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•TNI's NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

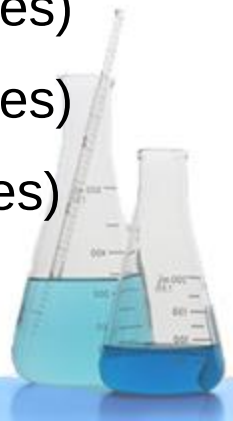
Changing to the 2009 nelac Standard

THE NEW NELAP STANDARDS

- Four Volumes = Four Standards
  - Volume 1: Requirements for Laboratories
    - 7 Modules (155 pages in all)
  - Volume 2: Requirements for Accreditation Bodies
    - 3 Modules (70 pages)
  - Volume 3: Requirements for PT Providers
  - Volume 4: Requirements for a PT Provider Accreditor

VOLUME 1

- Environmental Laboratory Requirements:
  - (Module 1): Proficiency testing (12 pages)
  - (Module 2): Personnel requirements & Quality system (40 pages)
  - (Modules 3-7) Technical requirements
    - M3: Asbestos testing (14 pages)
    - M4: Chemical testing (14 pages)
    - M5: Microbiological testing (10 pages)
    - M6: Radiochemical testing (14 pages)
    - M7: Toxicity testing (8 pages)



LABORATORY IMPLEMENTATION

- Buy and read the new standard
- Begin adding new requirements to be in compliance by July 1, 2011
- Stop PTRL reporting
- Consider removing obsolete NELAC requirements
- Implementing the 2009 TNI Standard.pdf

Translating TNI to ISO Language

TNI		ISO
Quality System	=	Management System
Client	=	Customer

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PROFICIENCY TESTING

PT STANDARDS

- Volume 1: Laboratory Requirements
  - Module 1: Proficiency Testing
- Volume 2: Accreditation Body Requirements
  - Module 2: Proficiency Testing
- Volume 3: Proficiency Testing Provider Requirements
- Volume 4: Proficiency Testing Oversight

4.1 Initial Accreditation

- "Successfully analyze" 2 PT samples
  - Within 18 months of application
  - **Last analysis must be within 6 months of application date**
  - At least 15 calendar days apart

4.2 – Continued Accreditation

- 2 TNI compliant PTs per year
  - **At least 5 and no more than 7 months apart**
  - Corrective Action PTs must be analyzed at least 15 days apart.
- Successfully analyze 2 of the last 3

4.2 Corrective Action PTs

- Not required
- If done, must be at least15 days after original analysis date
  - Not PT study closing date
- Section 6.1 requires sample to be from a different lot.

5.1 PT SAMPLE ANALYSIS

- Process as routine sample
- Test only per technology not method, except drinking water
- No sharing of information
- No sharing of PT samples between labs

ROUTINE ANALYSIS OF PT SAMPLES

- Scheduled as normal samples
- Diluted or prepared according to instructions
- Analysis by “normal” chemist
- No additional QC
- No extra analyses
- Document any exceptions

5.2 LOQ REPORTING

- Report PT data based on documented Limit of Quantitation (LOQ) or low point in curve.
  - Use LOQ for methods like ICP
  - Use low calibration point for methods with a calibration curve
- This allows the laboratories to analyze and report the PT samples in the same manner as their normal samples.
  - Removes issue of reporting to the PTRL.

EVALUATION OF RESULTS

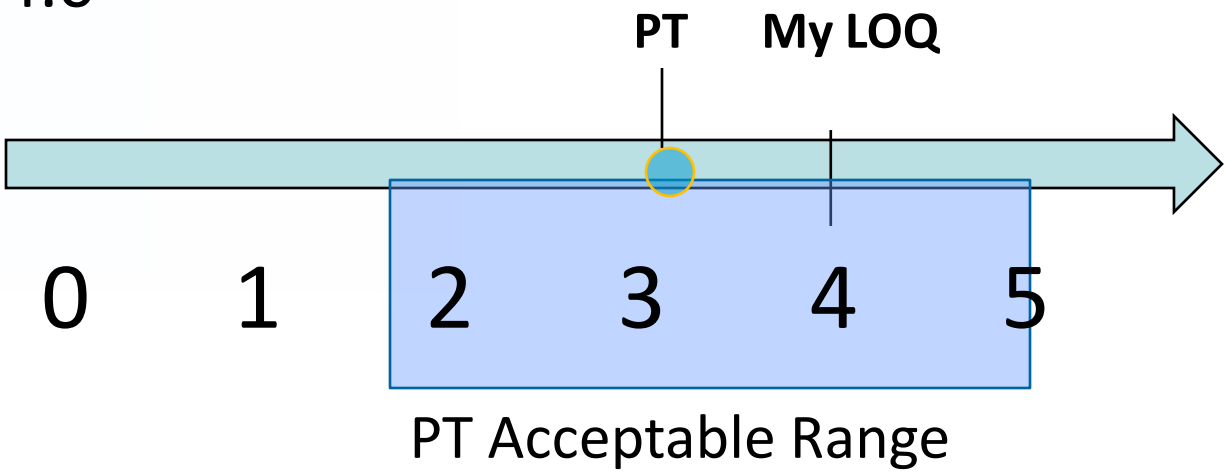
- See Volume 3, Section 10.3
- If the laboratory reports < LOQ and the LOQ value is greater than the lower acceptance limit, the reported < LOQ is evaluated as ‘Acceptable”

Evaluation of Results

PT true value = 3.2

PT Acceptance Range = 1.8 – 5.1

LOQ = 4.0



The Lab reports “<4”

Since LOQ value is greater than the lower acceptance limit, 1.8, the statement <4 is true.

Acceptable

5.3 RECORDS

- PT records 5 years
  - No statement about regulatory programs that have longer retention.
- Reporting forms used must be retained.
  - **Includes copy of on-line data entry summary or similar documentation.**

6.0 CORRECTIVE ACTION

- Handling “Not Acceptable” results
- Actions required
  - **Notify PTP that it is a corrective action sample**
  - At least 15 days between analyses, not closing date
  - Analyte does not have to be present
  - Analyzed like other samples

QUALITY SYSTEMS

Volume 1:

Module 2

QUALITY SYSTEM REQUIREMENTS

- Module 2 contains the General Requirements that apply to all laboratories

- Modules 3 though 7 are Technical Requirements for different types of labs
  - Method Selection, Validation and DOC
  - Instrument Calibration
  - Quality Control
  - Sample Handling

Summary of Quality System Changes

- V1M2 4.7 Customer feedback
- V1M2 4.10 Continual improvement
- V1M2 4.11 Document corrective actions
- V1M2 4.14 Follow up internal audits
- V1M2 5.9 Assuring quality
- V1M2 5.5.13 Support equipment: each day of use
- V1M2 5.6.4.2 Reagent traceability

4.1 Organization

- 4.1.5 (k) ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

- 4.1.6 ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

ISO 17025 Change

4.2 Management System

- 4.2.2 (e) and 4.2.3 Commitment to compliance and **to continually improving its effectiveness**.
- 4.2.4 Importance of meeting customer and regulatory requirements
- 4.2.7 Ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.

ISO 17025 Change

4.7.2 Service to Customer

- Customer feedback required
  - Feedback may be a survey
  - May be a review of reports with customer

This is a new activity

4.10 Improvement (New)

- The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

ISO 17025 Change

4.11 & 14 Corrective Action

- 4.11.3 Required changes to be documented and **implemented**. (Increased emphasis)
- A top ten common deficiency
- 4.14 Internal Audits:

  Follow-up required to verify corrective actions implemented

5.9 Assuring Quality of Results

- Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. (5.9.2)
- *This should not be something new!*

ISO 17025 Change

4.2.8 QUALITY MANUAL

- 4.2.8.3 The quality manual shall contain:
  a) Document title;
  b) 8 other items
- 4.2.8.4 The quality manual shall contain or reference:
  a) All maintenance, calibration and verification procedures used by the laboratory in conducting tests
  b) 19 other items

Requirements for contents of Title Page removed!

METHODS AND SOPS

- NELAC 5.5.4.1.1 and 5.5.4.1.2 reformatted into TNI section 4.2.8.5, under records.
- Improved clarity and consistency
  - Removal of “methods manual”
  - Refers to LOD and LOQ instead of “detection limit”

5.2 PERSONNEL

- Detailed NELAC requirements relating to personnel requirements deleted, but ISO *appropriate education, training, experience and/or demonstrated skills* maintains requirement

5.5.13 SUPPORT EQUIPMENT

nelac 5.5.5.2.1

- "Prior to use on each *working* day…"
- Who or what is working?
  - The analyst, the sample, or the equipment?

TNI 5.5.13

- "On each day the equipment is used…"
- What does "being used" mean?
  - Interacting with samples, e.g.,
  - Stored, incubated, extracted

No change in intent by authors, but maybe a change in perception by readers.

5.5.5 EQUIPMENT RECORDS

- Removed requirements for date received, placed in service and condition when received!!!
- This was never in ISO 17025.

5.6.4 STANDARDS & REAGENTS

- Expiration dates for original containers not required unless provided by manufacturer!!!
- Expiration dates for prepared reagents and standards must be on container
  - NELAC allowed to be documented in quality manual or SOP
- **Traceability of reagents**

5.10.2 REPORTING

- Not required to be included
  - Date of issue
  - Name or number of subcontractor on the report, (subcontract results must be identified)
  - Certification that the results meet all requirements or provide reasons and/or justification if they do not.
- "Report cannot be reproduced except in full" is now a *Note*
- A number of changes in this section that give more flexibility in report formats…

Technical Standards

- Volume 1 Laboratory Requirements
  - Module 3: Asbestos
  - **Module 4: Chemical (includes Air)**
  - **Module 5: Microbiological**
  - Module 6: Radiochemical
  - Module 7: Toxicological

"It says 'you may already be a Nobel Prize winner'."

Module 4: Chemistry (Air,too)

SUMMARY OF CHANGES

- Criteria for Method modification
- No longer have to relate LOD to LOQ
- DOC requirements more flexible
- No longer need Appendix C DOC form
- Low Std must be at or below LOQ
- Minimum # Cal Standards = 3
- Surrogate failure must be qualified
- Glassware cleaning SOP not required

1.4 METHOD SELECTION

- Allows the adding of analytes to reference method
- Method must be identified as modified

REFERENCE METHOD

- Parameter must meet all QC requirements in method
- If no QC in method, must meet QC in “the similar” method
- Method must be identified as modified

So, if you follow the QC requirements of Method 624, then acetone by 624 can be considered a Reference Method.

1.5.2 LIMIT OF DETECTION

- Combination of NELAC C.3.1 and D.1.2.1
- No changes to requirements
  - Determine using any procedure if data reported to LOD
  - Verify by analysis of QC sample
  - Verify annually or change in method

1.5.2 LIMIT OF QUANTITATION

- Combination of NELAC C.3.2 and D.1.2.2
- No changes to requirements
  - Determine using any documented procedure
  - Verify by analysis of QC sample
  - Verify annually or change in method
  - LOQ must be greater than LOD
- Removed: “must have procedures to relate LOD to LOQ”

1.6.2 INITIAL DOC

- Prior to using method
- Change in instrument type, personnel or method
- **If method not performed by an analyst within 12 months**

1.6 ON-GOING DOC

- Procedure needed
- Analyst(s) demonstrates on-going capability
  - Meets QC requirements
  - Document other approaches to DOC if not per method, lab SOP, regulation, client specifications

1.6 DOC

- 4 replicates is one option, but not required
- Form in NELAC Appendix C deleted, but requirements for documentation remain:
  - analyst(s);
  - b) matrix;
  - c) analyte(s);
  - d) identification of method(s) performed;
  - e) identification of laboratory-specific SOP;
  - f) date(s) of analysis; and
  - g) summary of analyses
- Not required to be in personnel file

1.7 CALIBRATION

- Initial Calibration
  - Comparable to NELAC 5.5.5.2.2.1
  - Low standard must be at or below LOQ
  - Minimum number of points changed to 3
- Continuing Calibration
  - Virtually identical to NELAC 5.5.5.10

1.7 QUALITY CONTROL

- No change from NELAC Appendix D.1
- Reorganized with evaluation criteria as a separate section
  - Method Blank
  - LCS
  - MS/MSD
  - MD
  - Surrogates
    - For failed surrogates, **must** qualify data (was a “should”)

Module 4 LANGUAGE REMOVED

- NELAC D.1.6 b
  - Glassware cleaning and storage procedure
  - Cleaned to meet test sensitivity
- Conscious decision of committee
  - Method blanks verify cleanliness

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Module 5: Microbiology

1.5 METHOD VALIDATION

- In order to demonstrate proficiency prior to first use
  - Analysis of one pure reference culture,
  - Analysis of a minimum of ten spiked samples whose matrix is representative of those normally submitted to the laboratory,
  - Verify responses in 10 samples
- If no reference method, validate to demonstrate method can meet intended use

1.6 INITIAL DOC

- Much more detail
  - One acceptable approach described
  - Other approaches acceptable
- Acceptable approach
  - 4 aliquots; calculate recovery and SD, or
  - For P/A tests, assess against criteria
  - For qualitative tests, blind study with blank, negative and positive

1.6 ON-GOING DOC

- Acceptable approaches
  - One spike sample, or
  - One duplicate set of analyses, or
  - One PT sample, or
  - Analyst review of QC samples

1.7.5 SAMPLE PRESERVATION

- Thermal preservation not required if analysis begins within 15 minutes of collection or samples refrigerated within 15 minutes
- Chlorine residual check requirement revised
  - Increased clarity and intent

Lab Water QC

- TOC and Ammonia/organic nitrogen added to QC for Lab Water used in Microbiology
- (requirement comes from SM 9020)

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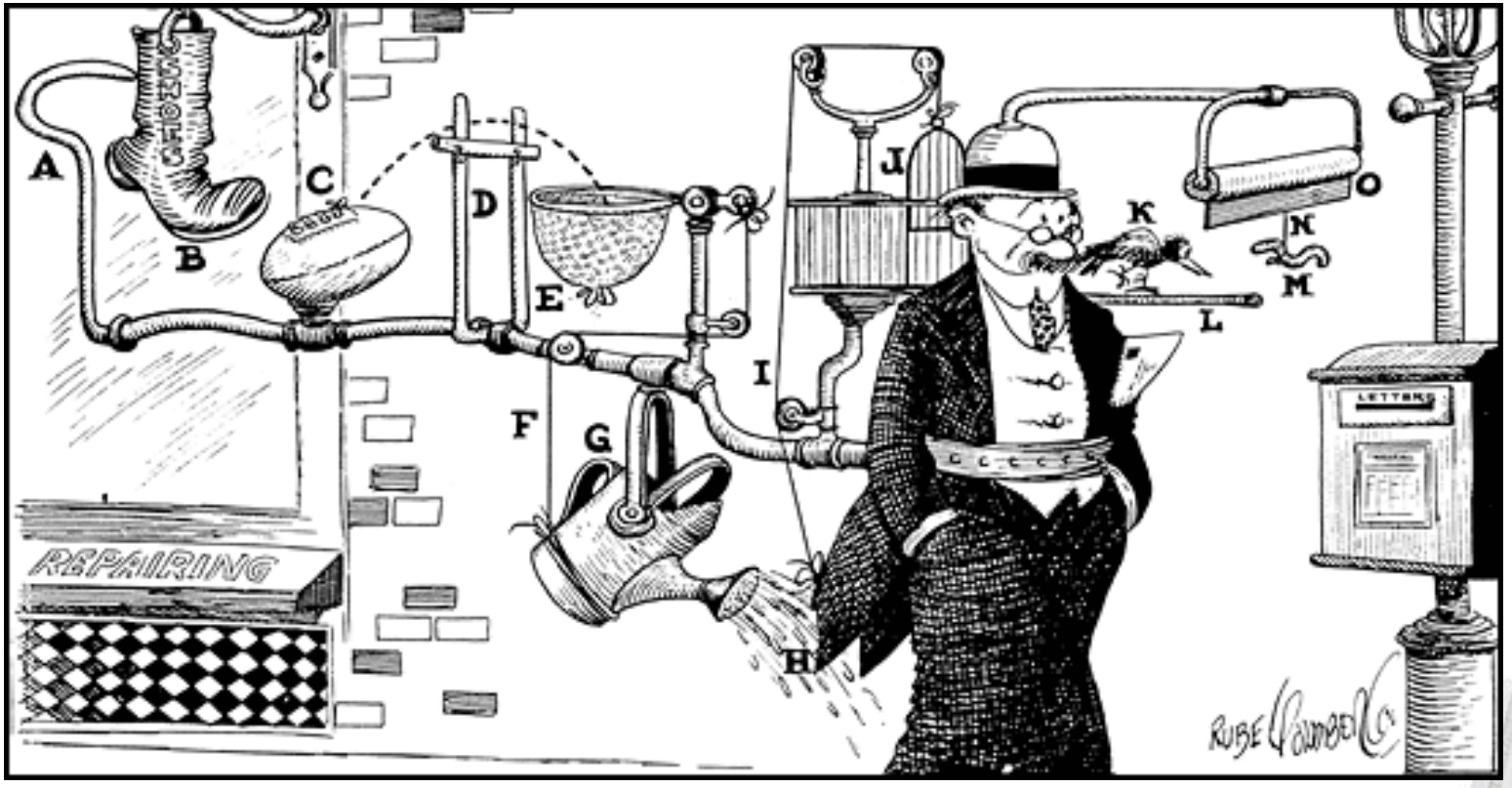
Now are you ready?



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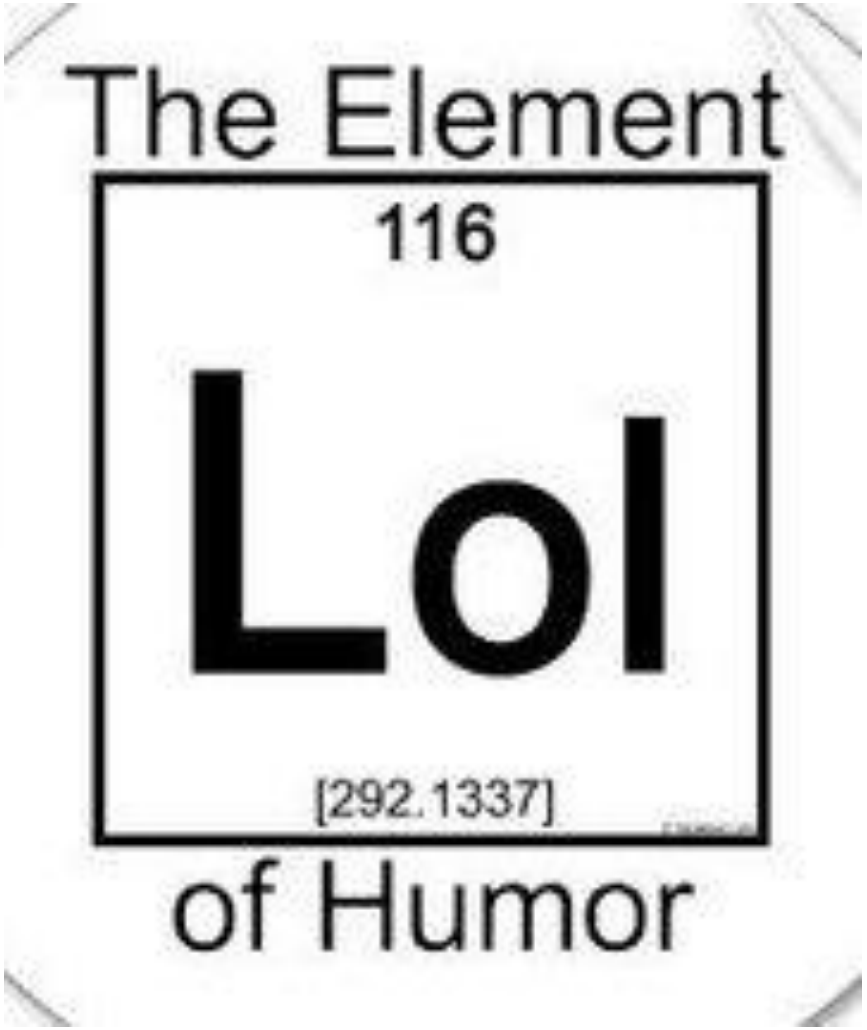

ACTION PLAN

- Obtain the new TNI Standards and **READ THEM**
- Implement new requirements that do not affect current NELAC accreditation
- Consider removing obsolete requirements
- Wait for further instructions on reporting on PT data
- Archive your 2003 NELAC standard.

Short Checklist:

- See OELA Last Minute Checklist handout
- See “Implementing the NEW TNI Standard” on the TNI website

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27 April 2011
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24 April 2011
TNI Comments on EPA Proposed Rule to Improve EP Regulations
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Guidance on Implementing th New TNI Standard
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Proposed Tentative Interim Amendment to the TNI Stationary Source Audit Sample Program Standard
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