NYSDOH ELAP Quality Systems Checklist

This checklist incorporates references to 'The NELAC Institute' 2016 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: _____

Assessments Dates:_____ Assessor Signature:_____

Name:	Title:	Reports Reviewed:

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

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	2016 NELAC	Y	N	N/A	Codes	Comments
1. INTRODUCTION						
A. All items identified in the quality system section of this standard are available for on-site inspection or data audit.	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. 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.	M1, 4.2.2				**502+r**	
a.) ___ The laboratory does 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,	M1, 4.1.5 (a) – (d)				**502a+r**	
b.) ___ The laboratory does 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,					**502b+r**	
c.) ___ The laboratory management & staff does not communicate with any individual at another laboratory (including intralaboratory communication) concerning the PT sample,					**502c+r**	
d.) ___ The laboratory management & staff does not attempt to obtain the assigned value of any PT sample from the PT Provider, and					**502d+r**	
e.) ___ The laboratory maintains 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.	M1,4.4.1				**502e+r**	

Relevant Aspect of Standards - INTRODUCTION	2016 NELAC	Y	N	N/A	Codes	Comments
E. The laboratory shall analyze and report a PT study at least twice per year for each accreditation FoPT for which it seeks to maintain accreditation in accordance (with the exception of Whole Effluent Toxicity Testing) with the following criteria: a) The closing dates of subsequent PT study samples for a particular accreditation FoPT shall be no more than seven (7) months apart. b) The opening date of PT study samples for a particular field of accreditation must be at least seven (7) calendar days after the closing date of a PT study for the same field of accreditation.	M1, 5.2.1.2 (a)				**5434r** **5434a** **5434b**	
F. For Whole Effluent Toxicity Testing the laboratory shall demonstrate to the Primary AB that it has received an acceptable evaluation for at least one (1) PT study to obtain initial accreditation. The study closing date of the most recent successful PT study shall be no more than twelve (12) months prior to obtaining initial accreditation from an AB. The laboratory shall continue to participate in PT studies annually from that point on.	M1,5.1.2				**5555**	
G. The laboratory satisfactorily analyzes **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						
H. The laboratory **posts or displays** their most recent NELAP accreditation certificate or its NELAP-accredited fields of testing in a **prominent place** in the laboratory facility.	NYS 55-2.2(d)				**503**	
I. Any non-accredited tests shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.	M2, 5.10.11(c)				**504r**	
J. The laboratory accompanies 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.	V2M1,8.3.3				**505r**	
K. The laboratory uses 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.	V2 M1,7.9.4.2.6				**506r**	
L. If, during the on-site assessment, the laboratory indicates **withdrawal for a portion of the approved scope** is desired, 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**	
M. If, during the on-site assessment, the laboratory indicates **additions be made to its scope**, 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**	

Relevant Aspect of Standards - INTRODUCTION	2016 NELAC	Y	N	N/A	Codes	Comments
2. LABORATORY MANAGEMENT ORGANIZATION						
A. The laboratory, or the organization of which it is part, is an entity that can be **held legally responsible**.	M2, 4.1.1	**X**			**542a+**	**This is confirmed by the ELAP Office upon application review (initial and renewal).**
B. The laboratory accepts 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.	M2, 4.1.2				**5412**	
C. The laboratory management system covers work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.	M2, 4.1.3				**542**	
D. The laboratory has managerial staff **with the authority and resources** needed to carry 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)				**543**	
E. The laboratory has policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.	M2, 4.1.5 (d)				**543a**	
F. The laboratory is 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.	M2,4.1.4 note 2; 4.1.5(b)				**544**	
G. The laboratory does not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.	M2,4.1.4 note 2				**545**	
H. If the laboratory is part of an organization performing activities other than environmental testing, the responsibilities of key personnel in the organization (having an involvement or influence on the environmental testing activities of the laboratory) are **defined in order to identify potential conflicts of interest**.	M2,4.1.4				**5414**	
I. Where a laboratory is part of a larger organization, 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.	M2,4.1.4 note 1				**5414a**	
J. The laboratory specifies the responsibility, authority, and interrelationships of all personnel who manage, perform or verify work affecting the quality of tests and/or calibration.	M2, 4.1.5(f)				**546**	
K. The laboratory defines the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services	M2, 4.1.5(e)				**546ar**	

Relevant Aspect of Standards - INTRODUCTION	2016 NELAC	Y	N	N/A	Codes	Comments
L. The laboratory **provides adequate supervision** of testing and calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each test or calibration, and the assessment of the results. **Note:** Refer to deficiencies in section 17 'Personnel', too.	M2, 4.1.5(g)				**547**	
M. The laboratory has **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.	M2, 5.2.1, 5.2.5				**549**	
N. The laboratory has technical management who have **overall responsibility** for the technical operations and the provision of resources needed to ensure the quality of laboratory operations.	M2, 4.1.5(h)				**5410r**	
O. 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.	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. The laboratory appoints 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. **Note:** Where staffing is limited, the quality manager may also be the technical director or deputy technical director.	M2,4.1.5(i) M2, 4.1.7.1				**5420**	
Q. The **QA officer** (and/or his/her designee(s)) has direct access to the technical directors and to the highest level of management where decisions are made on laboratory policy and resources.	M2, 4.1.5(i)				**5421r**	
R. The **QA officer** (and/or his/her designee(s)) serve as the focal point for QA/QC.	M2, 4.1.7.1(a)				**5422**	
S. The **QA officer** (and/or his/her designee(s)) take responsibility for the oversight and/or review of quality control data.	M2, 4.1.7.1(a)				**5423**	
T. The **QA officer** (and/or his/her designee(s)) have **functions independent** from laboratory operations for which they have QA oversight.	M2, 4.1.7.1(b)				**5424**	
U. The **QA officer** (and/or his/her designee(s)) evaluates data objectively and performs assessments without outside (e.g., managerial) influence.	M2, 4.1.7.1(c)				**5425**	
V. The **QA officer** (and/or his/her designee(s)) have documented training and/or experience in QA/QC procedures.	M2, 4.1.7.1(d)				**5426**	

Relevant Aspect of Standards - INTRODUCTION	2016 NELAC	Y	N	N/A	Codes	Comments
W. The roles and responsibilities of technical management and the QA officer, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.	M2, 4.2.6				**5427r**	
X. The **QA officer** (and/or his/her designee(s)) has general knowledge of the analytical test methods for which data review is being performed.	M2, 4.1.7.1(e)				**5428**	
Y. 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'.	M2, 4.1.7.1 (f)-(h) M2, 4.14.1; M2, 4.14.2				**5429+**	
Z. The **QA officer** (and/or his/her designee(s)) keeps the quality manual current.	M2, 4.2.8.2				**5431**	
AA. The laboratory **nominates deputies in the case of absence** of the technical director or QA officer.	M2, 4.1.5(j)				**5432**	
BB. ELAP has been notified in writing 1)___ **within 30 days** of a change in Technical Director OR 2) ___**within 35 days** of a temporary leave of the Technical Director	ELAP 55-2.6.c.1 and 55-2.10.d NELAC V1M2 4.1.7.2. e				**5439** **5440**	
CC. ELAP has 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	2016 NELAC	Y	N	N/A	Codes	Comments
3. LABORATORY QUALITY SYSTEM						
A. The laboratory establishes, implements, and maintains a **documented quality system** appropriate to the type, range and volume of environmental testing activities it undertakes.	M2,4.2.1				**551+**	
B. The **quality manual and related quality documentation** states the laboratory's policies and procedures established in order to meet the requirements of this Standard.						

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM	2016 NELAC	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.	M2, 4.2.1;M2, 4.2.8.3(h); M2, 4.2.5				**552**	
C. The quality documentation is **available to, understood by, and implemented by all** laboratory personnel.	M2, 4.2.1				**553**	
D. The laboratory's **quality system policies and objectives are defined** in a quality manual.	M2, 4.2.8.3(g,h) M2, 4.2.2				**5422ar**	
E. The **quality manual title page** lists the following: a.) ___ Document title; b.) ___ Laboratory's full name and address; c.) ___ The name, address), and telephone number of individual(s) responsible for the laboratory; d.) ___ The identification of all major organizational units covered by this quality manual; and the effective date of the version e.) ___ Identification of the laboratory's approved signatories f.)_____Signature and date of all responsible parties (quality manager, technical manager, laboratory director)	M2, 4.2.8.3 (a-f)				**554ar** **554br** **554cr** **554dr** **554er** **554**	**Document name:**_____ **Please list the effective date & version number of quality manual reviewed:** **Effective Date:** _____ **Revision/Version No.:** _____
F. 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.) __ The purpose of the management system related to quality; 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.	M2, 4.2.2(a-e)				**555ar** **555br** **555cr** **555dr** **555er**	
G. The **quality manual and related quality documentation** include the following: a.) ___ **Table of contents**, applicable lists of references and glossaries, and appendices;	M2, 4.2.8.3(i)				**5522**	
b.) ___ The organization and management structure of the laboratory, its place in any parent organization, and relevant **organizational charts**;	M2, 4.1.5(e); M2, 4.2.6; M2, 4.2.8.4(e)				**556**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM	2016 NELAC	Y	N	N/A	Codes	Comments
c.) ___ An outline of the structure of the **documentation used** in the quality system;	M2, 4.2.5				**5423b**	
d.) ___ Reference to the **supporting procedures** including technical procedures;	M2, 4.2.5				**5423a**	
e.) ___ Procedures to ensure that all records required under this Standard are **retained**; f.)____The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records.	M2, 4.2.8.4.(f) M2,4.13.3 (b)				**557r** **557a**	
g.) ___ The **relationship between** management, technical operations, support services, and the quality system;	M2, 4.1.5(e)				**557b**	
h.) ___ 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;	M2, 4.2.8.4(f)				**558**	
i.) ___ Job **descriptions of key staff** and reference to the job descriptions of other staff;	M2, 4.2.8.4(g)				**5423e**	
j.) ___ Procedures for achieving traceability of measurements;	M2, 4.2.8.4(h)				**559**	
k.) ___ **List of all methods** under which the laboratory performs its accredited testing;	M2, 4.2.8.4(i)				**5510**	
l.) ___ Mechanisms for ensuring that the laboratory **reviews all new work** to ensure that it has the appropriate facilities and resources before commencing such work;	M2, 4.2.8.4(j)				**5511**	
m.) ___ Policy addressing the use of unique electronic signatures where applicable;	M2, 4.2.8.4(r)				**5522z**	
n.) ___ Procedures for **handling submitted samples**;	M2, 4.2.8.4(k)				**5513**	
o.) ___ Reference the **major equipment and reference measurement standards used** as well as the facilities and services used by the laboratory in conducting tests;	M2, 4.2.8.4(b)				**5514**	
p.) ___ Reference to procedures for calibration, verification and maintenance of equipment;	M2, 4.2.8.4(a)				**5515**	
q.) ___ Reference to verification practices including inter-laboratory comparisons, and proficiency testing programs;	M2, 4.2.8.4(c)				**5516r**	
r.) ___ Procedures to be followed **for feedback and corrective action whenever testing discrepancies are detected**, or when departures from documented policies, procedures occur;	M2, 4.2.8.4(l)				**5517**	
s.) ___ Management arrangements for exceptionally permitting departures from standard operating procedures, policies or standard specifications;	M2, 4.2.8.4(m)				**5517a**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM	2016 NELAC	Y	N	N/A	Codes	Comments
t.) ___ Procedures for dealing with **complaints**; **Note:** This refers to resolution of complaints received from clients or other parties about laboratory activities.	M2, 4.2.8.4(n)				**5518**	
u.) ___ Processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training;	M2,4.2.8.4 (q)				**5519**	
v.) ___ Documented policies and procedures to ensure the **protection of clients' confidential information** and proprietary rights; This includes procedures for protecting the electronic storage and transmission of results.	M2, 4.2.8.4(o);M2, 4.1.5(c)				**5433a**	
w.) ___ Procedures for **audits and data review**; and	M2, 4.2.8.4(p)				**5430**	
x.) ___ Procedures for reporting analytical results	M2, 4.2.8.4(d)				**5521**	
y.) ___ Policy addressing the use of unique electronic signatures	M2,4.2.8.4 (r)				**5551**	

4. DOCUMENT CONTROL						
A. The laboratory establishes and maintains 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.	M2, 4.3.1				**5431a**	
B. All documents issued to personnel in the laboratory as part of the quality system are reviewed and approved for use by authorized personnel prior to issue.	M2, 4.3.2.1				**54321**	
C. The laboratory has 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.	M2, 4.3.2.1				**54321a**	
D. The adopted document control procedure ensures 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	M2,4.3.2.2 (a-d)				**54322a** **54322b** **54322c** **54322d**	

Relevant Aspect of Standards – LABORATORY QUALITY SYSTEM	2016 NELAC	Y	N	N/A	Codes	Comments
E. The quality system documents generated by the laboratory are 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)	M2, 4.3.2.3				**54323**	
F. Changes to documents are reviewed and approved by the same function that performed the original review unless specifically designated otherwise	M2, 4.3.3.1				**54331**	
G. The designated personnel have access to pertinent background information upon which to base their review and approval.	M2, 4.3.3.1				**54331a**	
H. Where practicable, the altered or new text is identified in the document or the appropriate attachments.	M2, 4.3.3.2				**54332**	
I. The laboratory defines the procedures and authorities if its document control system allows for amendment of documents by hand pending re-issue.	M2, 4.3.3.3				**54333**	
J. Such amendments are clearly marked, initialed, and dated.	M2, 4.3.3.3				**54333b**	
K. In the case of hand amendments, a revised document is formally re-issued as soon as practicable.	M2, 4.3.3.3				**54333c**	
L. Procedures are established to describe how changes in documents maintained in computerized systems are made and controlled.	M2, 4.3.3.4				**54334**	

Relevant Aspect of Standards – REVIEW OF REQUESTS, TENDERS AND CONTRACTS	2016 NELAC	Y	N	N/A	Codes	Comments
5. REVIEW OF REQUESTS, TENDERS AND CONTRACTS						
A. The lab establishes and maintains procedures for review of requests, tenders and contracts. **Note:** A contract may be any written or oral agreement to provide a customer with testing and/or calibration service.	M2, 4.4.1 M2,4.4.1 Note 3				**5441**	
B. 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	M2, 4.4.1 (a-c)				**5541a** **5541b** **5541c**	

Relevant Aspect of Standards – REVIEW OF REQUESTS, TENDERS AND CONTRACTS	2016 NELAC	Y	N	N/A	Codes	Comments
C. The laboratory informs 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	M2, 4.4.1				**5541b1r**	
D. The reviews of capability establishes 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.	M2, 4.4.1 Note 2				**5541b2r**	
E. Any differences between the request or tender and the contract are 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.	M2, 4.4.1				**54411r**	
F. The laboratory maintains records of reviews, including any significant changes.	M2, 4.4.2				**5442**	
G. The laboratory maintains 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.	M2, 4.4.2				**55421**	
H. Review records are 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.	M2, 4.4.2 Note				**54422ar** **54422br** **54422cr**	
I. The reviews covers any work that is subcontracted by the laboratory.	M2, 4.4.3				**5443**	
J. The client is informed of any deviation from the contract.	M2, 4.4.4				**5444**	
K. If a contract needs to be amended after work has commenced, the same contract review process is repeated, and any amendments are communicated to all affected personnel.	M2, 4.4.5				**5445**	
L. The laboratory reports any suspension of accreditation, revocation or accreditation, or voluntary withdrawal of accreditation to the client.	V2,M1,8.3.2 (e)				**54451+r**	

Relevant Aspect of Standards - SUBCONTRACTING	2016 NELAC	Y	N	N/A	Codes	Comments
6. SUBCONTRACTING						
A. The laboratory has records to indicate that it advises the client in writing of its intention to sub-contract any portion of the testing to another party, and when appropriate, gain the approval of the customer, preferably in writing.	M2, 4.5.2				**5141**	

Relevant Aspect of Standards - SUBCONTRACTING	2016 NELAC	Y	N	N/A	Codes	Comments
B. Where a laboratory sub-contracts any part of the testing covered under NELAP, 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 performing the tests and submitting results of tests performed.	M2, 4.5.1; M2, 4.5.5				**5142**	
C. Non-NELAC work is performed by a subcontracted laboratory and 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).	M2, 5.10.6				**5143r**	
D. The lab accepts responsibility for subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor to be used.	M2, 4.5.3				**5453**	
E. The lab maintains 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.	M2, 4.5.4				**5454**	

Relevant Aspect of Standards – PURCHASING SERVICES AND SUPPLIES	2016 NELAC	Y	N	N/A	Codes	Comments
7. PURCHASING SERVICES AND SUPPLIES						
A. Documented policies and procedures exist for the selection and purchasing of services and supplies used that affect the quality of environmental testing operations of the laboratory.	M2, 4.6.1				**5461**	
B. Documented procedures exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.	M2, 4.6.1				**51024**	
C. The laboratory ensures 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.	M2, 4.6.2				**5153**	
D. The services, and supplies used comply with specified requirements.	M2, 4.6.2				**5462a**	
E. Records are maintained of actions taken to check compliance.	M2, 4.6.2				**5462r**	
F. Purchasing documents, containing data describing the services and supplies ordered, are reviewed and approved for technical content prior to release.	M2, 4.6.3				**5463**	
G. The laboratory evaluates suppliers of critical consumables, supplies and services which affect the quality of environmental testing.	M2, 4.6.4				**5464a**	
H. The laboratory maintains records of evaluations of all suppliers from whom it obtains support services or supplies required for tests and list those approved.	M2, 4.6.4				**5464**	

Relevant Aspect of Standards – SERVICE TO THE CLIENT	2016 NELAC	Y	N	N/A	Codes	Comments
8. SERVICE TO THE CLIENT						
A. The lab offers 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. **Note:** Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.	M2, 4.7.1				**547A**	
B. The laboratory seeks feedback, both positive and negative, from its customers.	M2, 4.7.2				**547B**	.
C. The laboratory uses and analyzes the customer feedback to improve the management system, testing and calibration activities, and customer service.	M2, 4.7.2				**547C**	.

Relevant Aspect of Standards - COMPLAINTS	2016 NELAC	Y	N	N/A	Codes	Comments
9. COMPLAINTS						
A. The laboratory has documented policies and procedures for the resolution of complaints received from clients or other parties.	M2, 4.8				**547D**	
B. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.	M2, 4.8				**547E**	

Relevant Aspect of Standards – CONTROL OF NONCONFORMING WORK	2016 NELAC	Y	N	N/A	Codes	Comments
10. CONTROL OF NONCONFORMING WORK						
A. The laboratory has 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.	M2, 4.9.1				**5491**	
B. 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; b.)__ An evaluation of the significance 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	M2, 4.9.1(a-e)				**5491a** **5491b** **5491c** **5491d**	

Relevant Aspect of Standards – CONTROL OF NONCONFORMING WORK	2016 NELAC	Y	N	N/A	Codes	Comments
e.)__ The responsibility for authorizing the resumption of work is defined.					**5491e**	
C. The laboratory implements 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.	M2, 4.9.2				**5492**	

Relevant Aspect of Standards – CORRECTIVE ACTION	2016 NELAC	Y	N	N/A	Codes	Comments
11. CORRECTIVE ACTION						
A. The laboratory has established a corrective action policy and procedure.	M2, 4.11.1				**54101**	
B. The laboratory designates 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.	M2, 4.11.1				**54101a**	
C. The corrective action procedure starts with an **investigation of root cause(s)** of the problem.	M2, 4.11.2				**54102**	
D. The laboratory identifies potential corrective actions and selects and implements the action(s) most likely to eliminate the problem and to prevent recurrence.	M2, 4.11.3				**54103**	
E. Corrective actions are appropriate in degree to the magnitude and risk of the problem.	M2, 4.11.3				**54103a**	
F. The laboratory documents and implements any required changes resulting from corrective action investigations.	M2, 4.11.3				**54103b**	
G. The laboratory monitors the results to ensure that the corrective actions taken have been effective.	M2, 4.11.4				**54104**	
H. The laboratory ensures that appropriate areas of activity, identified or doubted as nonconforming or departure from policies and procedures, are promptly audited.	M2, 4.11.5				**54105**	
I. The laboratory has documented procedures to be followed when there are departures from documented policies, procedures, and QC occur.	M2, 4.11.6				**5532+**	
J. 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; 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.	M2, 4.11.6 M2, 4.11.6(a) M2, 4.11.6(b) M2, 4.11				**5533a** **5533b** **5533cr** **5533dr** **5533er**	

Relevant Aspect of Standards – PREVENTIVE ACTION AND IMPROVEMENT	2016 NELAC	Y	N	N/A	Codes	Comments
12. PREVENTIVE ACTION AND IMPROVEMENT						
A. The laboratory has a pro-active process to identifying opportunities for improvement.	M2,4.12.2 Note 1				**5411ar**	
B. Needed improvements and potential sources of non-conformances, either technical or concerning the quality system are identified.	M2, 4.12.1				**54111**	
C. The laboratory develops implements and monitors action plans where preventive action is required.	M2, 4.12.1				**54111a**	
D. Procedures for preventive action include the initiation of such actions and application of controls to ensure that they are effective.	M2, 4.12.2				**54112**	
E. The laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit responses, analysis of data, corrective and preventive actions, and management reviews.	M2, 4.10				**54112a**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2016 NELAC	Y	N	N/A	Codes	Comments
13. CONTROL OF RECORDS						
A. The laboratory maintains 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.	M2, 4.13.1.2				**5121r**	
B. The laboratory establishes and maintains procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.	M2, 4.13.1.1				**541211**	
C. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.	M2, 4.13.1.1				**541211a**	
D. The system produces unequivocal, accurate records, which document all laboratory activities.	M2, 4.13.3(a)				**5122**	
E. The laboratory retains on record all original observations, calculations and derived data, calibration records , a copy of the test report including hardware and software necessary for the historical reconstruction of electronic data for a **minimum of five years**. __ Records related to Potable Water chemical analyses are 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.	M2, 4.13.3(a-b)				**5123** **5123a**	
F. The laboratory has **established retention times of records**.	M2, 4.13.1.2				**5123b**	
G. All records, certificates and reports are held secure and in confidence to the client.	M2, 4.13.1.3				**51213**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2016 NELAC	Y	N	N/A	Codes	Comments
H. NELAP related records are available to the accrediting authority.	M2, 4.13.3(c)				**51214**	
I. All records are legible.	M2, 4.13.1.2				**541212**	
J. The record keeping system allows historical reconstruction of all laboratory activities that produced the resultant sample analytical data.	M2, 4.13.3 M2, 4.13.3(f)				**5124**	
K. The laboratory has 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.	M2, 5.8.8				**5124a**	
L. The laboratory has procedures to prevent unauthorized access to or amendment of records stored electronically.	M2, 4.13.1.4				**541214**	
M. Records that are stored or generated by computers or personal computers (PCS) have procedures to protect and back-up records.	M2, 4.13.1.4				**51216**	
N. The history of the sample is readily understood through the documentation including inter-laboratory transfers of samples and/or extracts.	M2, 4.13.3(a)				**5125**	
O. The records include the identity of personnel involved in sampling, preparation, calibration or testing and checking of results.	M2, 4.13.2.1				**5126**	
P. All information relating to the laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.	M2, 4.13.3(a)				**5127**	
Q. Records are stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. **Note**: The laboratory needs to have the supportive hardware & software necessary for data retrieval. Refer to deficiency 51219 in this section.	M2, 4.13.1.2 M2, 4.13.3(d)				**5128**	
R. All generated data, except those that are generated by automated data collection systems, recorded directly, promptly and legibly in permanent ink.	M2, 4.13.3(g)				**51210**	
S. Entries to electronically maintained records are changed so as to not erase or overwrite the files.	M2, 4.13.2.3				**541215f**	
T. The individual making the change to electronically maintained records are identified.	M2, 4.13.2.3				**51215fa**	
U. All changes to records entries are signed or initialed by responsible staff with the reason for the signature or initials clearly indicated in the records.	M2, 4.13.2.3				**5129**	
V. Entries in records are not obliterated by methods such as erasures, overwritten files or markings.	M2, 4.13.2.3				**51211**	
W. All corrections to record-keeping errors are 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	M2, 4.13.2.3 M2, 4.13.3(g)(i)				**51212**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2016 NELAC	Y	N	N/A	Codes	Comments
made illegible, with correct value entered alongside.						
X. 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.) __ The laboratory retains 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.) __ The records include the 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.	M2, 4.13.2.1				**541221** **541221a** **541221b**	
Y. Observations, data and calculations are recorded at the time they are made.	M2, 4.13.2.2				**541222**	
Z. Observations, data and calculations are identifiable to the specific task.	M2, 4.13.2.2				**541222a**	
AA. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.	M2, 4.13.2.3				**541223**	
BB. When corrections are made due to reasons other than transcription errors, the laboratory documents the reason for the correction.	M2, 4.13.3(g)(ii)				**541223a**	
CC. The laboratory has a **record management system** for control of laboratory notebooks; instrument logbooks; standards logbooks; and records for data reduction, validation storage and reporting.	M2, 4.13.1				**51217**	
DD. Access to **archived information is** documented with an access log.	M2, 4.13.3(e)				**51218**	
EE. Archived information is stored in a suitable environment to protect from damage and deterioration and to protect from loss.	M2, 4.13.1.2				**51219**	
FF. The laboratory has a plan to ensure that the records are maintained or transferred according to the clients' instructions and following regulatory and state requirements in the event that a laboratory **transfers ownership or goes out of business**.	M2, 4.13.3(h)				**51220**	
GG. The laboratory retains 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. e) __ laboratory facilities, equipment, and analytical methods.	M2, 4.13.3(a)				**51221a** **51221b** **51221c** **51221d** **51221e**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2016 NELAC	Y	N	N/A	Codes	Comments
HH. The laboratory retains: 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.	M2, 4.13.2.1, M2 4.13.3(f) (i-ii)				**51222a+** **51222br** **51222c** **51222d** **51222e** **51222f** **51222gr** **51222h**	
II. Strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include: a.) __ Laboratory sample ID code, b.) __ Date of analysis, and date 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, 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	M2, 4.13.3 (f)(iii – xvi)				**51223a** **51223b** **51223c** **51223d** **51223e** **51223f** **51223g** **51223h** **51223i** **51223j** **51223k** **51223l** **51223m** **51223n**	

Relevant Aspect of Standards – CONTROL OF RECORDS	2016 NELAC	Y	N	N/A	Codes	Comments
JJ. The following **administrative records** are 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	M2, 4.13.3 (f)(xviii) M2, 4.13.3 (f)(xix)				**51224a** **51224b** **51224c**	

Relevant Aspect of Standards – INTERNAL AUDITS	2016 NELAC	Y	N	N/A	Codes	Comments
14. INTERNAL AUDITS						
A. The laboratory conducts 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.	M2, 4.14.1; M2, 4.14.5(c)				**54131**	
B. The internal audit program addresses all elements of the quality system, **including testing activities**.	M2, 4.14.1				**54131a**	
C. Personnel audit their own activities only when it can be demonstrated that an effective audit will be carried out.	M2, 4.14.1				**54131b**	
D. The internal audit is conducted by personnel trained and qualified as auditors who, wherever possible, are independent of the activities being audited (e.g., QA Officer).	M2, 4.14.1				**5523**	
E. Timely corrective action is taken when audit findings cast doubt on the correctness or validity of the calibrations or test results	M2, 4.14.2				**5524**	
F. Clients are notified in a timely manner, in writing, when their work is affected by the findings from an internal audit.	M2, 4.14.2				**5525**	
G. The laboratory has 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.	M2, 4.14.5(a)				**5525a**	
H. All audits and review findings and any corrective actions that arise from them are recorded.	M2, 4.14.3				**5529+**	
I. The laboratory management ensures 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.	M2, 4.14.5(b) M2, 4.15.2				**5530**	
J. The implementation and effectiveness of the corrective action taken is verified and recorded from follow-up audit activities.	M2, 4.14.4				**54134**	

Relevant Aspect of Standards – MANAGERIAL REVIEWS	2016 NELAC	Y	N	N/A	Codes	Comments
15. MANAGERIAL REVIEWS						
A. The laboratory has a procedure for the **annual** management review of the quality system and it maintains records of review findings and actions.	M2, 4.15.2				**5526**	
B. An **annual** review of the quality system is completed by management to evaluate its continuing suitability and effectiveness and make any necessary changes or improvements.	M2, 4.15.1; M2, 4.15.3				**5527+**	
C. The **annual** review considers: a.) __ The suitability of policies and procedures; b.) __ Reports from managerial and supervisorial personnel; c.) __ The outcome of recent internal audits; 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; j.) __ Other relevant factors, such as quality control activities, resources and staff training. k) Recommendations for improvement	M2, 4.15.1				**5528a** **5528b** **5528c** **5528d** **5528e** **5528f** **5528g** **5528h** **5528i** **5528j** **5528k**	

Relevant Aspect of Standards – LABORATORY TECHNICAL REQUIREMENTS	2016 NELAC	Y	N	N/A	Codes	Comments
16. LABORATORY TECHNICAL REQUIREMENTS						
A. The laboratory takes 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).	M2, 5.1.1; M2, 5.1.2				**5526a**	
B. The laboratory takes into account all factors (listed above) in the training & qualification of personnel.	M2, 5.1.2				**5526b**	
C. The laboratory considers all factors (listed above) in the selection & calibration of the equipment it uses.	M2, 5.1.2				**5526c**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY PROCEDURES AND TRAINING	2016 NELAC	Y	N	N/A	Codes	Comments
17. PERSONNEL, INCLUDING DATA INTEGRITY PROCEDURES AND TRAINING						
A. The laboratory maintains records to indicate that it has **sufficient personnel**, having the **necessary** education, training, technical knowledge and experience for their assigned functions.	M2, 5.2.1				**561**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY PROCEDURES AND TRAINING	2016 NELAC	Y	N	N/A	Codes	Comments
Note: Refer to deficiencies 547 and 549 in section 2 'Laboratory Management Organization', too.						
B. The laboratory management **ensures the competence** of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports.	M2, 5.2.1				**561a**	
C. Personnel are responsible for **complying with all quality assurance/quality control** requirements that pertain to their organizational/technical function.	M2, 4.2.2(d)				**562**	
D. Each technical staff member has a **combination of experience and education** to adequately demonstrate a.) __ A specific knowledge of their particular function; and 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.	M2, 5.2.1				**563**	
E. Laboratory management ensures that staff who are undergoing training are provided with **appropriate supervision**.	M2, 5.2.1				**5521a**	
F. Laboratory management **formulate goals** with respect to the education, training and skills for laboratory personnel.	M2, 5.2.2				**5521b**	
G. The laboratory has a policy and procedures for **identifying training needs** and **providing training** of personnel.	M2, 5.2.2				**5521c**	
H. The training program is **relevant to the present and anticipated tasks** of the laboratory.	M2, 5.2.2				**5522a**	
I. The effectiveness of the training program is evaluated.	M2,5.2.2				**5522b**	
J. If the laboratory uses personnel under contract to the laboratory or if additional technical and key support personnel are used, the laboratory **ensures that such personnel are supervised and competent** and that they work in accordance with the laboratory's quality system**.**	M2, 5.2.3				**5523a**	
K. The laboratory **maintains current job descriptions** for all personnel who manage, perform, or verify work affecting the quality of testing.	M2, 5.2.4				**5524a**	
L. Laboratory management authorizes 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	M2, 5.2.5				**55251** **55252** **55253** **55254** **55255**	
M. The laboratory maintains **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.	M2, 5.2.5				**5525b**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY PROCEDURES AND TRAINING	2016 NELAC	Y	N	N/A	Codes	Comments
N. There is 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.	M2, 5.2.4				**564**	
O. The quality manual defines 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)	M2, 4.2.8.1; M2, 5.2.7				**5520**	
P. The laboratory management provides a mechanism for confidential reporting of data integrity issues within the laboratory. 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.	M2, 4.2.8.1(a)				**54231**	
Q. In instances of ethical concern, the mechanism includes a process whereby laboratory management are to be informed of any further detailed investigations.	M2, 4.2.8.1(b)				**54232**	
R. The data integrity procedures are signed and dated by senior management.	M2, 4.2.8.1				**54155**	
S. The data integrity procedures are annually reviewed and updated by management.	M2, 4.2.8.1				**54157**	
T. These procedures and the associated implementation records are properly maintained and made available for assessor review.	M2, 4.2.8.1				**54156**	
U. Reviews are conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity.	M2, 4.16				**54151**	
V. The discovery of potential issues is 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.	M2, 4.16				**54152**	
W. All investigations that result in findings of inappropriate activity are documented including any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.	M2, 4.16				**54153+**	
X. Senior managers acknowledge their support of these procedures by: 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				**54158**	
Y. Data integrity training includes: a.) __ Topics covered are 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,					**5527a** **5527b** **5527c** **5527d**	

Relevant Aspect of Standards – PERSONNEL, INCLUDING DATA INTEGRITY PROCEDURES AND TRAINING	2016 NELAC	Y	N	N/A	Codes	Comments
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, such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards. 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 of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in some way partially deficient. i.) ___ 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.	M2, 5.2.7 and 5.2.7(a-e)				**5527e** **5527f** **5527g** **5527h** **5527i**	
Z. Laboratory management ensures 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.	M2, 5.2.5 M2, 5.2.2 M2, 5.2.7 M2, 5.2.7 M2, 5.2.5 M2,4.3.2.1				**566a** **566b** **566c** **566d** **566er**	
AA. The laboratory **documents all analytical and operational activities** of the laboratory.	M2, 4.13.2				**568**	
BB. The laboratory management ensures **supervision of all personnel** employed by the laboratory.	M2, 4.1.5(g)				**5526e**	
CC. The laboratory management **ensures the quality of all data** reported by the laboratory.	M2,4.1.5(i)				**5610r**	

Relevant Aspect of Standards – PHYSCIAL FACILITIES (ACCOMMODATION & ENVIRONMENTAL CONDITIONS)	2016 NELAC	Y	N	N/A	Codes	Comments
18. PHYSICAL FACILITIES (ACCOMMODATION & ENVIRONMENTAL CONDITIONS)						
A. The laboratory accommodations, test areas, energy sources, lighting, and environmental. conditions **facilitate proper performance of tests**. **Note:** This also includes heating and ventilation.	M2, 5.3.1				**571**	
B. The environment in which these activities take place are such that the results are not invalidated, or the required accuracy of measurement is not adversely affected.	M2, 5.3.1				**572**	
C. The technical requirements for accommodation and environmental conditions that can affect the results of tests are documented.	M2, 5.3.1				**55311**	
D. The environment provides 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).	M2, 5.3.2				**573**	
E. Tests are stopped when the environmental conditions jeopardize the results.	M2, 5.3.2				**55321**	
F. There are **effective separations between neighboring areas** when the activities therein are incompatible (including culture handling or incubation areas and volatile organic chemicals handling areas).	M2, 5.3.3				**575**	
G. Measures are taken to **prevent cross contamination**.	M2, 5.3.3				**55331**	
H. Access to and use of neighboring areas where activities are incompatible are defined and controlled.	M2, 5.3.4				**576**	
I. Adequate measures are taken to ensure **good housekeeping** and to ensure that any contamination does not adversely affect data quality.	M2, 5.3.5				**577**	
J. Special procedures are prepared when necessary.	M2, 5.3.5				**578**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2016 NELAC	Y	N	N/A	Codes	Comments
19. ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION						
A. The laboratory uses **appropriate methods and procedures** for all test methods and laboratory activities within its scope. **Note:** It includes sample collection, sample handling, transport & storage, sample preparation, sample analysis, estimations of uncertainty, & statistical techniques.	M2, 5.4.1				**5101**	
B. The laboratory documents 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.	M2, 5.4.1				**5102a** **5102b**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2016 NELAC	Y	N	N/A	Codes	Comments
C. All instructions, standards, manuals and reference data relevant to the work of the laboratory are **maintained up-to-date and readily available** to the staff.	M2, 5.4.1				**5103**	
D. Deviations from test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.	M2, 5.4.1				**554111**	
E. The laboratory **maintains SOPs** that accurately reflect all phase of laboratory activities such as data integrity, corrective actions, handling customer complaints 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. Each test method includes or references all 23 points **where applicable**. The 23 points are: a) __ Identification of the test method, b) ___ Applicable matrix or matrices, c) ___ Detection limit and quantitation, d) ___ Scope and application, including analytes to be analyzed e) ___ Summary of the test method, f) ___ Definitions, g) ___ Interferences, h) ___ Safety, i) ___ Equipment and supplies, j) ___ Reagents and standards, 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,	M2, 4.2.8.5, M2, 4.2.8.5(a), (d) & (f) M2, 4.2.8.5 M2, 4.2.8.5 (f)(i-xxiii)				**55411** **5108** **5108a** **5108b** **5108c** **5108d** **5108e** **5108f** **5108g** **5108h** **5108i** **5108j** **5108k** **5108l** **5108m** **5108n** **5108o** **5108p** **5108q** **5108r** **5108s** **5108t** **5108u**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2016 NELAC	Y	N	N/A	Codes	Comments
v) ___ References, and w) ___ Any tables, diagrams, flowcharts and validation data.					**5108v** **5108w**	
F. Copies of SOPs are assessable to all personnel.	M2, 4.2.8.5(b)				**5104**	
G. The laboratory has and maintains an SOP for each accredited analyte or method.	M2,4.2.8.5 (e)				**511**	
H. Each SOP clearly indicates: a.) __ **Effective date** of the SOP, b.) __ **Revision number**, and c.) __ **Signature(s)** of approving authority	M2, 4.2.8.5(c)				**5105a** **5105b** **5105c**	
SELECTION OF METHODS						
I. The laboratory uses 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.	M2, 5.4.2				**5109**	
J. The laboratory ensures 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.	M2, 5.4.2				**55421a**	
K. When specific test methods are not required, the laboratory **uses only fully documented 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 need 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				**51012**	
L. The laboratory informs the client when the method proposed by the client is **considered to be inappropriate or out of date**.	M2, 5.4.2				**55421d**	
M. The introduction of laboratory-developed methods is a planned activity assigned to qualified personnel equipped with adequate resources.	M2, 5.4.3				**5543**	
N. Plans for laboratory-developed methods are updated as development proceeds and effective communication amongst all personnel involved ensured.	M2, 5.4.3				**5543a**	
O. When it is necessary to use non-standard methods, their use is subject to agreement with the client, including clear specification of client requirements and the purpose of the testing.	M2,5.4.4				**5544r**	
P. All non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods are validated to confirm they fit their intended use.	M2,5.4.4				**55452r**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2016 NELAC	Y	N	N/A	Codes	Comments
VALIDATION OF TEST METHODS / ESTIMATION OF UNCERTAINTY OF MEASUREMENT						
Q. The laboratory records 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 M3-M6,1.5	M3-M6, 1.5,M2,5.4.5.2				**55452ar** **55452b**	
R. The ranges and accuracy of the values obtainable from validated methods, is within the intended use, and relevant to the clients' needs.	M2,5.4.5.3				**55453r**	
S. If a laboratory is performing testing it has and implements 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.	M2,5.4.6.2				**55462r**	
T. In cases where it is not possible to calculate the uncertainty of measurement in a rigorous metrological and statistically significant way, the laboratory, at least, attempts to identify all the components of uncertainty and makes a reasonable estimation. **Note:** It is based on knowledge of the performance of the method, measurement scope, previous experience, and validation data.	M2,5.4.6.2				**55462ar**	
U. The laboratory ensures that the form of reporting does not give a wrong impression of the uncertainty of measurement.	M2,5.4.6.2				**55462br**	
V. All important uncertainty components are considered using appropriate methods of analysis.	M2,5.4.6.3				**55463r**	
CONTROL OF DATA						
W. Calculations and data transfers are subject to checks as established in the laboratory's SOP.	M2, 5.4.7.1				**51023**	
X. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that computer software developed by the user is **documented in sufficient detail** and is **suitably validated as being adequate** for use.	M2, 5.4.7.2(a)				**51032a**	
Y. Procedures are established and implemented for **protecting the integrity of data**.	M2, 5.4.7.2(b)				**51033r**	
Z. The procedures include, but are not be limited to: a.) __ Integrity of data entry or capture, b.) __ Data storage, c.) __ Data transmission, and d.) __ Data processing e.) __ Confidentiality 0f data entry or collection	M2, 5.4.7.2(b)				**51035r**	

Relevant Aspect of Standards – ENVIRONMENTAL TEST METHODS AND METHOD VALIDATION	2016 NELAC	Y	N	N/A	Codes	Comments
AA. Computer and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data.	M2, 5.4.7.2(c)				**51036**	
BB. The laboratory establishes and implements appropriate procedures for the **maintenance of security of data** including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.	M2,4.13.1.3-4.13.1.4				**51037r**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2016 NELAC	Y	N	N/A	Codes	Comments
20. EQUIPMENT AND REFERENCE MATERIALS						
A. The laboratory furnishes all items of **equipment (including reference materials)** required for the correct performance of tests for which accreditation is sought.	M2, 5.5.1				**581**	
B. Equipment **outside the permanent control** of the laboratory is handled so as to ensure that the requirements of the NELAC standard are met.	M2, 5.5.1				**582**	
C. The equipment and the software used for testing, calibration and sampling are capable of achieving the accuracy required and it complies with specifications relevant to the tests concerned.	M2, 5.5.2				**5552**	
D. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect of the results.	M2, 5.5.2				**55521**	
E. Before being placed into service, equipment (including that used for sampling) is calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications.	M2, 5.5.2				**55522**	
F. All support equipment is 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, freezers, incubators, water baths, thermometers, thermistors, thermal/pressure sample preparation devices, and mechanical dispensing devices.	M2, 5.5.13.1(b)				**5910r**	
G. All temperature measuring devices are **calibrated or verified at least annually**, using a recognized National Metrology Institute traceable reference such as NIST traceable references when available. a.) __ If the temperature measuring device is used over a range of 10 degrees C or less, then a single point verification within the range of use is performed. b.___ If the temperature measuring device is used over a range of greater than 10 degrees, then the verification brackets the range of use.	M2, 5.5.13.1(d)				**59111** **59111a** **59111b**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2016 NELAC	Y	N	N/A	Codes	Comments
H. The results of support equipment calibration or verification are within the specifications required of the application for which it is used.	M2, 5.5.13.1(a)				**5912r**	
I. Support equipment that is not within the specifications required of the application are **removed from service until repaired**.	M2, 5.5.13.1 (a)(i)				**5913r**	
J. The laboratory **maintains records of established correction factors** to correct measurements.	M2, 5.5.13.1 (a)(ii)				**5914r**	
K. All raw data records are retained to document equipment performance.	M2, 5.5.13.1(g)				**5915r**	
L. On each day that the equipment is used, balances, ovens, refrigerators, freezers, incubators and water baths are checked and documented.	M2, 5.5.13.1(c)				**5916**	
M. The acceptability for use or continued use are according to the needs of the analysis or application for which it is used.	M2, 5.5.13.1(c)				**5918r**	
N. Mechanical volumetric devices, are verified prior to first use and, are checked for accuracy on a **quarterly basis**. **Note:** Check is not needed for Class A glassware.	M2, 5.5.13.1 (e)(iii)				**5919r**	
O. Mechanical devices that are used at more than one volume are verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device.	M2,5.5.13.1(e) (iii)				**59920**	
P. Disposable or single use volumetric equipment are verified once per lot, prior to or in conjunction with the first use.	M2,5.5.13.1(e) (ii)				**59921**	
Q. All other volumetric support equipment is checked for use prior to or in conjunction with first use.	M2,5.5.13.1(e) (iv)				**59922**	
R. All other support equipment is calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable reference when available, bracketing the range of use.	M2,5.5.13.1(f)				**59923**	
S. Equipment is **operated by authorized personnel**.	M2, 5.5.3				**5553**	
T. All equipment is properly **maintained, inspected and cleaned**.	M2, 5.5.5(g)				**583r**	
U. Maintenance procedures are documented.	M2, 5.5.5(f)				**584r**	
V. Up-to-date instructions on the use & maintenance of equipment (including relevant manufacturer manuals) are **readily available** for use by appropriate personnel.	M2, 5.5.3				**584a**	
W. The laboratory has p**rocedures for safe handling, transport, storage, use, and planned maintenance** of measuring equipment to ensure proper functioning and to prevent contamination or deterioration.	M2, 5.5.6				**5556**	
X. 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, is **taken**	M2, 5.5.7				**585**	

Relevant Aspect of Standards – EQUIPMENT AND REFERENCE MATERIALS	2016 NELAC	Y	N	N/A	Codes	Comments
out of service, isolated to prevent use or clearly marked as being out of service until it has been repaired and shown by calibration, verification or test to perform satisfactorily.						
Y. The laboratory examines the effects of this defect or departures from specified limits on **previous tests and/or calibrations** and institutes the "Control of Nonconforming Work" procedure. **Note:** Refer to section 10 of checklist, "Control of Nonconforming Work".	M2, 5.5.7 M2. 4.9.1				**586**	
Z. Each item of equipment and its software used for environmental testing and significant to the result, are **uniquely identified** (when practicable). **Note**: Refer to deficiency 51223C in section 13 of checklist, "Control of Records", too.	M2, 5.5.4 M2, 4.13.3(f)				**586a**	
AA. Whenever practical, items of equipment under control of the laboratory and requiring calibration are **labeled, coded or otherwise identified to indicate its calibration status**, including the date when last calibrated and the date or expiration criteria when recalibration is due.	M2, 5.5.8				**587**	
BB. Records are maintained of each item of equipment and its software significant to the tests and /or calibrations include the following: a) ___ The identity of the item of equipment and its software, b) ___ The manufacturer's name, type identification, and serial number or other unique identification, c) ___ Checks that equipment comply with the specification, d) ___ Current location, where appropriate, e) ___ manufacturer's instructions, where available, or reference to their location 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	M2, 5.5.5(a)-(h)				**588a** **588b** **588c1** **588d** **588e1** **588f1** **588g1** **588h1**	
CC. If for any reason, equipment goes **outside the direct control of the laboratory**, the laboratory ensures that the function and calibration status of the equipment is checked and shown to be satisfactory before equipment is returned to service.	M2, 5.5.9				**5559**	
DD. The laboratory has procedures to **ensure that copies of new correction factors are correctly applied/updated** (e.g. in computer software).	M2, 5.5.11				**55511**	
EE. Test and calibration equipment, including both hardware and software, are **safeguarded from adjustments** which would invalidate the test and/or calibration results.	M2, 5.5.12				**55512**	

Relevant Aspect of Standards – MEASUREMENT TRACEBILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS	2016 NELAC	Y	N	N/A	Codes	Comments
21. MEASUREMENT TRACEABILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS						
A. All measuring operations and testing equipment having an effect on the accuracy or validity of tests are calibrated and/or verified **before being put into service and on a continuing basis**.	M2, 5.6.1				**591**	
B. The laboratory has **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.	M2, 5.6.1 M2, 5.6.3.1				**592** **5992**	
C. The laboratory ensures that the equipment used can **provide the uncertainty of measurement needed with an established program and procedure for the calibration of its equipment.**	M2, 5.6.1				**556221r**	
D. The overall program of calibration and/or verification & validation of equipment made by the lab is **traceable to national standards of measurement**.	M2, 5.6.2				**593**	
E. The laboratory provides satisfactory evidence of correlation of results in those cases where **traceability to national standards of measurement** is not applicable.	M2, 5.6.2.1.1 M2, 5.6.4.1				**595r**	
REFERENCE STANDARDS AND REFERENCE MATERIALS						
F. Reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) are **used for calibration only** and for no other purpose, unless it is demonstrated that their performance as reference standards has not been invalidated.	M2, 5.6.3.1				**596**	
G. Reference standards of measurement are 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 any adjustments.	M2, 5.6.3.1 M2, 5.6.3.2; M2, 5.6.4.1(a)				**597**	
H. There is a **program of calibration and verification** for reference standards. **Note:** Refer to deficiency 592 in this section, too.	M2, 5.6.3.1				**598**	
I. Internal reference materials are checked as far as technically and economically possible.	M2, 5.6.3.2				**599a**	
J. The laboratory has defined procedures and schedules for carrying out **checks of the calibration status** of reference, primary, transfer or working standards and reference materials.	M2, 5.6.3.3				**55633**	
K. The laboratory has 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.	M2, 5.6.3.4				**55634**	
L. Documented procedures exist for the **purchase, receipt and storage of consumable materials** used for the technical operations of the laboratory.	M2, 5.6.4.2				**55641**	

Relevant Aspect of Standards – MEASUREMENT TRACEBILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS	2016 NELAC	Y	N	N/A	Codes	Comments
M. a.)__The laboratory retains records for all standards, reagents, reference materials and media. This includes: a.1)__Manufacturer/vendor a.2.)__Manufacturers Certificate of Analysis (COA) a.3.)__Purity (if available) a.4.)__Date of receipt a.5.)__Recommended storage conditions	M2, 5.6.4.2(a)				**51025a1** **51025a2** **51025a3** **51025a4** **51025a5**	
b.)__For original containers, if an expiration date is provided by the manufacturer or vendor, it shall be recorded on the container	M2, 5.6.4.2(b)				**51025b**	
c.)__ Records shall be maintained on standard, reference material, and reagent preparation. This includes: c.1.)__Traceability to purchased stocks or neat compounds c.2.)__Reference to the method of preparation c.3.)__Date of preparation c.4.)__Expiration date c.5.)__Preparer's initials	M2, 5.6.4.2(c)				**51025c1** **51025c2** **51025c3** **51025c4** **51025c5**	
d.)__All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date.	M2, 5.6.4.2(d)				**51025d**	
e.)__ Prepared reagents meet the requirements of the method.	M2, 5.6.4.2(e)				**51025e**	
f.)___ Standards, reference materials, and reagents are not used after their expiration dates unless their reliability is verified by the laboratory.	M2, 5.6.4.2(f)				**51025f**	
N. The laboratory has **verified the purity of expired standards, reagents, & media** prior to their continued use.	M2, 5.6.4.2(f)				**51025a**	
O. Original reagent containers are **labeled with the expiration date**. **Note:** If an expiration date is not provided by the manufacturer or vendor it is not required.	M2, 5.6.4.2.(b)				**51026**	
P. Detailed records are maintained on standard and reference material preparation. **Note:** Refer to deficiency 51223i in section 13, 'Control of Records', too.	M2, 5.6.4.2(c)				**51027**	
Q. The records of standard and reference material preparation indicates traceability to purchased stocks or neat compounds, reference to method of preparation, date of preparation, expiration date, and preparer's initials. **Note:** Refer to deficiency 51223, f, g, and i in section 13, 'Control of Records', too.	M2, 5.6.4.2(c)				**51028**	

Relevant Aspect of Standards – MEASUREMENT TRACEBILITY, INCLUDING CALIBRATION AND REFERENCE STANDARDS & MATERIALS	2016 NELAC	Y	N	N/A	Codes	Comments
R. All containers of prepared standards , reference materials and reagents **bear a unique identifier and expiration date,** and can it be linked to the documentation of its preparation.	M2, 5.6.4.2(d)				**51029**	
S. Procedures are in place to ensure prepared reagents meet the requirements of the test method.	M2, 5.6.4.2(e)				**5564e**	
T. In methods where the purity of the reagents are not specified, analytical grade is used.	M4, 1.7.2.5(a)				**511030**	
U. Documentation of purity of reagents is available.	M4, 1.7.2.5(a)				**511031**	
V. The laboratory verifies the concentrations of titrants in accordance with written laboratory procedures.	M4, 1.7.2.5.(c)				**511032**	
W. The quality of the water sources are monitored and documented and meet the method specified requirement.	M4, 1.7.2.5.(b)				**511033**	

Relevant Aspect of Standards - SAMPLING	2016 NELAC	Y	N	N/A	Codes	Comments
22. SAMPLING						
A. If the laboratory carries out sampling, it has a **sample plan** and procedures.	M2, 5.7.1				**5571**	
B. The sampling plan and procedure is available **at the sampling location**.	M2, 5.7.1				**5571a**	
C. Sample plans, whenever reasonable, are based on **appropriate statistical methods**.	M2, 5.7.1				**5571b**	
D. The sampling process addresses the factors to be controlled to ensure the validity of the test results.	M2, 5.7.1				**5571c**	
E. Client required **deviations, additions, or exclusions** from the documented sampling procedure are recorded **in detail** with the appropriate sampling data and included in all documents containing test results and communicated to appropriate personnel.	M2, 5.7.2				**5572**	
F. The laboratory has procedures for recording **relevant data and operations** relating to sampling.	M2, 5.7.3				**5572a**	
G. Sampling records include: a.)__ The **sampling procedure** used, b.) __ The identification of the **sampler**, 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	M2, 5.7.3				**5573a** **5573b** **5573c** **5573d** **5573e**	
H. a.)__ Documentation includes the date and time of sampling. b.)__Any deviations from sampling procedures are documented.	M2, 5.7.4 (a)(b)				**5573f** **5573g**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2016 NELAC	Y	N	N/A	Codes	Comments
23. HANDLING OF SAMPLES, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY						
A. The laboratory has 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.	M2, 5.8.1				**5581**	
B. The laboratory has 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:** In cases where the sample collector and the analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the laboratory ID code may be the same as the field ID code. **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.	M2, 5.8.2 & 5.8.5				**5111**	
C. The system includes identification for all samples, sub-samples, preservations, sample containers, tests and subsequent extracts and/or digestates.	M2, 5.8.5(a)				**5112**	
D. The laboratory assigns a **unique identification (ID) code** to each sample container received in the laboratory.	M2, 5.8.5(a)				**5113**	
E. The laboratory sample code **maintains an unequivocal link with the unique field ID** code assigned each container.	M2, 5.8.5(b)				**5114**	
F. The laboratory ID code is placed on the sample container as a **durable mark**.	M2, 5.8.5(c)				**5115**	
G. The laboratory ID code is entered into the laboratory records and the link associates the sample with related laboratory activities such as sample preparation or calibration.	M2, 5.8.5(d)				**5116**	
SAMPLE RECEIPT PROTOCOLS & SAMPLE ACCEPTANCE POLICY						
H. The laboratory has a **written sample acceptance policy** that clearly outlines the circumstances under which samples will be accepted or rejected.	M2, 5.8.6				**5117**	
I. Data from any sample which does not meet the policy criteria is flagged in an unambiguous manner clearly defining the nature and substance of the variation.	M2, 5.8.6(g)				**5118+**	
J. The sample acceptance policy criteria includes 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	M2, 5.8.6 (a)-(g)				**51110a**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2016 NELAC	Y	N	N/A	Codes	Comments
___ any special remarks concerning the sample. b) ___ **Proper sample labeling** to include: ___ unique identification and ___ labeling 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 g)___ Qualification of any data that do not meet above requirements					**51110b** **51110c** **51110d** **51110e** **51110f** **51110g**	
K. Upon receipt, the **condition of the sample is recorded**, including any abnormalities or departures from standard condition as prescribed in the relevant test method.	M2, 5.8.3				**51111**	
L. When there is doubt as to the suitability of an item for test, or when an item does not conform to the description provided, or the test required is not specified in sufficient detail, the laboratory consults the customer for further instructions before proceeding and records the discussions.	M2, 5.8.3				**51111a**	
M. All samples, **which require thermal preservation**, are considered acceptable if the arrival temperature of a representative sample container is either within ± 2 °C of the required temperature or in the method specified range	M2, 5.8.9(a)(i), M4, 1.7.4(a); M5, 1.7.5.1; M6, 1.7.4.2(a)				**51113**	
N. In cases **where samples are hand delivered to the laboratory** immediately after collection and do not meet the temperature criteria are considered acceptable if: a)__ There is evidence that the chilling process has begun such as arrival on ice, OR; b)__ Sample analysis is begun within 15 minutes of collection, thermal preservation is not required, OR; c)__ Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within 15 minutes of collection.	M4,1.7.5 (a)(i-iii); M5,1.7.5.1				**51115a** **51115b** **51115c**	
O. The laboratory **implements procedures for checking chemical preservation** using readily available techniques, such as pH, free chlorine or temperature, prior to or during sample preparation or analysis. **Note:** An exception is allowed for volatile organic analyte analyses; chemical preservation may be checked after analysis.	M4,1.7.4(b); M5, 1.7.5.2; M6, 1.7.4.2(b)				**51117r**	
P. For samples with a specified temperature of 4 °C, samples are maintained within a temperature of just above freezing to 6 °C.	M2, 5.8.9(a)(i); M4, 1.7.4(a)				**51114r**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2016 NELAC	Y	N	N/A	Codes	Comments
Q. Items that have to be stored or conditioned under specified environmental conditions, the conditions shall be maintained, monitored and recorded.	M2, 5.8.4				**511188**	
R. Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory: a) ___ consults with the client for further instruction before proceeding, and b) ___ records the discussion with the client.	M2, 5.8.3				**51119a**	
S. The laboratory implements procedures for verifying and documenting preservation.	M2,5.8.7.1				**51119b**	
T. If the sample does not meet the sample receipt acceptance criteria, the laboratory: a) ___ **Retains correspondence and/or records of conversations** concerning the final disposition of rejected, or b) ___ **Fully documents any decision** to proceed with the analysis of samples not meeting acceptance criteria c) ___ At a minimum, **notes the condition** of the sample on the chain of custody or transmittal forms and on laboratory receipt documents d) ___ **Appropriately qualifies** the analysis data on the final report	M2, 5.8.7.2(a) M2, 5.8.7.2(b) M2, 5.8.7.2(b)(i) M2, 5.8.7(b)(ii)				**51120a** **51120b** **51120c** **51120d**	
U. The laboratory utilizes a **permanent chronological log**, such as a logbook or electronic record, to document receipt of all sample containers.	M2, 5.8.7.3				**51121**	
V. The following information is 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	M2, 5.8.7.3 (a)(i-iv)				**51122a** **51122b** **51122c** **51122d**	
W. The following information is unequivocally linked to the log in records, included as a part of the log, or if recorded/documented elsewhere, is 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 **Note:** The placement of the laboratory ID number on the sample container is not considered a permanent record.	M2, 5.8.7.3 (b)(i-iv)				**51123a** **51123b** **51123c** **51123d**	

Relevant Aspect of Standards – HANDLING OF SAMPLING, SAMPLE RECEIPT PROTOCOLS, & SAMPLE ACCEPTANCE POLICY	2016 NELAC	Y	N	N/A	Codes	Comments
X. The laboratory shall: a)___ have a system for identifying test and/or calibration items. b)___maintain the identification of test/calibration items throughout the life of the item in the laboratory. c)___have a system that ensures items cannot be confused physically or when referred to in records or other documents. d)___have a system, if appropriate, to accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.	M2,5.8.2				**569a** **569b** **569c** **569d**	
Y. The laboratory retains all documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter.	M2, 5.8.7.4				**51124**	
Z. If utilized, a complete chain of custody record is maintained.	M2, 5.8.7.5				**51125**	
AA. The laboratory has documented procedures to **avoid deterioration or damage** to the sample during storage, handling, preparation, and testing.	M2, 5.8.4				**51126**	
BB. Where items have to be stored or conditioned under specific **environmental conditions**, these conditions are **maintained, monitored and recorded**.	M2, 5.8.4				**51128r**	
CC. Samples are stored according to the conditions specified by preservation protocols.	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**.	M2, 5.8.9(a)(ii)				**51130**	
EE. Samples, sample fractions, extracts, leachates or other sample preparation fractions are 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.	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), the laboratory has **storage and security arrangements** that protect the condition and integrity of the secured items or portions concerned.	M2, 5.8.4				**51132**	
GG. The laboratory has standard operating procedures for the **disposal of** samples, digestates, leachates and extracts or other sample preparation products.	M2, 5.8.9(c)				**51133**	

Relevant Aspect of Standards – ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
24. ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS						
A. The laboratory **ensures 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 ▪ Correlation of results for different characteristics of an item.	M2, 5.9.1				**5531**	
B. The laboratory has quality control procedures for monitoring the validity of environmental tests and calibrations undertaken.	M2, 5.9.1				**5591**	
C. The resulting data is recorded in such a way that trends are detectable and, where applicable, statistical techniques are applied to the reviewing of the results.	M2, 5.9.1				**55911**	
D. The monitoring is planned and reviewed.	M2, 5.9.1				**55912**	
ESSENTIAL QUALITY CONTROL PROCEDURES						
E. The laboratory has 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.	M2,5.9.3 (a)(i-viii)				**5536a**	
F. All quality control measures are **assessed and evaluated on an on-going basis**, and quality control acceptance limits used to determine the usability of the data.	M2, 5.9.3(b)				**5535**	
G. The laboratory has procedures for the development of **acceptance/rejection criteria** where no method or regulatory criteria exist.	M2, 5.9.3(c)				**5536**	

Relevant Aspect of Standards – ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
H. The quality control protocols specified by the laboratory's method manual are followed. **Note:** The essential QC standards of 2016 TNI, mandated methods, or regulations (whichever are more stringent) 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.	M2, 5.9.3(c)				**5537**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
25. REPORTING THE RESULTS						
A. The laboratory reports 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.	M2, 5.10.1				**5131**	
B. The test report contains all information necessary for the interpretation of the test results and all information required by the method used.	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, the laboratory has 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.	M2, 5.10.10				**5132b**	
D. Unless the laboratory is operated by a facility whose sole function is to provide data for the facility or has a valid reason for not doing so, the report contains:						
a___ title,	M2, 5.10.2(a)				**5133a**	
b___ Name/address of laboratory,	M2, 5.10.2(b)				**5133b**	
c___ Location where analysis is carried out if different than the laboratory,	M2, 5.10.2(c)				**5133c**	
d___ **Unique identification of the test report** and on each page an identification in order to ensure that the page is recognized as a part of the test report, and a clear identification of the end of the test report.	M2, 5.10.2(d)				**5133d1**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
e___ Page numbers and total number of pages	M2, 5.10.2 Note:1				**5133e**	
f___ Name and address of client,	M2, 5.10.3.1(f)				**5133f**	
g___ Description of, condition of and unambiguous identification of the item tested,					**5133gr**	
h___ Where quality system requirements are not met, **a statement of compliance/noncompliance 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,	M2, 5.10.3.1(b) M2, 5.10.2(g)				**5133h** **5133i**	
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,	M2, 5.10.2(e)				**5133j**	
j___ Identification of the test method used **(This includes prep methods, if applicable.)**,						
k___ Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results.	M2, 5.10.2(h)				**5133kr**	
l___ **Any deviations from**, additions to or exclusions from the test method, and non-reference conditions that may have affected the quality of the results, and including the use of relevant data qualifiers and their meaning	M2,5.10.3.1(a)				**5133l+**	
m__ Qualification of any data that do not meet the written sample acceptance policy.	M2,5.8.6(g)				**5133m**	
n__ The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;	M2, 5.10.2(j)				**5133nr**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
E. The lab utilizes **qualifiers** that are **useful** and **meaningful** for the end user. If "N", list those qualifiers, or affix a copy of the report.	ELAP				**NA**	**For internal use**
F. The report contains the *following*:						
a___ **Environmental test** results with, where appropriate, the **units of measurement,** and results that are reported on a basis other than as received such as data are calculated on dry weight or wet weight, reporting units,	M2, 5.10.2(i) & 5.10.11(b)				**5134a**	
b___ When required, a statement of the estimated uncertainty of the test result,	M2, 5.10.3.1(c) M2, 5.10.2(j)				**5134b**	
c___ The name(s), function(s), and signature(s)or equivalent identification of person(s) authorizing the test report,	M2, 5.10.2(k)				**5134c**	
d___ A statement to the effect that the results relate only to the samples tested or calibrated,	M2, 5.10.2 – Note 2				**5134dr**	
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,	M2, 5.10.6				**5134e**	
f___ Clear identification of test results performed by subcontract laboratory, including its accreditation number, and	M2, 5.10.3.1(b)				**5134f**	
g___ Clear indication of numerical results with values outside of calibration range	M4, 1.7.1.1; M4, 1.7.2.2.1; M4, 1.7.3.3(c); M6, 1.7.2.1(j)				**5134gr**	
h___ If a QC measure is out of control and the data is to be reported, **data qualifiers** are 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.					**5135h**	
G. All applicable elements above are readily available for review if not issued in a formal report by 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, 5.10.1				**5135r**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
H. All applicable elements above are provided to another individual within the organization for preparation of regulatory reports if a formal report is not issued.	M2, 5.10.10(b)				**5136**	
I. The facility management ensures 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.	M2, 5.10.10(b)				**5137**	
J. When opinions and interpretations are included in the test reports, the laboratory documents the basis upon which the opinions and interpretations have been made.	M2, 5.10.5 M2, 5.10.3.1(d)				**55105a**	
K. Opinions and interpretations are clearly marked in test reports.	M2, 5.10.5 M2, 5.10.3.1(d)				**55105b**	
L. Where the certificate or report contains results of tests performed by subcontractors, these results are **clearly identified by subcontractor name or applicable accreditation number**, and the subcontractor's report made available to the client on request.	M2, 5.10.6, M2,4.5.5				**5138r**	
M. The format of the report is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.	M2, 5.10.8				**55108**	
N. When it is necessary to issue a **completely new test report**, it is uniquely identified and contains a reference to the original that it replaces.	M2, 5.10.9				**55109**	
O. Material amendments to a calibration certificate, test report or test certificate after issue are 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.	M2, 5.10.9				**51310**	
P. Amendments to the formal report meet all the relevant requirements of this standard.	M2, 5.10.9				**51311**	
Q. The laboratory has procedures that ensures, 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**.	M2, 5.10.7				**51313**	
R. Laboratory staff follows the documented procedures for the transmission of test results by telephone, telex, fax or other electronic or electromagnetic means.	M2, 5.10.7				**51314**	
S. The lab reports drinking water violations to the County Department of Health as required or requested by their client. Per Subpart 5-1.74 (c), 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 5-1.77 (a), the supplier of water shall make State	DOH BPWS 5-1.74 and 1.77				**51316**	

Relevant Aspect of Standards – REPORTING THE RESULTS	2016 NELAC	Y	N	N/A	Codes	Comments
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.						

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
26. DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION						
Note 1: The 2016 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, ; microbiology DOC requirements are found in V1M5,).						
A. The laboratory has an acceptable, written initial and on-going DOC procedure.	All MV1.6.1-1.6.2				**51014b**	
B. The laboratory confirms 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 The institution of any test method.	M2, 5.4.2				**51014a**	
C. The laboratory management maintains records to ensure that all technical laboratory staff have **demonstrated and documented initial and ongoing proficiency** in the activities for which they are responsible.	All MV,1.6.2				**565r**	
D. The laboratory completes a new demonstration of capability whenever there is a significant change in instrument type, personnel, or test method.	All MV1.6.1-1.6.2				**51014r**	
E. The laboratory completes a new demonstration of capability whenever there is an analyte added to an existing accredited method.	All MV1.6.1-1.6.2				**000C01**	
F. An **initial demonstration of capability** is made prior to using any method, and at any time there is a change in instrument type, personnel or method, or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period. **Note**: Refer to deficiency 51014 in Section 19, 'Environmental Test Methods and Method Validation', too.	All MV, 1.6.2				**00c11a**	
G. Initial and on-going demonstrations are **documented** and all data applicable to the demonstration retained and **readily available**. The laboratory documents each **initial DOC** in a manner such that information is readily available for each affected employee. The following information is documented: a)__ Analyst(s) involved in preparation and/or analysis b)__ Matrix c)__ Analyte(s), class of analyte(s), or measured parameter(s) or organisms d)__ Identification of method(s) performed e)__ Identification of laboratory specific SOP used for analysis, including revision number	All MV, 1.6.1-1.6.3				**000c11**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
f)__ Date(s) of analysis g)__ Summary of analysis						
H. If the method has not been performed by the analyst in a 12-month period, an initial DOC is performed.	All MV 1.6.3				**000c20**	
I. If the method or regulation do not specify an initial DOC, the following procedure is acceptable. The concentrate of the QC sample are diluted in a volume of clean matrix sufficient to prepare four (4) 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.	All MV, 1.6.2.2				**000c15**	
J. Four aliquots are prepared and analyzed according to the method either concurrently or over a period of days.	All MV, 1.6.2.2				**000c16**	
K. The mean recovery is calculated using all of the results and the standard deviation for each parameter of interest is calculated in the units used for reporting (such as mg/L).	All MV, 1.6.2.2				**000c17**	
L. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory assesses performance against established and documented criteria.	All MV, 1.6.2.2				**00c17a**	
M. The mean recovery and standard deviation meets the acceptance criteria for precision and accuracy of the method (if applicable) or in laboratory generated acceptance criteria (if there is no mandatory criteria).	All MV, 1.6.2.2				**000c18**	
N. If one or more of the test parameters does not meet the acceptance criteria, the problem is corrected followed by repeated analysis of the four aliquots for all parameters or at least for those that failed to meet criteria.	All MV, 1.6.2.2				**00c110**	
O. Additional initial DOC microbiological qualitative tests: acceptable performance in a blind study. Study must consist of at a minimum a blank, a negative culture and a positive culture for each test organism.	M5,1.6.2				**000c21**	
P. Laboratory management ensures that the training records of each of the technical staff is updated by including documentation of continuing proficiency may be one of the following.: a.) __ Acceptable performance of a blind sample; b.) __ Another initial demonstration of capability; c.) __ Successful analysis of a blind performance sample on a similar test method using the same technology; d.) __ Analysis of at least 4 consecutive lab control samples with acceptable levels of precision and accuracy; e.) __ A documented process of analyst review using QC samples. or f.) __ If one of the above cannot be performed, the analysis of real-world samples with results	All MV, 1.6.3				**567**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
within a predefined acceptance criterion are performed.						
Q. Additional ongoing DOC for microbiological tests: a.)__Performance of an alternate adequate procedure for the field of accreditation, the procedure and acceptance criteria documented in the laboratories quality system b.)__Analysis of one positive sample in duplicate for each target organism and test, with results meeting the laboratory acceptance criterion for precision.	M5,1.6.3.2				**000c22a** **000c22b**	
c.)__Analysis of one clean matrix fortified with a known quantity of the target organism, with results meeting the laboratory acceptance criteria for accuracy and where applicable to the testing technique, also meet the observational details expected for the presumptive, confirmed and completed phases defined in the method.	M5, 1.6.3.2				**000c22c**	
27.METHOD VALIDATION						
Limit of Detection (LOD), Detection Limit(DL), Method Detection Limit(MDL) and Limit of Quantitation (LOQ)						
A. If a mandated test method or applicable regulation includes protocols for determining detection limits, they are followed.	M4,1.5.2.1				**000c23**	
B. The laboratory DL and LOQ procedure, unless following a mandated test method or procedure, at a minimum incorporates language addressing the following requirements: a)__The DL reflects current conditions b)__The DL determination incorporated the entire analytical process c)__The DL determination includes data from low level spikes and routine method blanks prepared and analyzed over multiple days; at least one low level spike and routine method d)__A blank is analyzed on each applicable instrument; a minimum of 7 replicates required for both low level spikes and routine method blanks e)__Results from low level spikes used in the DL determination meet qualitative identification criteria in the methods and are above zero f)__The DL procedure includes criteria for and evaluation of false positive rates in routine method blanks g)__ The DL is determined for the analytes in each test methods in the quality system matrix of interest in which there are neither target analytes nor interferences at a concentration that would impact the results, or the DL is performed in the sample matrix of interest. **Note 1**: The DL study is not required for methods/analytes for which a detection limit is not applicable and any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate. **Note 2**: One option is to follow the USEPA MDL procedure effective September 27,2017.	M4, 1.5.2.1.1 (a-f)				**000c24a** **000c24b** **000c24c** **000c24d** **000c24e** **000c24f** **000c24g**	
C. The limit of detection and quantitation supporting data is retained.	All MV, 1.5.2				**000c25**	
D. If the method or regulation does not contain specific directions for determinations of the detection limit, the following requirements are followed:	M4,1.5.2.1					

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
E. The laboratory determines the Detection Limit (DL) for the analytes of interest for each method in the quality system matrix of interest in which there are neither targeted analytes nor interferences at a concentration that would impact the results, or the DL is performed in the sample matrix.	M4,1.5.2.1.1 (f)				**00c113a 00c113b**	
F. The DL reflects current operating conditions	M4, 1.5.2.1.1				**000c26**	
G. The DL procedures include criteria for evaluation of false positive rates in routine method blanks.	M4, 1.5.2.1.1				**000c27**	
H. Results from low level spikes used in the DL determination meet qualitative identification.	M4, 1.5.2.1.1				**000c28**	
I. Al sample-processing steps of the analytical method include the determination of the DL.	M4, 1.5.2.1.1 (b)				**00C114r**	
J. The DL determination includes data from low level spikes and routine method blanks prepared and analyzed over multiple days ; at least one low level spike and routine method blank must be analyzed on each applicable instrument; a minimum of 7 replicates is required for both low level spikes and routine method blanks, that are analyzed on each applicable instrument. This verification is performed on every instrument that is to be used for analysis of samples and reporting of data.	M4, 1.5.2.1.1(c)				**00c116a 00c116r**	
K. Where an DL study is not performed, the laboratory does not report a value below the Limit of Quantitation.	M4, 1.5.2.1				**00c117r**	
L. If results are not reported below the limit of quantitation (LOQ), an initial DL determination is performed, but ongoing DL determination is not required.	M4,1.5.2.1				**00c117a**	
LIMIT OF QUANTITATION and ON-GOING LOQ AND DL REQUIREMENTS						
M. The LOQ selected by the laboratory for each analyte is consistent with the needs of the client and greater than the DL	M4,1.5.2.2				**00c117b**	
N. All sample processing and analysis steps of the analytical method are included in the determination of the LOQ.	M4, 1.5.2.2(b)				**00c118ar**	
O. The laboratory determines the Limit of Quantitation (LOQ) for each analyte of concern according to a defined, documented procedure. **Note:** The 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).	M4,1.5.2.2				**0C118**	
P. Each selected LOQ is verified through analysis of initial verification sample which consists of a spiked matrix blank at or below the selected LOQ.	M4, 1.5.2.2(a)				**00c119r**	
Q. The LOQ is at or above the lowest corresponding calibration standard concentration with the exception of methods using a single point calibration.	M4,1.5.2.2 (c)				**00c126**	
R. The laboratory established acceptance criteria for accuracy of the LOQ verification spikes.	M4,1.5.2.2 (d)				**00c127**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
S. A minimum of 7 low level spikes at or below the LOQ concentration are processed through all steps of the method in at least 3 batches on 3 separate days. **Note:** Existing data may be used if compliant with the requirements for at least 3 batches generated within the last 2 years and representative of current operations.	M4,1.5.2.2.1(a) (b)				**00c128**	
T. If multiple instruments are assigned the same LOQ, then these low-level spikes are distributed across all of the instruments.	M4,1.5.2.2.1(a) (i)				**00c129**	
U. A minimum of 2 low level spikes are prepared and analyzed on different days are tested on each instrument.	M4,1.5.2.2.1(a) (ii)				**00c130**	
V. The LOQ is verified and the following criteria are met; a.)All results are quantitative. **Note**: Results are above zero and meet the qualitative identification criteria of the method. b.)The mean recovery of each analyte is within the laboratory established accuracy acceptance limits c.)The LOQ is greater than the established DL and at or above the spiking concentration	M4,1.5.2.2.1 (c)(i-iii)				**00c131a** **00c131b** **00c131c**	
W. a.)__Ongoing verification of the DL includes assessment of spikes at or below the LOQ and of method blanks at a minimum of one verification spike and one blank analyzed on each instrument during each quarter in which samples are analyzed and results reported below the LOQ. b.)__These results meet the requirements of meeting the qualitative identification of the methods and be above zero. c.)__If the DL verification samples are to be used for the LOQ verification they must also meet the criteria of the on-going LOQ requirements.	M4, 1.5.2.1.2				**00c132a** **00c132b** **00c132c**	
X. If the method is altered in anyway other than routine maintenance, and a change can be expected to elevate the detection limit, then a spike at or below the LOQ concentration and a blank are analyzed. If the spike at the LOQ concentration gives a result meeting qualitative identification criteria above zero, and the blank gives a result below the DL, then the DL is verified. If not the DL is redetermined.	M4, 1.5.2.1.2				**00c133a** **00c133b**	
Y. In the event that the verification fails, the laboratory performs a new DL study within 30 calendar days.	M4, 1.5.2.1.2				**00c134**	
Z. When a new DL is determined, the laboratory verifies that the LOQ is greater than the DL. If it is not, the laboratory raises the LOQ value to greater than the DL. **Note:** The EPA MDL procedure states that if the verified MDL is within 0.5 to 2.0 times the existing MDL, and fewer than 3% of the method blank results (for the individual analyte) have numerical results above the existing MDL, then the existing MDL may optionally be left unchanged. Otherwise , adjust the MDL to the new verification MDL. (EPA 821-R-16-006)	M4, 1.5.2.1.3				**00c135**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
AA. A new DL/LOQ verification is performed prior to analysis of client samples if no analysis was performed in a given year. **Note:** Verification of the DL/LOQ is not required if no analysis is performed in a given year.	M4,1.5.2.3				**00c136**	
BB. If the LOQ is less than or equal to the DL, the LOQ is raised to greater than the DL.	M4,1.5.2.2.1 (c)(iii)				**00c137**	
CC. For the ongoing verification of the LOQ the laboratory prepares and analyzes a minimum of one verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are analyzed for each quality system matrix, method and analyte. **Note:** If different spike concentrations were used for the initial DL and initial LOQ verification, then different spike concentrations are required for the ongoing verifications of the DL and LOQ as well.	M4, 1.5.2.2.2				**00c138a** **00c138b**	
DD. For the ongoing verification of the LOQ: the laboratory evaluated the results of each LOQ verification sample at the time of testing and meets the qualitative identification criteria of the method and laboratory SOP and the quantitated result is greater than the DL and meets the laboratory established accuracy criteria.	M4, 1.5.2.2.2(a)				**00c139r**	
EE. If a continuing LOQ verification test does not meet this requirement, the laboratory takes corrective action and documents a technically valid reason for the corrective action.	M4,1.5.2.2.2(b)				**00c140**	
FF. The corrective action is one of the following; a.)__Correcting method or instrument performance and repeating the verification test b.)__Evaluating the laboratory established control limits to ensure that they reflect current performance , or c.)__Raising the spike level(and the quantitation limit if the spike level is above it) and repeating the initial verification study within 30 calendar days of the initial failure.	M4,1.5.2.2.2(b) (i-iii)				**00c141**	
GG. Samples analyzed in a batch associated with a failing LOQ verification are reanalyzed or reported with qualifiers.	M4,1.5.2.2.2(b)				**00c142**	
HH. Annual assessment of on-going verification testing of the DL and LOQ is performed and uses all data representative of the current operations. **Note:** A minimum of 7 samples is required if generated in the last 2 years.	M4,1.5.2.4				**00c143**	
II. The following information is documented for the annual assessment of the DL and LOQ: a.)__Analytical and preparation methods used b.)__ Dates of preparation and testing c.)__ Batch identifiers d.)__Testing instrument e.)__Quality system matrix f.)__ Technology g.)__ Analyte	M4,1.5.2.4 (a)				**00c144a** **00c144b** **00c144c** **00c144d** **00c144e** **00c144f** **00c144g**	

Relevant Aspect of Standards – DEMONSTRATION OF CAPABILITY AND INITIAL TEST METHOD EVALUATION	2016 NELAC	Y	N	N/A	Codes	Comments
h.)__Concentration in the spiked sample with units i.)__Test result for each LOQ and/or DL verification test					**00c144h** **00c144i**	
JJ. The following information is documented for each analyte for the annual assessment of the DL and LOQ: a.)__ Percent recovery b.)__ The number of results(n) c.)__ Mean and standard deviation of the percent recovery d.)__ Spiking concentration of the spiked sample with units	M4,1.5.2.4 (b)				**00c145a** **00c145b** **00c145c** **00c145d**	
PRECISION AND BIAS						
KK. When using reference methods, the laboratory evaluates the precision and bias of a reference 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).	M4, 1.5.3(a)				**00C120**	
LL. When using non-reference methods for laboratory-developed test methods or non-reference test methods, the laboratory has a documented procedure to evaluate precision and bias.	M4, 1.5.3(b)				**00C121**	
MM. The laboratory compares results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory.	M4, 1.5.3(b)				**00C122**	
NN. The precision & bias measurements evaluate the test method across the analytical calibration range of the method. **Note:** Examples of systemic approach to evaluate precision & bias could be: (i) a validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process, 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 of interest.	M4, 1.5.3(b)				**00C123**	
OO. The laboratory evaluates precision and bias in the relevant quality system matrices	M4,1.5.3(b)				**00c124**	
EVALUATION OF SELECTIVITY						
PP. The laboratory evaluates 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.	M4, 1.5.4				**00C125**	