



Typical Differences in Dual-Program NELAC States Between NELAC and Non-NELAC Requirements

**Presented by Patrick A. Conlon
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Environmental Standards

- Why is Environmental Standards in a position to discuss this topic.
- Perform ~ 75 laboratory audits a year.
- Broad cross-section of industrial, municipal, and commercial laboratories.
- NELAC and Non-NELAC labs and states.
- Audits Include:
 - Contract laboratories for industrial clients.
 - In-house laboratories for industry and municipalities.

What's the Point?

- There has been vigorous debate whether:
 - States should have dual programs.
 - There should be allowances for non-commercial labs – sometimes called “NELAC lite”.
- There is notable variability in non-NELAC programs.
- We will not have a uniform national program until we standards that apply well to all environmental laboratories.

A sunset over a field with a blue gradient overlay at the top.

Focus of Comparison

- Laboratory practices as a manifestation of program differences.
- Differences that appear to result from laboratory certification program(s) either by code or by application.
- Areas that have notable differences.
- Differences that appear to be consequential.

A sunset over a body of water with silhouettes of trees and buildings in the distance. The sky is filled with orange and yellow clouds, and the sun is low on the horizon.

Topics That Made the Cut

- Management Systems & Responsibility.
- Personnel Documentation of Proficiency
- Document Control and Procedure Control.
- Measurement Traceability.
- Non-Conformances & Corrective Actions.
- Quality Controls.
- Customer Service – Complaints.
- Reporting.

Topics That Did Not Make the Cut

- Audits and Management Review.
- Subcontracting of Test.
- Purchasing Services and Supplies.
- Sample Management.
- Test Methods and Method Validation.
- Support Equipment Requirements.

Management Systems & Responsibility

NELAC vs. Non-NELAC programs

- Requirement for an Ethics Program with commitment to Quality and Ethical Practices.
- Management directly responsible for ensuring training and performance of all staff.
- QA Manager free of operations.
- “Undue Influence”.
- In non-NELAC labs observed differences between commercial and non-commercial.

Analyst Technical Proficiency

NELAC vs. Non-NELAC programs

- Both fairly comparable at the level of “read and understood statements”.
- In non-NELAC commercial laboratories, more common to find that demonstrations of capability (DOCs) are performed for the method and not for each individual analysts.
- Who does what simply not tracked as closely in larger non-NELAC facilities.
- Some exceptions observed in large municipals and industrials.

Scope of Document Control

- All Programs have Procedure Documentation and Control Requirements.
- Notable Difference in Activities Covered by Controlled SOPs.

Technical Focus (non-NELAC)

- Sampling
- Preparation
- Analysis
- QM = demonstrated compliance and acceptance criteria

Systems Focus (NELAC)

- Technical Focus items
- Quality System Documentation
- Training Program
- QA Activities
- Corrective Action Processes
- Review and Reporting
- Many more

Measurement Traceability

- NELAC laboratories for the most part do measurement traceability fairly.
- Non-NELAC do less well.
- Not typically considered important until there are problems.
- Level of measurement traceability appears to be directly proportional to the level of corrective actions.

Measurement Traceability (Cont.)

Non-NELAC vs. NELAC programs

Measurement Traceability (Lite)

- Weight and Thermometer Calibrations
- Save Certificates of Standards (maybe)
- Reagent Log (Various Levels of Completeness)
- Standards Prep Log (Maybe)
- If it's in the SOP it documents that I did it
- Rare to see lots of standards and reagents on paperwork
- Traceability to the extent that it exists relies on assumptions

Measurement Traceability

- Weight and Thermometer Calibrations
- Catalog Certificates of Standard
- Complete Reagent log (including daughters)
- Standard Prep Log (including daughters)
- All important activities must be documented as they are performed.
- Should see lots of standards and reagents on paperwork.
- Traceability is an unbroken chain of documentation.

Nonconformances, Corrective Actions, and Preventive Action

- Baseline: Audits and PT failures.
- In a non-NELAC lab, it is much more common to hear that the laboratory say they work on “zero defects” reporting.
- Not Tracking and Not Counting Issues = Zero Defects.
- Rerunning until it is correct = Zero Defects.
- No record of routine non-conformance = no record of how these are handled.
- All have difficulty tracking complaints.

Traceability and Non-conformances

- Measurement traceability and a proactive non-conformance system are directly related.
- Being able to “reconstruct events” is essential to determination of cause and being able to correct and limit the reoccurrence of problems.

Quality Controls

NELAC vs. Non-NELAC programs

- When a program has fairly prescriptive “reference” methods, most laboratories do a reasonably good job on QC.
- But does the laboratory know its error rate
- Actual Quote : “We don’t have non-conformances because our QC is never out.”
- Many analysts at the smaller laboratories work on the assumption that all QC must be acceptable for the data to be reported.
- Rerunning QC in some cases is not considered a Non-conformance or even a corrective action.

QC Requirement Exceptions

Example from Standard Methods

- Commercial Laboratory = blank, LCS, and at least 1 but often 2 types of matrix QC per batch.
- Non-Commercial Laboratory typically required to run a matrix QC every 20 samples or 1 per month.
- Concession to the fact that many Non-Commercial Laboratories may have batch sizes of 1-2 samples.
- Is this a reasonable exception?
- US EPA's R. Reding's recent memo may make this more problematic because both NELAC and later versions of Standard Methods do not have these allowances.

SW-846 Issues

- Differences among the programs extend to SW-846.
- Issues appear more focused on non-NELAC commercial.
- Many laboratories abuse method flexibility across the programs, but it is worse among the non-NELAC labs.
- Federal contract Laboratories, DoD laboratories, and laboratories approved by Environmental Standards do much better.
- NELAC requirements for client communications and reporting do help!
- More guidance from OSW on using SW-846 is expected to help.

Review of Requests, Client Service, and Tracking Complaints

- These topics are right out of ISO-17025.
- Appear to make laboratories more proactive and responsive.
- Not found in most non-NELAC programs.
- Very hard to audit unless you happen to be the client.
- Clearly applicable to commercial laboratories.
- Need to be translated for non-commercial laboratories.

Reporting of Results

NELAC Commercial Laboratories:

- So accustomed to reporting QC that a bare bones report typically includes basic QC.

Non-NELAC Commercial Laboratory:

- Report more likely to be COA without QC.
- Expanded data deliverable more likely to be a second sheet of paper.

Non-commercial industrial and municipal laboratory:

- Reports tend to be COA with basic batch QC.



Closing Thoughts

- States with dual programs manifest differences in allowances between commercial vs. non-commercial lab.
- There is genuine uncertainty in what from NELAC does and does not apply to non-commercial labs.
- Interpretation leads to variability.
- Why have dual programs -
 - Legacy issues and
 - The applicability of NELAC to non-commercial laboratories.



Closing Opinions

- All Commercial laboratories should be NELAC.
- About 80% - 90% of NELAC quality systems are applicable to non-commercials.
- Most of what can be applied should be applied.
- We should consider standards that incorporate reasonable exceptions for non-commercials.

Contact Information



“Setting the Standards for Innovative Environmental Solutions”

Patrick A. Conlon

Senior Quality Assurance Chemist

Environmental Standards, Inc.

1140 Valley Forge Road

P.O. Box 810

Valley Forge, PA 19482

610.935.5577

pconlon@envstd.com

www.envstd.com