UPDATE ON THE NELAC INSTITUTE

January 25, 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 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?

- ☐ Accredit laboratories
- ☐ Resolve disputes between laboratories and their Accreditation Bodies

TNI STRUCTURE

Board of Directors

Staff

Self-Governing Programs

Administrative Committees
- ❑ Finance
- ❑ Nominating
- ❑ Policy
- ❑ Information Technology
- ❑ Conference Planning

Individual Members

TNI PROGRAMS

- ❑ Advocacy Program

- ❑ Consensus Standards Development Program

- ❑ National Environmental Laboratory Accreditation Program (NELAP)

- ❑ National Environmental Field Activities Program (NEFAP)

- ❑ Proficiency Testing Program

- ❑ Technical Assistance (TAC) Program

- ❑ Stationary Source Audit Sample Program (SSAS)

TNI BOARDS

- We have a bunch!
  - Board of Directors
  - Program Boards
- May create more
- May come up with a different name for program boards

TNI BOARDS

Board of Directors

- □ Responsible for fiscal soundness and organizational risk
- □ Provides general direction and guidance
- □ Do not "manage" a program
- □ Approves all policies
- □ Decides what programs TNI should have

Program Boards

- □ Responsible for day-to-day management of a given program
- □ Develops policies and procedures for their program
- □ Work cooperatively with other programs

TNI BOARD OF DIRECTORS

- Monitored progress of TNI programs

- Formed Consistency Improvement Task Force

- Adopted new Seals for NELAP and NEFAP

ADVOCACY PROGRAM

SUMMARY OF PROGRAM

- Promote a national program for the accreditation of environmental laboratories
  - Establish relationships with organizations that have an interest in accreditation issues.
  - Establish relationships with EPA program offices.
  - Assist with publication of the newsletter.
  - Provide outreach at national, regional and local meetings.

ADVOCACY ANNUAL REPORT

2009 Accomplishments

- Formed Small Laboratory Advocacy Group (SLAG)
- Presentations at >10 regional and national meetings
- Published 3 newsletters

2010 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/
- Len Schantz; City of Rochester
  - lgs@cityofrochester.gov
- Seeks input from small laboratories and provides advice to TNI
- Raises concerns of small laboratories with high visibility within TNI

CONSENSUS STANDARDS DEVELOPMENT PROGRAM

SUMMARY OF PROGRAM

- Expert committees develop standards for 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

CSDB ANNUAL REPORT

2009 Accomplishments

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

2010 Plans

- A few other TIAs (maybe)
- Begin process to take TIAs through consensus
- More guidance and related tools

LABORATORY ACCREDITATION SYSTEM PROGRAM

SUMMARY OF PROGRAM

□ Develop a system for the accreditation of environmental laboratories

  ➤ policies and procedures, interpretations, guidance documents, and any related tools used to implement NELAP.

LASP ANNUAL REPORT

2009 Accomplishments

- **Thorough review of the TNI standards**
- Standards Interpretation Requests
- Developed and recommended new Seals for NELAP and NEFAP

2010 Plans

- Review any new TIAs
- Standards Interpretation Requests
- Follow-up on TNI Standard Review Recommendations: Proposed Policy/SOP/ Guidance Documents

STANDARDS INTERPRETATION REQUEST

- On-line process available on TNI website:
  - Home/Standards/Request for Interpretation
- 16 Interpretations posted
  - Home/Standards/Interpretation & Clarifications
- > 50 in Progress
- Not to be used in a dispute between a lab and an AB

NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

SUMMARY OF PROGRAM

- TNI develops consensus requirements (i.e., standards) that are voluntarily adopted by states agencies approved as accreditation bodies (ABs).

- TNI's NELAP Board oversees accreditation bodies to assure uniformity.

- State grants accreditation, which is unconditionally recognized, by other participating ABs.

NELAP ANNUAL REPORT

2009 Accomplishments

- Adopted new TNI standards
- Evaluation and Approval of Accreditation Bodies
  - Virginia New AB!
- Standards Interpretation Requests
- Added EPA representative to board

2010 Plans

- Prepare to implement new standards
- Evaluate new AB applications
  - Minnesota
  - Oklahoma (tentative)
- SW-846 methods
- Mutual Recognition 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

- □ Fall 2009   Begin to change state regulations;
- □ 2010   Training and outreach;
- □ 2010   Guidance and related tools;
- □ Late 2010   New Quality Manual template;
- □ Summer 2010   TIA's for PT acceptance criteria
  - ➢ Micro, WET, radiochemistry, air
- □ July 1, 2011   Replace NELAC 2003.

FINAL VERSION: November 2009

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

Very few new requirements!

2010 WORKSHOPS

Chicago 29, 2010

SUMMARY

- Major reorganization to simplify understanding

- Very few new requirements

- 18 months to prepare

- Special workshop on Friday

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 Board 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 & MEASURMENT 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 ANNUAL REPORT

2009 Accomplishments

- Develop plan for program
- Formed NEFAP Board
- Began efforts in two key areas:
  - Lead-based paint
  - Stack testing

2010 Plans

- Revise TNI Bylaws to accommodate NEFAP
- Build AB recognition process
- Review/Develop Policies & Procedures to assure consistent implementation
- Implement NEFAP

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

PTP ANNUAL REPORT

2009 Accomplishments

- Established FoPT for WET
- Reassessment of A2LA
- Review A2LA Scope of Work
- Adopted TNI Vol 3 and 4.
- Review of A2LA SSAS Documents: General Requirements and SSAS audit checklist.
- Establish NPW FoPT LL Mercury and LL Total Residual Chlorine

2010 Plans

- Revise FoPTs for Drinking Water, Non-Potable Water and Solids
- Establish FoPT for Air and Emissions
- Remove experimental analytes

TECHNICAL ASSISTANCE PROGRAM

SUMMARY OF PROGRAM

☐ Provide tools, training, and other resources to enable stakeholders to efficiently participate, adopt, implement and comply with the TNI standards.

  ➢ Tools and templates
  ➢ Training
  ➢ Assessment Forums
  ➢ Mentoring Sessions

TAC ANNUAL REPORT

2009 Accomplishments

- 2 Assessment Forums
- 3 Mentoring Sessions
- 9 Training Courses
- Standard Interpretation Requests

2010 Plans

- 2 Assessment Forums
- 2-3 Mentoring Sessions
- 2-4 Training Courses
- 12 + Workshops
- Guidance and Tools
  - LOD/LOQ
  - Quality Manual

STATIONARY SOURCE AUDIT SAMPLE PROGRAM (SSAS)

SUMMARY OF 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

SSAS ANNUAL REPORT

2009 Accomplishments

- Adopted 3 consensus standards
- Began efforts on a SSAS database
- Established analytes and acceptance criteria

2010 Plans

- Implement SSAS program
- Implement SSAS database
- Develop guidance

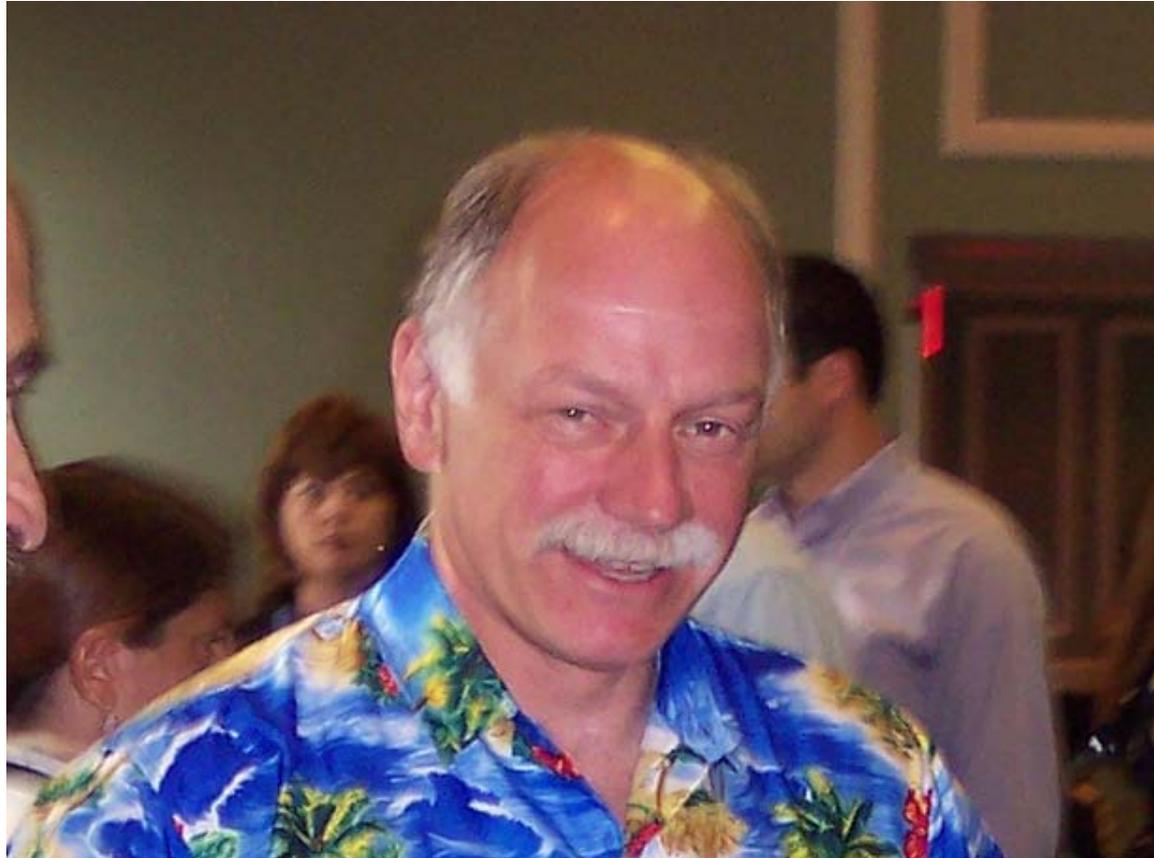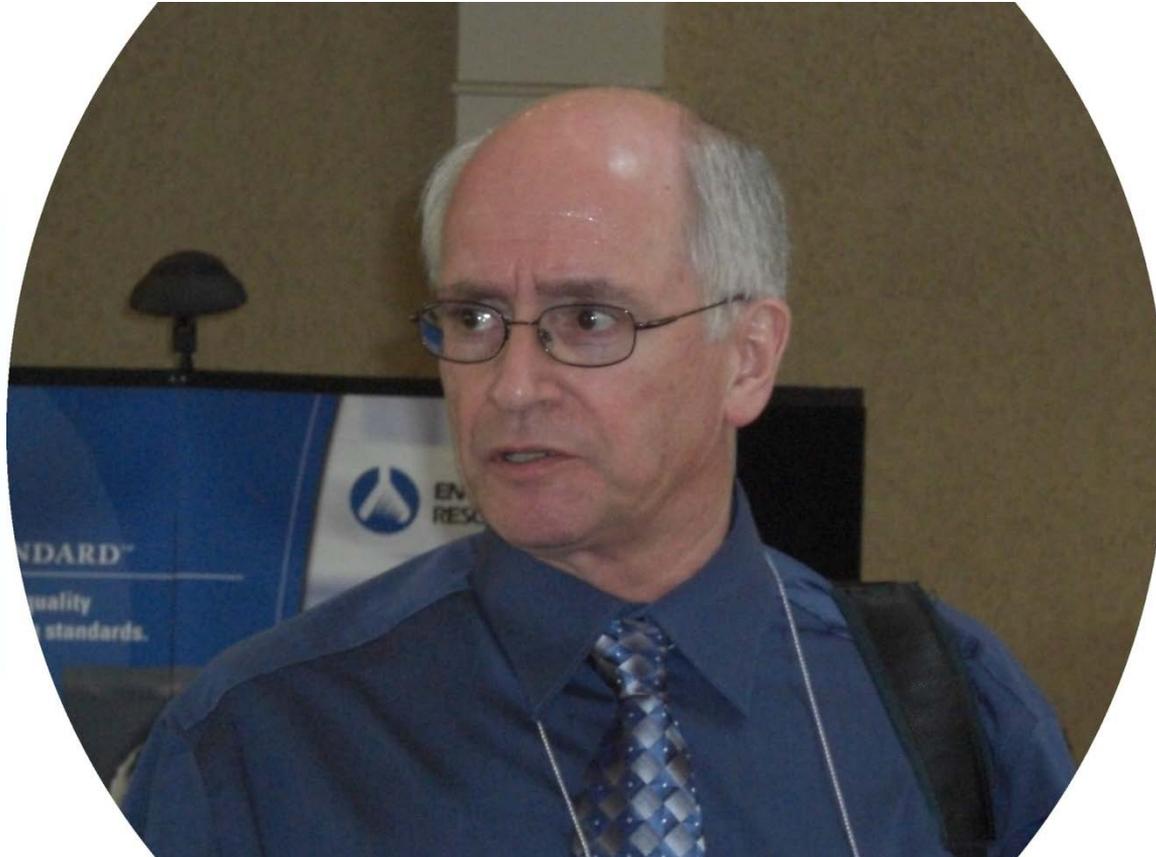# ADMINISTRATIVE COMMITTEES

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

FINANCE

INFORMATION TECHNOLOGY COMMITTEE

SUMMARY OF PROGRAM

- 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)

IT ANNUAL REPORT

2009 Accomplishments

- Began work on LAMS
- Continued improvements to website
  - Standard Interpretation Requests
  - SLAG Bulletin Board
  - Document listing
- Merged National Database and Website Committees

2010 Plans

- Implement LAMS
- Continue to improve website

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

NOMINATING

POLICY COMMITTEE

SUMMARY OF PROGRAM

- ➢ Develop policies and procedures that affect all of TNI

- ➢ Review policies and procedures from other programs

POLICY ANNUAL REPORT

2009 Accomplishments

□ Reviewed SOPs from NELAP and PT Boards

□ Began work on new SOPs for guidance documents and dispute resolution

2010 Plans

❑ SOP for use of guidance documents

❑ SOP for dispute resolution

❑ Bylaw revisions to accommodate NEFAP and SSAS

❑ New IRS rules for non-profits

CONFERENCE PLANNING

SUMMARY OF PROGRAM

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

2010 ENVIRONMENTAL MEASURMENT SYMPOSIUM

- Forum on Laboratory Accreditation

  +

- National Environmental Monitoring Conference

  - August 9-13, 2010
  - Washington, DC
  - www.nemc.us

FUTURE MEETINGS

Winter Meeting

- Savannah, GA
  - February 4-7, 2011

Summer Meeting

- Seattle, WA
  - July 18-22, 2011
- Washington, DC
  - August 5-9, 2012
- San Antonio, TX
  - August 6-10, 2013

CHICAGO FORUM

- Implementation of the Laboratory Standards
- TNI committee and board meetings
- Mentoring and training
- Networking

MENTORING AND TRAINING

- Assessment Forum
- Workshop on new TNI Standards
- Special mentoring session on LOD and LOQ
- Training course
  - ICP and ICPMS

COMMITTEE MEETINGS

- All are fully open to all attendees
- Working session
- Active participation of attendees encouraged

GROUND RULES FOR PARTICIPATION

➢ Wait to be recognized

➢ State your name and affiliation

➢ Speak slowly and clearly

➢ Be considerate of others

➢ Turn cell phone off

THE PEDWAY

□ Access to fast food, shops, Marshall Fields, etc without going outside.

SUMMARY

- TNI has had a terrific 2009 and is planning continued growth for 2010

- We invite you to actively participate in our activities

- Have a great time in Chicago