



UPDATE ON THE NELAC INSTITUTE

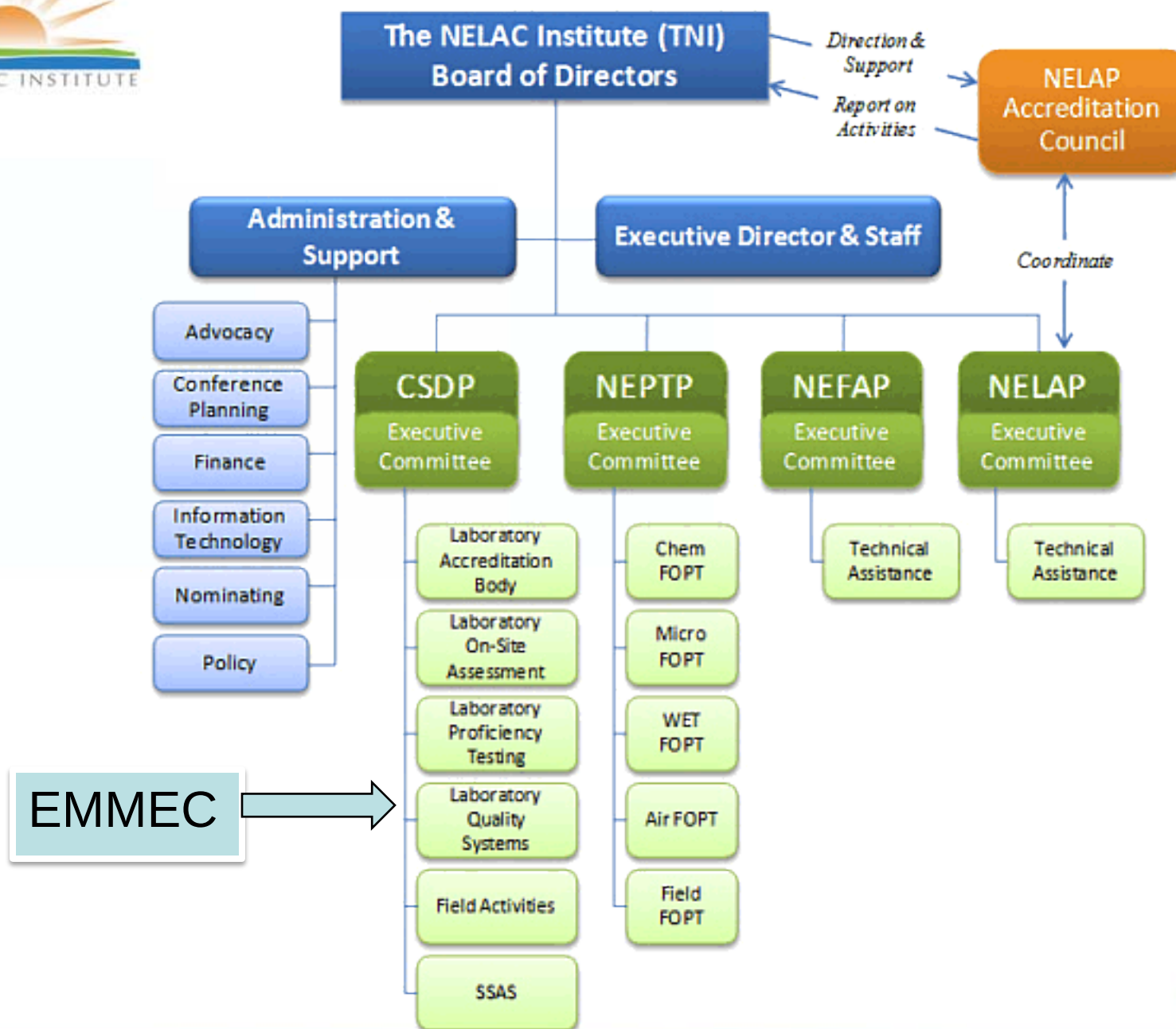
November 17, 2010



WHO IS TNI?

- ❑ A 501(c)3 non-profit organization
- ❑ A member organization managed by a Board of Directors
- ❑ A voluntary consensus standards development organization accredited by the American National Standards Institute (ANSI)







WHAT DOES TNI PROVIDE?

- ❑ Infrastructure for stakeholders
- ❑ Consensus building for establishing requirements for:
 - Organizations that accredit
 - Organizations that are accredited
 - Proficiency testing programs
- ❑ Recognition of organizations that operate accreditation programs
- ❑ Assistance to members and others



WHAT DOES TNI *NOT* DO?

- ❑ Accredite laboratories
- ❑ Resolve disputes between laboratories and their Accreditation Bodies
- ❑ Interpret questions on methods





2010 ACCOMPLISHMENTS

- ❑ 17 Regional workshops on new NELAP standards with more planned
- ❑ Draft Quality Management Plan
- ❑ Strategic Plan for 2010 to 2015
- ❑ Awarded funding for two cooperative agreements from EPA competitions for years 2010 – 2015
- ❑ New Field Sampling and Measurement Organizations (FSMO) accreditation program created
- ❑ Several new groups formed to tackle specific issues
- ❑ New Quality Manual Template designed



2011 PLANS

- ❑ Implement the newly adopted NELAP standards
- ❑ Implement the FSMO accreditation program
- ❑ Implement a Stationary Source Audit Sample Program
- ❑ Form a new Expert Committee to tackle method issues
- ❑ Develop a comprehensive training program
- ❑ Implement a national database of accredited laboratories





TNI PROGRAMS

- ❑ Consensus Standards Development Program
- ❑ National Environmental Laboratory Accreditation Program (NELAP)
- ❑ National Environmental Field Activities Program (NEFAP)
- ❑ Proficiency Testing Program
- ❑ Stationary Source Audit Sample Program (SSAS)
- ❑ Administration and Support





CONSENSUS STANDARDS DEVELOPMENT

- ❑ Expert committees develop standards consistent with TNI's mission, using a consensus process
- ❑ Expert Committees
 - Accreditation Body
 - Field Activities
 - On-Site Assessment
 - Proficiency Testing
 - Quality Systems
 - Stationary Source Audit Sample

**NEW: Environmental
Measurement Methods**





CONSENSUS STANDARDS DEVELOPMENT ACTIVITIES

Accomplishments

- ❑ Tentative Interim Amendments (TIAs) and editorial changes to laboratory standards
- ❑ Standards Interpretation Requests
- ❑ Guidance and other tools
- ❑ 3 SSAS standards

Plans

- ❑ Begin process to take TIAs through consensus
- ❑ Develop more guidance and related tools
- ❑ Finish and publish Working Draft Standard for Quality Systems
- ❑ Form Environmental Measurement Methods Expert Committee (EMMEC)





STANDARDS INTERPRETATIONS

- ❑ On-line process available on TNI website:
 - Home/Standards/Request for Interpretation
 - Electronic approval by NELAP Accreditation Council
- ❑ 30 Interpretations posted
 - Home/Standards/Interpretation
- ❑ Many in Progress





INTERPRETATION PROCESS

- ❑ Complete on-line request form
 - www.nelac-institute.org/interpret-request.php
- ❑ Request sent to:
 - NELAP AC Chair, LASEC Chair, TNI Staff
- ❑ Request then directed to:
 - LASEC, Expert Committee, TAC, NELAP AC
- ❑ Preliminary opinion developed
- ❑ Opinion endorsed by NELAP AC
- ❑ Interpretation posted on website
- ❑ 4-6 week process





STANDARDS INTERPRETATION REQUEST

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



Home

About TNI

Membership

Calendar

Accreditation ▶

Standards ▶

Committees

Conferences ▶

Products ▶

Discussions

Documents ▶

General Info ▶

Member Page

The NELAC Institute

Member Page

Standards Interpretation

TNI has established an avenue for resolution of questions submitted electronically on interpretation of the 2003 NELAC Standard. The method for submittal is to complete the form below. Use of this entry form ensures that a question is automatically accepted, cataloged and emailed to the NELAP Board Chair, the LASC Chair and the TNI Program Administrator for review. A consensus of these three individuals shall determine who oversees the final disposition of the question. Timelines are defined for the NELAP Board Chair and LASC Chair to ensure a timely response to the question. Publication of the consensus resolution is then made to the affected parties via email and on the TNI web site. Please remember that any disputes between a laboratory and their AB regarding accreditation are to be handled through the appropriate appeals process established by applicable state laws and regulations. Your question should be clearly stated.

Please use this form to submit a request for standard interpretation to TNI.

Request for 2003 NELAC Standards Interpretation

Name *

First

Last

Email *

Phone

 - -

(###)

###

####

Organization *

Address

Street Address

Address Line 2

City

State / Province / Region

Postal / Zip Code

Country

Are there others who should receive the TNI response as well?

Done

INTERPRETATION PROCESS

- ❑ Process is NOT to be used to escalate a dispute between a laboratory and an Accreditation Body
- ❑ Some requests relate to method or EPA program interpretations
 - *Laboratories should attempt to reconcile all such interpretations with the applicable EPA program and/or method authors*





THE INTERPRETATIONS

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



- Home
- About TNI
- Membership
- Calendar
- Accreditation
- Standards
- Committees
- Conferences
- Products
- Discussions
- Documents
- General Info
- Member Page

The NELAC Institute

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2003 NELAC Standard Interpretations

[Open All](#) [Close All](#)

- ▶ Chapter 1 - Program Policy & Structure
- ▶ Chapter 2 - Proficiency Testing
- ▶ Chapter 3 - On-Site Assessment
- ▶ Chapter 4 - Accreditation Process
- ▼ Chapter 5 - Quality Systems

5.4.3.2.2 (b)

Frequency of Document Review (10/25/2008)

[View Request & Final Response Online](#)

5.4.12.2.2

Technical Records (12/19/2008)

[View Request & Final Response Online](#)

5.5.4.1.1

Standard Operating Procedures (SOPs) (10/25/2008)

[View Request & Final Response Online](#)

5.5.4.2.2

Demonstration of Capability (10/25/2008)

[View Request & Final Response Online](#)

STANDARDS INTERPRETATION REQUEST

Section: 5.4.3.2.2 (b)

REQUEST:

The above section requires documents to be reviewed "periodically". I have interpreted this to mean that NELAC wants the documents reviewed but requires the lab to establish the frequency. NELAC further supports this position by specifically requiring data integrity procedure to be reviewed annually (5.4.2.6). However, some assessors with whom I work take the position that since 5.4.14.1 requires labs to annually review the "suitability of procedures" and 5.4.13.1 requires labs to annually conduct audits on "all elements of the quality system" that these are inferred or indirect requirements to annually review all procedures. Since 5.4.3.2.2.b addresses the issue directly, I take the position that it prevails over any indirect or inferred interpretation of the standard. Agree? Disagree?

TNI FINAL RESPONSE:

(Quality Systems Expert Committee/NELAC Board, 10-25-08)

The Quality Systems Committee sees no conflict here. The internal audits must show compliance with the laboratories policies and procedures. This is a procedural review for compliance and suitability.

The periodic review of SOPs is set by the lab and does require that technical management review current procedures. This can be done with internal method audits. If the AB finds issues that would indicate that periodically has been stretched too long, then the AB could impose a finding that would require the timeframe be shortened.

Also, support procedures can be allowed to have longer periods between review, such as when changes are needed due to a change in laboratory practice.

news

Nominations for 2010 Board of Directors
16 February 2010

(Updated) Workshops on Implementing the New TNI Standards Planned In 2010
11 February 2010

[MOVE](#) [PRINT](#) [CLOSE](#)

Mon, Mar 1 1:30pm

Chemistry FoPT Call





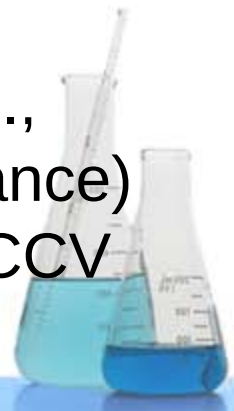
M4 1.7.2 CONTINUING CALIBRATION

Question

- ❑ A laboratory routinely will set up two consecutive CCVs. If the first CCV passes, the laboratory will not evaluate the second. However, if the first CCV fails and the second one passes, the laboratory will report all preceding and trailing samples as being acceptable.

Response

- ❑ Running a second CCV in a sequence is not the intent of the standard. This practice would require that the laboratory evaluate each of them on every occasion. There must be a form of corrective action (i.e., instrument maintenance) prior to the second CCV being evaluated.



M4 1.7.4.2 LCS

Question

- ❑ Can control limits include 0?

Response

- ❑ The laboratory would have to demonstrate how its data can meet all other aspects of the method and still generate control limits that include a 0% recovery. However, there is no restriction on control limits using 0 - look at PT criteria for soil.





M4 1.5 METHOD MODIFICATIONS

Question

- For Method 524.2, if DOC and MDL studies show that a 2 minutes desorb time achieves equal or greater method performance as the 4 minute desorb time, will this method modification meet requirements for drinking water volatile analysis?

Response

- *The statement of "about 4 minutes" was to avoid issues with people demanding that desorb time be exactly 4.00000 minutes. It should be interpreted as times that could be rounded to 4, such as 3.5 to 4.4. It was not meant to allow drastically shorter times.*

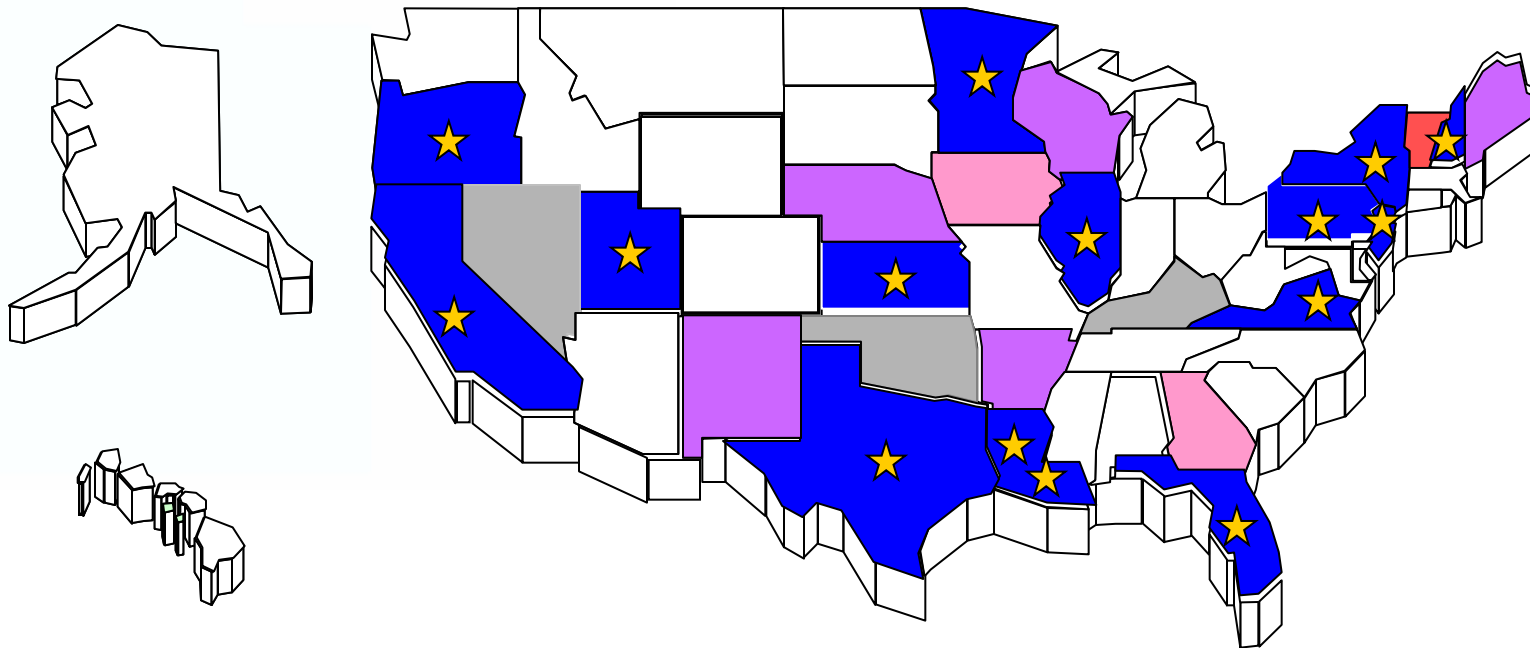




NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)



NELAP ABs



-  NELAP Accredited Body
-  Working on Program/Application
-  Require Program
-  Recognize Program
-  Incorporated Program Components





NELAP

ACCOMPLISHMENTS

- ❑ Developed comprehensive plan for implementation of new TNI Standards
- ❑ Added two ABs: Minnesota and Virginia (Total now 15)
- ❑ Added EPA representative to Accreditation Council
- ❑ Formed a Consistency Improvement Task Force to focus on assessor competency
- ❑ Developed SOP for general complaint resolution and reaffirmed existing procedures
- ❑ Revising Evaluation SOP to incorporate new TNI standard and address issues concerning interpretation and provisional recognition





CONSISTENCY IMPROVEMENT TASK FORCE

- ❑ Establishing realistic expectations about consistency
- ❑ Exploring processes for improving on-site assessments of laboratories
- ❑ Exploring processes for improving evaluations of ABs
- ❑ Considering a system to help laboratories and users of laboratory services
- ❑ CITF to develop White Paper on audit consistency by January 2011



AB TASK FORCE

- ❑ Formed in August to address new concerns on AB capabilities
 - ❑ Triggered by impacts on state budgets
- ❑ Gathering data on AB issues
- ❑ Developing solutions, short and long-term



COMPLAINT PROCEDURES

- ❑ General SOP in early draft form and will be implemented in 2010
- ❑ Complaint procedures for laboratory assessments are the authority of the AB
 - This is the internationally accepted approach
- ❑ Complaint procedures for standards development are contained in CSDP SOP



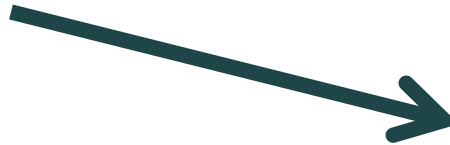
ACCREDITATION STANDARDS

NELAC

- ❑ 1997
- ❑ 1998
- ❑ 1999
- ❑ 2000
- ❑ 2001
- ❑ 2002
- ❑ 2003

TNI

- ❑ 2009





The 2003 NELAC Standard

- ❑ Uses ISO 17025 quality system approach,
 - ❑ Adds specificity to improve clarity and help with consistency for environmental testing,
 - ❑ Requires conformance to EPA mandated methods, but otherwise allows flexibility in meeting requirements,
 - ❑ Represents best professional practice,
 - ❑ Allows for multiple Accreditation Bodies to implement consistently,
 - ❑ Appropriate level of proficiency testing, and
 - ❑ Includes data integrity component missing from 17025.
- **NELAC 2003 is the best accreditation program for environmental laboratories currently in use.**



The 2003 NELAC Standard

- ❑ Refers to an organization that no longer exists,
 - ❑ Hard to find all the laboratory requirements,
 - ❑ Written by chemists for chemists,
 - ❑ Some language could be improved,
 - ❑ Not a true consensus standard,
 - ❑ Does not incorporate ISO 17011 for Accreditation Bodies, and
 - ❑ Muddled and outdated version of ISO 17025.
- **New TNI Standards correct these weaknesses**





THE NEW TNI STANDARDS

- ❑ Removal of outdated *NELAC* language
- ❑ Incorporation of ISO 17011
- ❑ Faithful incorporation of current version of ISO 17025
- ❑ Volume/Modular approach simplifies understanding
- ❑ Improved clarity on Technical Requirements
- ❑ True consensus standard!!!





STATUS OF TNI STANDARDS

- ❑ All TNI Standards have been approved for adoption into NELAP.
- ❑ TNI Standards will replace the 2003 NELAC Standard on July 1, 2011.
- ❑ All laboratories must be in compliance with the requirements by July 1, 2011.
- ❑ Laboratories will be inspected on their normal 2-year cycle, and thus may not be assessed to the new standard until June 30, 2013.





PLAN FOR IMPLEMENTING LABORATORY STANDARDS

- ❑ 2010 Training and outreach
- ❑ 2010 Guidance and related tools
- ❑ Late 2010 New Quality Manual
template
- ❑ July 1, 2011 Replace NELAC 2003



FINAL VERSION: November 2009

- ❑ Editorial changes
- ❑ Tentative Interim Amendments
- ❑ Copies automatically provided to previous buyers of ISO version





Requirements that can be implemented before July 1, 2011

- ❑ Ensure personnel awareness of contribution to management system objectives. (4.1.5 (k))
- ❑ Establish communication processes regarding the effectiveness of the management system. (4.1.6)
- ❑ Ensure the integrity of the management system is maintained. (4.2.7)
- ❑ Seek feedback from customers. (4.7.2)
- ❑ Continually improve management system effectiveness. (4.10)
- ❑ Analyze QC data, and take action to correct problems and to prevent reporting incorrect results. (5.9.2)
- ❑ Analyze PT samples every 5 to 7 months. (4.2.1)





Requirements that can be implemented after July 1, 2011

- ❑ May revise Quality Manual to new specifications. (4.2.8)
- ❑ May eliminate “artificial” expiration dates. (5.6.4)
- ❑ May discontinue the use of the NELAC form for DOC.



PT STANDARDS

- ❑ “Experimental” analytes *
- ❑ Use of Non-accredited PT providers *
- ❑ Time frames based on analysis dates rather than opening or shipping and closing dates
- ❑ LOQ Reporting



SUMMARY

- ❑ Major reorganization to simplify understanding
- ❑ **Very few new requirements**
- ❑ 7-8 months left to prepare





NATIONAL ENVIRONMENTAL FIELD ACTIVITIES PROGRAM (NEFAP)



SUMMARY OF PROGRAM

- ❑ Consensus standards that are voluntarily adopted by states agencies **or third parties** approved as accreditation bodies (ABs).
- ❑ TNI's NEFAP Executive Committee oversees accreditation bodies to assure uniformity.
- ❑ AB grants accreditation, which is unconditionally recognized by other participating ABs.
- ❑ Program applies to Field Sampling and Measurement Organizations (FSMOs)



FIELD SAMPLING & MEASUREMENT ORGANIZATION (FSMO)

- ❑ Organization engaged in:
 - environmental sampling for laboratory analysis and/or
 - field measurement outside of an enclosed structure which meets the requirements of fixed or mobile laboratory.





NEFAP ACTIVITIES

Accomplishments

- ❑ Began efforts in two key areas:
 - ❑ Lead-based paint
 - ❑ Stack testing
- ❑ Revised TNI Bylaws to accommodate NEFAP
- ❑ Built AB recognition process
- ❑ Developed Policies & Procedures

Future Plans

- ❑ Recognize ABs
- ❑ Conduct training and outreach
- ❑ Accept applications from FSMOs



THE FSMO STANDARDS

Adopted May 2007

Volume 1: General Requirements for Field Sampling and Measurement Organizations (FSMO-V1-2008)

Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations (FSMO-V2-2008)





SCOPE OF ACCREDITATION

- ❑ **Field Sampling**

- ❑ Accreditation by Media
- ❑ Specific techniques defined by SOPs and Practices

- ❑ **Field Measurement**

- ❑ Accreditation by Technology
- ❑ Specific techniques defined by SOPs and Practices





PROFICIENCY TESTING PROGRAM

Accomplishments

- ❑ Established FoPT for WET
- ❑ Adopted TNI Vol 3 and 4
- ❑ Established NPW FoPT LL Mercury and LL Total Residual Chlorine

Future Plans

- ❑ Revise FoPTs for Drinking Water, Non-Potable Water and Solid & Chemical Materials
- ❑ Establish FoPTs for Air and Emissions
- ❑ Address experimental analytes





STATIONARY SOURCE AUDIT SAMPLE PROGRAM

- ❑ Develop standards for manufacture and analysis of audit samples for source emission testing.
- ❑ Used to evaluate whether a stack test or laboratory can produce results within specified criteria.
- ❑ Implement a program with these standards as the basis.





TNI COOPERATIVE AGREEMENTS WITH EPA

Former (2006 to 2010)

- ❑ \$400,000 for Standards Development and Technical Assistance
- ❑ \$300,000 to manage the National Environmental Monitoring Conference

New (2010 to 2015)

- ❑ \$750,000 to develop measurement tools, accreditation standards and technical support
- ❑ \$500,000 to manage the National Environmental Monitoring Conference





MEASUREMENT TOOLS

- ❑ Establish the Environmental Measurement Methods Expert Committee (EMMEC).
- ❑ Implement a comprehensive educational delivery system.
- ❑ Provide assessor training, support outreach to organizations that are not accredited and refine TNI's consensus standards to meet EPA program needs.
- ❑ Establish a robust and effective on-line Methods Compendium





ENVIRONMENTAL MEASUREMENT METHODS EXPERT COMMITTEE

- ❑ In process of being created
- ❑ Chartered to work on LOD/LOQ, instrument calibration and other fundamental concepts
- ❑ Goal will be to have new consensus standards by 2012
- ❑ Funding support from a grant from EPA
- ❑ Applications to join will be accepted thru November 2010
- ❑ First meeting will be February 3, 2011





ADMINISTRATION AND SUPPORT

- ❑ Advocacy
- ❑ Finance
- ❑ Information Technology
- ❑ Nominating
- ❑ Policy
- ❑ Conference Planning





ADVOCACY ACTIVITIES

Recent Accomplishments

- ❑ Formed Small Laboratory Advocacy Group (SLAG)
- ❑ Presentations at regional and national meetings
- ❑ Published 3 newsletters

Future Plans

- ❑ Provide feedback to other TNI committees from survey comments
- ❑ Continue outreach at meetings
- ❑ Continue publication of newsletters
- ❑ Explore MOU with EPA
- ❑ Meet with EPA program offices





SMALL LABORATORY ADVOCACY GROUP

- ❑ Open to TNI members and non-members
 - <http://www.nelac-institute.org/board/>
- ❑ Keith Chapman, City of Salem
 - kchapman@cityofsalem.net
- ❑ Seeks input from small laboratories and provides advice to TNI
- ❑ Raises concerns of small laboratories with high visibility within TNI





INFORMATION TECHNOLOGY

- ❑ Develop and maintain the TNI website
- ❑ Develop and maintain TNI databases
 - Analyte codes, Method codes, etc.
- ❑ Develop and maintain the TNI Laboratory Accreditation Management System (LAMS)



LAMS

❑ Primary Purpose

- Assist ABs with secondary accreditation

❑ Secondary Purposes

- Allows labs to verify information about their lab
- Allow the public to find labs
- Allow vendors to find labs





POLICY COMMITTEE

- ❑ Develop policies and procedures that affect all of TNI
- ❑ Review policies and procedures from other programs





FUTURE MEETINGS

Winter Meeting

- ❑ Savannah, GA
 - January 2011
- ❑ Sarasota, FL
 - January 2012

Summer Meeting

- ❑ Seattle, WA
 - August 2011
- ❑ Washington, DC
 - August 2012
- ❑ San Antonio, TX
 - August 2013

HYATT.





Thank You!

The NELAC Institute

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