods? Note: These documents may be equipment manuals, published methods, or internally written SOPs with adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result. Copies of published methods that contain sufficient information to perform the tests do not need to be supplemented or rewritten as internal procedures, if the documents are written in a way that they can be used as written. M2, 5.4.1 and 5.4.2 does not include a 'Laboratory Methods Manuals' section and the 23 items that need to be addressed in a SOP.	5.5.4.1.1 a., b., f. [M2, 4.2.8.5, M2, 4.2.8.5 (d) & (f)]				**55411**	
Does each test method include or reference all 23 points **where applicable**?	5.5.4.1.2 [M2, 4.2.8.5]				**5108**	
The 23 points are: a) __ Identification of the test method, b) ___ Applicable matrix or matrices, c) ___ Detection limit, d) ___ Scope and application, e) ___ Summary of the test method, f) ___ Definitions, g) ___ Interferences, h) ___ Safety, i) ___ Equipment and supplies, j) ___ Reagents and standards,	5.5.4.1.2.b 1-23 [M2, 4.2.8.5 (f)(i-xxiii)]				**5108a** **5108b** **5108c** **5108d** **5108e** **5108f** **5108g** **5108h** **5108i** **5108j**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
k) ___ Sample collection, preservation, shipment and storage, l) ___ Quality control, m) ___ Calibration and standardization, n) ___ Procedure, o) ___ Data analysis and calculations, p) ___ Method performance, q) ___ Pollution prevention, r) ___ Data assessment and acceptance criteria for quality control measures, s) ___ Corrective actions for out-of-control data, t) ___ Contingencies for handling out-of-control or unacceptable data, u) ___ Waste management, v) ___ References, and w) ___ Any tables, diagrams, flowcharts and validation data.					**5108k** **5108l** **5108m** **5108n** **5108o** **5108p** **5108q** **5108r** **5108s** **5108t** **5108u** **5108v** **5108w**	
F. Are copies of **SOPs organized and assessable** to all personnel?	5.5.4.1.1.c, d [M2, 4.2.8.5(b)]				**5104**	
G. Does each SOP clearly indicate a.) __ **effective date** of the SOP, b.) __ **revision number**, and c.) __ **signature(s)** of approving authority?	5.5.4.1.1.e [M2, 4.2.8.5(c)]				**5105a** **5105b** **5105c**	
SELECTION OF METHODS						
H. Does the laboratory use test methods and procedures, which meet the needs of the client**,** for all tests and related activities within its responsibility (including sample collection, handling, transport, storage, preparation, and analysis)? Note: The laboratory shall use test methods published in international and regional or national standards. Laboratory-developed methods may also be used if they are appropriate for the intended use and if they are validated.	5.5.4.2 [M2, 5.4.2]				**5109**	
I. Does the laboratory ensure that it **uses the latest valid edition** of a standard source of methods? Note: When necessary, the standard shall be supplemented with additional details to ensure consistent application.	5.5.4.2.1.a [M2, 5.4.2]				**55421a**	
J. Does the laboratory use only the test method specified when the test method is mandated or requested?	5.5.4.2.1.b				**51011**	
K. When specific test methods are not required, does the laboratory **use only fully documented**	5.5.4.2.1.c				**51012**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
and validated test methods that are appropriate for the intended use and made available to the client and other recipients of relevant reports? Note: The labs needs to select appropriate test methods published in international, regional or national standards; by reputable technical organizations; in relevant scientific texts or journals; or as specified by the manufacturer of the equipment.	[M2, 5.4.2]					
L. Does the laboratory inform the client when the method proposed by the client is **considered to be inappropriate or out of date**?	5.5.4.2.1.d [M2, 5.4.2]				**55421d**	
M. a) __ Does the laboratory confirm that it can properly operate all methods before introducing the environmental tests and repeat such confirmations each time the method changes? Note: This is applicable to records of initial demonstration of method capability prior to institution of any test method. b) __ Does the laboratory complete a new demonstration of capability whenever there is a **significant change in instrument type, personnel, or test method**? Note: This is referenced in Section 1.6 of 2009 Standards: V1M4, V1M5, V1M6, and V1M3.	5.5.4.2.2 5.5.4.2.2a, c, & e. [M2, 5.4.2]				**51014a** **51014**	
N. Is the introduction of laboratory-developed methods a planned activity assigned to qualified personnel equipped with adequate resources?	5.5.4.3 [M2, 5.4.3]				**5543**	
O. Are plans for laboratory-developed methods updated as development proceeds and effective communication amongst all personnel involved ensured?	5.5.4.3 [M2, 5.4.3]				**5543a**	
P. When it is necessary to use non-standard methods, is their use subject to agreement with the client, including clear specification of client requirements and the purpose of the testing?	5.5.4.4 [M3-M7, 1.4]				**5544**	
Q. Are all non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods validated to confirm they fit their intended use?	5.5.4.4 [M3-M7, 1.4] 5.5.4.5.2 [M3-M6, 1.5]				**55452**	
VALIDATION OF TEST METHODS / ESTIMATION OF UNCERTAINTY OF MEASUREMENT						
R. Does the laboratory record the results of validations, the procedure used, and a statement as to whether the method is fit for the intended use? Note: The minimum requirements shall be the initial test method evaluation requirements given in Appendix C.3 of 2003 Standard.	5.5.4.5.2 [M3-M6, 1.5]				**55452a**	
S. Is the range and accuracy of the values obtainable from validated methods, within the	5.5.4.5.3				**55453**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
intended use, relevant to the clients needs?						
T. If a laboratory is performing testing does it have and implement a procedure to estimate the uncertainty of measurement? NOTE: In those cases where a well recognized method specifies limits to the values of all major sources of measurement uncertainty and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.	5.5.4.6.1				**55462**	
U. In cases where it is not possible to calculate the uncertainty of measurement in a rigorous metrological and statistically significant way, does the laboratory, at least, attempt to identify all the components of uncertainty and make a reasonable estimation? Note: It is based on knowledge of the performance of the method, measurement scope, previous experience, and validation data.	5.5.4.6.1				**55462a**	
V. Does the laboratory ensure that the form of reporting does not give a wrong impression of the uncertainty of measurement?	5.5.4.6.1				**55462b**	
W. Are all important uncertainty components taken into account using appropriate methods of analysis?	5.5.4.6.2				**55463**	
CONTROL OF DATA						
X. Does the laboratory establish SOP to ensure that the reported data is free from **transcription and calculation errors**?	5.5.4.7.1.a				**51021**	
Y. Does the laboratory establish SOP to ensure that all quality control measures are reviewed, and evaluated before data is reported?	5.5.4.7.1.b				**51022**	
Z. Are calculations and data transfers subject to checks as established in the laboratory's SOP?	5.5.4.7.1 [M2, 5.4.7.1]				**51023**	
AA. Does the laboratory establish Standard Operating Procedures addressing **manual calculations including manual integrations**?	5.5.4.7.1.c				**51023A**	
BB. When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the laboratory ensure that computer software developed by the user is **documented in sufficient detail** and is **suitably validated as being adequate** for use?	5.5.4.7.2.a [M2, 5.4.7.2(a)]				**51032a**	
CC. Are procedures established and implemented for **protecting the integrity of data**?	5.5.4.7.2.b [M2, 5.4.7.2(a)]				**51033**	
DD. Do the procedures include, but are not be limited to: a.) __ Integrity of data entry or capture,	5.5.4.7.2.b [M2,				**51035**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
b.) __ Data storage, c.) __ Data transmission, and d.) __ Data processing?	5.4.7.2(a)].b					
EE. Are computer and automated equipment maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data?	5.5.4.7.2.c [M2, 5.4.7.2(c)]				**51036**	
FF. Does the laboratory establish and implement appropriate procedures for the **maintenance of security of data** including the prevention of unauthorized access to, and the unauthorized amendment of, computer records?	5.5.4.7.2.d				**51037**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
20. EQUIPMENT AND REFERENCE MATERIALS						
A. Does the laboratory furnish all items of **equipment (including reference materials)** required for the correct performance of tests for which accreditation is sought?	5.5.5.1 [M2, 5.5.1]				**581**	
B. Is equipment **outside the permanent control** of the laboratory handled so as to ensure the requirements of the NELAC standard are met?	5.5.5.1 [M2, 5.5.1]				**582**	
C. Is the equipment and the software used for testing, calibration and sampling capable of achieving the accuracy required and does it comply with specifications relevant to the tests concerned?	5.5.5.2 [M2, 5.5.2]				**5552**	
D. Are calibration programs established for key quantities or values of the instruments where these properties have a significant effect of the results?	5.5.5.2 [M2, 5.5.2]				**55521**	
E. Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications?	5.5.5.2 [M2, 5.5.2]				**55522**	
F. Is all support equipment maintained in proper working order and records of all activities including service calls kept? Note: These Standards apply to analytical support equipment, including, but not limited to, balances, ovens, refrigerators, incubators, water baths, thermometers, thermistors, and volumetric dispensing devices (if quantitative results are dependent on their accuracy).	5.5.5.2.1.a [M2, 5.5.13.1(a)]				**5910**	
G. Is all support equipment **calibrated annually**, using NIST traceable references when available, **over the entire range** in which the equipment is used?	5.5.5.2.1.b [M2, 5.5.13.1(b)]				**5911**	
H. Are the results of support equipment calibration within the specifications required of the	5.5.5.2.1.b				**5912**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
application for which it is used?	[M2, 5.5.13.1(b)]					
I. Is support equipment that is not within the specifications required of the application **removed from service until repaired**?	5.5.5.2.1.b.1 [M2, 5.5.13.1(b)]				**5913**	
J. Does the laboratory **maintain records of established correction factors** to correct measurements?	5.5.5.2.1.b.2 [M2, 5.5.13.1(b)]				**5914**	
K. Are **all raw data records retained** to document equipment performance?	5.5.5.2.1.c [M2, 5.5.13.1(c)]				**5915**	
L. Prior to use on each working day, are balances, ovens, refrigerators, freezers, incubators and water baths checked with NIST traceable references (where commercially available) in the expected use range?	5.5.5.2.1.d [M2, 5.5.13.1(d)]				**5916**	
M. Is the acceptability for use or continued use according to the needs of the analysis or application for which it is used?	5.5.5.2.1.d [M2, 5.5.13.1(d)]				**5918**	
N. Are **mechanical volumetric devices**, including burettes, checked for accuracy on a **quarterly basis**? Note: Check is not needed for Class A glassware.	5.5.5.2.1.e [M2, 5.5.13.1(e)]				**5919**	
O. Do **glass microliter syringes** come with a certificate attesting to established accuracy or is the accuracy initially demonstrated and documented by the laboratory?	5.5.5.2.1.e [M2, 5.5.13.1(e)]				**5919a**	
P. Is equipment **operated by authorized personnel**?	5.5.5.3 [M2, 5.5.3]				**5553**	
Q. Is all equipment properly **maintained, inspected and cleaned**?	5.5.5.3 [M2, 5.5.3]				**583**	
R. Are maintenance procedures documented?	5.5.5.3 [M2, 5.5.3]				**584**	
S. Are **up-to-date instructions** on the use & maintenance of equipment (including relevant manufacturer manuals) **readily available** for use by appropriate personnel?	5.5.5.3 [M2, 5.5.3]				**584a**	
T. Does the laboratory have p**rocedures for safe handling, transport, storage, use, and planned maintenance** of measuring equipment to ensure proper functioning and to prevent	5.5.5.6 [M2, 5.5.6]				**5556**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
contamination or deterioration?						
U. Is any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, **taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired** and shown by calibration, verification or test to perform satisfactorily?	5.5.5.7 [M2, 5.5.7]				**585**	
V. Does the laboratory examine the effect of this defect or departure from specified limits on **previous tests and/or calibrations** and institute the "Control of Nonconforming Work" procedure? Note: Refer to section 10 of checklist, "Control of Nonconforming Work".	5.5.5.7 [M2, 5.5.7] 5.4.9 [M2,. 4.9.1]				**586**	
W. Is each item of equipment and its software used for environmental testing and significant to the result **uniquely identified** (when practicable)? Note: Refer to deficiency 51223C in section 13 of checklist, "Control of Records", too.	5.4.12.2.5.3.c [M2, 4.13.3(f)] 5.5.5.4 [M2, 5.5.4]				**586a**	
X. Are all items of equipment including reference materials **labeled, marked or otherwise identified to indicate its calibration status**, including the date when last calibrated and the date or expiration criteria when recalibration is due?	5.5.6.4.c 5.5.6.4.d 5.5.5.8 [M2, 5.5.8]				**587**	
Y. Do **records of major equipment and reference materials** include the following: a) ___ The name of the item of equipment and its software, b) ___ The manufacturer's name, type identification, and serial number or other unique identification, c) ___ Checks that equipment comply with the specification, d) ___ Current location, where appropriate, e) ___ Copy of the manufacturer's instructions, where available, f) ___ Dates and results of calibrations and/or verifications and date of the next calibration and/or verification, g) ___ Details of maintenance carried out to date and planned for the future, h) ___ History of any damage, malfunction, modification or repair, i) ___ Date received and date placed in service, and j) ___ Condition when received (e.g. new, used, reconditioned)?	5.5.5.5a-j [M2, 5.5.5(a)-(g)]				**588a** **588b** **588nm** **588d** **588f** **588g** **588h** **588i** **588c** **588e**	
Z. If for any reason, equipment goes **outside the direct control of the laboratory**, does the laboratory ensure that the function and calibration status of the equipment is checked and shown to be satisfactory before equipment is returned to service?	5.5.5.9 [M2, 5.5.9]				**5559**	
AA. Does the laboratory have procedures to **ensure that copies of new correction factors are**	5.5.5.11				**55511**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
correctly applied/updated (e.g. in computer software)?	[M2, 5.5.11]					
BB. Is test and calibration equipment, including both hardware and software, **safeguarded from adjustments** which would invalidate the test and/or calibration results?	5.5.5.12 [M2, 5.5.12]				**55512**	

Relevant Aspect of Standards – MEASUREMENT TRACEBILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
21. MEASUREMENT TRACEABILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS						
A. Are all measuring operations and testing equipment having an effect on the accuracy or validity of tests calibrated and/or verified **before being put into service and on a continuing basis**?	5.5.6.1 [M2, 5.6.1]				**591**	
B. Does the laboratory have **an established program for the calibration and verification** of its measuring and test equipment **including balances, thermometers and control standards**? Note: Such a program shall include a system for selecting, using, calibrating, checking, controlling, & maintaining measurement standards, reference materials used as measurement standards, and measuring & testing equipment used to perform the test.	5.5.6.1 [M2, 5.6.1] 5.5.6.3.1 [M2, 5.6.3.1]				**592**	
C. Does the laboratory ensure that the equipment used can **provide the uncertainty of measurement needed**?	5.5.6.2.1 [M2, 5.6.2]				**556221**	
D. Is the overall program of calibration and/or verification & validation of equipment made by the labs **traceable to national standards of measurement**?	5.5.6.2.1.a [M2, 5.6.2]				**593**	
E. Does the laboratory provide satisfactory evidence of correlation of results in those cases where **traceability to national standards of measurement** is not applicable? Note: When this is not possible, the lab needs to have traceability to certified reference materials, agreed methods, or consensus standards. Also, lab could participate, for example, in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.	5.5.6.2.2 [M2, 5.6.2] [M2, 5.6.4.1]				**595**	
REFERENCE STANDARDS AND REFERENCE MATERIALS						
F. Are reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) **used for calibration only** and for no other purpose, unless it is demonstrated that their performance as reference standards has not been invalidated?	5.5.6.3.1 [M2, 5.6.3.1]				**596**	
G. Are reference standards of measurement calibrated by a body that can provide, where possible**, traceability to national or international standard** reference materials? Note: Reference standards need to be calibrated before and after nay adjustments.	5.5.6.3.1 [M2, 5.6.3.1] 5.5.6.3.2				**597**	

Relevant Aspect of Standards – MEASUREMENT TRACEBILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	[M2, 5.6.3.2; M2, 5.6.4.1(a)]					
H. Is there a **program of calibration and verification** for reference standards? Note: Refer to deficiency 592 in this section, too.	5.5.6.3.1 [M2, 5.6.3.1]				**598**	
I. Are **internal reference materials checked** as far as technically and economically possible?	5.5.6.3.2 [M2, 5.6.3.2]				**599a**	
J. Does the laboratory have defined procedures and schedules for carrying out **checks of the calibration status** of reference, primary, transfer or working standards and reference materials?	5.5.6.3.3 [M2, 5.6.3.3]				**55633**	
K. Does the laboratory have procedures for **safe handling, transport, storage, and use of reference standards and reference materials** in order to protect their integrity, and prevent contamination and/or deterioration?	5.5.6.3.4 [M2, 5.6.3.4]				**55634**	
L. Do documented procedures exist for the **purchase, reception and storage of consumable materials** used for the technical operations of the laboratory?	5.5.6.4 [M2, 5.6.4.2]				**55641**	
M. Does the laboratory retain records for all standards, reagents, reference materials and media? Note: This includes: manufacturer/vendor, manufacturer's Certificate of Analysis or purity (if supplied), date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless verified by the laboratory.	5.5.6.4.a [M2, 5.6.4.2(a)]				**51025**	
N. Has the laboratory **verified the purity of expired standards, reagents, & media** prior to their continued use?	5.5.6.4.a [M2, 5.6.4.2(f)]				**51025a**	
O. Are original reagent containers **labeled with the expiration date**?	5.5.6.4.b [M2, 5.6.4.2.(b)]				**51026**	
P. Are detailed records maintained on standard and reference material preparation? Note: Refer to deficiency 51223i in section 13, 'Control of Records', too.	5.5.6.4.c [M2, 5.6.4.2(c)]				**51027**	
Q. Do the records of standard and reference material preparation indicate traceability to purchased stocks or neat compounds, reference to method of preparation, date of preparation,	5.5.6.4.c [M2,				**51028**	

Relevant Aspect of Standards – MEASUREMENT TRACEBILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
expiration date, and preparer's initials? Note: Refer to deficiency 51223, f, g, and i in section 13, 'Control of Records', too.	5.6.4.2(c)]					
R. Do all containers of prepared standards and reference materials **bear a unique identifier and expiration date** and can it be linked to the documentation of its preparation?	5.5.6.4.d [M2, 5.6.4.2(d)]				**51029**	
S. Are procedures in place to ensure prepared reagents meet the requirements of the test method?	5.5.6.4.e [M2, 5.6.4.2(e)]				**5564e**	
T. Do all containers of prepared reagents **bear a preparation and expiration date** or is it documented elsewhere as indicated in the laboratory's quality manual or SOP?	5.5.6.4.f [M2, 5.6.4.2(d)]				**5564f**	

Relevant Aspect of Standards - SAMPLING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
22. SAMPLING						
A. If the laboratory carries out sampling, does it have a **sample plan** and procedures?	5.5.7.1 [M2, 5.7.1]				**5571**	
B. Is the sampling plan and procedure available **at the sampling location**?	5.5.7.1 [M2, 5.7.1]				**5571a**	
C. Are sample plans, where ever reasonable, based on **appropriate statistical methods**?	5.5.7.1 [M2, 5.7.1]				**5571b**	
D. Does the sampling process address the factors to be controlled to ensure the validity of the test results?	5.5.7.1 [M2, 5.7.1]				**5571c**	
E. Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures and appropriate techniques to obtain **representative sub-samples**?	5.5.7.1 [M2, 5.7.1]				**51020**	
F. Are client required **deviations, additions, or exclusions** from the documented sampling procedure recorded **in detail** with the appropriate sampling data and included in all documents containing test results and communicated to appropriate personnel?	5.5.7.2 [M2, 5.7.2]				**5572**	
G. Does the laboratory have procedures for recording **relevant data and operations** relating to sampling?	5.5.7.3 [M2, 5.7.3]				**5572a**	
H. Do sampling records include: a.)__ the **sampling procedure** used, b.) __ the identification of the **sampler**,	5.5.7.3 [M2, 5.7.3]				**5573** **5573a** **5573b**	

Relevant Aspect of Standards - SAMPLING	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
c.)__ **environmental conditions** (if relevant), d.)__ diagrams or other equivalent means to identify the **sampling location**, and e.)__ if appropriate, the **statistics** the sampling procedure is based on?					**5573c** **5573d** **5573e**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
23. HANDLING OF SAMPLES, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY						
A. Does the laboratory have procedures for **the transportation, receipt, handling, protection, storage, retention and/or disposal of samples**, including provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the client?	5.5.8.1 [M2, 5.8.1]				**5581**	
B. Does the laboratory have a **documented system for uniquely identifying the items to be tested**, to ensure that there can be no confusion regarding the identity of such items at any time? Note: The sample identification is to be retained throughout the life of the sample in the lab. Also, the sample identification system is to accommodate a sub-division of groups of samples and the transfer of samples within & from the lab.	5.5.8.2.a [M2, 5.8.2 & 5.8.5]				**5111**	
C. Does the system include identification for all samples, sub-samples and subsequent extracts and/or digestates?	5.5.8.2.a [M2, 5.8.5(a)]				**5112**	
D. Does the laboratory assign a **unique identification (ID) code** to each sample container received in the laboratory? Note: Use of container shape, size, or other physical characteristic, such as amber glass or purple top, is not an acceptable means of sample identification.	5.5.8.2.a [M2, 5.8.5(a)]				**5113**	
E. Does the laboratory sample code **maintain an unequivocal link with the unique field ID** code assigned each container?	5.5.8.2.b [M2, 5.8.5(b)]				**5114**	
F. Is the laboratory ID code placed on the sample container as a **durable label**?	5.5.8.2.c [M2, 5.8.5(c)]				**5115**	
G. Is the laboratory ID code entered into the laboratory records and does the link associate the sample with related laboratory activities such as sample preparation or calibration?	5.5.8.2.d [M2, 5.8.5(d)]				**5116**	
SAMPLE RECEIPT PROTOCOLS & SAMPLE ACCEPTANCE POLICY						
H. Does the laboratory have a **written sample acceptance policy** that clearly outlines the circumstances under which samples will be accepted or rejected?	5.5.8.3.2 [M2, 5.8.6]				**5117**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
I. Is data from any sample which does not meet the policy criteria flagged in an unambiguous manner clearly defining the nature and substance of the variation?	5.5.8.3.2 [M2, 5.8.6(g)]				**5118+**	
J. Is the sample acceptance policy made available to sample collecting personnel?	5.5.8.3.2				**5119**	
K. Does the sample acceptance policy criteria include the following at a minimum: a) ___ **Proper, full, and complete documentation**, which includes: ___ sample identification, ___ location, ___ date and time of collection, ___ collector's name, ___ preservation type, ___ sample type, and ___ any special remarks concerning the sample. b) ___ **Proper sample labeling** to include: ___ unique identification and ___ abeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink. c) ___ Use of **appropriate sample containers**, d) ___ Adherence to **specified holding times**, e) ___ **Adequate sample volume** to perform the necessary tests, and f) ___ Procedures to be used when samples show **signs of damage or contamination**?	5.5.8.3.2a-f [M2, 5.8.6(a)-(f)]				**51110a** **51110b** **51110c** **51110d** **51110e** **51110f**	
L. Upon receipt, is the **condition of the sample recorded**, including any abnormalities or departures from standard condition as prescribed in the relevant test method?	5.5.8.3 [M2, 5.8.3]				**51111**	
M. Are all items specified in sample acceptance policy criteria checked?	5.5.8.3.1.a				**51112**	
N. Are all samples, **which require thermal preservation**, considered acceptable if the arrival temperature is either within ± 2 °C of the required temperature or in the method specified range?	5.5.8.3.1.a.1 [M2, 5.8.9(a)(i); M4 & M5, 1.7.5(a); M6, 1.7.4(a)]				**51113**	
O. For samples with a specified temperature of 4 °C, are samples maintained within a temperature of just above freezing to 6 °C?	5.5.8.3.1.a.1 5.5.8.4.a.1 [M2,				**51114**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	5.8.9(a)(i); M4 & M5, 1.7.5(a); M6, 1.7.4(a)]					
P. In cases **where samples are hand delivered to the laboratory** immediately after collection and do not meet the temperature criteria considered acceptable, is there evidence that the chilling process has begun such as arrival on ice?	5.5.8.3.1.a.1 [M4 & M5, 1.7.5(a); M6, 1.7.4(a)]				**51115**	
Q. Does the laboratory **implement procedures for checking chemical preservation** using readily available techniques, such as pH, free chlorine or temperature, prior to or during sample preparation or analysis?	5.5.8.3.1.a.2 [M4 & M5, 1.7.5(b); M6, 1.7.4(b)]				**51117**	
R. Are the results of all checks recorded?	5.5.8.3.1.b [M2, 5.8.4]				**51118**	
S. 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, does the laboratory: a) ___ consult with the client for further instruction before proceeding, and b) ___ establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory?	5.5.8.3.1.c [M2, 5.8.3]				**51119**	
T. If the sample does not meet the sample receipt acceptance criteria, does the laboratory do any of the following: a) ___ **Retain correspondence and/or records of conversations** concerning the final disposition of rejected, or b) ___ **Fully document any decision** to proceed with the analysis of samples not meeting acceptance criteria c) ___ At a minimum, **note the condition** of the sample on the chain of custody or transmittal forms and on laboratory receipt documents d) ___ **Appropriately qualify** the analysis data on the final report?	5.5.8.3.1.c.1 [M2, 5.8.7.2(a)] 5.5.8.3.1.c.2 [M2, 5.8.7.2(b)] 5.5.8.3.1.c.2.i [M2,				**51120**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	5.8.7.2(b)(i)] 5.5.8.3.1.c.2.ii [M2, 5.8.7(b)(ii)]					
U. Does the laboratory utilize a **permanent chronological log**, such as a logbook or electronic record, to document receipt of all sample containers?	5.5.8.3.1.d [M2, 5.8.7.3]				**51121**	
V. Is the following information recorded in the laboratory's chronological log: a) ___ Client/Project Name, b) ___ Date and time of laboratory receipt of sample, c) ___ Unique laboratory ID code, and d) ___ Signature or initials of the person making the entries?	5.5.8.3.1.d.1.i-iv [M2, 5.8.7.3(a)(i-iv)]				**51122a** **51122b** **51122c** **51122d**	
W. Is the following information unequivocally linked to the log in records, included as a part of the log, or if recorded/documented elsewhere, is it a part of the laboratory's permanent records, easily retrievable upon request, and readily available to individuals who will process the sample? a) ___ **Field ID code** linked to laboratory ID code in the sample receipt log b) ___ **Date and time of sample collection** linked to the sample container and to the **date and time received** in the laboratory c) ___ **Requested analyses** (including applicable approved test method numbers) linked to the laboratory ID code d) ___ Any **comments** resulting from inspection for sample rejection linked to the laboratory ID code	5.5.8.3.1.d.2.i-iv. [M2, 5.8.7.3(b)(i-iv)]				**51123a** **51123b** **51123c** **51123d**	
X. Does the laboratory retain all documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter retained?	5.5.8.3.1.e [M2, 5.8.7.4]				**51124**	
Y. If utilized, is a complete chain of custody record maintained?	5.5.8.3.1.f [M2, 5.8.7.5]				**51125**	
Z. Does the laboratory have documented procedures to **avoid deterioration or damage** to the sample during storage, handling, preparation, and testing?	5.5.8.4 [M2, 5.8.4]				**51126**	
AA. Does the laboratory **follow any relevant instructions** from the client in regards to the storage of a sample?	5.5.8.4 [M2,				**51127**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
	5.8.9(a)]					
BB. Where items have to be stored or conditioned under specific **environmental conditions**, are these conditions **maintained, monitored and recorded**?	5.5.8.4 [M2, 5.8.9(a)]				**51128**	
CC. Are samples stored according to the conditions specified by preservation protocols?	5.5.8.4.a [M2, 5.8.9(a)]				**51129**	
DD. Are samples stored away from all standards, reagents, food and other potentially contaminating sources in such a manner as to **prevent cross contamination**?	5.5.8.4.a.2 [M2, 5.8.9(a)(ii)]				**51130**	
EE. Are samples, sample fractions, extracts, leachates or other sample preparation fractions stored according to the conditions specified by preservation protocols or according to the test method? Note: Storage needs to ensure thermal preservation is met and achieved, cross contamination is prevented, and storage with potentially contaminating sources is avoided.	5.5.8.4.b [M2, 5.8.9(b)]				**51131**	
FF. Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), does the laboratory have **storage and security arrangements** that protect the condition and integrity of the secured items or portions concerned?	5.5.8.4.b [M2, 5.8.4]				**51132**	
GG. Does the laboratory have standard operating procedures for the **disposal of** samples, digestates, leachates and extracts or other sample preparation products?	5.5.8.4.c [M2, 5.8.9(c)]				**51133**	

Relevant Aspect of Standards – ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
24. ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS						
A. Does the laboratory **ensure the quality** of results provided to clients by implementing checks to **monitor the quality** of the laboratory's analytical activities? Examples are as follows: ▪ Internal quality control procedures (using statistical techniques whenever possible); ▪ Participation in PT or other inter-laboratory comparisons; ▪ Reference material and/or in-house quality control using secondary reference materials; ▪ Replicate testing; ▪ Re-testing of retained samples; and/or	5.5.9.1.a-e [M2, 5.9.1]				**5531**	

Relevant Aspect of Standards – ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
▪ Correlation of results for different parameters of a sample.						
B. Does the laboratory have quality control procedures for monitoring the validity of environmental tests and calibrations undertaken?	5.5.9.1.a-e [M2, 5.9.1]				**5591**	
C. Are the resulting data recorded in such a way that trends are detectable and, where applicable, statistical techniques are applied to the reviewing of the results?	5.5.9.1.a-e [M2, 5.9.1]				**55911**	
D. Is the monitoring planned and reviewed?	5.5.9.1.a-e [M2, 5.9.1]				**55912**	
ESSENTIAL QUALITY CONTROL PROCEDURES						
E. Does the laboratory have a **detailed written protocol** in place to monitor quality controls? Examples are as follows: ▪ Positive and negative controls such as blanks, spikes, and reference toxicants; ▪ Adequate tests to define variability and/or repeatability such as replicates; ▪ Measures to assure the accuracy of the method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures; ▪ Measures to evaluate method capability, such as limit of detection and limit of quantitation or range of applicability such as linearity; ▪ Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses; ▪ Selection and use of reagents and standards of appropriate quality; ▪ Measures to assure the selectivity of the test for its intended purpose; and ▪ Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method such as temperature, humidity, light or specific instrument conditions.	5.5.9.2.a.1-8 [M2, 5.9.3(a)(i-viii)]				**5536a**	
F. Are all quality control measures **assessed and evaluated on an on-going basis**, and quality control acceptance limits used to determine the usability of the data?	5.5.9.2.b [M2, 5.9.3(b)]				**5535**	
G. Does the laboratory have procedures for the development of **acceptance/rejection criteria** where no method or regulatory criteria exist?	5.5.9.2.c [M2, 5.9.3(c)]				**5536**	
H. Are the quality control protocols specified by the laboratory's method manual followed? Note: The essential QC standards of 5.5.4(a) of 2003 NELAC and 4.2.8.5 of 2009 TNI, mandated methods, or regulations must be incorporated into method manual. The QC requirements in the mandated methods or regulations are to be followed when it is not apparent which QC is more stringent.	5.5.9.2.d [M2, 5.9.3(c)]				**5537**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
25. REPORTING THE RESULTS						
A. Does the laboratory report the results of **each test or series of tests** carried out by the laboratory in a test report that reports the data **accurately, clearly, unambiguously, and objectively**? Note: The results also need to be reported in accordance with any specific instructions in the test method.	5.5.10.1 [M2, 5.10.1]				**5131**	
B. Does the test report contain all information necessary for the interpretation of the test results and all information required by the method used?	5.5.10.1 [M2, 5.10.1				**5132**	
C. If the laboratory is operated by a facility whose sole function is to provide data to the facility management, does the laboratory have all the required test report information readily available for review? Note: This information does not need to be included in a formal test report if the in-house laboratory is itself responsible for preparing regulatory reports (e.g., DMR) or the laboratory provides information to another individual within the organization for preparation of the regulatory report. In addition, the facility management must ensure that all required report items are included in the facility's regulatory report.	5.5.10.1 [M2, 5.10.10]				**5132b**	
D. Unless the laboratory is operated by a facility whose sole function is to provide data for the facility, does the report contain a___ A title, b___ Name/address of laboratory, c___ Location where analysis is carried out if different, d___ Phone number and name of contact person, e___ **Unique identification of the test report** and **unique identification of each page**, and the **total number of pages**. This requirement may be presented in the several ways: 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 2.___ Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (ex: 3 of 10, 1 of 20) 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	5.5.10.2.a [M2, 5.10.2(a)] 5.5.10.2.b [M2, 5.10.2(b)] 5.5.10.2.b [M2, 5.10.2(b)] 5.5.10.2.b 5.5.10.2.c [M2, 5.10.2(c)]				**5133a** **5133b** **5133c** **5133d** **5133e**	**Prep methods need to be specified on reports, if applicable.**

Relevant Aspect of Standards – REPORTING THE RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
the report contains a specified number of pages. f___ Name and address of client (and project name if applicable),	5.5.10.2.d [M2, 5.10.2(d)]				**5133f**	
g___ Description and unambiguous identification of the tested sample including the client identification code,	5.5.10.2.f [M2, 5.10.2(f)]				**5133g**	
h___ Where quality system requirements are not met, **a statement of compliance/non compliance with requirements and/or specifications,** including identification of results derived from samples that did not meet NELAC acceptance requirements such as improper container, holding time, or temperature,	5.5.10.3.1.b [M2, 5.10.3.1(b)]				**5133h+**	
i___ Date of receipt of sample, date and time of sample collection, date(s) of performance 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,	5.5.10.2.g [M2, 5.10.2(g)]				**5133i**	
j___ Identification of the test method used **(This includes prep methods, if applicable.)**,	5.5.10.2.e [M2, 5.10.2(e)]				**5133j**	
k___ If the laboratory collected the sample, reference to sampling plan and procedure, and	5.5.10.2.h [M2, 5.10.2(h)]				**5133k**	
l___ **Any deviations from**, additions to or exclusions from the test method, and non-standard conditions that may have affected the quality of the results, and including the use of relevant data qualifiers and their meaning?	5.5.10.3.1.a [M2, 5.10.3.1(a)]				**5133l+**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
E. Does the lab utilize **qualifiers** that are **useful** and **meaningful** for the end user? If "N", then list those qualifiers, or affix a copy of the report.	ELAP				**NA**	**For internal use**
F Does the report contain the following: a___ **Environmental test** results with, where appropriate, the **units of measurement,** and any failures (such as failed quality control) identified and whether data are calculated on dry weight or wet weight, reporting units, b___ When required, a statement of the estimated uncertainty of the test result, c___ A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue, d___ A statement to the effect that the results relate only to the samples tested or calibrated, e___ At the lab's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory, f___ Clear identification of test results performed by subcontract laboratory, including its accreditation number, and g___ Clear indication of numerical results with values outside of quantitation limits?	5.5.10.2.i [M2, 5.10.2(i) & 5.10.11(b)] 5.5.10.3.1.c [M2, 5.10.3.1(c)] 5.5.10.2.j [M2, 5.10.2(j)] 5.5.10.2.k [M2, 5.10.2(k)] 5.5.10.2.l [M2, 5.10 Note 2] 5.5.10.5 [M2, 5.10.6] 5.5.10.3.1.f [M2, 5.10.11(d)]				**5134a** **5134b** **5134c** **5134d** **5134e** **5134f** **5134g**	
G When test reports include the results of sampling, do the reports include, where necessary for the interpretation of test results, a___ Date of sampling, b___ Unambiguous identification of the substance, material or product sampled, c___ Location of sampling, including any diagrams, sketches or photographs, d___ Reference to sampling plan and procedures used, e___ Details of environmental conditions during sampling that may affect the interpretation of the test results, f___ Any standard or other specification for the sampling method or procedure, g___ Any deviations, additions, or exclusions from the specification concerned? Note: Refer to section 22, 'SAMPLING,' which deals with sampling plan and records.	5.5.10.3.2. a-f [M2, 5.10.3.2(a-f)] 7.1 [FMSO V1]			**X** **X** **X** **X** **X** **X** **X**	**NA**	**These items are addressed in other questions in this section, 'REPORTING THE RESULTS'.**
H Are all applicable elements above readily available for review if not issued in a formal report by	5.5.10.1				**5135**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
an in-house laboratory? Note: If the laboratory has a **written agreement with the client**, the test results may be reported in a simplified way.	[M2, 5.10.10] 5.5.10.1.a [M2, 5.10.10(a)]					
I Are all applicable elements above provided to another individual within the organization for preparation of regulatory reports if a formal report is not issued?	5.5.10.1 [M2, 5.10.10] 5.5.10.1.b [M2, 5.10.10(b)]				**5136**	
J. Does the facility management ensure that the appropriate report items are in the report to the regulatory authority if the report is prepared by another individual within the organization? Note: This information does not need to be included in a formal test report if the in-house laboratory is itself responsible for preparing regulatory reports (e.g., DMR) or the laboratory provides information to another individual within the organization for preparation of the regulatory report. In addition, the facility management must ensure that all required report items are included in the facility's regulatory report.	5.5.10.1.b [M2, 5.10.10(b)]				**5137**	
K. When opinions and interpretations are included in the test reports, does the laboratory document the basis upon which the opinions and interpretations have been made?	5.5.10.4 [M2, 5.10.5] 5.5.10.3.1.d [M2, 5.10.3.1(d)]				**55105a**	
L. Are opinions and interpretations clearly marked in test reports?	5.5.10.4 [M2, 5.10.5] 5.5.10.3.1.d [M2, 5.10.3.1(d)]				**55105b**	
M. Where the certificate or report contains results of tests performed by subcontractors, are these results **clearly identified by subcontractor name or applicable accreditation number**, and the subcontractor's report made available to the client on request?	5.5.10.5 [M2, 5.10.6]				**5138**	
N. Is the format of the report designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse?	5.5.10.7 [M2, 5.10.8]				**55108**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
O. When it is necessary to issue a **complete new test report**, is this uniquely identified and does it contain a reference to the original that it replaces?	5.5.10.8 [M2, 5.10.9]				**55109**	
P. Are material amendments to a calibration certificate, test report or test certificate after issue made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number…", or equivalent form of wording?	5.5.10.8 [M2, 5.10.9]				**51310**	
Q. Do **amendments to the formal report** meet all the relevant requirements of this standard?	5.5.10.8 [M2, 5.10.9]				**51311**	
R. 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 amendment to a report or certificate?	5.4.13.2				**51312**	
S. Does the laboratory have procedures that ensure, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, that the requirements of this Standard are met and that **confidentiality is preserved**?	5.5.10.6 [M2, 5.10.7]				**51313**	
T. Do laboratory staff follow the documented procedures for the transmission of test results by telephone, telex, fax or other electronic or electromagnetic means?	5.5.10.6 [M2, 5.10.7]				**51314**	
U. Does the laboratory certify that the test results meet all requirements of NELAC (TNI) or provide reasons and/or justification if they do not?	5.5.10.2.m				**51315**	
V. Does the lab report drinking water violations to the County Department of Health as required or requested by their client? Per Subpart 55-1.74 (b), the owner of a water system shall require the approved environmental laboratory performing the analyses to send laboratory results directly to the department and in a manner prescribed by the department. Per 55-1.77 (a), the supplier of water shall make State notification within 24 hours of learning of the existence or potential existence of a public health hazard, or within 48 hours for any other violation or situation that may pose a risk to public health.	DOH BPWS 55-1.74 and 1.77				**51316**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
26. DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION						
Note 1: For chemistry, microbiology, radiochemistry, air, and asbestos testing, the initial test method evaluation requirements are contained in 2003 [2009] NELAC Appendices D.1 [V1M4], D.3 [V1M5], D.4 [V1M6], D.5 [not applicable], and D.6 [V1M3], respectively. Note 2: The 2009 Standards incorporate the initial and ongoing demonstration of capability (DOC) as a sub-section (Sec. 1.6) within each discipline's module (e.g., radiochemistry DOC requirements are found in V1M6, 1.6.1-1.6.3; microbiology DOC requirements are found in V1M5, 1.6.1-1.6.3).						
A. Is an **initial demonstration of capability** made prior to using any method, and at any time there is a change in instrument type, personnel or method, or any time that a method has not	C.1 [All MV,				**00c11a**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
been performed by the laboratory or analyst in a twelve (12) month period? Note: Refer to deficiency 51014 in Section 19, 'Environmental Test Methods and Method Validation', too.	1.6.2]					
B. Are initial and on-going demonstrations **documented** and all data applicable to the demonstration retained and **readily available**? Note: Refer to deficiency 567 in Section 17, 'Personnel, Including Data Integrity Training', too, as well as, the next few deficiencies listed below.	C.1, C.2 [All MV,. 1.6.1-1.6.3]				**000c11**	

For **initial** demonstrations, the laboratory shall document each initial DOC in a manner such that the following information is readily available for each affected employee:
a) analyst(s) involved in preparation and/or analysis;
b) matrix;
c) analyte(s), class of analyte(s), or measured parameter(s);
d) identification of method(s) performed;
e) identification of laboratory-specific SOP used for analysis, including revision number;
f) date(s) of analysis; and
g) summary of analyses.

If the method or regulation does not specify an **initial** DOC, the following procedure is acceptable.
a) The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four (4) aliquots at the concentration specified, or if unspecified, to a concentration of one (1) to four (4) times the limit of quantitation.
b) At least four (4) aliquots shall be prepared and analyzed according to the method(s) either concurrently or over a period of days.
c) Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory shall assess performance against established and documented criteria.
d) Compare the information from (c) above to the corresponding acceptance criteria for
precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not meet the acceptance criteria, the performance is unacceptable for that parameter.
e) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to i) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with b) above, OR ii) Beginning with b) above, repeat the test for all parameters that failed to meet criteria.
f) Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with b).
g) When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited method, an initial demonstration shall be performed for that analyte.

For **on-going** demonstration, it may be one of the following:
a) acceptable performance of a blind sample (single blind to the analyst);
Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests.
b) another initial DOC;
c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCSs for each method for each analyst each year;
d) a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;
e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
C. Is the concentrate of the QC sample diluted in a volume of clean matrix sufficient to prepare four aliquots at the required method volume to a concentration specified in the method, or, if unspecified, to a concentration of 1-4 times the limit of quantitation?	C.1.b [All MV, 1.6.2.2)]				**000c15**	
D. Are four aliquots prepared and analyzed according to the method either concurrently or over a period of days?	C.1.c [All MV, 1.6.2.2)]				**000c16**	
E. Is the mean recovery and standard deviation for each parameter of interest calculated in the units used for reporting (such as mg/L)?	C.1.d [All MV, 1.6.2.2)]				**000c17**	
F. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?	C.1.d [All MV, 1.6.2.2)]				**00c17a**	
G. Does the mean recovery and standard deviation meet the acceptance criteria for precision and accuracy of the method (if applicable) or in laboratory generated acceptance criteria (if there is no mandatory criteria)?	C.1.e [All MV, 1.6.2.2)]				**000c18**	
H. If one or more of the test parameters does not meet the acceptance criteria, is the problem corrected followed by repeated analysis of the four aliquots for all parameters or at least for those that failed to meet criteria?	C.1.f [All MV, 1.6.2.2)]				**00c110**	
LIMIT OF DETECTION						
I. Does the laboratory determine the Limit of Detection (LOD) for the method for each target analyte of concern in the matrices approved?	C.3.1.a [M4, 1.5.2.1(a)]				**00C113**	
J. Do **all sample-processing steps of the analytical method** include the determination of the LOD?	C.3.1.a [M4, 1.5.2.1]				**00C114**	
K. Is the validity of the LOD confirmed by qualitative identification of the analyte(s) in a QC sample in each approved matrix containing the analyte at no more than 2-3 X the LOD for single analyte tests and 1-4 X the LOD for multiple analyte tests?	C.3.1.b [M4, 1.5.2.1(b)]				**00C115**	
L. Is this verification performed on every instrument that is to be used for analysis of samples and reporting of data?	C.3.1.b [M4, 1.5.2.1]				**00C116**	
M. Where an LOD study is not performed, does the laboratory not report a value below the Limit of Quantitation?	C.3.1.c [M4, 1.5.2.1]				**00C117**	
LIMIT OF QUANTITATION						

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
N. Are **all sample processing and analysis steps** of the analytical method included in the determination of the LOQ?	[M4, 1.5.2.2(a)]				**00C118a**	
O. Does the laboratory determine the Limit of Quantitation (LOQ) for each analyte of concern according to a defined, documented procedure? Note: Tthe LOQ study is not required for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).	C.3.2.a [M4, 1.5.2]				**00C118**	
P. Is the validity of the LOQ confirmed by successful analysis of a QC sample containing the analytes of concern in each approved matrix 1-2 times the claimed LOQ? Note: A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.	C.3.2.c [M4, 1.5.2.2(c)]				**00C119**	
Q. When the LOD is determined or verified by the laboratory, is the LOQ above the LOD?	[M4, 1.5.2.2(d]				**00C119a**	
R. Does the laboratory verify the LOQ annually for each quality system matrix, technology, and analyte? Note: The annual LOQ verification is not required if the LOD was determined or verified annually on that instrument.	[M4, 1.5.2.2(e)]				**00C119b**	
PRECISION AND BIAS						
S. When using standard methods, does the laboratory evaluate the precision and bias of a standard method for each analyte of concern for each quality system matrix according to the single-concentration four-replicate recovery study procedures (or alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available)?	C.3.3.a [M4, 1.5.3(a)]				**00C120**	
T. When using non-standard methods for laboratory-developed test methods or non-standard test methods, did the laboratory have a documented procedure to evaluate precision and bias? Note: This standard does not apply to test methods in use by the laboratory before July 2003.	C.3.3.b [M4, 1.5.3(b))]				**00C121**	
U. Does the laboratory compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory?	C.3.3.b [M4, 1.5.3(b)]				**00C122**	
V. Do the precision & bias measurements evaluate the laboratory-developed or non-standard test method across the analytical calibration range of the method? Note: Examples of systemic approach to evaluate precision & bias could be: (i) avalidation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process, or (ii) replicate analysis of quality control samples at or near the LOQ, at the upper range of the calibration, & at a mid-range concentration, processed on different days as 3 sets of samples through the entire measurement system for each analyte	C.3.3.b [M4, 1.5.3(b)]				**00C123**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2003 NELAC [2009 TNI]	Y	N	N/A	Codes	Comments
of interest (see Appendix C.3.3(b) to NELAC Chapter 5 for further details)."						
EVALUATION OF SELECTIVITY						
W. Does the laboratory evaluate selectivity by following the checks established within the method? Note: This may include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.	C.3.4 [M4, 1.5.4]				**00C125**	