NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE (NELAC)

ON-SITE LABORATORY ASSESSMENT

QUALITY SYSTEMS CHECKLIST (45 PAGES TOTAL)

LABORATORY: _____

Physical Address: _____

_____

Mailing Address: _____
(if different from above)

_____

Telephone Number: _____ Facsimile Number: _____

E-mail address: _____

INSPECTED BY: (Name) (Affiliation)

_____ _____

_____ _____

_____ _____

INSPECTION DATES: _____

LABORATORY TECHNICAL DIRECTORS AND MANAGEMENT:
(Name) (Title)

_____ _____

_____ _____

_____ _____

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GENERAL INSTRUCTIONS: Before each item is a blank line and a NELAC Standard citation in **Bold Numerals**.

This checklist is based on the 2003 version of the NELAC Standards.

Place a check mark (__----) in the blank if the laboratory meets the NELAC Standard referenced.

Place an X-mark (X) in the blank if the Standard is not met and the laboratory must devise an acceptable Plan of Correction and estimated completion date. **The NELAC Standard reference must be cited in in the on-site assessment report.**

Mark **"N/A"** in the blank if the NELAC Standard is not applicable to this laboratory, either because of the nature of its business mission, because of the analytical tests it performs, or because of the situation never ever happening.

If the laboratory appears to meet a particular NELAC Standard but does not have the documentation to back up its claim, use the following:

_____ **5.0** Does the laboratory have **all items** identified in NELAC Chapter 5 Quality Systems **available** for on-site inspection or data audit

LABORATORY CONDUCT DURING PROFICIENCY TESTING

_____ **2.5** Does the laboratory's records show that **PT samples are handled** (i.e., managed, analyzed, & 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, & frequency of analysis

_____ **2.5.1(a)** Does the laboratory **not send any PT sample**, or portion of a PT sample, **to another laboratory** for any analysis for which it seeks accreditation, or is accredited

_____ **2.5.1(b)** Does the laboratory **not knowingly receive any PT sample** or portion of a PT sample **from another laboratory** for any analysis for which the sending laboratory seeks accreditation, or is accredited

_____ **2.5.1(c)** Does the laboratory management & staff **not communicate with** any indicidual at **another laboratory** (including intralaboratory communication) concerning the PT sample

_____ **2.5.1(d)** Does the laboratory management & staff **not attempt to obtain the assigned value** of any PT sample from the PT Provider

_____ **2.5.2** Does the laboratory maintain **copies of all written, printed, & electronic records** resulting from the analysis of any PT sample for **5 years** or for as long as is required by the applicable regulatory program, whichever is greater

Note: These records include bench sheets, instrument strip charts or printouts, data calculations, data reports, & PT study report forms used by the laboratory to record PT results

COMMENT: (list all applicable Standards where the accompanying data was not available for review)

LABORATORY MANAGEMENT ORGANIZATION

____ **5.4.1.1** Is the laboratory, or the organization of which it is part, an entity that can be **held legally responsible**

____ **5.4.1.2** Does the laboratory **accept responsibility** to carry out its environmental testing activities in such a way as to **meet the requirements of the NELAC Standards** and to **satisfy the needs of the client, the regulatory authorities,** or organizations providing recognition

____ **5.4.1.3** Does the **laboratory management system cover work** carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities

____ **5.4.1.4** If the laboratory is part of an organization performing activities other than environmental testing, are the **responsibilities of key personnel** in the organization that having an involvement or influence on the environmental testing activities of the laboratory **defined** in order to **identify potential conflicts of interest**

____ **5.4.1.4(a)** Where a laboratory is part of a larger organization, are the organizational arrangements such that **departments having conflicting interests** (e.g., production, financing, or commercial marketing) **do not adversely influence** the laboratory's compliance with the requirements of the NELAC Standards

____ **5.4.1.4(b)** Is the laboratory able to demonstrate that **it is impartial** & that it has personnel that are **free from any undue commercial, financial, or other pressures** which might influence their technical judgment

____ **5.4.1.4(b)** Does the laboratory not engage in any activities that may **endanger the trust in its independence of judgment & integrity** in relation to its environmental testing activities

____ **5.4.1.5(a)** Does the laboratory have **managerial staff** with the authority & resources needed to carry out their duties

___ **5.4.1.5(a)** Does the managerial staff have the authority & resources needed to **identify departures from the quality system**, or from the procedures for performing environmental tests

____ **5.4.1.5(a)** Does the managerial staff have the authority & resources needed to **initiate actions to prevent such departures** from the quality system

____ **5.4.1.5(b)** Does the laboratory have processes to ensure that its **personnel are free from** commercial, financial, or other **undue pressures** which might adversely affect quality of their work

____ **5.4.1.5(c)** Does the laboratory have **documented policy & procedures** for ensuring the protection of clients' **confidential information & proprietary rights**, including procedures for protecting the electronic storage & transmission of results
(**Note:** may not be applicable to in-house laboratories)

____ **5.4.1.5(d)** Does the laboratory have policies & procedures to **avoid involvement** in any activities that would **diminish confidence** in its competence, impartiality, judgment, or operational integrity

____ **5.4.1.5(e)** Does the laboratory **define its organization & management structure**, its place in any parent organization, & the relationship between quality management, technical operations, & support services

____ **5.4.1.5(f)** Does the laboratory specify the **responsibility, authority, & interrelationship** of all personnel who manage, perform, or verify work affecting the quality of tests

____ **5.4.1.5(f)** Does the documentation include a clear description of the **lines of responsibility** in the laboratory & proportioned such that **adequate supervision** is ensured

____ **5.4.1.5(g)** Does the laboratory have **adequate supervision** of environmental testing staff, including trainees

____ **5.4.1.5(g)** Does the laboratory provide supervision by persons **familiar** with the test methods & procedures, the objective of the test, and the assessment of the results

____ **5.4.1.5(h)** Does the laboratory have **technical management** who have overall responsibility for the technical operations & the provision of resources needed to ensure the quality of laboratory operations

____ **5.4.1.5(h)** Does the laboratory have **documented certifications** that personnel with appropriate educational and/or technical backgrounds perform all tests for which the laboratory is accredited

____ **5.4.1.5(h)** Does the technical director(s) **meet the personnel qualifications** in NELAC Standard 4.1.1.1

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

Chemical analysis - Bachelor's degree in chemical, environmental, biological, physical sciences or engineering; at least 24 semester hours college credit in chemistry & at least 2 years experience in environmental analysis of representative inorganic & organic analytes for which the laboratory is accredited (Master's degree or doctorate may substitute for 1 year of experience)

Nonmetal Inorganic Chemical analysis (only) - associates degree in chemical, physical, or environmental sciences OR 2 years equivalent, successful college education with at least 16 semester hours college credit in chemistry; plus 2 years experience performing such analysis

Microbiological or Biological analysis - Bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical science or engineering with at least 16 semester hours college credit in general microbiology and biology, plus at least 2 years experience in environmental analysis of representative analytes for which the laboratory is accredited (Master's degree or doctorate may substitute for 1 year of experience)

Fecal Coliform, Total Coliform, & Standard Plate Count (only) - associates degree in the appropriate sciences or applied science OR 2 years equivalent successful college education, including 4 semester credit hours in general microbiology; plus 1 year experience in environmental analysis

Radiological analysis - Bachelor's degree in chemistry, physics, or engineering with at least 24 semester hours college credit in chemictry; plus at least 2 years experience in radiological analysis of environmental samples (Master's degree or doctorate may substitute for 1 year of experience)

Transmission Electron Microscope examination of Asbestos - Bachelor's degree, successful completion of course in the use of the instrument, & at least 1 year experience, under supervision, in using the instrument (including the identification of minerals)

Polarized Light Microscope examination of Asbestos - Associates degree or at least 2 years college study, successful formal course completion in polarized light microscopy, & at least 1 year experience, under supervision, in using the instrument (including the identification of minerals)

Phase Contrast Microscope examination of airborne fibers - associates degree or at least 2 years college study, successful formal course completion in phase contrast microscopy, & at least 1 year experience, under supervision, in using the instrument

Radon in air - associates degree or at least 2 years college study, plus at least 1 year experience in radiation measurements of radon and/or radon progeny

Potable Water System or Wastewater Treatment Plant (doing only regulatory permit work on its samples) - full-time employee with valid treatment plant operator's certificate

Industrial Waste Treatment facility (doing only regulatory permit work on its samples) - full-time employee with at least 1 year experience under supervision in environmental analysis

____ **5.4.1.5(i)** Does the laboratory appoint a **quality manager** (however named) who has defined responsibility & authority for ensuring that the quality system is implemented & followed at all times

____ **5.4.1.5(i)** Does the QA officer have **direct access** to the technical director(s) and to the highest level of management where decisions are made on laboratory policy & resources

Note: Where staffing is limited, the quality manager may also be the technical director or deputy technical director

____ **5.4.1.5(i)(1)** Does the QA officer serve as the **focal point for QA/QC** & take responsibility for the oversight and/or review of quality control data

____ **5.4.1.5(i)(2)** Does the QA officer have functions **independent from laboratory operations** for which they have quality assurance oversight

____ **5.4.1.5(i)(3)** Is the QA officer able to **evaluate data objectively** & perform assessments without outside (e.g. managerial) influence

____ **5.4.1.5(i)(4)** Does the QA officer have **documented training and/or experience in QA/QC procedures** & have knowledge in the quality system as defined under NELAC

____ **5.4.1.5(i)(5)** Does the QA officer have **general knowledge of the analytical test methods** for which data review is being performed

____ **5.4.1.5(i)(6)** Does the QA officer arrange for or conduct **internal audits** on the entire laboratory technical operation **annually**

____ **5.4.1.5(i)(7)** Does the QA officer notify laboratory management of **deficiencies in the quality system** & monitor corrective action

____ **5.4.1.5(j)** Does the laboratory **nominate deputies** for key managerial personnel including the technical directors and/or QA manager

____ **5.4.1.5(k)** **D.1.3(c)** **D.3.3(b)** Does the laboratory participate in available interlaboratory comparisons & proficiency testing programs (**Note:** Compliance with NELAC Chapter 2 is **mandatory** for obtaining & maintaining accreditation for Fields of Accreditation in which Fields of Proficiency Testing are also available)

COMMENTS:

LABORATORY QUALITY SYSTEM

____ **5.4.2.1** Has the laboratory established, implemented, & maintained a **quality system**, based on the required elements of NELAC Chapter 5, that is appropriate to the **type, range, & volume of environmental testing activities** it undertakes

____ **5.4.2.1** Are the laboratory's policies, systems, programs, procedures, & instructions **documented** to the extent necessary to **assure the quality of environmental test results**

____ **5.4.2.1** Is the **quality system documentation** communicated to, understood, by, available to, & implemented by the appropriate personnel

____ **5.4.2.2** Does the laboratory define its **quality system policies & objectives** in a **quality manual**
Note: NELAC 5.4.2.2(c) requires the laboratory management to ensure that these policies & objectives are documented in a quality manual)

____ **5.4.2.2** Are the overall objectives documented in a **quality policy statement**, issued under the authority of the chief executive

____ **5.4.2.2(a)** Does the laboratory define & document its **policies & objectives** for, & its **commitment to accepted laboratory practices** & quality of testing services

Does the quality policy statement include at least the following:

____ **5.4.2.2(a)** the laboratory management's commitment to **good professional practice** and to the **quality of its environmental testing** in servicing its clients

____ **5.4.2.2(b)** the management's statement of the laboratory's **standard of service**

____ **5.4.2.2(c)** the **objectives of the quality system**

____ **5.4.2.2(d)** requirement that all personnel concerned with environmental testing activities within the laboratory **familiarize themselves** with the quality documentation & **implement the policies & procedures** in their work

____ **5.4.2.2(e)** the laboratory management's **commitment to compliance with the NELAC Standards**

____ **5.4.2.3** Does the Quality Manual and related quality documentation **state the laboratory's policies and procedures** established in order to meet the requirements of the NELAC Standards
Note: When the laboratory Quality Manual contains the necessary requirements, a separate SOP or policy is not required

____ **5.4.2.3** Does the Quality Manual's **title page** list:
a document title
laboratory's full name and address
name, address, and telephone number of individual(s) responsible for the laboratory
name of the quality assurance (QA) officer (however named)
all major organizational units covered by this Quality Manual
effective date of this Quality Manual version

____ **5.4.2.3(f)** Does the Title Page have the **signed concurrence** (with appropriate position titles) of the QA officer, technical director(s), and the agent in charge of all laboratory activities (e.g. laboratory director or laboratory manager)

Does the Quality Manual and related quality documentation also contain:

EFFECTIVE DATE & VERSION NUMBER OF QUALITY MANUAL REVIEWED: _____

____ **5.4.2.3** reference to the **supporting procedures** including **technical procedures**

____ **5.4.2.3** an outline of the **structure of the documentation** used in the quality system

____ **5.4.2.3(v)** a **Table of Contents**, and applicable lists of references, glossaries, and appendices

____ **5.4.2.3(a)** a **quality policy statement**, including objectives and commitments, by top management

____ **5.4.2.3(b)** the laboratory's **organization & management structure**, its place in any parent organization, and relevant organizational charts

____ **5.4.2.3(c)** the **relationship** between management, technical operations, support services, & quality system

____ **5.4.2.3(d)** procedures to **ensure that all records** required under NELAC Chapter 5 **are retained**

____ **5.4.2.3(d)** procedures for **control & maintenance of documentation** through a document control system, which ensures that all standard operating procedures, manuals, & documents clearly indicate the **time period** during which the procedure or document **was in force**

____ **5.4.2.3(e)** **job descriptions** of key staff and reference to the job descriptions of other staff

____ **5.4.2.3(f)** identification of the laboratory's **approved signatories**

____ **5.4.2.3(g)** the laboratory's procedures for achieving **traceability of measurements**

____ **5.4.2.3(h)** a list of **all test methods** under which the laboratory performs its **accredited testing**

____ **5.4.2.3(i)** mechanisms for ensuring that the laboratory **reviews all new work** to ensure that it has the **appropriate facilities & resources** before commencing such work

____ **5.4.2.3(j)** reference to the **calibration** and/or **verification test procedures** used

____ **5.4.2.3(k)** procedures for **handling submitted samples**

____ **5.4.2.3(l)** reference to the **major equipment & reference measurement standards** used, plus the **facilities & services** used by the laboratory in conducting tests

____ **5.4.2.3(m)** reference to procedures for **calibration, verification, & maintenance of equipment**

____ **5.4.2.3(n)** reference to **verification practices**
Note: Such practices may include interlaboratory comparisons, proficiency testing programs, use of reference materials, & internal quality control schemes

____ **5.4.2.3(o)** procedures to be followed for **feedback & corrective action** whenever testing discrepencies are detected, or departures from documented policies & procedures occur

____ **5.4.2.3(p)** the laboratory management arrangements for **exceptionally permitting departures** from documented policies & procedures or from standard specifications

____ **5.4.2.3(q)** procedures for **dealing with complaints**

____ **5.4.2.3(r)** procedures for **protecting confidentiality & proprietary rights** (including national security)

____ **5.4.2.3(s)** procedures for **audits & data review**

____ **5.4.2.3(t)** processes/procedures for establishing that personnel **are adequately experienced** in the duties they are expected to carry out and/or **receive any needed training**

____ **5.4.2.3(u)** reference to procedures for **reporting analytical results**

____ **5.4.2.4** **roles & responsibilities** of the **technical management & the quality manager**, including their responsibility for ensuring compliance with the NELAC Standards

____ **5.4.2.6** **data integrity procedures**, defined in detail

Note: The four required elements in a data integrity system are:

- data integrity training
- signed data integrity documentation for all laboratory employees
- in-depth periodic monitoring of data integrity
- data integrity procedure documentation

____ **5.4.2.5** Is the Quality Manual **maintained current** under the responsibility of the QA officer

____ **5.4.2.6** Are the data integrity procedures **signed & dated** by senior management

____ **5.4.2.6** Are the data integrity procedures & the associated implementation records **properly maintained & made available** for assessor review

____ **5.4.2.6** Are the data integrity procedures **annually reviewed & updated** by management

____ **5.4.2.6.1** Does the laboratory management provide a mechanism for **confidential reporting of data integrity issues** in the laboratory

Note: A primary element of this mechanism is to assure confidentiality & a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern

____ **5.4.2.6.2** In instances of ethical concern, does the mechanism include a process whereby laboratory management are **to be informed of the need** for any **further detailed investigation**

COMMENTS:

DOCUMENT CONTROL

____ **5.4.3.1** Are procedures established & maintained to **control all documents** that form part of the laboratory's quality system

Note: Documents can be internally generated of from external sources & can include policy statements, procedures, tables, charts, textbooks, posters, memoranda, plans, etc. These documents may be on either hardcopy or electronic media & may be digital, analog, photographic, or written

____ **5.4.3.2.1** Are all documents issued to laboratory personnel as part of the quality system **reviewed & approved for use** by authorized personnel **prior to use**

____ **5.4.3.2.1** Is there an established **master list** or equivalent document control procedure identifying the **current revision status & distribution of documents** in the quality system

____ **5.4.3.2.1** Are the master lists or document control procedures readily available to **preclude the use of invalid and/or obsolete documents**

Do the adopted document control procedures ensure that:

____ **5.4.3.2.2(a)** Authorized editions of appropriate documents **are available at all locations** where operations essential to the effective functioning of the laboratory are performed

____ **5.4.3.2.2(b)** Documents are **periodically reviewed** and, where necessary, **revised** to ensure continuing suitability & compliance with applicable requirements

____ **5.4.3.2.2(c)** Invalid or obsolete documents **are promptly removed** from all points of issue or use, or otherwise assured against unintended use

____ **5.4.3.2.2(d)** Obsolete documents **retained for legal or knowledge preservation** are suitably marked

____ **5.4.3.2.3** Are the quality system documents in the laboratory **uniquely identified** to include issue date and/or revision identification, page numbering, total number of pages (or mark to signify the end of the document), & the issuing authority(ies)

____ **5.4.3.3.1** Are **changes to documents** reviewed & approved by the same function that performed the original review, unless specifically designated otherwise

Note: The designated personnel must have access to pertinent background information upon which to base review & approval

____ **5.4.3.3.2** Where practicable, is the **altered or new text identified** in the document or appropriate attachments

____ **5.4.3.3.3** If allowed in the quality system, does the laboratory define the procedures & authorities for **amendment of documents by hand**, pending the reissue of the documents

____ **5.4.3.3.3** Are all amendments to documents **clearly marked, initialed, & dated**, with a revised document formally re-issued as soon as practicable

____ **5.4.3.3.4** Are procedures established to describe how changes in documents **maintained in computerized systems** are made & controlled

COMMENTS:

REVIEW OF REQUESTS, TENDERS, & CONTRACTS

____ **5.4.4.1** Are procedures established & maintained for the **review of requests, tenders, & contracts**

Do the policies & procedures for reviews leading to a contract for environmental testing ensure that:

____ **5.4.4.1(a)** Requirements, including methods to be used, are **defined, documented, & understood**

____ **5.4.4.1(b)** The laboratory has the **capability & resources** to meet the requirements

____ **5.4.4.1(c)** The **appropriate test method** is selected & capable of meeting the client's requirements

Note: The purpose of this review is to establish that the laboratory possesses the necessary physical, personnel, & information resources, and that the laboratory personnel have the skills & expertise necessary to perform the environmental tests in question. The review may encompass the results of earlier participation in interlaboratory comparisons or proficiency tests and/or the running of trial environmental test programs using samples or items of known values in order to determine uncertainties of measurement, detection limits, or other essential quality control requirements.

____ **5.4.4.1(b)** Does the laboratory review its **current accreditation status** in reviews that may lead to a contract

____ **5.4.4.1(b)** Does the laboratory **inform the client** of the results of its review if it indicates any potential conflict, deficiency, lack of accreditation status, or inability on the laboratory's part to complete the client's work

____ **5.4.4.1** Are any **differences** between the request or tender & the contract **resolved before any work commences**

____ **5.4.4.1** Is each contract **acceptable to both** the laboratory & the client

Note: A contract may be any oral or written agreement to provide the client with env. testing services

____ **5.4.4.2** Does the laboratory **maintain records of such reviews**, including any significant changes

____ **5.4.4.2** Does the laboratory maintain records of **pertinent discussions with a client** relating to the client's requirements or the results of the work during the execution period of the contract

Note: For reviews of routine & other simple tasks, the date & initials of the person responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial inquiry stage & on granting the contract for on-going routine work performed under a general agreement with the client, provided the client's requirements remain unchanged. For new, advanced, or complex environmental testing tasks, a more comprehensive record should be maintained.

____ **5.4.4.3** Does the review cover any work that is **subcontracted by the laboratory**

____ **5.4.4.4** Is the client informed of any **deviation from the contract**

____ **5.4.4.5** Does the laboratory **repeat the same contract review process** if a contract needs to be amended after work has commenced

____ **5.4.4.5** Are any contract amendments **communicated to all affected personnel**

____ **5.4.4.5** Does the laboratory **report any suspensions, revocations, or voluntary withdrawals** of accreditation to the client

COMMENTS:

SUBCONTRACTING OF ENVIRONMENTAL TESTS

Note: The following Standards apply if the laboratory **subcontracts** any portion of testing of a client's sample to another party

____ **5.4.5.1** Does the laboratory submit **any subcontract work** for testing covered under NELAP **only** to a laboratory **accredited under NELAP** for the tests to be performed

Note: The subcontractor can also be a laboratory that **meets applicable statutory & regulatory requirements** for performing the tests & submitting the results of tests performed

____ **5.4.5.1** Does the laboratory **indicate in final reports the laboratory** performing **subcontracted work**

____ **5.4.5.1** Does the laboratory **clearly identify** in final reports **non-NELAP accredited work**

____ **5.4.5.2** Does the laboratory **advise its clients in writing** of its intentions to subcontract **any portion of testing** to **another party**

Note: When possible, approval of the client needs to be gained, preferably in writing

____ **5.4.5.3** Does the laboratory accept **responsibility to the client** for the subcontractor's work, except when the client or the regulatory authority specifies which subcontractor is to be used

____ **5.4.5.4** Does the laboratory **retain a register** of all subcontractors used & **records** demonstrating that its subcontract laboratories are accredited under NELAP or applicable statutory & regulatory requirements

PURCHASING SERVICES & SUPPLIES

____ **5.4.6.1** Does the laboratory have policy & procedures for **selection & purchasing of services & supplies** it uses that affect the quality of the environmental tests

____ **5.4.6.1** Do procedures exist for the **purchase, reception, & storage** of reagents & consumable materials relevant for the environmental tests

____ **5.4.6.2** Does the laboratory ensure that purchased supplies, reagents, & consumable materials are not used until they are **inspected or otherwise verified** as complying with standard specifications or requirements defined in the methods for the environmental tests concerned

____ **5.4.6.2** Does the laboratory ensure that supplies & services **comply with specified requirements**

____ **5.4.6.2** Does the laboratory **maintain records** of actions taken to check compliance with these requirements

____ **5.4.6.3** Do **purchasing documents** for items affecting the quality of laboratory output contain data describing the services & supplies ordered

____ **5.4.6.3** Are these purchasing documents **reviewed & approved for technical content** prior to release

____ **5.4.6.4** Does the laboratory **evaluate suppliers** of critical consumables, supplies, & services that affect the quality of environmental testing

____ **5.4.6.4** Does the laboratory **maintain records** of these evaluations and **list those (suppliers) approved**

SERVICE TO THE CLIENT

____ **5.4.7** Does the laboratory **afford clients** or their representatives **cooperation** to clarify the client's request & to monitor the laboratory's performance in relation to the work performed (provided that the laboratory ensures confidentiality to other clients)

____ **5.4.8** Does the laboratory have documented policies & procedures for the **resolution of complaints** received from clients or other parties

____ **5.4.8** Does the laboratory **maintain records** of all such complaints and of the investigations & actions taken by the laboratory

CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK

____ **5.4.9.1** Does the laboratory have policies & procedures to be implemented when **any aspect** of environmental testing work, or results of this work, **do not conform** to its own procedures or to the agreed requirements of the client

Do these policies & procedures ensure that:

____ **5.4.9.1(a)** Responsibilities & authorities for the management of non-conforming work are **designated & actions are defined & taken** when non-conforming work is identified
Note: Such actions include the halting of work & withholding of test reports, as necessary

____ **5.4.9.1(b)** An evaluation of the **significance** of the non-conforming work is made

____ **5.4.9.1(c)** Corrective actions are **taken immediately**, together with any decision about the acceptability of the non-conforming work

____ **5.4.9.1(d)** Where the data quality is or may be impacted, the client is **notified** and work may be **recalled**

____ **5.4.9.1(e)** The responsibility for **authorizing the resumption of work** is defined

____ **5.4.9.2** Does the laboratory **implement corrective action procedures** (see Section 5.4.10) promptly when the evaluation indicates that non-conforming work could recur or there is doubt about compliance of the laboratory's operations with its own policies & procedures

COMMENTS:

CORRECTIVE ACTION

____ **5.4.10.1** Has the laboratory established policies & procedures for **implementing corrective actions** when non-conforming work or departures from policies & procedures in the quality system or technical operations have been identified

____ **5.4.10.1** Has the laboratory **designated appropriate authorities** for implementing corrective actions when non-conforming work or departures from policies & procedures in the quality system or technical operations have been identified

____ **5.4.10.2** Do the procedures for corrective action **start with an investigation** to determine the **root cause(s) of the problem**

____ **5.4.10.3** Where corrective actions are needed, does the laboratory **identify potential corrective actions**

____ **5.4.10.3** Does the laboratory **select & implement** the corrective action(s) **most likely** to eliminate the problem & to prevent recurrence

____ **5.4.10.3** Are the corrective actions **to a degree appropriate to the magnitude & risk** of the problem

____ **5.4.10.3** Does the laboratory **document & implement any required changes** resulting from corrective action investigations

____ **5.4.10.4** Does the laboratory **monitor the results** to ensure that corrective actions taken have been effective

____ **5.4.10.5** Where the identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies & procedures, or on its compliance with the NELAC Standards, does the laboratory ensure that the appropriate areas of activity **undergo internal auditing procedures** (see Section 5.4.13)

____ **5.4.10.6(a)** Does the laboratory implement general procedures to be followed when **departures** from documented policies, procedures, & quality control have occurred

In implementing these general procedures, does the laboratory:

____ **5.4.10.6(a)(1)** Identify the individual(s) responsible for **assessing each QC data type**

____ **5.4.10.6(a)(2)** Identify the individual(s) responsible for **initiating and/or recommending corrective actions**

____ **5.4.10.6(a)(3)** Define how the analyst **treats a data set** if associated QC measurements are unacceptable

____ **5.4.10.6(a)(4)** Specify how out-of-control situations & subsequent corrective actions **are to be documented**

____ **5.4.10.6(a)(5)** Specify procedures for management & the QA officer to **review corrective action reports**

____ **5.4.10.6(b)** To the extent possible, are sample test results **reported only if all QC measures are acceptable**

____ **5.4.10.6(b)** Does the laboratory report samples with the **appropriate laboratory defined data qualifier(s)** when a quality control measure associated with that sample analysis was found to be out of control and the data is to be reported

COMMENTS:

PREVENTIVE ACTION

____ **5.4.11.1** Does the laboratory **identify needed improvements or potential sources of nonconformances**, either technical or concerning the quality system

____ **5.4.11.1** If preventive action is required, are **action plans** developed, implemented, & monitored to reduce the occurrence of nonconformances & to take advantage of opportunities for improvement

____ **5.4.11.2** Do the procedures for preventive actions **include the initiation** of such actions & **application of controls** to ensure their effectiveness

CONTROL OF RECORDS

____ **5.4.12** Does the laboratory maintain a **record system** to suit its particular circumstances & to comply with any applicable regulations

____ **5.4.12** Does the record system produce **unequivocal, accurate records** which document **all laboratory activities**

____ **5.4.12** Does the laboratory **retain on record** all original observations, calculations & derived data, calibration records, and a copy of the test report for **at least 5 years**

____ **5.4.12** Does the laboratory have a **written SOP** for carrying out **legal chain-of-custody** if a client specifies that a sample will be **used for evidentiary purposes**

____ **5.4.12.1.1** Has the laboratory **established & maintained procedures** for the identification, collection, indexing, access, filing, storage, maintenance, & disposal of **quality & technical records**

Note: Quality records include reports from internal audits & management reviews as well as records of corrective & preventive actions; records may be in any media, such as hardcopy or electronic media

____ **5.4.12.1.2** Are all records **legible**

____ **5.4.12.1.2** Are all records stored & retained in such a way that they are **easily retrievable in facilities** that provide a suitable environment to **prevent damage or deterioration** & to prevent loss

____ **5.4.12.1.2** Has the laboratory established **retention times** of records

____ **5.4.12.1.3** Are all records **held secure & in confidence**

____ **5.4.12.1.4** Does the laboratory have procedures to **protect & back-up records stored electronically** & to prevent unauthorized access to or amendment of these records

____ **5.4.12.1.5** Does the record keeping system allow **historical reconstruction** of **all laboratory activities** that produced the resultant sample analytical data

____ **5.4.12.1.5** Is the history of the sample **readily understood** through the documentation (including **interlaboratory transfers** of samples and/or extracts)

____ **5.4.12.1.5(a)** Do the records include the **identity of personnel** involved in sampling, sample receipt, preparation, calibration, & testing

____ **5.4.12.1.5(b)** Has the laboratory documented **all information** relating to the laboratory facilities equipment, analytical test methods, & related **laboratory activities** (e.g. sample receipt, sample preparation, & data verification)

____ **5.4.12.1.5(c)** Does the record keeping system facilitate the **retrieval** of all **working files** & **archived records** for inspection & verification purposes (e.g., set format for naming electronic files)

____ **5.4.12.1.5(d)** Are all **changes to records** signed or **initialed by responsible staff**

____ **5.4.12.1.5(d)** Is the **reason** for the signature or initials **clearly indicated** in the records (e.g. "sampled by," "prepared by," or "reviewed by")

____ **5.4.12.1.5(e)** Is all generated data recorded **directly, promptly, & legibly** in **permanent ink**
Note: This does not include data generated by automated data collection systems

____ **5.4.12.1.5(f)** Are entries in records **not obliterated** by **erasures, overwritten files, or markings**

____ **5.4.12.1.5(f)** Are all **corrections** to record-keeping errors made by **one line marked** through the error, with the individual making the correction **signing** (or **initialing**) & **dating** the correction
Note: This also applies to electronically maintained records

____ **5.4.12.2.1** Does the laboratory retain records of **original observations, derived data, & sufficient information** to establish an audit trail, calibration records, staff records, & a copy of each test report issued for a **defined period**

____ **5.4.12.2.1** Do the records for each environmental test contain sufficient information to **facilitate the identification of factors** affecting the uncertainty & to **enable the environmental test to be repeated** under conditions as close as possible to the original

____ **5.4.12.2.1** Do the records include the **identity of personnel** responsible for the sampling, performance of the environmental test, & checking the results

____ **5.4.12.2.2** Are observations, data, & calculations **recorded at the time they are made** & identifiable to the specific task

____ **5.4.12.2.3** When mistakes occur in the records, is each mistake **crossed out, not erased or made illegible or deleted, with correct value entered** alongside

____ **5.4.12.2.3** Are all such alterations to records **signed or initialed** by the person making the correction

____ **5.4.12.2.3** Does the laboratory **take equivalent measures** to avoid loss or change of original data in **records stored electronically**

____ **5.4.12.2.3** When corrections are due to reasons **other than transcription errors**, does the laboratory document the **reason for the correction**

____ **5.4.12.2.4(a)** Are all laboratory records & reports **safely stored, held secure, & in confidence** to the client

____ **5.4.12.2.4(a)** Are all **NELAP-related records available** to the accrediting authority

____ **5.4.12.2.4(b)** Are all laboratory records retained for a **minimum of 5 years** from **generation of the last entry in the records**

____ **5.4.12.2.4(b)** Does the laboratory maintain all information **necessary** for the **historical reconstruction** of data

____ **5.4.12.2.4(b)** If records are stored only on electronic media, does the laboratory have the **supportive hardware & software** necessary for **data retrieval**

____ **5.4.12.2.4(c)** Do laboratory records stored or generated **by computers** have **hard-copy** or **write-protected back-up** copies

____ **5.4.12.2.4(d)** Has the laboratory established a **record management system** for control of laboratory notebooks, instrument logbooks, standards logbooks, & records for data reduction, validation, & reporting

____ **5.4.12.2.4(e)** Does the laboratory have an **access log** to document access to **archived information**

____ **5.4.12.2.4(e)** Are the archived laboratory records **protected** against **fire, theft, loss,** environmental **deterioration, & vermin**

____ **5.4.12.2.4(e)** Are archived **electronic records** protected against **electronic or magnetic sources**

____ **5.4.12.2.4(f)** Does the laboratory have a **plan** to ensure that records are **maintained or transferred** according to **clients' instructions** in the event that the laboratory **transfers ownership** or **goes out of business**
Note: In cases of bankruptcy the laboratory must **follow appropriate regulatory & state legal requirements** concerning laboratory records

Does the laboratory maintain records of the following **procedures & activities** to which a **sample is subjected** while it is in the **laboratory's possession**:

____ **5.4.12.2.5.1(a)** Sample **preservation**, appropriateness of **sample container**, & compliance with **holding times**

____ **5.4.12.2.5.1(b)** Sample **identification, receipt, acceptance or rejection,** & **log-in**

____ **5.4.12.2.5.1(c)** Sample **storage & tracking**
Note: Records include shipping receipts & transmittal forms (chain-of-custody form)

____ **5.4.12.2.5.1(d)** Documented procedures for **receipt & retention** of test items, including all provisions to protect the integrity of samples

____ **5.4.12.2.5.2(a)** Does the laboratory retain **all original raw data**, whether hard copy or electronic, for calibrations, sample analyses, & quality control measures
Note: Raw data includes analyst work sheets & data output records (chromatograms, strip charts, & other instrument response readout records)

____ **5.4.12.2.5.2(b)** Does the laboratory retain a written description or reference to the **specific test method** used
Note: This includes description of the specific computational steps used to translate parametric observations into reportable analytical values

____ **5.4.12.2.5.2(c)** Does the laboratory retain copies of **final reports**

____ **5.4.12.2.5.2(d)** Does the laboratory retain **archived standard operating procedures**

____ **5.4.12.2.5.2(e)** Does the laboratory retain **correspondence** relating to its activities for a **specific project**

____ **5.4.12.2.5.2(f)** Does the laboratory retain **all corrective action reports, audits, & audit responses**

____ **5.4.12.2.5.2(g)** Does the laboratory retain **proficiency test results & raw data**

____ **5.4.12.2.5.2(h)** Does the laboratory retain results of **data review, verification, & cross checking** procedures

Does the laboratory's **analytical records** on strip charts, tabular printouts, computer data files, analytical notebooks, & run logs include the following **essential information**:

____ **5.4.12.2.5.3(a)** Laboratory **sample ID** code

____ **5.4.12.2.5.3(b)** **Date of analysis, & time** of analysis if holding time is 72 hr or less or when time critical steps are included in the analysis (e.g., extractions & incubations)

____ **5.4.12.2.5.3(c)** Instrumentation **identification** & instrument **operating conditions/parameters** (or reference to such data)

____ **5.4.12.2.5.3(d)** Analysis **type**

____ **5.4.12.2.5.3(e)** All manual **calculations** (e.g., manual integrations)

____ **5.4.12.2.5.3(f)** Analyst or operator **initials/signature**

____ **5.4.12.2.5.3(g)** Sample **preparation**
Note: These records include cleanups, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, & reagents used

____ **5.4.12.2.5.3(h)** Sample **analysis**

____ **5.4.12.2.5.3(i)** **Standard & reagent** origin, receipt, preparation, & use

____ **5.4.12.2.5.3(j)** **Calibration** criteria, frequency, & acceptance criteria

____ **5.4.12.2.5.3(k)** **Data & statistical calculations**, review, confirmation, interpretation, assessment, & reporting conventions

____ **5.4.12.2.5.3(l)** **Quality control** protocols & assessment

____ **5.4.12.2.5.3(m)** Electronic **data security**

____ **5.4.12.2.5.3(m)** **Software** documentation & verification

____ **5.4.12.2.5.3(m)** Software & hardware **audits**

____ **5.4.12.2.5.3(m)** **Backups** of automated data entries

____ **5.4.12.2.5.3(m)** Records of any **changes** to automated data entries

____ **5.4.12.2.5.3(n)** **Method performance criteria** including expected quality control requirements

Does the laboratory maintain the following **administrative records**:

____ **5.4.12.2.5.4(a)** Personnel **qualifications, experience, & training** records

____ **5.4.12.2.5.4(b)** Records of **demonstration of capability** for **each analyst**

____ **5.4.12.2.5.4(c)** Log of **names, initials, & signatures** for all individuals responsible for signing or initialing **any laboratory record**

INTERNAL AUDITS

____ **5.4.13.1** Does the laboratory arrange for **annual internal audits** to verify that its operations continue to comply with the requirements for the laboratory's quality system

____ **5.4.13.1** Does the **internal audit program** address all elements of the quality system, including the environmental testing activities

____ **5.4.13.1** Does the QA Manager **take responsibility to plan & organize** internal audits as required **by schedule & as required by management**

____ **5.4.13.1** Is the QA officer or designee conducting the internal audits **trained & qualified as an auditor** and, where possible, **independent** of the activity being audited

Note: Personnel can audit their own activities ONLY when it can be demonstrated that an effective audit can be carried out

____ **5.4.13.2** Does the laboratory take **timely corrective action** when the internal audit findings cast doubt on the correctness or validity of the laboratory's test results

____ **5.4.13.2** Does the laboratory **immediately notify**, in writing, any **client whose work was involved** in the the internal audit findings

____ **5.4.13.2** Does the laboratory **notify clients promptly, in writing**, of any event that casts **doubt on the validity** of results given in any test report or amendment to a test report (e.g. identification of defective measuring or test equipment)

____ **5.4.13.2** Does the laboratory specify **in its Quality Manual** the **time frame for notifying a client** of events that cast doubt on the validity of the test results

____ **5.4.13.3** Does the laboratory **document** all internal audit findings plus any corrective actions that arise from them

____ **5.4.13.3** Does the laboratory management ensure that **corrective actions are discharged** within the appropriate & agreed time frame as indicated in the quality manual and/or SOP's

____ **5.4.13.4** Are **follow-up audit activities** conducted that verify & record the implementation & effectiveness of the corrective action taken

COMMENTS:

MANAGEMENT REVIEWS

____ **5.4.14.1** Does the laboratory management **annually conduct a review** of its quality system & its testing activities, in order to ensure its **continuing suitability & effectiveness** and to introduce any **necessary changes or improvements** in the quality system & laboratory operations

____ **5.4.14.1** Does the annual management review **take into account:**

- suitability of policies & procedures
- reports from managerial & supervisory personnel
- outcomes from recent internal audits
- corrective & preventive actions
- assessments by external bodies
- results from interlaboratory comparisons or proficiency tests
- changes in the volume & type of work undertaken
- feedback from clients
- complaints
- other relevant factors, such as quality control activities, resources, & staff training

____ **5.4.14.2** Does the laboratory have a **procedure** for the annual management review of the quality system

____ **5.4.14.2** Does the laboratory **maintain records** of management review findings & actions

____ **5.4.14.2** Does the laboratory management ensure that **corrective actions are discharged** within the appropriate & agreed time frame

____ **5.4.15** Does the laboratory ensure that a review is conducted with respect to any evidence of **inappropriate actions or vulnerabilities** related to data integrity

____ **5.4.15** Does the laboratory handle the discovery of potential issues in a **confidential manner** until such time that a follow-up investigation, full investigation, or other appropriate actions have been completed & the issues clarified

____ **5.4.15** Are all investigations resulting in a finding of inappropriate activity **documented** and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients

____ **5.4.15** Does the laboratory maintain all documentation of these investigations & actions taken for **at least 5 years**

COMMENTS:

LABORATORY TECHNICAL REQUIREMENTS

____ **5.5.1.2** Does the laboratory take account of the **following factors** in **developing environmental test methods & procedures**:

- human factors
- environmental test methods & method validation
- equipment
- measurement traceability
- sampling
- handling of samples

____ **5.5.1.2** Are the above factors taken into account in the **training & qualification of personnel**

____ **5.5.1.2** Are the above factors taken into account in the **selection & calibration of the equipment** it uses

PERSONNEL

____ **5.5.2.1** Does the laboratory management **ensure the competence** of all who operate specific equipment, perform environmental tests, evaluate procedures, & sign test reports

____ **5.5.2.1** When using staff who are undergoing training, is **adequate supervision** provided

____ **5.5.2.1** Are the personnel performing specific tasks **qualified** on the basis of **appropriate** education, training, experience, and/or demonstrated skills, as required

____ **5.5.2.1** Does the laboratory have sufficient personnel, having the necessary **education, training, technical knowledge, & experience**, for their assigned functions

____ **5.5.2.1** Are all laboratory personnel **responsible for complying with all quality assurance / quality control (QA/QC) requirements** pertaining to their organizational/technical functions

____ **5.5.2.1** Does **each technical staff member** have adequate experience & education to **demonstrate a specific knowledge of his/her particular function** & general knowledge of laboratory operations, test methods, QA/QC procedures, & records management

____ **5.5.2.2** Has the laboratory management formulated goals with respect to the **education, training, & skills** of the laboratory personnel

____ **5.5.2.2** Does the laboratory have policies & procedures for identifying the **training needs & providing training** of personnel

____ **5.5.2.2** Is the training program **relevant** to the present & anticipated tasks of the laboratory

____ **5.5.2.3** Does the laboratory use personnel **employed by or under contract to** the laboratory

____ **5.5.2.3** Where **contracted & additional** technical & key support **personnel** are used, does the laboratory ensure that personnel are **supervised & competent**

____ **5.5.2.3** Does the laboratory ensure that the contracted & additional personnel work **in accordance with the laboratory's quality system**

____ **5.5.2.4** Does the laboratory maintain **current job descriptions for all personnel** who manage, perform, or verify work affecting the quality of the environmental tests

____ **5.5.2.5** Does the laboratory management **authorize specific personnel** to perform particular types of sampling & environmental testing, to issue test reports, to give opinions & interpretations, and to operate particular types of equipment

____ **5.5.2.5** Does the laboratory **maintain records** of the relevant authorizations, competence, educational & professional qualifications, training, skills, & experience of all technical personnel, including contracted personnel

____ **5.5.2.5** Are these records **readily available**

____ **5.5.2.5** Do these records include the **date** on which authorization and/or competence **is confirmed**

____ **5.5.2.5** Does the laboratory **maintain records** on the relevant qualifications, skills, & experience of the technical personnel & records on **demonstrated proficiency for each laboratory test method**

____ **5.5.2.6(a)** Does the laboratory management define the **minimal level of qualification, skills, & experience** necessary for all positions in the laboratory

Note: Basic laboratory skills such as using a balance, pipeting, colony counting, & aseptic or quantitative techniques must also be considered

____ **5.5.2.6(b)** Does the laboratory ensure **& document** that all technical staff have demonstrated **capability** in the activities for which they are responsible

Note: In laboratories with specialized work cells (a well-defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this documentation must be fully documented

____ **5.5.2.6(c)(1)** Does the laboratory have evidence on file demonstrating that each employee has **read, understood, & is using the latest version** of the laboratory's quality documentation that relates to his/her job responsibilities

____ **5.5.2.6(c)(2)** Does the laboratory document the **training courses or workshops** on specific equipment, analytical techniques, or laboratory procedures for each technical staff member

____ **5.5.2.6(c)(3)** Does the laboratory's analyst **training files** contain **certification** that each analyst has read, understood, & agreed to perform the **most recent version** of the test method

Note: The most recent version is the **approved method or SOP** defined by the laboratory **document control system** in Section 5.4.2.3(d)

____ **5.5.2.6(d)** Does the laboratory document **all its analytical & operational activities**

____ **5.5.2.6(e)** Is the management responsible for **supervising all personnel** employed by the laboratory

____ **5.5.2.6(f)** Does the laboratory management ensure that all **sample acceptance criteria** are verified, samples are properly logged into the **sample tracking system**, & samples are **properly labeled & stored**

____ **5.5.2.6(g)** Does the laboratory **document the quality of all data** reported

____ **5.5.2.7** Does the laboratory provide **data integrity training** as a formal part of new employee orientation and **annually** for current employees

____ **5.5.2.7** Are the **topics covered** in data integrity training **documented in writing & provided** to all trainees

____ **5.5.2.7** Do the key topics covered during data integrity training **include organizational mission** & its relationship to the critical need for **honesty & full disclosure** in all analytical reporting, how & when to **report data integrity issues**, & record-keeping

____ **5.5.2.7** Does data integrity training **include discussion** regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring, & data integrity procedure documentation

____ **5.5.2.7** Are employees **required to understand** that **any infractions** of the laboratory data integrity procedures will **result in a detailed investigation** that could lead to very serious **consequences** including immediate termination, debarment, or civil/criminal prosecution

____ **5.5.2.7** Does the data integrity training & annual refresher training have a **signature attendance sheet** or other forms of documentation demonstrating that **all staff have participated & understand their obligations** related to data integrity

Note: Senior managers acknowledge their support of these procedures by upholding the spirit & intent of the organization's data integrity procedures & effectively implementing the specific requirements of the procedures

Note: Specific examples of breaches of ethical behavior include:
- improper data manipulations
- adjustments of instrument time clocks
- inappropriate changes in concentrations of standards

Note: Data integrity training procedures could include:
- emphasis on proper written narration in cases where analytical data may be useful, but are partially deficient
- written ethics agreements
- examples of improper practices
- examples of improper chromatographic manipulations
- requirements for external ethics program training
- any external resources available to employees

COMMENTS:

ACCOMMODATION & ENVIRONMENTAL CONDITIONS

____ **5.5.3.1** Is the laboratory's facilities for environmental testing, including **energy sources, lighting, & environmental conditions,** such as to facilitate the correct performance of these tests

____ **5.5.3.1** Does the laboratory environment in which its activities are taken **not invalidate** the results or **adversely affect** the required accuracy of measurement

Note: Particular attention must be noted when laboratory activities are at **sites other than its permanent premises**

____ **5.5.3.1** Does the laboratory document the **technical requirements** for accommodation & environmental conditions that can affect the results of environmental tests

____ **5.5.3.2** Does the laboratory provide for **effective monitoring, control, & recording** of appropriate environmental conditions (such as biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound & vibration levels)

____ **5.5.3.2** Does the laboratory **stop environmental tests** when the environmental conditions jeopardize the results of the environmental tests

____ **5.5.3.3** Does the laboratory have **effective separation** between neighboring areas when the activities therein are **incompatible** (including culture handling or incubation areas, & volatile organic chemicals handling areas)

____ **5.5.3.3** Does the laboratory take measures to **prevent cross-contamination**

____ **5.5.3.4** Does the laboratory control **access to & use of all areas** affecting the quality of the environmental tests (the extent of control is determined based on its particular circumstances)

____ **5.5.3.5** Does the laboratory take adequate measures to ensure **good housekeeping** in the laboratory & to ensure that any contamination does not adversely affect data quality

____ **5.5.3.5** Are **special procedures** prepared where necessary

____ **5.5.3.6** Does the laboratory's available work spaces ensure an **unencumbered work area**

Work areas include:

- Access and entryways to the laboratory
- Sample receipt area(s)
- Sample storage area(s)
- Chemical & waste storage area(s)
- Data handling & storage area(s)

COMMENTS:

ENVIRONMENTAL TEST METHODS

____ **5.5.4.1** Does the laboratory use **appropriate test methods & procedures** for all tests & related activities within its responsibility

Note: Includes sample collection, sample handling, transport & storage, sample preparation, sample analysis, estimations of uncertainty, & statistical techniques

____ **5.5.4.1** Does the laboratory have documented **instructions on the use & operation** of all relevant equipment, and on the **handling & preparation** of samples (where the absence of such instructions could jeopardize the tests)

____ **5.5.4.1** Are all instructions, standards, manuals, & reference data relevant to the work of the laboratory **maintained up-to-date**

____ **5.5.4.1** Are all instructions, standards, manuals, & reference data relevant to the work of the laboratory **readily available to the staff**

____ **5.5.4.1** Do **deviations** from environmental test methods occur only if the deviations are **documented, technically justified, authorized, & accepted** by the client

____ **5.5.4.1.1** Does the laboratory have **standard operating procedures** that accurately reflect **all phases of current laboratory activities** such as assessing data integrity, corrective actions, handling customer complaints, and **all test methods**

Note: These documents may be equipment manuals provided by the manufacturer or internally written documents **with adequate detail** to allow someone similarly qualified, other than the analyst, to **reproduce the procedures** used to generate the test result

Note: The test methods may be copies of published methods as long as **any changes or selected options** in the methods are **documented & included in the methods manual**

____ **5.5.4.1.1(c)** Are copies of these standard operating procedures **accessible to all personnel**

____ **5.5.4.1.1(d)** Are the standard operating procedures **organized**

____ **5.5.4.1.1(e)** Does each standard operating procedure indicate the **effective date** of the document, **revision number**, & **signature** of the approving authority

____ **5.5.4.1.1(f)** Does the laboratory document & include in the methods manual **any changes**, including the **use of a selected option**, to perform the test

SELECTION OF TEST METHODS

____ **5.5.4.2** Does the laboratory **use methods for sampling & environmental testing** that meet the needs of the client & are appropriate for the environmental tests it undertakes

____ **5.5.4.2.1(a)** Does the laboratory **preferentially use** test methods published in **international, regional, or national standards**

____ **5.5.4.2.1(a)** Does the laboratory ensure that the **latest valid edition of a standard** is used, unless it is not appropriate or possible to do so

____ **5.5.4.2.1(a)** When necessary, is the standard **supplemented with additional details** to ensure consistent application

____ **5.5.4.2.1(b)** When the use of specific test methods for sample analysis are mandated or requested, does the laboratory **use only those methods**

The following Standards apply when the client does not specify the test method to be used or where methods are employed that are not required.

____ **5.5.4.2.1(c)** Is the laboratory's developed test method **fully documented & validated**

____ **5.5.4.2.1(c)** Does the laboratory make its test method **available to the client & other recipients** of the relevant reports

____ **5.5.4.2.1(c)** Does the laboratory **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

____ **5.5.4.2.1(c)** Are **laboratory-developed or laboratory-adopted methods** used only if they are **appropriate for the intended use** & if they are **validated**

____ **5.5.4.2.1(c)** Does the laboratory **inform the client** as to the test method chosen

____ **5.5.4.2.1(d)** Does the laboratory inform the client when the test method proposed by the client is considered to be **inappropriate or out of date**

____ **5.5.4.2.2** Does the laboratory confirm that it can **properly operate all methods** before introducing the environmental tests

____ **5.5.4.2.2** Does the laboratory **repeat** such confirmations **each time** the method **changes**

____ **5.5.4.3** Is the introduction of environmental test methods **developed by the laboratory** for its own use a **planned activity**

____ **5.5.4.3** Is the introduction of environmental test methods **assigned to qualified personnel** equipped with **adequate resources**

____ **5.5.4.3** Does the laboratory **update plans** as development proceeds & ensure **effective communication** among all personnel involved

____ **5.5.4.4** Does the laboratory’s choice to use methods **not covered by standard methods** subject to **agreement with the client** & include a **clear specification** of the client’s requirements & the purpose of the environmental test

____ **5.5.4.4** Is the method developed **validated appropriately** before use

COMMENTS:

VALIDATION OF TEST METHODS

____ **5.5.4.5.2** Does the laboratory **validate** non-standard methods, laboratory designed/developed methods, standard methods used outside their published scope, and amplifications/modifications of standard methods **to confirm** that the methods **are fit for the intended use**

____ **5.5.4.5.2** Was the validation **extensive as necessary** to meet the needs of the given application or field of application

____ **5.5.4.5.2** Has the laboratory **recorded** the results obtained, the procedure used for the validation, & a statement as to whether the method is fit for intended use

Note: The minimum requirements are the **initial test method evaluation requirements** given in Appendix C.3 (see pages 44-45)

____ **5.5.4.5.3** Are the **range & accuracy** of the values obtainable, as assessed for the intended use, **relevant** to the client's needs

Note: The values obtainable include the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences, and/or cross-sensitivity against interference from the sample matrix)

ESTIMATION OF UNCERTAINTY OF MEASUREMENT

____ **5.5.4.6.1** Does the laboratory **have & apply** procedures for **estimating uncertainty of measurement**

____ **5.5.4.6.1** At a minimum, does the laboratory attempt to **identify all the components** of uncertainty & **make a reasonable estimation**

____ **5.5.4.6.1** Does the laboratory ensure that the **form of reporting** of the test result does not **give a wrong impression** of the uncertainty

____ **5.5.4.6.1** Is the reasonable estimation (of the uncertainty) based on **knowledge of the performance** of the method & on the measurement scope

____ **5.5.4.6.1** Is the reasonable estimation make use of **previous experience & validation data**

Note: In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement, and specifies the form of the calculated results, the laboratory is considered to have satisfied this clause by following the test method & reporting instructions

____ **5.5.4.6.2** When estimating the uncertainty of measurement, does the laboratory take into account **all uncertainty components** which are of importance in the given situation using **appropriate methods of analysis**

COMMENTS:

CONTROL OF DATA

____ **5.5.4.7.1** Does the laboratory **subject calculations & data transfers to appropriate checks** in a systematic manner

____ **5.5.4.7.1(a)** Has the laboratory established standard operating procedures to ensure that reported data is **free from transcription & calculation errors**

____ **5.5.4.7.1(b)** Has the laboratory established standard operating procedures to ensure that **all quality control measures** are **reviewed & evaluated** before data are reported

____ **5.5.4.7.1(c)** Has the laboratory established **SOP's for manual calculations & manual integrations**

The following standards are applicable when computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data.

____ **5.5.4.7.2(a)** Is all the laboratory's **computer software documented** in sufficient detail & suitably **validated as being adequate** for use

Note: Commercial off-the-shelf software in general use within their designated application range is considered to be sufficiently validated; however, laboratory software configurations or modifications must be validated

____ **5.5.4.7.2(b)** Has the laboratory established & implemented procedures for **protecting electronic data**

Note: Must include the integrity & confidentiality of data entry or collection, data storage, data transmission, & data processing

____ **5.5.4.7.2(c)** Are the laboratory's **computers & automated equipment** maintained to ensure **proper functioning**

____ **5.5.4.7.2(c)** Are the computers & automated equipment provided with the **environmental & operating conditions** necessary to maintain the integrity of test data

____ **5.5.4.7.2(d)** Has the laboratory established & implemented appropriate procedures for the maintenance of **electronic data security** (includes the prevention of unauthorized access to & unauthorized amendment of computer records)

COMMENTS:

EQUIPMENT

____ **5.5.5.1** Is the laboratory furnished with all items of **equipment & reference materials** required for the correct performance of tests for which accreditation is sought or maintained

____ **5.5.5.1** Does the laboratory ensure that **equipment outside its permanent control meets the relevant requirements** of these NELAC Standards

____ **5.5.5.2** Does the equipment & its software used for sampling & testing capable of **achieving the accuracy required** & comply with specifications relevant to the environmental tests concerned

____ **5.5.5.2** Does the laboratory **calibrate and/or verify** all equipment (including that used for sampling) to establish that it meets specified requirements & complies with the relevant standard specifications, **before being put into service**

Note: These Standards pertain to **analytical support equipment**, including balances, ovens, refrigerators, freezers, incubators, water baths, temperature monitoring devices (including thermometers & thermistors), & volumetric dispensing devices (if quantitative results are dependent on their accuracy).

____ **5.5.5.2.1(a)** Is the support equipment maintained in **proper working order**

____ **5.5.5.2.1(a)** Does the laboratory keep records of all **repair & maintenance activities** including service calls

____ **5.5.5.2.1(b)** Is the support equipment calibrated or verified **at least annually**, using NIST-traceable references when available, over the **entire range of use**

____ **5.5.5.2.1(b)** Are the **results of calibration or verification** for all support equipment **within the specifications required** for the application for which the equipment is used

____ **5.5.5.2.1(b)** Does the laboratory **remove** support equipment **from service** or **establish & maintain correction factors** to correct all measurements for the deviation when the results of the annual calibration are not within the specifications required for the support equipment

____ **5.5.5.2.1(c)** Does the laboratory **retain raw data records** to document support equipment performance

____ **5.5.5.2.1(d)** Does the laboratory check balances, ovens, refrigerators, freezers, and water baths with NIST-traceable references (where commercially available) **prior to use** on **each working day** in the **expected use range**

____ **5.5.5.2.1(e)** Are mechanical volumetric dispensing devices & burettes (except Class A glassware) **checked for accuracy** on a **quarterly** use basis

Note: Glass microliter syringes must come with a certificate attesting to established accuracy, or else the accuracy must be initially demonstrated & documented by the laboratory

____ **5.5.5.2.1(f)** Does the laboratory document the temperature, cycle time, & pressure of each use of the **autoclave** for **chemical tests** with the appropriate chemical indicators or temperature recorders & pressure gauges

____ **5.5.5.3** Is the test equipment operated only **by authorized personnel**

____ **5.5.5.3** Are **up-to-date instructions** on the use & maintenance of equipment (including relevant manuals provided the manufacturer) **readily available for use** by appropriate laboratory personnel

____ **5.5.5.3** Is all equipment properly **maintained, inspected, & cleaned**

____ **5.5.5.3** Does the laboratory **document maintenance procedures** for all its equipment

____ **5.5.5.4** Is each item of equipment & its software used for environmental testing, & significant to the result, **uniquely identified** (when practicable)

____ **5.5.5.5** Does the laboratory **maintain records** of each **major item of equipment & all reference materials** significant to the environmental tests performed

Do these records include:

____ **5.5.5.5(a)** The **identity** of the item of equipment & its software

____ **5.5.5.5(b)** **Manufacturer's name, type identification, & serial number** or other unique identification

____ **5.5.5.5(c)** **Checks** that the equipment **complies with the specification** (see Section 5.5.5.2)

____ **5.5.5.5(d)** Current **location**

____ **5.5.5.5(e)** Copy of the **manufacturer's instructions**, where available, or reference to their location

____ **5.5.5.5(f)** Dates, results, & copies of **reports & certificates** of all calibrations, adjustments, acceptance criteria, & due date of the next calibration

____ **5.5.5.5(g)** The maintenance plan, where appropriate, & **maintenance carried out** to date, documentation on all routine & non-routine maintenance activities & reference material verifications

____ **5.5.5.5(h)** Any **damage, malfunction, modification, or repair** to the equipment

____ **5.5.5.5(i)** Date **received** & date **placed into service**, if available

____ **5.5.5.5(j)** **Condition** of the equipment when received, if available (e.g. new, used, reconditioned)

____ **5.5.5.6** Does the laboratory have procedures for the **safe handling, transport, storage, use, & planned maintenance** of measuring equipment, to ensure proper functioning & to prevent contamination or deterioration

____ **5.5.5.7** Does the laboratory clearly **identify, isolate, & remove from service** any item of equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown by verification or otherwise to be **defective**

____ **5.5.5.7** Does the laboratory not place any defective equipment back into service until the equipment has been **repaired** & shown by calibration, verification, or testing to **perform satisfactorily**

____ **5.5.5.7** Does the laboratory evaluate the effect(s) of any defective equipment on **previous environmental tests** (& institute Section 5.4.9)

____ **5.5.5.8** Is each item of equipment under the control of the laboratory & requiring calibration (wherever practicable) **labeled, marked, or otherwise identified** to indicate its calibration status, including the date when last calibrated and the date or calibration criteria when recalibration is due

____ **5.5.5.9** When equipment goes **outside the direct control of the laboratory**, does the laboratory ensure that the function & calibration status of the equipment are **checked & shown to be satisfactory** before the equipment is returned to service

____ **5.5.5.11** Where calibrations give rise to a set of **correction factors**, does the laboratory have procedures to ensure that copies (e.g., in computer software) are **correctly updated**

____ **5.5.5.12** Does the laboratory **safeguard** its test equipment, including both hardware & software, from **adjustments** that would **invalidate the test results**

COMMENTS:

MEASUREMENT TRACEABILITY

____ **5.5.6.1** Does the laboratory **calibrate and/or verify** all measurement operations & test equipment having an effect on the accuracy or validity of tests **before being put into service**

____ **5.5.6.1** Does the laboratory **calibrate and/or verify** all measurement operations & test equipment having an effect on the accuracy or validity of tests **on an on-going basis**

____ **5.5.6.1** Does the laboratory have an **established program** for the calibration & verification of its measuring & test equipment
Note: This includes balances, thermometers, & control standards

___ **5.5.6.1** Does this program include a system for **selecting, using, calibrating, checking, controlling, & maintaining** measurement standards, reference materials used as measurement standards, and measuring & test equipment used to perform environmental tests

____ **5.5.6.2.1** Does the laboratory ensure that the equipment used can **provide the uncertainty of measurement needed**

____ **5.5.6.2.1** Is the overall program of calibration and/or verification & validation of equipment **designed & operated** such that laboratory measurements are **traceable to national standards of measurement**

____ **5.5.6.2.2** When traceability to the International System of Units (SI) is not possible or not relevant, is there traceability to **certified reference materials, agreed methods, or consensus standards**

____ **5.5.6.2.2** Does the laboratory provide satisfactory evidence of **correlation of results** in those cases where traceability to national standards of measurement is not applicable
(examples include: interlaboratory comparisons, proficiency testing, or independent analysis)

REFERENCE STANDARDS & REFERENCE MATERIALS

____ **5.5.6.3.1** Does the laboratory have a **program & procedure for calibration** of its reference standards

____ **5.5.6.3.1** Are the reference standards held by the laboratory **calibrated by a body** that can provide traceability (this applies to Class S standard weights or traceable thermometers)
Note: Where commercially available, this traceability must be to a national standard of measurement

____ **5.5.6.3.1** Are the reference standards **held by the laboratory** (e.g. Class S or equivalent weights, traceable thermometers) used for **calibration only** & for no other purpose

____ **5.5.6.3.1** If reference standards held by the laboratory are used for purposes in addition to calibration, has the laboratory **demonstrated** that their performance as reference standards has **not been invalidated**

____ **5.5.6.3.1** Are reference standards calibrated **before & after any adjustments**

____ **5.5.6.3.2** Are the reference materials **traceable**
Note: Where commercially available, this traceability must be to national or international standard reference materials or standards of measurement

____ **5.5.6.3.2** Are internal reference materials **checked** as far as is technically & economically practicable

____ **5.5.6.3.3** Are **checks** needed to maintain confidence in the calibration status or reference, primary, transfer, or working standards & reference materials carried out according to **defined procedures & schedules**

____ **5.5.6.3.4** Does the laboratory have procedures for the **safe handling, transport, storage, & use** of reference standards & reference materials in order to **prevent contamination or deterioration** & in order to **protect their integrity**

____ **5.5.6.4** Does the laboratory have **documented procedures** for purchasing, receiving, & storing **consumable materials** that are used for its technical operations

____ **5.5.6.4(a)** Does the laboratory **retain records** for **all standards, reagents, & media** including:
manufacturer/vendor
manufacturer's Certificate of Analysis or purity (if supplied)
date of receipt (at the laboratory)
recommended storage conditions
expiration date after which the material shall not be used
(unless verified by the laboratory)

____ **5.5.6.4(a)** Has the laboratory **verified** the purity of **expired standards, reagents, & media** prior to their continued use

____ **5.5.6.4(b)** Does the laboratory **label** the original containers of standards & reagents (provided by the manufacturer) with an **expiration date**

____ **5.5.6.4(c)** Does the laboratory maintain records on **reagent & standard preparation**

____ **5.5.6.4(c)** Do the records on reagent & standard preparation indicate:
Traceability to purchased stocks or neat compounds
Reference to the method of preparation
Date of preparation
Expiration date
Preparer's initials

____ **5.5.6.4(d)** Do **all** containers of prepared standards & reference materials bear a **unique identifier, expiration date, & link** to its specific **preparation record**

____ **5.5.6.4(e)** Are procedures in place to ensure that prepared reagents **meet the requirements of the test method** (see the scientific discipline & technology checklists for specific requirements)

Note: Reagents of appropriate quality must be selected and used. In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than specified in the test method shall not be used. Checks of the container label to verify that the purity of the reagents complies with the test method must be documented.

____ **5.5.6.4(f)** Do containers of **prepared reagents** bear a **preparation date**

____ **5.5.6.4(f)** Is the expiration date for each prepared reagent **defined on the container or documented elsewhere** as indicated in the laboratory's quality manual or SOP

COMMENTS:

SAMPLING

____ **5.5.7.1** Does the laboratory **have a sampling plan & procedures for sampling** when it carries out sampling for substances, materials, or products for subsequent environmental testing

____ **5.5.7.1** Are the sampling plan & sampling procedures **available at the location** where the sampling is undertaken

____ **5.5.7.1** Whenever reasonable, are the sampling plans **based on appropriate statistical methods**

____ **5.5.7.1** Does the sampling process **address factors to be controlled** to ensure the validity of the environmental test results

____ **5.5.7.1** Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures & appropriate techniques to **obtain representative subsamples**

____ **5.5.7.2** Are **deviations, additions, or exclusions** required by the client from the documented sampling procedure **recorded in detail** with the appropriate sampling data

____ **5.5.7.2** Are these deviations, additions, & exclusions **included on all documents** containing environmental test results

____ **5.5.7.2** Are any deviations, additions, or exclusions **communicated to the appropriate personnel**

____ **5.5.7.3** Does the laboratory have procedures for **recording** relevant data & operations **relating to sampling** that forms part of the environmental testing that is undertaken

____ **5.5.7.3** Do these records include the **sampling procedure** used, **identification** of the sampler, **environmental conditions** (if relevant), **diagrams** or other equivalent means to identify the **sampling location**, & (if appropriate) the **statistics** the sampling procedures are based upon

COMMENTS:

HANDLING OF SAMPLES

____ **5.5.8.1** Does the laboratory have procedures for the **transportation, receipt, handling, protection, storage, retention, and/or disposal of samples**, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory & the client

____ **5.5.8.2** Does the laboratory have a **system for identifying samples**

____ **5.5.8.2** Is the sample identification **retained throughout the life of the sample** in the laboratory

____ **5.5.8.2** Is the sample identification system designed & operated so as to ensure that samples **cannot be confused physically** or when referred to in records or other documents

____ **5.5.8.2** Does the sample identification system, if appropriate, **accommodate a sub-division** of groups of samples, and the **transfer of samples within & from the laboratory**

____ **5.5.8.2(a)** Does the laboratory have a documented system for **uniquely identifying items** to be tested, such that there is **no confusion** regarding the identity of such items **at any time**

____ **5.5.8.2(a)** Does this system include identification for **all samples, subsamples,** & subsequent **extracts & digestates**

____ **5.5.8.2(a)** Does the laboratory assign a **unique identification (ID) code** to **each sample container** received in the laboratory

Note: Use of container shape, size, or other physical characteristic, such as amber glass or a purple top, **is not** an **acceptable** means of identifying the sample

____ **5.5.8.2(b)** Does this unique laboratory ID code maintain an **unequivocal link** with the **unique field ID code** assigned each container

Note: Section **5.5.8.2(e)** allows the laboratory ID code may be the **same** as the field ID code in cases where the sample collector & analyst are the **same individual** or the laboratory **preassigns numbers** to sample containers

____ **5.5.8.2(c)** Is the laboratory ID code placed on the sample container as a **durable label**

____ **5.5.8.2(d)** Is the laboratory ID code **the link** that associates the sample with **related laboratory activities**, such as sample preparation or calibration

COMMENTS:

SAMPLE RECEIPT PROTOCOLS

____ **5.5.8.3** Does the laboratory record the **condition of the sample**, including any **abnormalities or departures** from standard condition as prescribed in the relevant test method, **upon receipt** at the laboratory

____ **5.5.8.3** Does the laboratory attempt to **consult the client** where there is **doubt** on the sample's **suitability for testing**, sample **does not conform** to the description provided, or the test required is **not fully specified**, before proceeding

____ **5.5.8.3** Are such discussions with the client **recorded**

____ **5.5.8.3.1(a)** Does the laboratory **check each sample for all the items** specified in its **sample acceptance policy**

Note: See NELAC 5.5.8.3.2 for the minimum list of items that the laboratory must check

____ **5.5.8.3.1(a)(1)** For samples that require thermal preservation, does the laboratory consider acceptable **only those samples** where the arrival temperature is **within 2 degrees Celsius** of the required temperature or method-specified range OR is **within 0-6 degrees Celsius** (where the specified temperature is 4 degrees C)

Note: For samples hand-delivered to the laboratory on the same day that they are collected, samples are considered acceptable if there is evidence that the chilling process has begun (e.g. arrival on ice)

____ **5.5.8.3.1(a)(2)** Does the laboratory implement procedures to **check chemical preservation** using readily available techniques (e.g. pH, free chlorine) **prior to or during** sample preparation or analysis

____ **5.5.8.3.1(b)** Does the laboratory **record the results** of all such checks for proper preservation & sample acceptability

If the sample **does not meet** the laboratory's acceptance criteria or receipt protocols, does the laboratory **EITHER:**

____ **5.5.8.3.1(c)(1)** **Retain correspondence** and/or **records of conversations** regarding the **final disposition** of rejected samples **OR**

____ **5.5.8.3.1(c)(2)** **Fully document any decision** to proceed with the analysis of samples not meeting acceptance criteria

If the decision is made to **proceed with the analysis** of samples not meeting acceptance criteria:

____ **5.5.8.3.1(c)(2)(i)** Does the laboratory note the **condition of these samples** on the **chain-of-custody or transmittal** forms & on **laboratory receipt documents**

____ **5.5.8.3.1(c)(2)(ii)** Does the laboratory **appropriately "qualify"** the analysis data on the **final report**

____ **5.5.8.3.1(d)** Does the laboratory utilize a **permanent chronological record** (e.g. log book or electronic database) to document receipt of all sample containers

____ **5.5.8.3.1(d)(1)** Does this sample receipt log record the following:
- Client or project name
- Date & time of laboratory receipt
- Unique laboratory ID code
- Signature or initials of person making the entries

____ **5.5.8.3.1(d)(2)** During the log-in process, is **sample collection information** unequivocally linked to the **log record** or included as part of the log

____ **5.5.8.3.1(d)(2)(i)** Is the **field ID code** which identifies each sample container **linked** to the **laboratory ID code** in the sample receipt log

____ **5.5.8.3.1(d)(2)(ii)** Is the date & time of **sample collection linked** to the sample container and to the date & time of **receipt in the laboratory**

____ **5.5.8.3.1(d)(2)(iii)** Are the **requested analyses** (including applicable approved test method numbers) **linked** to the **laboratory ID code**

____ **5.5.8.3.1(d)(2)(iv)** Are any **comments** resulting from inspection for **sample rejection linked** to the **laboratory ID code**

____ **5.5.8.3.1(d)(2)** If the **above information** on field ID codes, laboratory ID codes, sample collection date & time, sample receipt date & time, requested analyses, and sample rejection comments **is not linked** to the **sample receipt log**, is this information recorded & documented **elsewhere** as part of the **laboratory's permanent records, easily retrievable** upon request, & **readily available** to the individuals who will process the sample

Note: Placement of laboratory ID number on the sample container is not considered a permanent record

____ **5.5.8.3.1(e)** Does the laboratory **retain** all documentation that is **transmitted to the laboratory** by the sample transmitter (e.g. memos or transmittal forms)

____ **5.5.8.3.1(f)** If utilized, does the laboratory maintain a **complete chain-of-custody record**

COMMENTS:

SAMPLE ACCEPTANCE POLICY

____ **5.5.8.3.2** Does the laboratory have a written **sample acceptance policy** that clearly outlines the circumstances under which samples will be accepted

____ **5.5.8.3.2** Is this sample acceptance policy made **available to sample collection personnel**

Does the sample acceptance policy include the following **areas of concern**:

____ **5.5.8.3.2(a)** **Proper, full, & complete documentation**, which includes:
sample identification
location of sample collection
date & time of collection
collector's name
preservation type
sample type
any special remarks concerning the sample

____ **5.5.8.3.2(b)** **Proper sample labeling** to include unique identification

____ **5.5.8.3.2(b)** **Labeling system** for the samples with requirements concerning the **durability** of the labels (water resistant) and the use of **indelible ink**

____ **5.5.8.3.2(c)** Use of **appropriate sample containers**

____ **5.5.8.3.2(d)** Adherence to **specified holding times**

____ **5.5.8.3.2(e)** **Adequate sample volume** to perform the necessary tests (including a matrix spike if this sample is randomly selected from the test batch for this purpose)

____ **5.5.8.3.2(f)** Procedures to be used if the sample shows signs of **damage, contamination, or inadequate preservation**

____ **5.5.8.3.2** For samples that **do not meet** the laboratory's sample acceptance policy, is the data **flagged** in an **unambiguous manner** clearly defining the nature & substance of the variation

____ **5.5.8.4** Does the laboratory have **documented procedures & appropriate facilities** to **avoid damage, deterioration, or contamination** to the sample during storage, handling, preparation, & testing

____ **5.5.8.4** Does the laboratory **follow any relevant instructions** that may be **provided** with the test item

____ **5.5.8.4** Does the laboratory maintain, monitor, & **record** any necessary **specific environmental conditions** whenever test items have to be stored or conditioned under such conditions

____ **5.5.8.4(a)** Are samples **stored** according to the conditions specified by **preservation protocols**

____ **5.5.8.4(a)(1)** For samples that require thermal preservation, does the laboratory store the samples **under refrigeration** which is:
within 2 degrees Celsius of the specified preservation temperature, OR
meets method-specific criteria, OR
between 0-6 degrees Celsius when the specified storage temperature is 4 C

____ **5.5.8.4(a)(2)** Are samples stored **away from** all standards, reagents, food, & other potentially **contaminating sources**

____ **5.5.8.4(a)(2)** Are samples stored in such a manner as to **prevent cross-contamination**

____ **5.5.8.4(b)** Does the laboratory also store sample **fractions, extracts, leachates,** & other sample **preparation products** such that:

- specifications in the test method are achieved
- any necessary thermal preservation is ensured
- conditions specified by the preservation protocol are achieved
- cross-contamination is prevented
- storage with potentially contaminating sources is avoided

____ **5.5.8.4(c)** Does the laboratory have **storage & security arrangements** that protect the condition & integrity of sample or portions of samples, when those items or portions are to be held secure (e.g. for reasons of record, safety, or value; or to enable check calibrations or tests to be performed later)

____ **5.5.8.4(d)** Does the laboratory have standard operating procedures for the **disposal** of samples, digestates, leachates, extracts, & other preparation products

COMMENTS:

ASSURING THE QUALITY OF ENVIRONMENTAL TESTS

____ **5.5.9.1** Does the laboratory **have quality control procedures to monitor the validity** of environmental tests undertaken

____ **5.5.9.1** Is the resulting quality control data recorded in such a way that **trends are detectable** and, where practicable, **statistical analyses can be applied** to the reviewing of the results

____ **5.5.9.1** Is the quality control monitoring **planned & reviewed**

Note: Examples of such monitoring include:

- internal QC procedures using statistical techniques
- participation in proficiency testing or other interlaboratory comparisons
- use of certified reference materials
- in-house QC with secondary reference materials
- replicate testing using the same or different test methods
- re-testing of retained samples
- correlation of results for different parameters of a sample (e.g. [Total Phosphorus] >= [Orthophosphate])

COMMENTS:

ESSENTIAL QUALITY CONTROL PROCEDURES

Does the laboratory **have detailed written protocols** in place to monitor the following **quality controls**:

____ **5.5.9.2(a)(1)** Adequate **positive & negative controls** to monitor tests (e.g. blanks, spikes, reference toxicants)

____ **5.5.9.2(a)(2)** Adequate tests to define **repeatability and/or variability** of laboratory results (e.g. replicates)

____ **5.5.9.2(a)(3)** Measures to **assure test method accuracy** that include sufficient calibration and/or continuing calibrations, use of certified reference materials, & proficiency test samples

____ **5.5.9.2(a)(4)** Measures to **evaluate test method capability** (e.g. limit of detection & limit of quantitation) or **range of applicability** (e.g. linearity)

____ **5.5.9.2(a)(5)** Selection of **appropriate formalae** to reduce raw data to final results (e.g. regression analysis, statistical analyses, & comparison to internal/external standard calculations)

____ **5.5.9.2(a)(6)** Selection & use of **reagents & standards of appropriate quality**

____ **5.5.9.2(a)(7)** Measures to assure the **selectivity of the test** for its intended purpose

____ **5.5.9.2(a)(8)** Measures to assure **constant & consistent test conditions** (both environmental & instrumental) where required by the test method (e.g. temperature, humidity, light, or specific instrumental conditions)

____ **5.5.9.2(b)** Does the laboratory **assess & evaluate** all quality control measures on an **on-going basis**

____ **5.5.9.2(b)** Does the laboratory use **quality control acceptance criteria** to determine the usability of the data

____ **5.5.9.2(c)** Does the laboratory have procedures for the development of **sample acceptance/rejection criteria** where no method or regulatory criteria exist

____ **5.5.9.2(d)** Are the quality control protocols **specified by the laboratory's method manual followed**

____ **5.5.9.2(d)** Does the laboratory assure that the essential standards in Appendix D to NELAC Chapter 5 (see **5.5.4(a)** above), mandated methods, or regulations are **incorporated** into the **test method manuals**

Note: The QC requirements in the **mandated methods or regulations are to be followed** when it is not apparent which QC is more stringent

COMMENTS:

REPORTING THE RESULTS

____ **5.5.10.1** Does the laboratory **report** the results of **each test** or **series of tests** carried out by the laboratory

Note: These results must also be reported **accurately, clearly, unambiguously, objectively,** & in accordance with any specific instructions in the environmental test methods

____ **5.5.10.1** Does the laboratory's **test reports** contain all information **requested by the client** & **necessary** for the **interpretation of test results** & all information **required by the methods** used

____ **5.5.10.1** Is any test report information not reported to the client **readily available in the laboratory** that carried out the environmental test

Note: If the laboratory has a **written agreement with the client**, the test results may be reported in a **simplified way**

____ **5.5.10.1** If **not all required information** is included in the laboratory's test reports, because the report is complying with **specific regulatory reporting requirements** or formats, does the laboratory still **supply all the required information** to its clients for preparing these reports

____ **5.5.10.1** If the laboratory is operated by a **facility** whose **sole function** is to provide data to the **facility management**, does the laboratory have **all 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 facility laboratory** is responsible for **preparing** the **regulatory reports** or the laboratory provides information to **someone else within the organization** for preparing the regulatory report

____ **5.5.10.1** Does the facility management for the in-house laboratory ensure that **all required report items** are included in the facility's **regulatory reports**

Note: This may be a state-specific requirement; the primary accrediting authority is responsible for assessing whether the laboratory complies with such format or report requirements in the state where the laboratory resides

Does **each** laboratory report to an **outside client** include the following **information** (unless the laboratory has valid reasons for not doing so):

____ **5.5.10.2(a)** A **title** (e.g. "Test Report," "Laboratory Results," "Certificate of Results")

____ **5.5.10.2(b)** Laboratory **name & address**

____ **5.5.10.2(b)** **Phone number & contact person** name to whom questions should be directed

____ **5.5.10.2(b)** **Location** where the **tests were carried out**, if different from the laboratory's address

____ **5.5.10.2(c)** **Unique identification** of the test report (e.g. serial number) and of **each page** & the **total number of pages**

Note: The total number of pages may be listed on the first page of the report as long as subsequent pages are identified by the unique report identification number & consecutive numbers

Note: Each page of the test report can also be identified with the unique report identification number, with the pages identified as a number of the total report pages (e.g. "3 of 10," "1 of 20")

Note: Other methods of identifying the pages in a test report are acceptable as long as it is clear that **discrete pages** are associated with a **specific report** & that the report contains a **specified number of pages**

___ **5.5.10.2(d)** **Client name & address**, where appropriate, & **project name**, if applicable

____ **5.5.10.2(e)** Identification of the **test method used**, or unambiguous **description** of any **non-standard method used**

____ **5.5.10.2(f)** **Description** & unambiguous **identification** of the **tested sample**, including the **client identification code**

____ **5.5.10.2(g)** **Date of sample receipt** by the laboratory, where critical to the validity & application of the test results

____ **5.5.10.2(g)** **Date & time** of sample **collection**

____ **5.5.10.2(g)** **Date** of performance **test** (analysis)

____ **5.5.10.2(g)** **Time** of sample preparation and/or analysis if the required **holding time** for either activity is less than or equal to **72 hours**

____ **5.5.10.2(h)** Reference to the **sampling plan & procedure used** by the laboratory or other bodies, where relevant to the validity or application of the results

____ **5.5.10.2(i)** **Environmental test results,** with **any failures** identified, as appropriate

____ **5.5.10.2(i)** Identification as to whether data was calculated on a **dry weight or wet weight basis**

____ **5.5.10.2(i)** Identification of **reporting units** (e.g. ug/L & mg/kg)

____ **5.5.10.2(i)** Identification of any **statistical packages used** (especially for Whole Effluent Toxicity)

____ **5.5.10.2(j)** **Name(s), function(s), & signature(s)**, or equivalent electronic identification(s), of the **person(s) authorizing** the test report

____ **5.5.10.2(j)** **Date of issue** for the test report

____ **5.5.10.2(k)** A statement to the effect that the results **relate only to the samples**

____ **5.5.10.2(m)** For laboratories already NELAP-accredited, **certification** that the test results **meet all requirements** of the NELAC Standards, or the reasons and/or justification if they do not

COMMENTS:

Where **necessary for the interpretation** of the test results, do the test reports include:

____ **5.5.10.3.1(a)** Any **deviations** from (e.g. failed quality control), **additions** to, or **exclusions** from the **test method** (e.g. environmental conditions)

____ **5.5.10.3.1(a)** Any **non-standard conditions** that may have affected the quality of results

____ **5.5.10.3.1(a)** **Use & definition** of **data qualifiers**

____ **5.5.10.3.1(b)** Where **quality system requirements are not met**, a statement of compliance or non-compliance with requirements and/or specifications, including **identification of test results** derived from any sample that **did not meet** NELAC sample **acceptance requirements** (e.g. improper container, holding time, or temperature)

____ **5.5.10.3.1(c)** Statement of the **estimated uncertainty** of **measurement**, where applicable
Note: Information on uncertainty is needed when required by the client

____ **5.5.10.3.1(d)** Where appropriate & needed, **opinions & interpretations** (see Section 5.5.10.5)

____ **5.5.10.3.1(e)** **Additional information required** by specific methods, clients, or groups of clients

____ **5.5.10.3.1(f)** Qualification of **numerical results** with values **outside of the working range**

When test reports **include the results of sampling**, do the reports include, where necessary for the Interpretation of test results:

____ **5.5.10.3.2(a)** **Date of sampling**

____ **5.5.10.3.2(b)** Unambiguous identification of the **substance, material, or product sampled** (including the name of the manufacturer, model or type of designation, & serial number as appropriate)

____ **5.5.10.3.2(c)** **Location of sampling**, including any diagrams, sketches, or photographs

____ **5.5.10.3.2(d)** Reference to the **sampling plan & procedures** used

____ **5.5.10.3.2(e)** Details of any **environmental conditions** during sampling that may affect the interpretation of the test results

____ **5.5.10.3.2(f)** Any **standard or other specification** for the sampling method or procedure

____ **5.5.10.3.2(f)** Any **deviations, additions, or exclusions** from the specification concerned

____ **5.5.10.4** When they are included, does the laboratory **document the basis** upon which the **opinions & interpretations** have been made

____ **5.5.10.4** Are opinions & interpretations **clearly marked** as such in the test report

COMMENTS:

____ **5.5.10.5** Does the laboratory clearly **identify the subcontract laboratory name or accreditation number** in reports that contain results of tests from sub-contractors

____ **5.5.10.5** Does the laboratory require the subcontractor to **report the results in writing or electronically**

____ **5.5.10.5** When **requested by the client**, does the laboratory make a copy of the subcontractor's report **available to the client**

____ **5.5.10.6** Does the laboratory ensure that **all required items** are present in test reports that are **transmitted by electronic or electromagnetic means** such as telephone, telex, or facsimile

____ **5.5.10.6** Does the laboratory ensure that all reasonable steps are taken to **preserve confidentiality** in test reports that are transmitted by telephone, telex, facsimile, or other **electronic or electromagnetic means**

____ **5.5.10.7** Is the **format of the test report** designed to accommodate each type of environmental test carried out & to **minimize the possibility of misunderstanding** or misuse

____ **5.5.10.8** Does the laboratory issue **amendments** to a test report **only as a separate document** or **data transfer**, which includes a statement such as "Supplement to Test Report, serial number …" or equivalent wording

____ **5.5.10.8** Do the test report **amendments meet all relevant requirements** of the NELAC Standards

____ **5.5.10.8** When necessary to issue a complete new test report, is this report uniquely identified & **contain a reference to the original** that it replaces

USE OF NELAP ACCREDITATION

____ **6.8(a)(1)** Does the laboratory **post or display its most recent NELAP accreditation certificate** or its NELAP-accredited fields of testing in a **prominent place** in the laboratory facility

____ **6.8(a)(2)** Does the laboratory **make accurate statements** concerning its NELAP accreditation status & its NELAP-accredited fields of testing

____ **6.8(a)(3)** Does the laboratory accompany the accrediting authority's name or the NELAC/NELAP logo with the **phrase "NELAP accredited" & its accreditation number**, when the accrediting authority's name is used on catalogs, advertising, business solicitations, proposals, quotations, analytical reports, or other materials

____ **6.8(a)(4)** Does the laboratory use its NELAP Certificate, accreditation status, or NELAC/NELAP logo in a manner so as **not to imply endorsement** by the accrediting authority

COMMENTS:

INITIAL TEST METHOD EVALUATION

Notes: For **Toxicity testing & Microbiology testing**, the initial test method evaluation requirements are contained in **Appendices D.2 & D.3**, respectively.

For **all test methods** other than Toxicity & Microbiology, the requirements on **Limit of Detection & Limit of Quantitation** apply.

For **evaluation of precision & bias** of a **Standard Method**, the Demonstration of Capability procedure in **Appendix C.1** to NELAC Chapter 5 applies. Otherwise, for a **Non-Standard Method**, the precision & bias measurements must evaluate the method **across the analytical calibration range** of the method.

LIMIT OF DETECTION

____ **C.3.1(a)** Has the laboratory **determined the Limit of Detection (LOD)** for each target analyte of concern in the quality system matrix.

____ **C.3.1(a)** Does the laboratory **include all sample processing steps** of the analytical method in the determination of the LOD

____ **C.3.1(b)** Has the laboratory **confirmed the validity of the LOD** by **qualitative identification** of the analyte(s) in a quality control sample in each quality system matrix containing the analyte at **no more than 2-3x** the LOD for single-analyte tests and **1-4x** the LOD for multiple analyte tests

____ **C.3.1(b)** Is the LOD verification performed **on every instrument that is to be used** for analysis of samples & reporting of data

____ **C.3.1(c)** Where a LOD study is not performed, does not laboratory **not report** a value **below the Limit of Quantitation**

Note: A LOD study is not required for any component for which spiking solutions or quality control samples are not available (e.g., Temperature), or when test results are **not to be reported to the LOD** (versus the Limit of Quantitation or working range of instrument calibration according to Appendices D.1.2, D.4.5, D.5.4, and D.6.6 to NELAC Chapter 5).

LIMIT OF QUANTITATION

____ **C.3.2(a)** Has the laboratory **determined 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).

____ **C.3.2(c)** Has the laboratory **confirmed the validity of the LOQ** by **successful analysis** of a quality control sample, containing the analytes of concern in each quality system matrix **1-2 times** the claimed LOQ

Note: A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy.

Note: This single analysis is not required if the **bias & precision** of the measurement system are e**valuated at the LOQ**

COMMENTS:

PRECISION AND BIAS

____ **C.3.3(a)** Has the laboratory **evaluated the precision & bias** of a **Standard Method** for each analyte of concern for each quality system matrix according to the **single-concentration 4-replicate recovery study procedures** in Appendix C.1 to NELAC Chapter 5 (see the technology-specific and scientific discipline checklists for these Standards)

Note: When the analyte cannot be spiked into the sample matrix and quality control samples are not commercially available, an **alternate procedure documented in the quality manual** is acceptable.

____ **C.3.3(b)** For **laboratory-developed or non-standard test methods**, does the laboratory have a **documented procedure to evaluate precision & bias**

Note: This Standard does not apply to test methods in use by the laboratory **before July 2003**

Note: Laboratory-developed test methods are defined as environmental test methods developed by the laboratory for its own use.

Note: Non-standard test methods are defined as methods not covered as standard methods.

____ **C.3.3(b)** Has the laboratory **compared results** of the precision & bias measurements for laboratory-developed & non-standard methods with:

criteria established by the client,
criteria given in the reference method, or
criteria established by the laboratory

____ **C.3.3(b)** Do the precision & bias measurements evaluate the laboratory-developed or non-standard test method **across the analytical calibration range** of the method

Note: Examples of systematic approach to evaluate precision & bias could be:
a **validation protocol**, such as the Tier I, Tier II, & Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process, or
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 (see Appendix C.3.3(b) to NELAC Chapter 5 for further details).

EVALUATION OF SELECTIVITY

____ **C.3.4** Has the laboratory **evaluated selectivity** by following the checks established within the test method

Note: These evaluations may include mass spectral tuning, second-column confirmation, chromatography retention time windows, ICP inter-element interference checks, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, & electrode response factors.

COMMENTS: