



The History and Future of National Environmental Laboratory Accreditation





Origin of National Program

- Drinking water certification program established in 1978
- State programs began to expand into other media in 1980's
- EPA Contract Laboratory Program (CLP) became de facto national program in 1980's





Impact of Early Beginnings

- Inconsistent/nonexistent inspections;
- No reciprocity among states;
- Accreditation in all areas was not available;
- Customers had no access to information;
and
- Programs generally viewed as inadequate.





Impetus for Change

- 1986 Report to Congress
 - EPA explore feasibility of a uniform, national environmental laboratory accreditation program
- 1990 EMMC Report
 - A national program is a viable option,
 - EPA consult with representatives of all stakeholders, and
 - Establish a federal advisory committee.





The Beginnings of NELAC

- Committee on National Accreditation of Environmental Laboratories (CNAEL)
 - July 1991 – July 1992
- State – EPA Focus Group
 - January 1993 – September 1994





CNAEL Recommendations

- National program implemented by state agencies with federal oversight
- Key elements of program are:
 - Performance evaluation testing
 - On-site audits
 - Laboratory process and quality assurance certification
- Program should be self-supporting





Work of the EPA/State Focus Group

- Developed a set of accreditation requirements based on ISO Guide 25
 - Proficiency testing
 - Quality system
 - On-site assessment
- Developed a proposed organizational structure
 - Conference of state and federal officials





Formation of NELAC

- Organization of state and federal officials who vote on requirements.
- Input from others considered.
- Implementation a voluntary decision by individual states.
- National Environmental Laboratory Accreditation Conference (NELAC) created on February 16, 1995.





NELAC Programs

- **Develop** uniform accreditation standards
- **Adopt** standards for use in accreditation programs
- Develop system for **recognition** of state agencies (Accrediting Authorities)
- Implementation of the accreditation program done voluntarily by those states who chose to participate





NELAC Timeline

- 1995 – 1997 Development of standards
- 1997 – Approval of first standards
- 1999 – First Accrediting Authorities recognized
- January 24, 2001 – First class of laboratories accredited
- 2002 – Decision to become a standards adoption body only
- June 6, 2003 – NELAC standards development committees ceased operation
- 2005-2006 – Explore options for self-sufficiency





Maturation of Program

- Institute for National Environmental Laboratory Accreditation (INELA) formed in 2002 to fill gap in standards development effort
- NELAC recognition of need for self-supporting program
- EPA provided funding support to assist in the transition





Status in October 2006

- The program had achieved some success.
 - 13 Accrediting Authorities.
 - > 2000 accredited laboratories.
 - Recognized competency standard.
- Much more needed to be done.
 - The 2003 NELAC standard perceived as onerous.
 - Many states were not participating.
- Program too reliant on EPA funding.





October 2006

- MOU between INELA and NELAC to explore options for working together
- The newly formed PPT had developed several recommendations
- Meeting scheduled for November 6, 2008
- Much was clear; some critical items unresolved





The Chesapeake Summit





Outcome from Chesapeake

- New name, bylaws, board
- Mission, vision, programs, membership, etc adopted
- 17 new committees created and staffed
- Plans for moving forward





THE NELAC INSTITUTE





TNI: A 501(c)3 Organization

Board of Directors

Self-Governing Programs

- NELAP
- LASP
- TAP
- CSDP
- PTP
- Forum
- NEMC

Staff

Administrative Committees

- Policy
- Advocacy
- Website
- Conference Planning

Individual Members





Mission

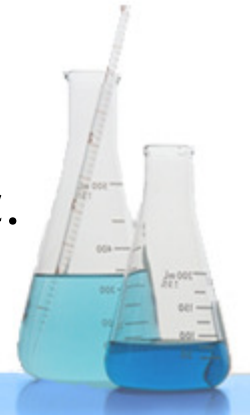
The purpose of the organization is to foster the generation of environmental data of known and documented quality through an open, inclusive and transparent process that is responsive to the needs of the community.



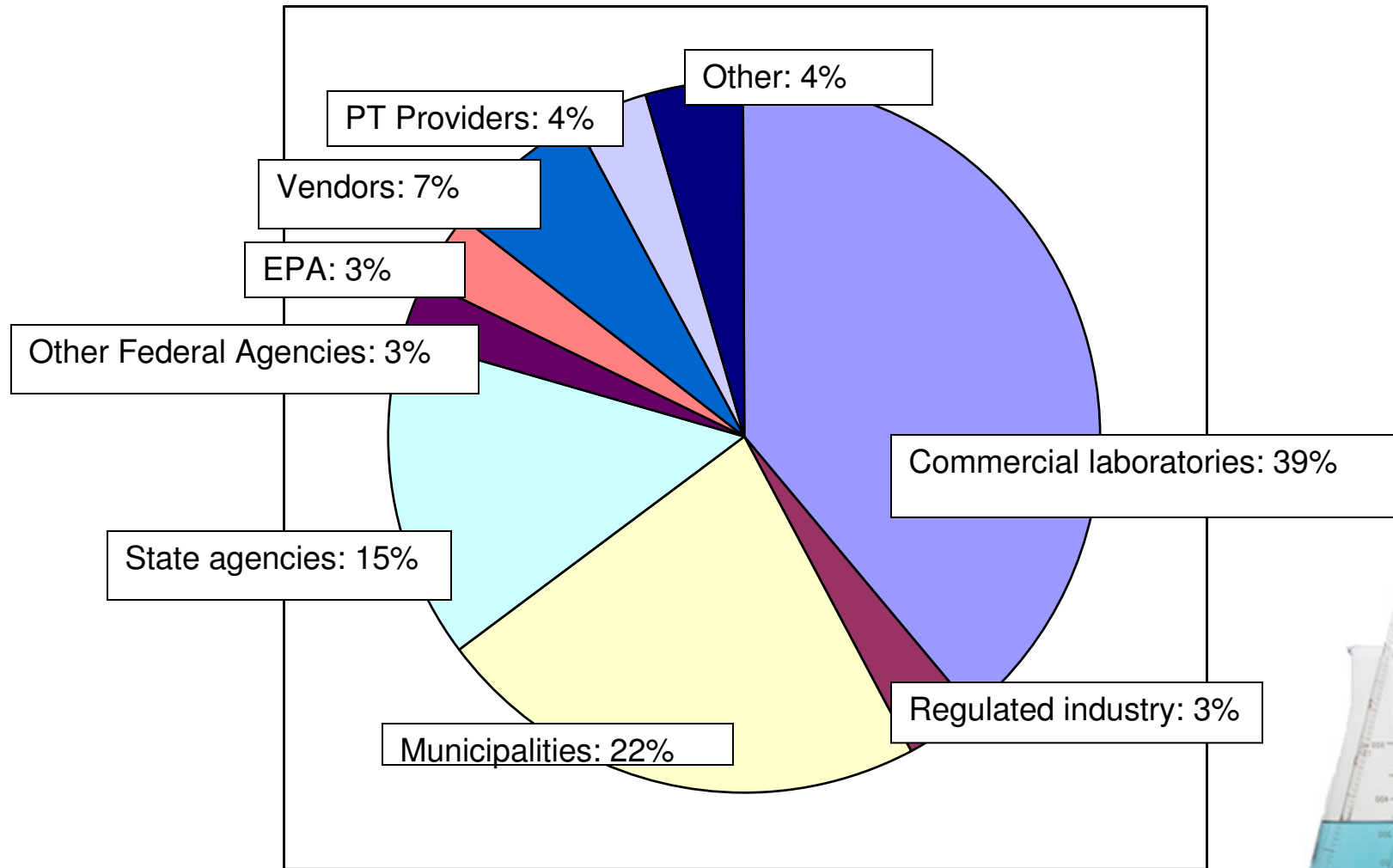


Who Are Our Members?

- **Organizations that accredit laboratories**
 - Recognized accreditation bodies
 - States that are not recognized accreditation bodies
 - Federal agencies that operate accreditation programs
- **Accredited laboratories**
 - Commercial, Municipal, University, State, Federal, etc.
- **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





Members

- Individual Members
 - May vote
 - May serve on committees or the Board
 - Entitled to member discounts
 - Access to members area of website
- Organizational Members
 - May appoint individual members
 - Are recognized
 - May not vote





Governing Principles

- Consensus standards process used to the degree possible and required for standards development
- Implementation of the program will continue to be voluntary by states
- The concept of “balance” used where possible
- Each of the TNI programs are self governing





Balance

- No stakeholder group will have dominance on any committee or board of TNI
- Stakeholder groups are:
 - Organizations that operate accreditation programs (Accreditation Bodies, or ABs)
 - Accredited laboratories
 - Others
- One exception: NELAP Board





Board of Directors

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





2007 TNI BOARD

- Judy Duncan, OK DEQ
- David Speis, Accutest
- Sharon Mertens, City of Milwaukee
- Steve Arms, FL DOH
- Joe Aiello, NJ DEP
- Jack Farrell, AEX
- Ken Jackson, NY DOH
- Tom McAninch, LCS
- Dave Mendenhall, UT DOH
- Judy Morgan, ESC
- Ken Olsen, Datachem
- Alfredo Sotomayor, WI DNR
- Aurora Shields, KS DHE
- Bob Wyeth, CAS

Ex-Officio

Brooke Connor, USGS

George Detsis, DOE

Barbara Finazzo, EPA Region 2

TBD, DOD





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.





Programs of TNI

- Consensus Standards Development
- Laboratory Accreditation System
- National Environmental Laboratory Accreditation
- Proficiency Testing
- Technical Assistance
- Forum on Laboratory Accreditation
- National Environmental Monitoring Conference (NEMC)





Consensus Standards Development Program

Consensus Standards Development Board

- Expert Committees
- Develop standards for the accreditation of environmental laboratories.
- Assist the other programs with guidance.





Expert Committees

- Accreditation Body
- Field Activities
- On-site Assessment
- Proficiency Testing
- Quality Systems





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
 - Module 1 – General Requirements
 - Module 3 – On-Site Assessment
 - Module 2: Proficiency Testing
- 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

Volume 2: General Requirements for
Accreditation Bodies Accrediting FSMOs





Laboratory Accreditation System Program

Laboratory Accreditation System Committee

- Develop a system for the accreditation of environmental laboratories:
 - policies and procedures, interpretations, guidance documents, and any related tools used by ABs to implement a national environmental laboratory accreditation program.
- Subcommittee:
 - National Database Committee





National Environmental Laboratory Accreditation Program (NELAP)

The purpose of NELAP is to establish and implement a program for the accreditation of environmental laboratories.

The primary components of this program are:

- The recognition of accreditation bodies,
- The adoption of acceptance limits for proficiency testing developed in the Proficiency Testing (PT) Program, and
- The adoption of the laboratory accreditation system developed in the Laboratory Accreditation System Program (LASP).





The NELAP Board

The NELAP Board is not the same as the TNI Board of Directors.





NELAP Board Membership

- One representative and one alternate from each NELAP-recognized Accrediting Body.
- Each representative and alternate is officially appointed by the Accreditation Body to represent their state program.
- A chairperson is selected by the members of the NELAP Board.
- Program administrator to help with administrative functions.





Primary

George Kulasingam
Stephen Arms
Scott Siders
Jack McKenzie
Paul Bergeron
Louis Wales
Bill Hall
Michael Miller
Kenneth Jackson
Daniel Hickman
Aaren Alger
Stephen Stubbs
David Mendenhall

Alternate

Jane Jensen
Carl Kircher
Jim Shaw
Aurora Shields
David Boucher
Ginger Hutto
Jeanne Chwasciak
Joe Aiello
Dan Dickinson
RaeAnn Haynes
Ron Houck
Steve Gibson
Paul Ellingson

California DHS
Florida DoH
Illinois EPA
Kansas DHE
Louisiana DEQ
Louisiana DHH
New Hampshire DES
New Jersey DEP
New York DoH
Oregon DEQ
Pennsylvania DEP
Texas CEQ
Utah DoH





NELAP Board

- Final authority for implementation of the program for the accreditation of environmental laboratories.
- Implements the policies and procedures that govern the operation of this program, and
- Responsible for ensuring the successful implementation of the program.





NELAP Board

Other duties include:

- Receiving questions or complaints about implementation and directing them to the proper body for action.
- Ensuring the consistency of application of the current standards by NELAP ABs.





NELAP Board

- The authority to administer an accreditation program comes from state statute and regulation, and is the same under TNI as it was under NELAC.





Proficiency Testing (PT) Program

PT Board

- Recommend the selection of a PT Provider Accreditor (PTPA).
- Monitor the PTPA to assure they are following the requirements set forth by TNI.
- Facilitate an annual caucus on proficiency testing.
- Review and evaluate PT data for the purpose of determining the appropriateness of study limits.
- Provide recommendations to the NELAP Board as to acceptance limits.





Technical Assistance Program

Technical Assistance Committee

- Develop tools and templates to assist laboratories and accreditation bodies with implementing accreditation programs.
- Ensure that training programs relevant to the needs of the stakeholder community are provided.
- Ensure that laboratory assessors have a forum to discuss common issues.
- Develop a mentoring program to assist both laboratories and accreditation bodies with implementing accreditation programs.





National Environmental Monitoring Conference



- Annual technical meeting focused on the latest innovations in environmental monitoring
- Co-hosted with EPA and the Independent Laboratories Institute
- August 11-15, 2008
Washington, DC
- www.nemc.us





Forum on Laboratory Accreditation

- Semiannual meeting where TNI committees, members, and others meet to discuss common issues
- January 18-22, 2008, Newport Beach, CA
- August 11-15, 2008, Washington, DC





Administration and Support

- Advocacy Committee
- Conference Planning Committee
- Policy Committee
- Website Committee

- Administrative staff





Advocacy Committee

- Promote a national program for the accreditation of environmental laboratories
 - 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.





Policy Committee

- Serve as a resource for the development of policies.
- Review policies from all programs for conformity with respect to style and for consistency with one another and with the overall mission of TNI.
- Develop general policies for TNI (e.g., purchasing, conflict of interest, etc.).
- Review and evaluate requests for policies received from the membership and others.





Website Committee

- Duties are to provide recommendations as to the design and content of the website.
- Primary focus:
 - Functionality and content of TNI site
 - Migration of old EPA NELAC site
- Major redesign underway





Staff

- Executive Director
 - Implement plans as directed by the Board
- Program Administrators
 - Support the activities of key programs
- Meeting Planner
- Support Staff
 - Clerical, website





Summary

- The NELAC Institute is poised to take national accreditation to the next level
 - Improve the accreditation requirements
 - Approve more states as accreditation bodies
 - Be responsive to stakeholder needs
 - Provide technical assistance
- We need your help!
 - Join our organization
 - Join a committee





The NELAC Institute

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