



Florida's Perspective Recap & Summary of the TNI Workshop

<http://www.doh.state.fl.us/lab/EnvLabCert/WaterCert.htm>

<http://www.NELAC-Institute.org>

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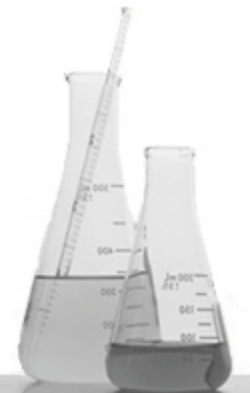
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TNI Standards

- Volume 1 Laboratory Requirements
 - Module 1: Proficiency Testing
 - Module 2: Quality Systems General Requirements
 - Module 3: Asbestos Testing
 - Module 4: Chemical Testing
 - Module 5: Microbiological Testing
 - Module 6: Radiochemical Testing
 - Module 7: Toxicity Testing
- Volume 2 Accreditation Body Requirements
 - Module 1: General Requirements
 - Module 2: Proficiency Testing
 - Module 3: On-Site Assessment
- Volume 3 Proficiency Test Provider Requirements
- Volume 4 Proficiency Testing Oversight





Status of Standards

- All Standards have been approved for adoption into NELAP.
- TNI NELAP Standards will replace the 2003 NELAC Standard on July 1, 2011.
- All laboratories will be subject to the new standards on July 1, 2011.
- Laboratories will be inspected on their normal cycle, and thus may not be assessed to the new standard until the first assessment after July 1, 2011.





Proficiency Testing

nelac 2003

- PTRL Reporting
- PT Scheduling calculated on study open/close dates
- Some program requirements not in standard (Exp. PT)
- Continued accreditation PT time frame “approximately 6 months apart”

TNI 2009

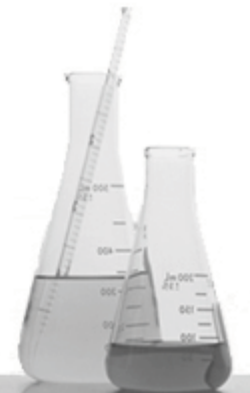
- LOQ Reporting
- PT Scheduling calculated from analysis dates
- All program requirements included in standard
- Time frame “at least 5 months apart, and no longer than 7 months apart”





4.1 Initial Accreditation

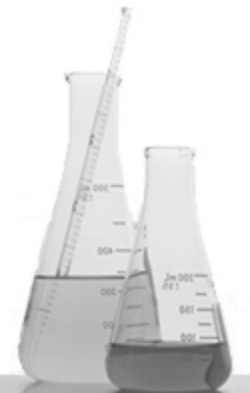
- “Successfully analyze” 2 PT samples
 - Within 18 months prior to application
 - **Last analysis must be within 6 months of application date**
 - At least 15 calendar days apart
- Provision to obtain from non-accredited PT provider
 - Highly unlikely this will ever be used





4.2 Continued Accreditation

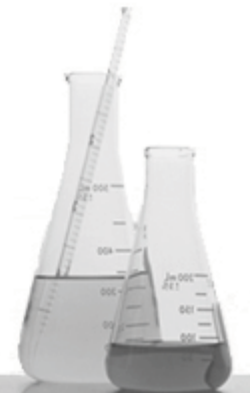
- 2 TNI-compliant PTs per year
 - **At least 5 and no more than 7 months apart**
 - Corrective Action PTs must be analyzed at least 15 days apart.
- Successfully analyze 2 of the last 3
- Provision to obtain from non-accredited provider
 - Highly unlikely this will ever be used
- Provision for experimental PTs
 - Highly unlikely this will ever be used





5.1 PT Sample Analysis

- Process as routine sample
- Test only per technology not method
 - except drinking water certified methods reported at least once per year (*Note implies every study*)
- No sharing of information
- No sharing of PT samples between labs





Routine Analysis of PT Samples

- Tracked as normal samples
- Diluted according to PTP instructions and prepared according to normal procedures
- Analysis by “normal” analyst
- 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 $< \text{LOQ}$ and the LOQ value is greater than the lower acceptance limit, the reported $< \text{LOQ}$ is evaluated as 'Acceptable'





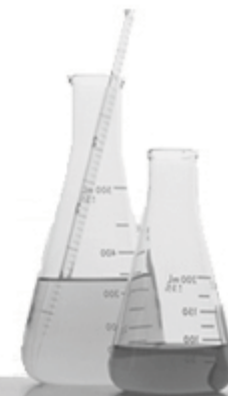
LOQ Reporting

- No change for most laboratories
- May be a change for labs that had reported results less than LOQ that were greater than PTRL
- For these few labs, continue current practice until July 1, 2011



6.0 Corrective Action

- Required as described in V1M2
- Supplemental PT not necessarily required
- 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 routine samples





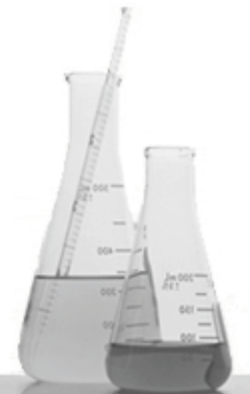
Suspension and Revocation

Suspension

- The laboratory receives an unacceptable score in 2 out of the last 3
- The laboratory does not provide a corrective action report to the primary AB within 30 days of request

Revocation

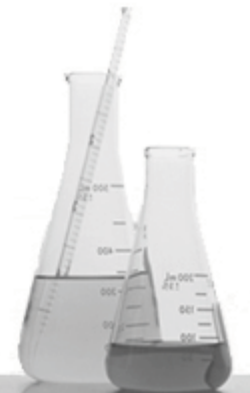
- The laboratory does not participate in the PT program
- The laboratory submits results for PT samples that were generated by another laboratory





Quality Systems

- Module 2 contains the General Requirements that apply to all laboratories
 - Much, but not all of NELAC Chapter 5
 - Updated to 2005 version of 17025
 - 17025 language clearly identified and not modified
 - Personnel requirements from NELAC Chapter 4
- Modules 3 through 7 are Technical Requirements for different types of laboratories
 - Method Selection, Validation and DOC
 - Instrument Calibration
 - Quality Control
 - Sample Handling





Summary of QS Changes

- ISO 17025 Changes
- Removal of some redundant language
- Increased clarity
- Removal of some non-essential language





Changes in ISO 17025

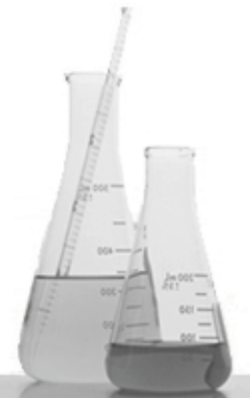
- Quality System changed to Management System
- New sections on laboratory management responsibilities
- New section on improvement (4.10)
 - The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
- New QC language (5.9.2)
 - Quality control data shall be analysed 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.



4.2.8 Quality Manual

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

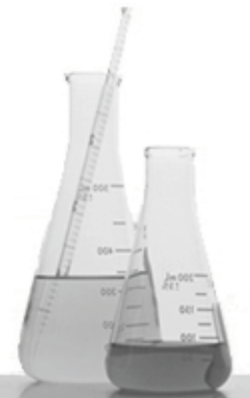
Requirements for contents of Title Page removed!





5.6.4 Standards & Reagents

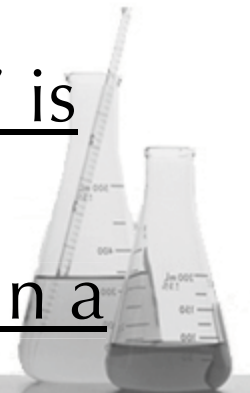
- Expiration dates for original containers not required unless provided by manufacturer!!!
- Expiration dates for prepared reagents and standards must be on container
 - NELAC allowed to be documented in quality manual or SOP
- **Traceability of reagents**





5.10.2 Reporting

- No longer required:
 - Date of issue
 - Name or number of subcontractor on the report, (subcontract results must be identified) (BUT still a FDEP DW requirement!)
 - Certification that the results meet all requirements or provide reasons and/or justification if they do not.
- “Report shall not be reproduced except in full” is now a recommendation in a Note
- Page numbers and total number of pages also in a



Reporting: Uncertainty

nelac

5.5.10.3.1

- where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed when a client's instruction so requires;

TNI 5.10.3.1

- where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, **or when the uncertainty affects compliance to a specification limit;**

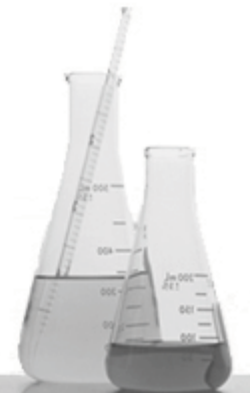
ISO 17025 Change





V1 Tech Mod 1.6.2 IDOC

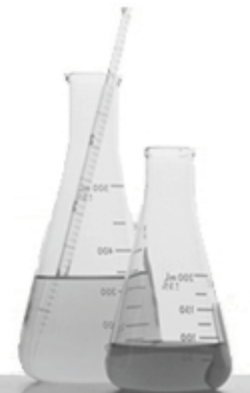
- Prior to using any test method, with a change in instrument type, personnel or test method or any time that a method has not been performed by the *laboratory or analyst* in a twelve-month period
- Examples given
- Other adequate approaches





V1 Tech Mod 1.6.3 ODOC

- Documented procedure
- The *analyst(s)* demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard.
- Examples given
- Other adequate approaches





1.7 Quality Control

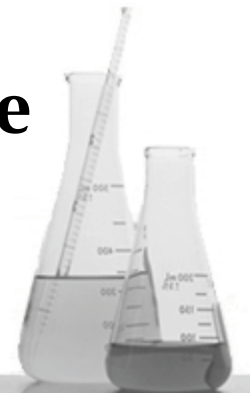
- Reorganized with evaluation criteria as a separate section
 - Method Blank
 - LCS
 - MS/MSD
 - MD
 - Surrogates
 - ✦ For failed surrogates, must qualify data (was a “should”)





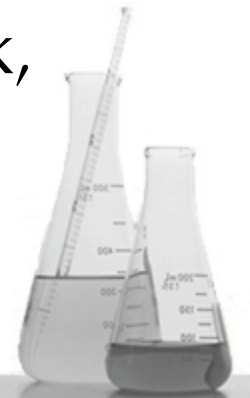
1.5 Method Validation

- **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**



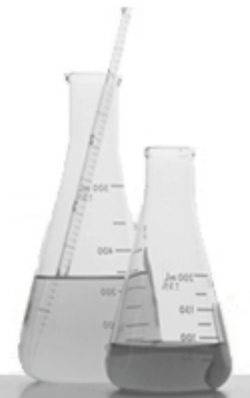
1.6 Initial DOC

- 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

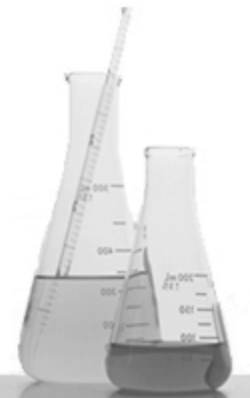
- Acceptable approaches
 - One spike sample, or
 - One duplicate set of analyses,
or
 - One PT sample, or
 - Analyst review of QC samples





1.7.5 Sample Preservation

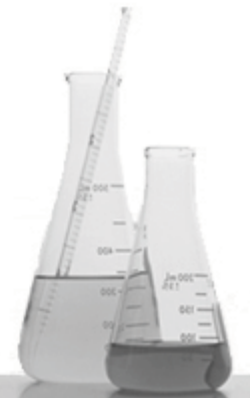
- Thermal preservation not required if analysis begins within 15 minutes of collection or samples refrigerated within 15 minutes
- Chlorine residual check requirement revised
 - Increased clarity and intent





Chlorine Check

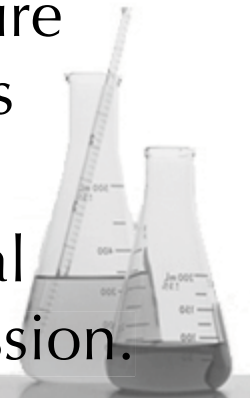
- Samples from known chlorinated sources (such as wastewater effluent), unknown sources where chlorine usage is suspected (such a new client or a new source) and all potable water sources (including source water) shall be checked for absence of chlorine residual.





Chlorine Check

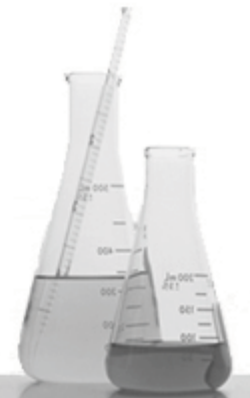
- Sample from potable water sources (including source water) that have a demonstrated history of acceptable preservation may be checked once per month if:
 - the sample containers are from the laboratory;
 - sufficient sodium thiosulfate was added to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;
 - one container from each batch is checked to ensure efficacy of the sodium thiosulfate and the check is documented;
 - chlorine residual is checked in the field and actual concentration is documented with sample submission.





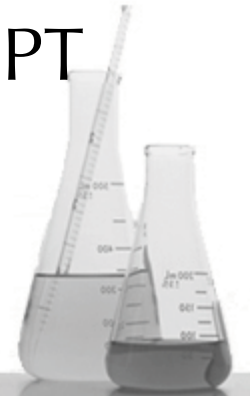
8.0 Lab Responsibilities

- Fulfill PT and Quality System requirements
- Allow AB to inspect operation
- Provide AB necessary documents
- Not misuse accreditation status
- Pay fees
- Notify AB of significant changes



Module 2 - PT

- Specific requirements for accreditation bodies regarding PT
- Criteria is consistent with current NELAC
 - 2 samples per year; pass 2 out of last 3
 - **Evaluation of sample analysis process during on-site**
 - **Review results and evaluate data**
 - Suspend or revoke accreditation based on PT failures



Types of Assessments

- Initial
- **Reassessment**
- **Surveillance**
- Follow-up
- **Extraordinary**





7.0 Changes in CAB Capabilities

- 30 day notice to AB of changes to:
 - Legal, commercial, ownership or organizational status
 - The organization, top management and key personnel*
 - Main policies
 - Resources and premises*
 - Scope of accreditation
 - Other such matters that may affect the ability to fulfill requirements for accreditation.*

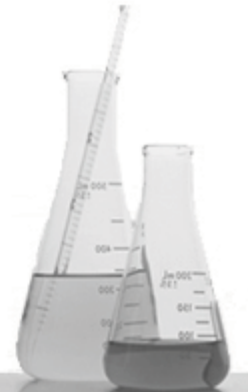




Getting the Standards

- Some TNI Standards contain copyright protected language from either ISO 17025 or ISO 17011.
- A free version of all Standards without the ISO language is available.
- Each lab will be responsible for obtaining a copy of the standards.

<http://www.nelac-institute.org/standards.php>





Recommendations

- ***Obtain and read the new TNI Standard***
- Do not waste your time comparing the new standard to NELAC 2003
- Implement new requirements that do not affect current NELAC accreditation
- Consider removing obsolete requirements
- Over a year to prepare, but.





Have Fun!

