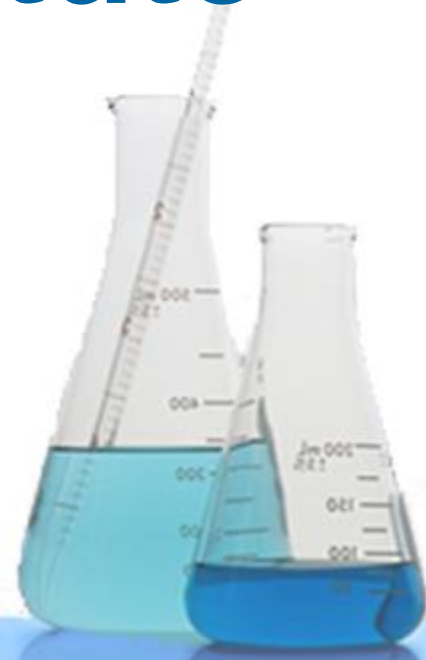




Update on the Activities of The NELAC Institute (TNI)

February 2, 2015



The NELAC Institute

Board of Directors

NELAP AC

Executive Director and Staff

Admin

CSDP

NEFAP

PTP

NELAP

Advocacy
Finance
IT
Nominating
Policy

CSDP EC

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

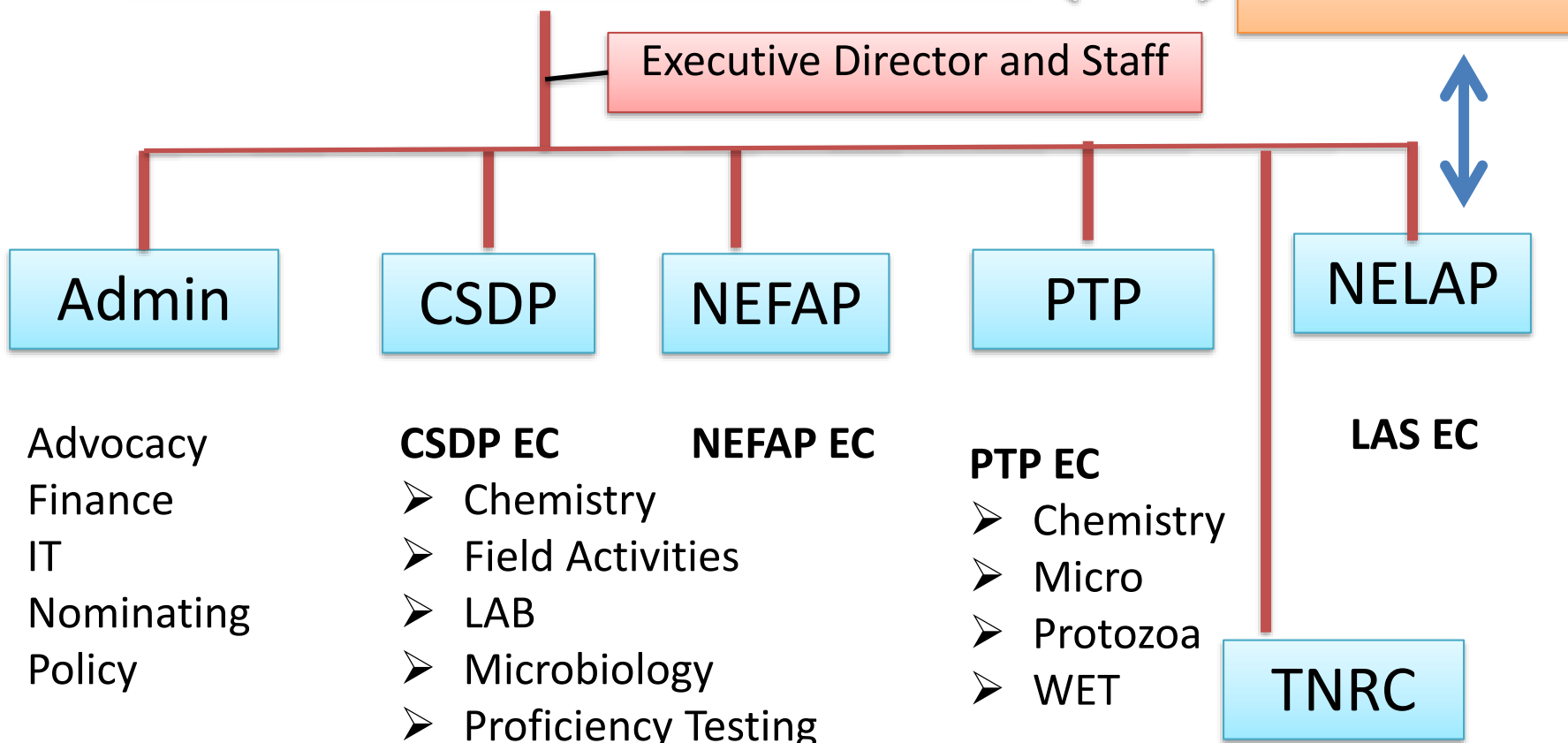
NEFAP EC

PTP EC

- Chemistry
- Micro
- Protozoa
- WET

LAS EC

TNRC





Reports on TNI Programs

- Consensus Standards Development Program (CSDP)
 - Bob Wyeth – CSD EC Chair
- National Environmental Field Activities Program (NEFAP)
 - Kim Watson - (NEFAP EC Chair)
- National Environmental Laboratory Accreditation Program (NELAP)
 - Judy Morgan - LASEC Chair
- Proficiency Testing Program (PTP)
 - Maria Friedman – PTP EC Chair
- General and Administrative
 - Jerry Parr – TNI Executive Director
 - Steve Arms – Advocacy Committee Chair







CONSENSUS STANDARDS DEVELOPMENT PROGRAM (CSDP)

The purpose is to develop standards. The Consensus Standards Development Executive Committee (CSDEC) is responsible for managing this program. The CSDEC consists of the Chair of each Expert Committee plus additional at-large members representing other stakeholder interests. This core program has a support role in assisting the LASEC Committee in developing the laboratory accreditation system.



CSDP Membership

- The CSDEC consists of the chair of every Expert Committee
 - Quality systems
 - Proficiency Testing
 - Accreditation Body
 - Stationary Source Audit Sample
 - Chemistry
 - Microbiology
 - Radiochemistry
 - Field Activities
- The CSDEC also has 3 members-at -large



Current Members

- ❑ Bob Wyeth (EC Chair; Member-at-large/Other)
- ❑ Jessica Evans (Member-at-large/Other)
- ❑ JoAnn Boyd (Member-at-large/Lab)
- ❑ Paul Junio (Quality Systems Committee Chair/Lab)
- ❑ Carl Kircher (Accreditation Body Committee Chair/AB)
- ❑ Tom Widera (SSAS Committee Chair/Other)
- ❑ Shawn Kassner (Proficiency Testing Committee Chair/Other)
- ❑ Richard Burrows (Chemistry Committee Chair/Lab)
- ❑ Robin Cook (Microbiology Chair/Lab)
- ❑ Justin Brown (Field Activities Committee Chair/Other)
- ❑ Bob Shannon (Radiochemistry Chair/Other)

- ❑ Program Administrator: Ken Jackson





Content of the Annual Report

Each Expert and Executive Committee operates under a Charter posted on the TNI website (www.nelac-institute.org) which details the committees' Mission Statement, objectives and measures of success.

This annual report will present activities, accomplishments, and plans for 2015 of the CSDEC and each of the Expert Committees.





CSDPEC Accomplishments

- Implementation of the Standards Development Work Group of the BoD.
- Revised approach to standard development and revision of SOP 2-100 (Procedures Governing Standards Development).
- Revised SOP 2-101 (Procedures for Expert Committee Operations), effective 1/8/2015.
- Webinars to inform stakeholders of standards development activity.





CSDPEC Accomplishments (Cont)

- Standards Review Council established
- Continue development of a Guidance document for development and maintenance of standards
- Implementation plan for 2015 Environmental Sector standard
- 2015 Charters prepared for all Expert Committees
- Implementation plan for 2015 Environmental Sector standard



CSDPEC 2015 Plans

- Approval of WET Expert Committee; move to BoD for final approval
- Finalize draft of Guidance Document for the Preparation of Policies, Consensus Standards, Operating Procedures and Belief Statements.
- Revision of SOP 2-100 (Procedures Governing Standards Development)
- Approve and post all 2015 Expert Committee and CSDEC Charters





Quality Systems Expert Committee

□ Accomplishments

- Reviewing Small Lab Handbook for consistency with the QS standard
- Reviewing Quality Manual Template for consistency with the QS standard

□ Plans

- Complete re-write of the Small Lab Handbook to remove inconsistencies and provide a single 'voice' to the document.





Proficiency Testing Expert Committee

□ Accomplishments

- Hosted Webinar on proposed standards changes
- V1M1 and V2M2 VDS, working on comments
- Completed V3 and V4 WDS

□ Plans

- Set to move V3 and V4 to VDS
- Present at the Summer meeting:
V1M1 and V2M2 Interim Stds; V3 and V4 VDS





Laboratory Accreditation Body Expert Committee

□ Accomplishments

- Prepared a proposal for third-party assessors
- Worked on a generic application form for laboratory accreditation
- Confirmed the Technical Review Checklist for current NELAP AB evaluation cycle
- Peer-reviewed links between TNI Method Codes and Technology Keys for LAMS





Laboratory Accreditation Body Expert Committee

□ Plans

-

- Monitor and report on ISO CASCO (Conformity Assessment Committee) Work Group revisions to ISO/IEC 17011 (affects accreditation body volumes of EL, FSMO, and SSAS sector TNI Standards)
- Assist with other tasks as needed and requested, consistent with Charter





SSAS Expert Committee

□ Accomplishments

- Final draft of revised standard “General Requirements for Participation in the SSAS Program”
- Final draft of revised standard “General Requirements for SSAS Providers”

□ Plans

- Subcommittee to address Method 8 Issues.
- Revise standard “General Requirements for an Accreditor of SSAS Sample Provider”





Chemistry Expert Committee

Accomplishments

- Interim standard for Calibration (V1M4) passed.
- Modified the EPA MDL procedure (App. B to Part 136); published by EPA in the Federal Register
- Working draft standard language for detection and quantitation published

Plans

- Move detection and quantitation language through the standard approval process





Microbiology Expert Committee

□ Accomplishments

- WDS for V1M5 presented and comments received
- MWDS presented and webinar hosted to receive additional comments

□ Plans

- Prepare VDS
- Work with QS Committee – some comments would be a good fit for the Small Lab Handbook





Radiochemistry Expert Committee

□ Accomplishments

- Reviewed V1M6 to prepare for WDS
- Prepared WDS for V1M6
- Incorporated comments received to prepare a MWDS for V1M6
- V1M6 is in the final stages of polishing prior to being balloted as a VDS

□ Plans

- Continued development of V1M6 consistent with policies and procedures, and the Charter

Tuesday,
8:00 – 5:00





Field Activities Expert Committee

- **Accomplishments**
 - Finalized Standard Revision in January 2014
 - Continued discussion on mobile lab issues
 - Completed FSMO tools
 - Priority Elements of Standard for FSMOs
 - Overview of accreditation process for FSMOs
 - Summary of changes in 2014 Standard revision
- **Plans**
 - Continue to develop tools to aide FSMOs
 - Present the standard to ANSI for approval as an American National Standard
 - Consider working on Sample Container Document







NATIONAL ENVIRONMENTAL FIELD ACTIVITIES PROGRAM (NEFAP)

The purpose of the National Environmental Field Activities Program is to establish and implement a program for the accreditation of field sampling and measurement organizations.





NEFAP EC MISSION

The Executive Committee is committed to establishing and maintaining a program in support of the TNI FSMO standards that will assure continual improvement of FSMO accreditation processes and which incorporate practical, effective, and clear standards of performance that are consistent with the needs of the environmental community as well as regulatory and industry specific requirements. The NEFAP accreditation assures the organization is technically competent to generate data of known and documented quality that meet the needs of the client.





NEFAP EC Membership

- 6 FSMO
- 5 ABs
- 5 Other
- 3 Associate Members
- Resignations: 2 FSMOs - Will be seeking new members!





NEFAP Accomplishments

- ❑ Consistent and moderately timely evaluation of ABs.
- ❑ Consistent assessment of FSMOs to a single national standard.
- ❑ Number of training courses and tools (e.g., ex. Checklists, Accreditation Summary, 2007 vs 2014 Standard Comparison) developed.
- ❑ Implementation of an accreditation program that is acknowledged by EPA, government agencies and organizations.





NEFAP Accomplishments

- ❑ Increasing support and input from stakeholders including ABs, FSMOs, Industry, and Standards Setting Organizations.
- ❑ Field accreditation standards are adopted by those performing environmental sampling and field measurements, including those not under a regulatory mandate to do so.





NEFAP Accomplishments

- ❑ Acceptance of the 2014 Standard with an implementation date of March 15, 2015.
- ❑ 2014 DEMOGRAPHICS
 - ABs Recognized – 4
 - Potential New ABs - 1
 - FSMOs Accredited - 7
 - Potential In-Hand Applications - 6
 - Inquiries – Air Testing and other Industries



NEFAP Needs

- ❑ FSMOs Globally – Thousands
- ❑ Defining the Need: Accreditation provides an objective way of demonstrating that an organization has an established quality management system and possesses the technical competence to perform the services they provide. Accreditation benefits all stakeholders in the process in different ways.



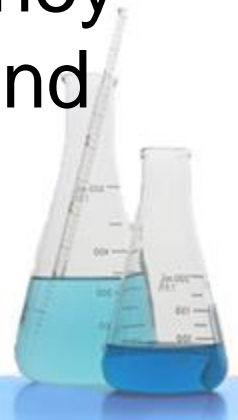
NEFAP Needs

- ❑ For the public ... Accreditation ...
- ❑ For the data user ... Accreditation provides ...
- ❑ For the industry ... Accreditation advances ...
- ❑ For governmental agencies ...
Accreditation serves ...



NEFAP Needs

- For the FSMO: Accreditation promotes ongoing self-evaluation and facilitates continuous improvement through preventive and corrective actions, which are especially beneficial to the organization. Accreditation allows the FSMO to effectively evaluate their own performance to determine if they are meeting the established standard and provides them with a benchmark for maintaining that competence.





NEFAP Goals/Plans - 2015

- Maintain and expand an effective national program for the accreditation of field sampling and measurement organizations (FSMOs).
 - Ensure the implementation of a national program for FSMO accreditation that is consistent with the TNI FSMO Standard requirements.
 - Develop a more streamlined process for recognition of ABs.
 - Develop tools to help streamline accreditation of FSMOs.





NEFAP Goals/Plans - 2015

- Develop and implement a plan for treatment of mobile labs among NELAP ABs and between NELAP and NEFAP.
- Develop an advocacy program to expand the use of accredited FSMOs (e.g. encourage industry contracts requiring NEFAP, reach out to engineering firms).
- Seeking recognition requirements or acceptance (Federal, State or private) for accrediting FSMOs.





NEFAP Goals/Plans - 2015

- FEM Policy update in December 2014 to uphold standards in FSM. Recognition of NEFAP to meet US EPA policy.
- Mobile laboratory accreditation across State Borders.
- State ABs recognition of third party accreditations.







NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

- 14 active Accreditation Bodies in 13 states
- Accredits approximately 1700 laboratories:
 - US states and territories
 - Canadian provinces
 - US military lab in South Korea

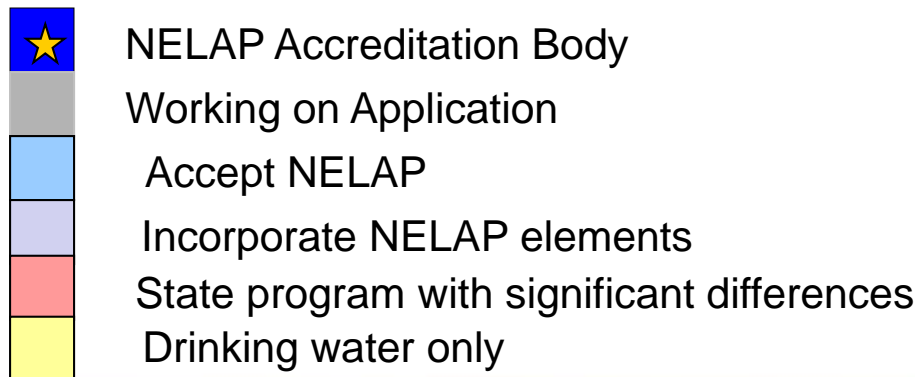
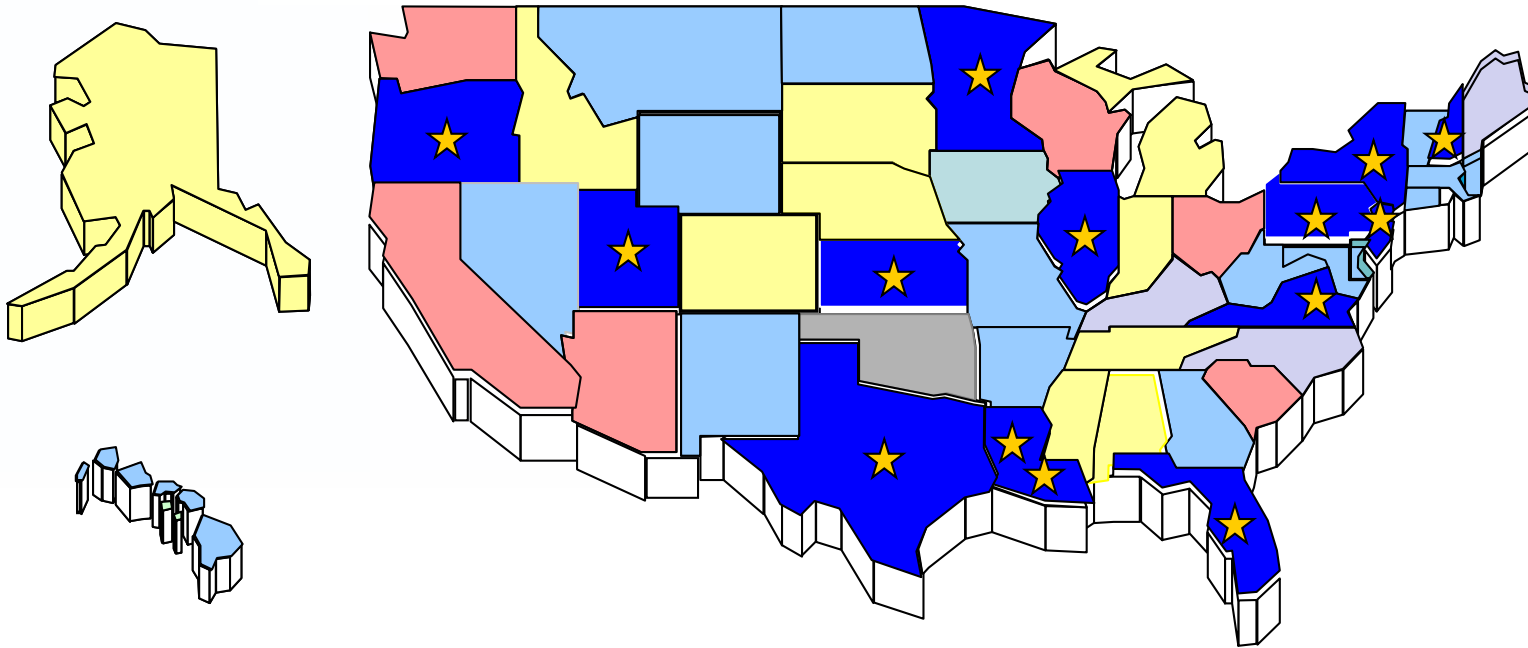


NELAP

- California ELAP was reorganized to its new home in the CA Water Resources Control Board in summer 2014
- NELAP and TNI have held several teleconference meetings to support CA ELAP and look forward to welcoming its return to NELAP in the future
- Looking forward to receiving Oklahoma's application to be a NELAP AB, later this year



The National Program Today





NELAP Accomplishments - 2014

- New evaluation cycle underway – 4 renewals thus far
- With LAS EC, completed elimination of SIR backlog
 - Of 284 submitted SIRs, 8 await vote and <12 in review
 - Created Standards Implementation Guidance to address important issues not meeting SIR criteria
 - ✓ 11 have been approved and are awaiting posting to website
- Actively engaged in reviewing standards documents at all revision stages – both LASEC and AC
 - Updated SOPs for review and acceptance of standards
- Began identifying policies needed
 - LASEC and LAB Expert will assist in drafting these
- Continued training
 - Assessment Forum, Mentor Sessions, Assessor Calls





NELAP Plans - 2015

- Continue active engagement in standards revision process
- Continue renewal evaluations for ABs
 - 5 evaluations presently underway; remaining 5 will begin before the end of calendar 2015
- Continue implementing all functions of the national accreditation database, “Laboratory Accreditation Management System (LAMS)”
- Sustain SIR progress
 - Supplement SIRs with Implementation Guidance for non-SIR questions



215 Assessment Forum

- Tracking Quality Control in the Wet Chemistry Laboratory
 - Standards, reagents and traceability
 - Equipment maintenance
 - Sample collection
 - Raw data records
 - Common findings

- How to prevent a government inquiry
 - Data protection
 - Audit trails
 - Manual integration







Mission

The purpose of the Proficiency Testing Program Executive Committee (PTPEC) is to establish and maintain certain elements of a national PT Program to support TNI's Accreditation Programs and other TNI activities.





PT Program Key Elements

- Organizations are approved as PT Provider
Accreditors
- List of accredited PT Providers posted on TNI
website
- Fields of Proficiency Testing (FoPT) Tables
 - Analytes, Matrices, Concentrations, and Acceptance
Limits appropriate for the scope of monitoring
performed
 - Used by NELAP and NEFAP
 - Used by other states and DMR-QA





PT Provider Accreditors and Accredited PT Providers

American Association for Laboratory Accreditation (A2LA)

- Advanced Analytical Solutions
- ERA
- New York State DOH
- Phenova

ANSI-ASQ National Accreditation Board / ACLASS

- Absolute Standards
- NSI Solutions
- 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 (SCM)





Fields of Proficiency Testing Tables

- Other FoPT Tables
 - Lead Field Testing
 - Protozoa for Drinking Water





2014 PTPEC Accomplishments

- Approved Drinking Water Protozoa FoPT (effective 10-6-2014)
- Approved update to Non-Potable Water FoPT (effective 3-16-2015)
- Continued data review for update of the SCM FoPT Table





2014 PTPEC Accomplishments

- Reconstituted FoPT Table Format subcommittee
- Addressed complaints
- First use of the Table Management SOP – addition of new analytes



PTPEC Plans - 2015

- Continue development and update of FoPT Tables
- Continue development and update of FoPT Table Format:
 - Add CAS numbers to all FoPT tables
 - Add methods to Drinking Water FoPT table
 - Add technologies to Non-Potable Water and SCM FoPT tables
- Develop better procedures to obtain PT data for PTPEC review of FoPT acceptance limits and other investigations





PTPEC Plans - 2015

- Complete update of committee SOPs
- Update PTPA Evaluation Checklist
- Periodically evaluate the effectiveness of the PT Provider oversight program and the FoPTs
- Develop a long-term plan for self-sufficiency



PTPEC Membership

- New Chair in PTPEC
- New Chair in FoPT Table Format Subcommittee
- Membership composition
 - PT Providers
 - PT Provider Accreditors
 - NELAP and Non-NELAP Accreditation Bodies
 - Laboratories and FSMO
 - Others



PTPEC Meetings

- Conference calls the third Thursday of the month from 1:00-2:30 Eastern Time
- Face-to-Face with attendee participation at annual Environmental Measurement Conferences and Forum on Laboratory Accreditation Conferences
- Public meeting
 - Subcommittee updates
 - PTPA Reports
 - Attendee comments and input







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





2014 Significant Board Actions

- Bylaws Revision
 - Streamline process for approval of Policies and SOPS
- Strategic Planning
 - Plan to be approved in March 2015
 - Strategies, Goals and Objectives
 - Specific objectives will then be assigned to various committees and staff





2015 Strategic Plan

- **Strategy 1:** Establish and maintain national programs for the accreditation of environmental laboratories, field sampling and measurement organizations, and other organizations directly involved in the generation of environmental monitoring data.





2015 Strategic Plan

- **Strategy 2:** Brand TNI as the resource for all activities related to generating environmental measurement data.
- **Strategy 3:** Improve infrastructure to ensure TNI's future success and financial sustainability.





NGAB Working Group

- Implement a program to be used by TNI to approve Non-Governmental Accreditation Bodies to grant environmental laboratory accreditations in conformance with the TNI standards, and to assure that the NGAB is capable of managing an accreditation program in a consistent, uniform manner.





NGAB Working Group

- Finalized evaluation SOP.
- TNI Board appointed members of the TNRC.
 - Judy Morgan, Chair
- Developed training course for evaluators.
- Will issue an RFP for lead evaluator next week.
- Poised to accept recognition applications late spring.
- Anticipate scheduling evaluations this fall.





Advocacy Activities

Recent Accomplishments

- ❑ Future of National Accreditation
- ❑ Presentations at regional and national meetings
- ❑ Published 3 newsletters

Future Plans

- ❑ Develop more Position Statements
- ❑ Lab Handbook
- ❑ Support conference planning
- ❑ Continue newsletters
- ❑ Implement recommendations from Futures effort





Exploring the Future of National Environmental Laboratory Accreditation




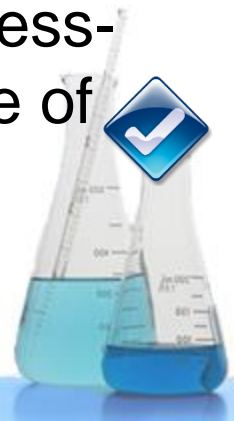
Issues Identified

- Technical Issues
 - Method vs Quality System Audits
 - 1 vs 2 PT samples
 - Harmonization with EPA Cert Manual
 - Simplify TNI Standard and Accreditation Process
- EPA/State Issues
 - Recognition of NELAP accreditation by other states
 - Encourage more EPA involvement
 - Consistency among NELAP states
 - Accreditation of State labs
- Communications and Outreach
 - Help for small labs
 - Outreach to Non-NELAP states
 - Technical resources








Technical Issues

- Misperception that these two approaches are not already integrated. TNI should better publicize how the quality systems approach supports a method based approach. 
- ~~□ Open to change PT only if there was a guarantee that non-participating states would join. Look at all the compromises that went into the 2 PTs per year decision.~~
- ~~□ TNI standard is more than DW. Don't want to force all labs into DW requirements. If incorporate into the TNI standard, need to make DW a consensus standard.~~
- Generic application. Guidance to help labs with process-mentors, tools. Surveillance assessments. Better use of tools and technology for ABs to manage programs






EPA/State Issues

- Work at the grass roots level with lab associations. Assign a TNI ambassador to every non-NELAP state. 
- Re-visit the crosswalk with TNI standard and DW certification manual.
- Develop an bi-annual “State of National Accreditation” report and offer briefings to EPA 
- Increase management oversight of assessments
- Promote assessor calls and assessor forum to disseminate information. 
- Encourage state labs to use non-governmental accreditation bodies (NGABs). 
- Promote EPA lab competency policy. 



Communication and Outreach

- Explore website changes. Consider a “tool box” format with flow charts, diagrams, templates, examples and other graphics to make information more readily available. 
- Establish a mentoring group for small labs and FSMOs.
- Consistently have a seminar at NEMC to introduce new labs to TNI. 
- Develop a free webinar to introduce TNI and highlight the benefits of accreditation. 





“Handbook on Good Practices for Environmental Laboratories”

- Purpose: To update EPA’s 1979 “*Handbook for Analytical Quality Control in Water and Wastewater Laboratories*”
- Justification: Modernization of 35 year old information and consolidation into one place for ease of accessibility
- Summary: Multiple chapters, based on content of original document with updated content and format.



Chapters

- ❑ INTRODUCTION
- ❑ IMPORTANCE OF QUALITY CONTROL
- ❑ LABORATORY SERVICES
- ❑ SAMPLE HANDLING AND PREPARATION
- ❑ INSTRUMENT SELECTION
- ❑ GLASSWARE
- ❑ REAGENTS, SOLVENTS, AND GASES
- ❑ QUALITY CONTROL FOR ANALYTICAL PERFORMANCE



Chapters

- ❑ DATA HANDLING AND REPORTING (INCLUDING STATISTICS)
- ❑ SPECIAL REQUIREMENTS FOR TRACE ORGANIC ANALYSIS
- ❑ SKILLS AND TRAINING
- ❑ SAMPLE COLLECTION
- ❑ MICROBIOLOGY
- ❑ LABORATORY SAFETY
- ❑ WASTE MANAGEMENT
- ❑ AQUATIC BIOLOGY



Volunteers Needed!

- Large-scale project +
 - Long-term project +
 - Broad-based project
- = *Lots of room to contribute*





CONFERENCE PLANNING

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





Future Meetings

Summer Meeting

- ❑ Chicago, IL
 - August 2015
- ❑ Orange County, CA
 - August 2016

Winter Meeting

- ❑ Tulsa, OK
 - February 2-5, 2015





Summer Meeting

- In conjunction with National Environmental Monitoring Conference
- August 4-8
- Washington, DC
- www.nemc.us

Abstracts Due!

NEMC





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)



IT ACTIVITIES

Accomplishments

- Major redesign of Website
 - Come see and critique!
- Methods compendium

Future Plans

- Continue to implement LAMS
- Continue to improve website
- Generic application
- Complete methods compendium



POLICY ACTIVITIES

Accomplishments

- Reviewed SOPs and Policies from other TNI programs
- New policies on ethics and complaints

Plans

- Continue to develop and review policies and SOPs
- Complete Quality Management Plan for TNI





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





Future Training Goals

- Develop and implement a comprehensive training program for stakeholders.
- Increase usage of technology.
- Increase use of available training materials already developed.
- Explore issuing certificates for completion of multiple trainings within a specific training track (e.g. Quality Systems).



Summary

- TNI has had a terrific 2014 and is planning continued growth for 2015
- 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

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