



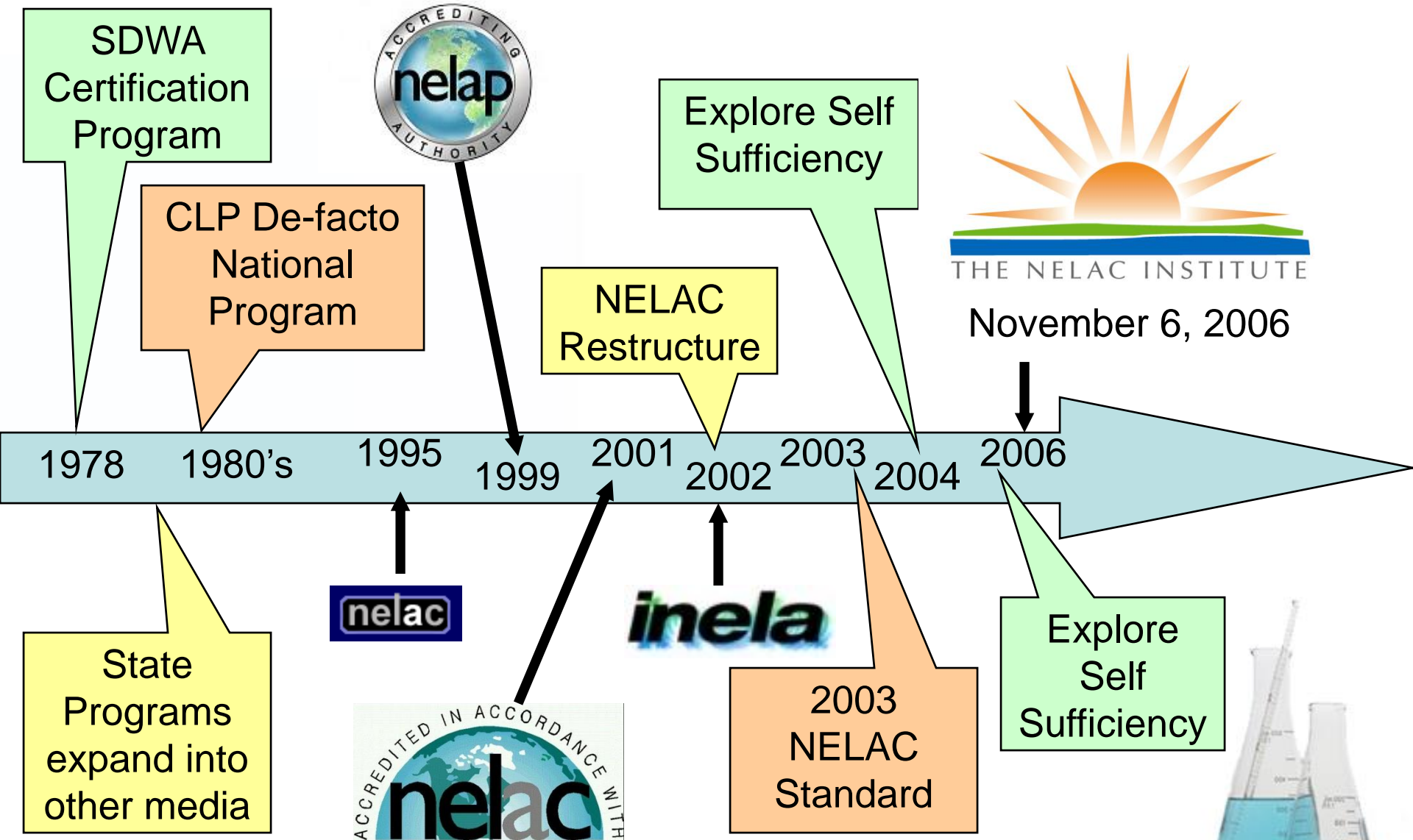
# The NELAC Institute (TNI)

January 25, 2016





# OUR HERITAGE



# 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).
- ❑ An organization that functions through volunteer efforts of its members





# Mission

*The purpose of the organization is to foster the generation of environmental data of known and documented quality through an open, inclusive and transparent process that is responsive to the needs of the community.*



# The NELAC Institute

Board of Directors

NELAP AC

Executive Director and Staff

Admin

CSDP

NEFAP

PTP

NELAP

TNRC

- Advocacy
- Finance
- IT
- Nominating
- Policy

## CSDP EC

- Chemistry
- Field Activities
- LAB
- Microbiology
- Proficiency Testing
- Radiochemistry
- SSAS
- WET

## NEFAP EC

## PTP EC

- Chemistry
- Micro
- Protozoa
- WET

## LAS EC

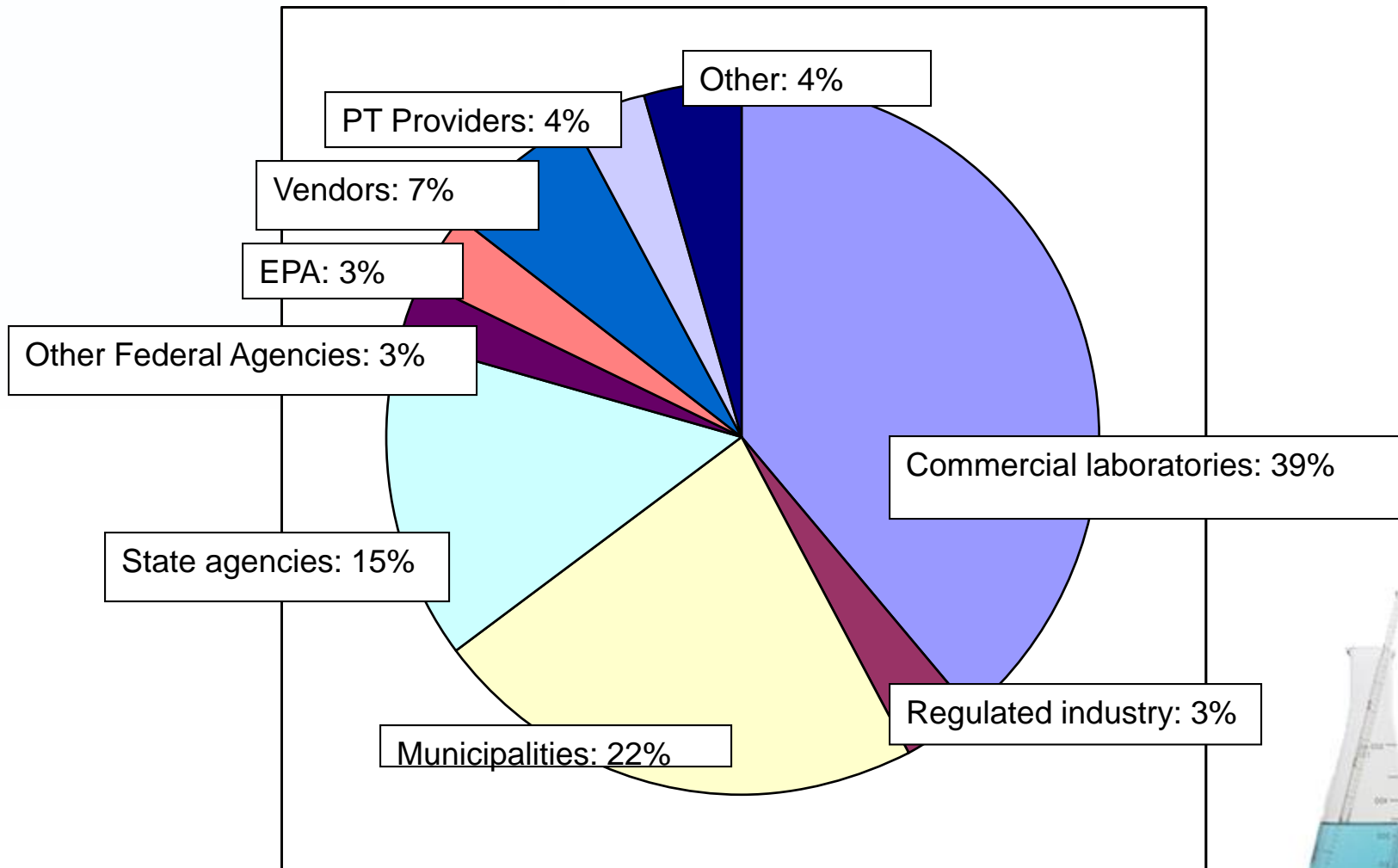


# Who Are Our Members?

- **Organizations that accredit laboratories**
  - Recognized accreditation bodies
  - States that are not recognized accreditation bodies
  - Federal agencies that operate accreditation programs
- **Accredited organizations**
  - Laboratories
  - Field Sampling and Measurement Organizations
- **Others**
  - State and federal agencies that do not operate accreditation programs
  - Data users, consultants, PT Providers, vendors, etc.
  - Anyone interested in laboratory accreditation



# Member Demographics





# Membership has great benefits!

- Newsletter subscription
- Substantial discounts for training courses
- Discounts on meetings and publications.
- Access to the membership directory.
- Access the TNI Methods Compendium, an on-line portal to copies of over 3000 environmental testing methods.





# There's more!

- ❑ No charge for members to use the TNI Generic Laboratory Application
- ❑ Access to the Members Only portion of the TNI Website.
- ❑ Access the Stationary Source Audit Sample Statistics for no charge
- ❑ The opportunity to take part in Standards Development and to review standards before they are finalized.



- TNI individual members may be an associate member of any TNI expert committee.
- They may also serve as full members on committees or the Board.





## And, most importantly...

- Individual members have the opportunity and responsibility to review and vote on all of the TNI Standards as part of the standards development process. Any individual's comments made on the draft standard(s) will be considered by the Expert Committee.
- Individual members also vote to select the TNI Board of Directors. This year's vote starts this week!





# Organizational Memberships

## Several levels

- Partner
- Sponsor
- Patron
- Corporate
- Consulting

Organizations **CANNOT** vote but individual memberships are part of each organizational package.

For more information, see website.



# Board of Directors

- 10-18 Elected Directors
- 3-4 Appointed Directors
- Balanced Stakeholder representation
  - At least 3 accreditation bodies
  - At least 3 accredited laboratories
  - Others representing stakeholder interests





# Duties of the Board

- Supervise, control and direct the business affairs:
  - Actively pursue the mission.
  - Manage the budget.
  - Appoint agents to assist with the above activities.
  
- Support key programs:
  - Review and approve an annual budget for each program.
  - Evaluate how well the program is achieving its goals.
  
- Review policies for organizational impact.





# 2015 Board of Directors

Jordan Adelson

US Navy

Aaren Alger

Pennsylvania DEP

Steve Arms

Florida DOH

Justin Brown

EMT, Inc

Scot Cocanaur

Promium

George Detsis

Department of Energy

Zonetta English

Louisville & Jefferson Co

Jack Farrell

Anaytical Excellence

Keith Greenaway

ANAB

Myron Gunsalus

Kansas DHE

Sharon Mertens

Milwaukee MSD

Judy Morgan

Pace Analytical

Lara Phelps

USEPA

Patsy Root

IDEXX Laboratories

Alfredo Sotomayor

Milwaukee MSD

David Speis

Eurofins QC Inc.

Elizabeth Turner

North Texas MWD





# 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







# Governing Principles

- Consensus standards process used for the development of accreditation standards (Expert Committees)
- The concept of “balance” used where possible
- Each core program of TNI operates semi-autonomously





# WHAT DO WE 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 DO WE NOT DO?

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





# CONSENSUS STANDARDS DEVELOPMENT PROGRAM

- Expert committees develop standards for consistent with TNI's mission, using a consensus process
- Expert Committees

CSDP EC Chair: Bob Wyeth, Independent Consultant  
TNI Staff: Ken Jackson





# EXPERT COMMITTEES

- Chemistry
- Field Activities
- Microbiology
- Proficiency Testing
- Radiochemistry
- Laboratory Accreditation Body
- Laboratory Quality Systems
- Stationary Source Audit Sample
- Whole Effluent Toxicity





# CONSENSUS STANDARD ORGANIZATIONS

- Must meet requirements of Federal policy on the use of voluntary consensus standards (OMB A-119)
  - Balance of interest,
  - Openness,
  - Due process,
  - Consensus, and
  - Appeals process.
- May become accredited by ANSI.





# American National Standards

- TNI laboratory standards now recognized by ANSI as American National Standards
- Provides additional credibility



# Balance of Interest

## *ANSI Requirements*

- Participants from diverse interest categories
  - No single interest category constitutes a majority of the membership of the consensus body
- Standards development process shall not be dominated by any single interest category, individual or organization

## *TNI Policy*

- Committee Members selected to provide balance
  - Serve on only one committee
  - Represent stakeholder group
    - ✦ Accreditation Bodies
    - ✦ Laboratories
    - ✦ Other interests
  - No stakeholder group can be a majority





# Openness

## *ANSI Requirements*

- Anyone interested in the activities of the organization may participate
- Not required to become a member of the organization
- No undue financial barrier

## *TNI Policy*

- Anyone can participate on any committee
  - Committee Members
    - ✦ 5-15 per committee, must meet balance criteria
    - ✦ Must vote, vote is counted
  - Associate Committee Members
    - ✦ Unlimited number, no criteria for balance
    - ✦ May vote, negative vote must be considered
- Committee minutes published on the website
- Public may provide input



# Due Process & Appeals

## *ANSI Requirements*

- Any person with a direct and material interest has a right to participate by:
  - Expressing a position and its basis
  - Having that position considered
  - Having the right to appeal
- Identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural complaints regarding any action or inaction

## *TNI Policy*

- Anyone can appeal any action
- Appeal process uses ANSI guidance
- All comments and their disposition are public information



# Consensus

## *ANSI Requirement*

- General agreement, but not necessarily unanimity.
- Process for attempting to resolve objections by interested parties
- Fair consideration of all comments/objections
- Disposition & reasons provided to commenter
- Consensus body members are given an opportunity to change their votes after reviewing comments.

## *TNI Policy*

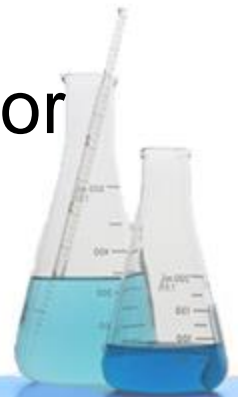
- All negative comments must be addressed
  - Can be ruled persuasive, non-persuasive, or hold for next revision cycle
- Any member may appeal





# Cycle for Standard Development

- Committee develops language
- Language provided to membership for review and comment (Working Draft Standard)
- Committee redrafts Standard, and after vote and consideration of negatives, publishes Interim Standard
- Committee votes on Interim Standard
- Appeals considered
- Standard approved
- Tentative Interim Amendment can be used for emergencies





# TNI Accreditation Standards

## Environmental Sector

- **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: Toxicological Testing**
  
- **Volume 2 Accreditation Body Requirements**
- **Volume 3 Proficiency Testing Provider Requirements**
- **Volume 4 Proficiency Testing Oversight**





# TNI Accreditation Standards

## Field Sampling and Measurement Organization Sector

**Volume 1: General requirements for FSMOs  
Final Standard**

**Volume 2: General Requirements for  
Accreditation Bodies Accrediting FSMOs  
Final Standard**





# TNI Accreditation Standards

## Stationary Source Sampling Sector

**Volume 1: General requirements for FSMOs  
Final Standard**

**Volume 2: General Requirements for  
Accreditation Bodies Accrediting FSMOs  
Final Standard**



# What does a standard look like?

As an example, Vol 1, Module 2 (General QS Requirements) is ISO 17025 + additional requirements:

## 4.14 Internal Audits (*ISO/IEC 17025:2005(E), Clause 4.14*)

### 4.14.5 Additional Items

- (a) The laboratory must specify the timeframe for notifying a client of events that cast doubt on the validity of the results.
- (b) The laboratory management shall ensure that these actions are discharged within the agreed time frame.
- (c) The laboratory shall conduct a review of any evidence of inappropriate actions.







# STANDARDS INTERPRETATION REQUEST

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



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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 \*

<input type="text"/>	<input type="text"/>
First	Last

Email \*

Phone

<input type="text"/>	-	<input type="text"/>	-	<input type="text"/>
(###)		###		####

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?



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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

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# 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*





# NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

- Accredits over 1600 laboratories
  - 49 states and territories
  - 9 countries



NELAP AC Chair: Aaren Alger, Pennsylvania DEP  
LASEC Chair: Judy Morgan, ESC Lab Sciences  
TNI Staff: Lynn Bradley





# Why was NELAP created?

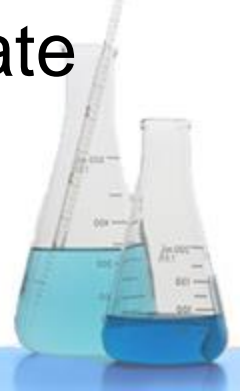
- Inconsistent / nonexistent inspections
- No reciprocity among states
- Loss of accreditation in one state does not affect status in another
- Accreditation in all areas is not available
- Customers have no access to information
- Accreditation not recognized in foreign markets
- Programs generally viewed as inadequate





# Vision

- TNI develops consensus standards that are voluntarily adopted by states recognized as NELAP-Accreditation Bodies
- TNI oversees these state ABs to assure uniformity
- State grants accreditation, which is **recognized** by other participating ABs
- Laboratories can voluntarily apply to any approved authority if their home state does not participate



# Current Status

- 13 states recognized as NELAP ABs
  - Most offer comprehensive programs
  - OK expected to join in 2016
  - CA may decide to reapply
- 18 states Drinking Water only
- 17 states have expanded beyond drinking water
- 2 states require accreditation, but from somewhere else
- 13 states accept NELAP



# Status of NELAP

- True consensus standard widely recognized as highly effective in ensuring laboratory competence
- Program being effectively implemented across the US and internationally
- PT program used by virtually everyone
- Program will continue to evolve
  - Improvements to standards
  - Additional ABs



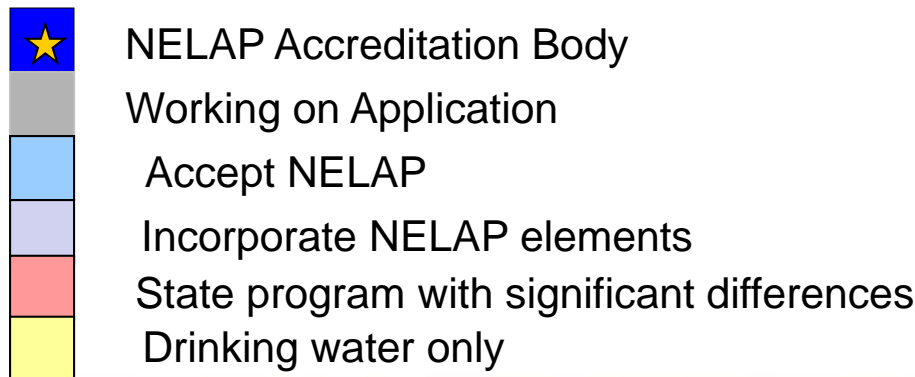
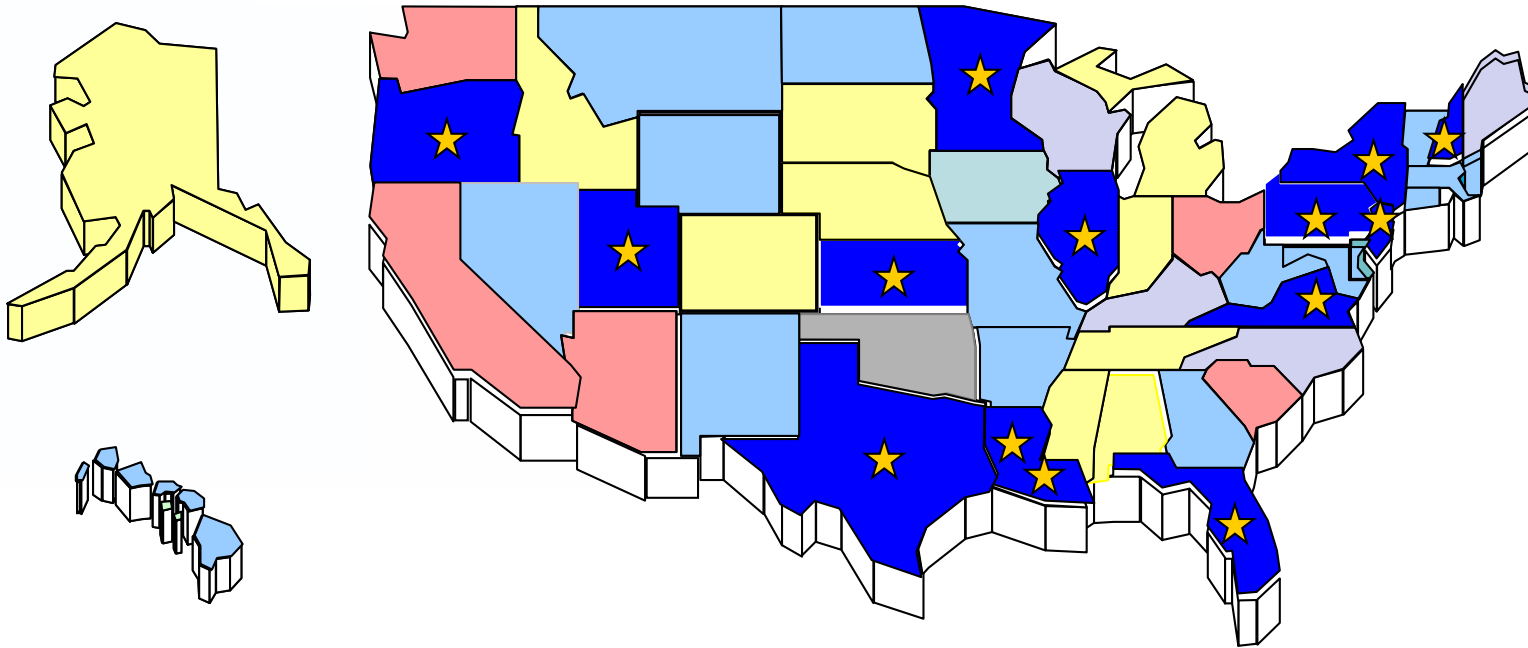


# Summary

- A comprehensive national program for accreditation of environmental laboratories exists
- Every lab in the US may choose to participate
- 27 states accept this program
- Much more remains to be done
  - More than DW in every state
  - Apply to all laboratories
  - Remove conflicting requirements from some states
  - Allow participation of NGABs



# The National Program Today





# Accreditation Process

- State serves as accrediting authority and administers program
- Labs apply for accreditation in their state of operation, if available
- Accreditation is reciprocal between states
- Lab must apply, and pay fees, to every state where work is performed
- State supplemental requirements are limited





# Voluntary Options for States

- Current (non–NELAP) program
- Comprehensive
- SDWA only
- SDWA / CWA only
- Required
- Voluntary
- Tiered
- Require NELAP from another state





# Voluntary Options for Many Labs

- Apply in one state
- Apply in all states
- Don't apply





# TNI and NELAP

- Accreditation Council
- Laboratory Systems Executive Committee





# Accreditation Council

- One delegate and one representative from each AB
- Responsible for implementation of program





# Laboratory Accreditation System Executive Committee

- Developing and/or establish policies and procedures, standards interpretations, guidance documents, and any related tools used by accreditation bodies to implement NELAP.
- Provide an Assessment Forum and Mentor Session at TNI meetings.







# NATIONAL ENVIRONMENTAL FIELD ACTIVITIES PROGRAM (NEFAP)



NEFAP EC Chair: Kim  
Watson, Stone  
Environmental  
TNI Staff: Ilona Taunton





# 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.





# 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





# Four NEFAP ABs Approved

- A2LA\*
- ACLASS
- L-A-B\*
- Perry Johnson Accreditation

\* Exhibiting at the 2016 Forum





# Summary of FSMO Program

- You may now apply to one of the four NEFAP ABs for accreditation
- No state agency has applied to become a NEFAP AB
- Program is voluntary





# PT Program

To establish and maintain a national PT program to support TNI's National Environmental Laboratory Accreditation Program, and participate in other activities pertaining to proficiency testing.



PTPEC Chair: Maria Friedman,  
TestAmerica  
TNI Staff: Ilona Taunton







# Benefits of TNI PT Program

- For the public,
  - promotes confidence that environmental decisions are based on reliable, authentic data.
- For data users,
  - provides assurance that the laboratory has been evaluated and has met accepted standards established by and with the profession.
- For the profession,
  - advances the field by promoting accepted standards of practice and advocating rigorous adherence to these standards.
- For government agencies,
  - serves as a basis to ensure that environmental monitoring data are adequate for their intended purpose.
- For the laboratory,
  - promotes ongoing self-evaluation and continuous improvement, provides an effective system for accountability, and enhances its reputation.





# PT Program Executive Committee

- Recognize organizations to be PT Provider Accreditors
- Establish Fields of Proficiency Testing
  - Used by NELAP
  - Used by other states
  - Used by DMRQA





# Proficiency Testing Provider Accreditors and PT Providers

- A2LA
  - Advanced Analytical Solutions
  - ERA
  - New York State DOH
  - Phenova
- ACLASS
  - Absolute Standards
  - NSI
  - Sigma Aldrich RTC





# Fields of Proficiency Testing Tables

- NELAP FoPT Tables
  - Drinking Water
    - ✦ Chemistry and Microbiology
    - ✦ Radiochemistry
  
  - Non-Potable Water
    - ✦ Chemistry and Microbiology
    - ✦ Whole Effluent Toxicity
  
  - Solid and Chemical Materials





# 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





# Administration and Support

- Board of Directors
  - Advocacy
  - Finance
  - Information Technology
  - Nominating
  - Policy

Educational  
Delivery  
System





# TNI Board of Directors

- Monitor activities of all programs and committees
- Review and approve policies and SOPs
- Organizational and fiduciary leadership
- Form ad-hoc groups for special topics
  - Non-Governmental Accreditation Body (NGAB) Working Group





# ADVOCACY COMMITTEE

## Promote TNI's efforts

- Establish relationships with other organizations (e.g., ACIL, AWWA, APHL, WEF) that have an interest in accreditation issues.
- Establish relationships with EPA program offices.
- Develop presentations and papers to promote national accreditation.
- Publish the TNI newsletter
- Develop Position Statements

Committee Chair: Steve Arms, Florida DOH  
TNI Staff: Carol Batterton







# CONFERENCE PLANNING

- Put on two conferences for TNI each year
- Winter Conference
  - Forum on Laboratory Accreditation
- Summer Conference
  - Environmental Measurement Symposium





# 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)

Committee Chair: John Kuhn

TNI Staff: Jerry Parr

Database Manager: Dan Hickman

IT Administrator: William Daystrom



# 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

Committee Chair: Alfredo Sotomayor,  
Milwaukee MSD  
TNI Staff: Lynn Bradley





# Educational Delivery System

- EDS page on TNI website
  - Educational opportunities
  - Application to provide training
- Training developed by TNI and others
  - “Live” training courses
  - Webinars
  - Webcasts

Training Coordinator: Ilona Taunton





# Downloadable Webcasts

- Corrective Action Process and Root Cause Analysis
- Theoretical and Practical Consideration for Establishing Sensitivity of Measurements
- Internal Audits and Management Review
- Ethics Training for the Environmental Professional
- Establishing a Data Integrity Plan
- Defining Organizational Responsibilities
- Method Selection and Validation
- Etc...



# Other Tools

- ❑ Small Laboratory Advocacy Group
- ❑ Small Laboratory Handbook
- ❑ Quality Manual Template
- ❑ SOP Templates
- ❑ Audit Process (in development)
- ❑ Accreditation Profiles





# Small Laboratory Advocacy Group (SLAG)

- Open to TNI members and non-members
  - <http://www.nelac-institute.org/board/>
- Elizabeth Turner, NTMWD
  - [eturner@ntmwd.com](mailto:eturner@ntmwd.com)
- Seeks input from small laboratories and provides advice to TNI
- Raises concerns of small laboratories to high visibility in TNI







# Accreditation / Certification Profiles

- New web site area
  - <http://www.nelac-institute.org/abdb.php>
- Profiles for all 50 states
- Summary information
  - Scope of program
  - Summary of fees
- Contact information
- Links



# Tulsa Forum

- ELAB
- General Session
- Committee meetings
- Assessment Forum and Mentor Session
- Training Course
- Receptions



# Meeting Formats

- General Sessions: primarily for speakers to share information
- Committee Meetings: highly interactive sessions
- Receptions: open to everyone





# Recommendations for Committee Meetings

- Be Prepared
- Stay focused on specific topic
- Offer constructive comments
- Be brief
- Allow others the opportunity to participate
- Follow Ground Rules





# Ground Rules for Committee Meetings

- Step up to the microphone
- Wait to be recognized
- State your name and affiliation
- Speak slowly and clearly
- Be considerate of others
- Turn cell phone off





# Tulsa Forum

- This is a working meeting
- Prioritize which sessions to attend
- Participate in the process according to the Ground Rules
- Help us become more successful





# SUMMARY

- We invite you to actively participate in our activities
- Join TNI
- Join a TNI committee





# Contact TNI

Jerry Parr, Executive Director

- [www.nelac-institute.org](http://www.nelac-institute.org)
- [jerry.parr@nelac-institute.org](mailto:jerry.parr@nelac-institute.org)
- 817-598-1624



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