Update on the Activities of The NELAC Institute (TNI)

March 28, 2012
DOD Workshop
AGENDA

- Program Updates
  - CSDP
  - NELAP
    - AB Task Force
  - NEFAP
    - FSMO Accreditation
  - PT Program
- Small Laboratory Handbook
- Other Stuff
Expert committees develop standards consistent with TNI’s mission, using a consensus process.

- Expert Committees
  - Laboratory Accreditation Body
  - Field Activities
  - Proficiency Testing
  - Quality Systems
  - Stationary Source Audit Sample
  - Environmental Measurement Methods
Expert Committee Activities

- Accreditation Body Committee
  - Merged with On-Site Assessment Committee
  - Focused on ABTF Issues

- Proficiency Testing Committee
  - Working Draft Standard (WDS) under development.
  - Will contain new approach for LOQ reporting.
Expert Committee Activities (cont.)

- **Quality Systems Committee**
  - Voting Draft Standard
  - Assessment checklist

- **Environmental Measurement Methods Committee**
  - Working on a background guidance document for calibration
  - Outline of consensus standard on calibration developed
Accredits over 1600 laboratories
- 49 states and territories
- 9 countries
NELAP

NELAP Accreditation Body
Working on Application
Accept NELAP
Incorporate NELAP elements
NELAP Plans

- Implement the 2009 TNI standard
- Continue renewal evaluations for ABs
  - 9 are under way
- Implement national database of accredited laboratories (LAMS)
- Complete Standard Interpretation Requests
Laboratory Accreditation Management System (LAMS)

- Assist ABs with secondary accreditation
- Allow accredited labs to verify information about their lab
- Allow the public to find NELAP-accredited labs
- Allow vendors to find labs

www.nelac-institute.org/lams
Accreditation Body Task Force: Findings and Recommendations
Accreditation Body Task Force

Mission

- To identify means for TNI to assist ABs to eliminate bottlenecks and to deal with financial and personnel strains while promoting continuation of nationally recognized full accreditation services to laboratories.
Preliminary Observations

- ABs are facing financial stress, budget cutbacks, and significant financial scrutiny of operations.
- State AB staffs are shrinking, their travel is being restricted, and their support functions being reduced or disappearing.
- Some ABs are not able to keep up with obligations such as review of PT data, approval of secondary (reciprocal) accreditations, scope expansions, and even timely renewal assessments and delivery of assessment reports.
Preliminary Observations

- Some ABs are being forced to restrict or eliminate their program’s power to grant primary accreditation to laboratories outside their state boundaries.
- Possible impacts of these problems upon laboratories led the TNI Board to charter a task force to investigate what assistance TNI might provide.
ABTF Findings and Recommended Options
1. Training

- Identify training needs, priorities, best delivery method, learning objectives and content

Basic Assessor Training
  - May 7-9, Richmond, CA
  - June 19-21, Harrisburg, PA

Assessing Organic Chemistry
  - May 10-12, Richmond, CA

Assessing Microbiology
  - June 14-15, Ft. Meade, MD

Lead: Technical Assistance Committee
2. Administrative Support Services

- Develop a generic TNI application & central database for laboratory applications
- Promote the use of the Minnesota ELDO that enhances AB activities for:
  - Applications
  - PT data
  - Corrective actions

Lead: Accreditation Body Committee
3. National Database

- Continue the implementation of the database as a high priority
- All laboratory demographic data are now in database
- Fields of Accreditation entered for 7 states
- Preview database at www.nelac-institute.org/lams

Lead: Information Technology Committee
4. Use of Third Party Assessors

- Develop a process for TNI to qualify third-party assessors
- Develop a model solicitation template for states to use in contracting
- Develop a process for performance review of third-party assessors that TNI qualifies.
- Develop a service for a state to contract with TNI to obtain the use of third-party assessors

Lead: Accreditation Body Committee
5. Use of Assessments Performed by Other Accreditation Bodies

- Explore the feasibility of partnering with DoE and the DoD-approved ABs to use their assessment reports

Lead: NELAP Accreditation Council
6. Sharing of Information and Resources

- Explore sharing assessors or assessment reports between states
- Develop a process for sharing example form letters for AB assessments and related activities
- Use TNI’s Assessment Forum and Mentor Sessions to share best practices among ABs.
- Establish a Discussion Board comparable to the Discussion Board for the Small Laboratory Advocacy Group

Lead: Accreditation Body Committee
7. Surveillance Assessments

- Investigate how surveillance assessments could be implemented in a formal and objective process with consistent criteria
- Develop a model on how surveillance assessments could be used to extend the frequency of a full reassessment for more than two years
- Use the results from this effort to develop a recommendation on changing Volume 2

Lead: Laboratory Accreditation System Committee
8. Non-Governmental Accreditation Bodies

- Develop a process for Third Party ABs to be authorized to grant NELAP accreditations in accordance with the TNI Environmental Laboratory Sector Standard.
- Develop a process for Third Party accreditations to be accepted by government NELAP ABs.

Lead: New Task Force chartered on 3/14/12
NEFAP

- Consensus standards that are voluntarily adopted by state agencies or third parties approved as Accreditation Bodies (ABs)
- AB grants accreditation, which is unconditionally recognized by other participating ABs
- Program applies to Field Sampling and Measurement Organizations (FSMOs)
Field Sampling and Measurement Organization (FSMO)

Organization engaged in:

- environmental sampling for laboratory analysis and/or
- field measurement outside of an enclosed structure
Four NEFAP ABs Approved

- A2LA
- ACLASS
- L-A-B
- Perry Johnson Accreditation
FSMO Training Course

- August 6, 2012
- Washington, DC
  - In conjunction with TNI summer meeting
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

- Formed a Field PT Subcommittee
  - FoPT table for Lead in soil, paint films, and dust wipes effective January 3, 2012
- Formed a Protozoa PT Subcommittee
- Retired the Experimental FoPT tables

New: email notification of changes to FoPT
Chemistry FoPT

**Non-Potable Water**
- Effective October 3
- 19 new analytes
- Changes to acceptance limits
- New footnotes

**Solid & Chemical Materials**
- Effective January 3
- 23 new analytes
- Changes to acceptance limits
- New footnotes

**Drinking Water**
- Effective January 3
- 7 new analytes
- Changes to acceptance limits
- New footnotes
Identifying which endpoints make sense and if there are some that do not make sense

Temperature variation has been eliminated to increase WET study sizes

Discussing the possibility of eliminating the hypothetical estimates (such as NOEC) and substitute an endpoint test (such as IC25)

Review of the FoPT table to be completed within a year
PT Program Plans for 2012

- Update the WET table
- Implement a Field FoPT table (Lead in paint)
- Implement a Protozoa FoPT table (Cryptosporidium)
- Define and implement a process for addition and removal of analytes from FoPT tables
The Initial Inspiration...
Guidance Manual
for
Laboratories Seeking NELAC Accreditation

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The TNI Standard

Guidance For Small Labs

1st Edition

Use this guide to:

- Help explain the requirements of the TNI Standard, and to
- Obtain guidance on how to develop policies and procedures that will be in compliance with the Standard.
Contents match QM Template outline
4.3 Document Control

This chapter ensures that all documents related to the management system are uniquely identified and that they are created, approved, issued, and change documented procedures.

Key points are:

- All official documents should be authorized and controlled. Documents are regularly reviewed and updated if necessary. The review frequency depends on the document itself. Typical review cycles are between one and three years.
- Changes to documents should follow the same review process as for development of initial documents.
- Forms help to make computer system validation consistent and effective.
- Retention times and disposal of obsolete documents should be defined.
Some Examples are included

Example Quality Policy Statement

The objective of the quality/management system and is to consistently provide our customers with data of high quality that meets their requirements. Our policy is to use good practices in order to maintain quality, to uphold the highest quality of service, to meet the requirements of the Standard. The laboratory ensures that personnel are not exposed to financial, and other undue pressures, which might adversely affect their work. This policy is implemented and enforced through the quality management, at all levels, to the Quality Assurance (QA) system outlined in this manual. However, the primary responsibility falls on the laboratory's management.
One of the most commonly mishandled records are those generated by Excel spreadsheets. All calculations should be defined on the print-out so that any result can be recalculated. More importantly, all calculation cells must be protected from inadvertent changes. This is easily done by write-protecting (not password protecting) the cell. In addition, the calculations should be periodically verified.

NELAP SIR: There is nothing in the Standard that states that records must be hard copy. If instrument records are maintained electronically in a secure manner (presumably with audit trails and password protection), all of the items required in this section are maintained, and any other requirements for records and records maintenance are met, electronic instrument records are allowed.
Summary:

- Many years of NELAC experience compressed into 91 pages in hopes that the small laboratory will be spared a fair amount of learning from your mistakes.
- It should also benefit the assessors by making laboratories more prepared for their first assessment.
Advocacy Activities

Recent Accomplishments

- Presentations at >10 regional and national meetings
- Published newsletters
- Exhibited at ASDWA meeting
- Accreditation / Certification Profiles

Future Plans

- Continue outreach to stakeholders
- Continue publication of newsletters
- Meet with EPA program offices
- Work with APHL
- Develop position statements
Accreditation / Certification Profiles

- New web site area
- Profiles for all 50 states
- Summary information
  - Scope of program
  - Summary of fees
- Contact information
- Links
Small Laboratory Advocacy Group (SLAG)

- 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 to high visibility in TNI
Future Meetings

Summer Meeting
- Washington, DC
  - August 2012

Winter Meeting
- Denver, CO
  - January 2013
Summer Meeting

- In conjunction with National Environmental Monitoring Conference
- August 6-10
- Washington, DC
- www.nemc.us
NEMC Technical Sessions

- Collaborative Efforts to Improve Environmental Monitoring;
- Academic Collaboration in Environmental Measurement and Monitoring;
- Laboratory Accreditation;
- Topics in Drinking Water;
- Analysis of Metallic Species and Organometallics;
- Innovative and Emerging Technologies for Environmental Contaminants;
- Field Measurements, Sensors and In-Situ Monitoring;
- Operational and Advocacy Issues Impacting the Environmental Laboratory Industry;
- EPA Method Updates
- Current Topics in Microbiology;
- Air Methods / Monitoring;
- Contaminated Sediments;
- Topics in Shale Gas Exploration;
- Forensic Chemistry;
- Advances in Sample Preparation and Clean-up; and
- Data Management and Usability.
- Geospatial Tools for Linking Monitoring and Modeling

21 Technical Sessions with 175 presentations
Training Courses

- Basic Chemistry and Operation of Currently Approved Wet Chemical Methods
- Being Audited for the Correct Use of Standard Methods
- Accreditation Demonstrates Competency for Field Activities
- Getting Ready for NEFAP
- A Practical Foundation in ISO/IEC 17025:2005
- How to Manage an Effective Quality Management System
TNI Cooperative Agreements with EPA

Former (2006 – 2010)
- $400,000 for Standards Development and Technical Assistance
- $300,000 to manage the National Environmental Monitoring Conference

- $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
- Establish a robust and effective on-line Methods Compendium
Educational Delivery System

- New EDS/training pages on TNI website
  - Educational opportunities
  - Application to provide training
  - Needs survey

- Training developed by TNI and others
  - “Live” training courses
  - Webinars
  - Webcasts
Training and Outreach

- Training Curriculum being developed
  - Technical training
  - QA Manager training
  - Assessor training

- Goal is to move most training on-line

- Increase relationships with other organizations such as EDQW
New Quality Manual Template

- Now available
- Organized according to V1, M2
- Price is $95 for TNI members
  - $250 for non-members
- Will include free access to Webinar/Webcast for training
- $50 credit for those that purchased the old template
2012 and Beyond

- Implement the adopted NELAP standards
- Implement the FSMO accreditation program
- Implement a Stationary Source Audit Sample Program
- Develop and refine a comprehensive training program
- Implement a national database of accredited laboratories
- Continue to develop consensus standards that meet the needs of the community
Summary

- TNI has had a terrific 2011 and is planning continued growth for 2012
- We invite you to actively participate in our activities
- Join TNI – Now over 850 active members!
- Join a TNI committee – Nothing happens without our volunteers!
Contact TNI

Jerry Parr, Executive Director

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