



THE NEW TNI NATIONAL LABORATORY ACCREDITATION STANDARDS

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August 10, 2009





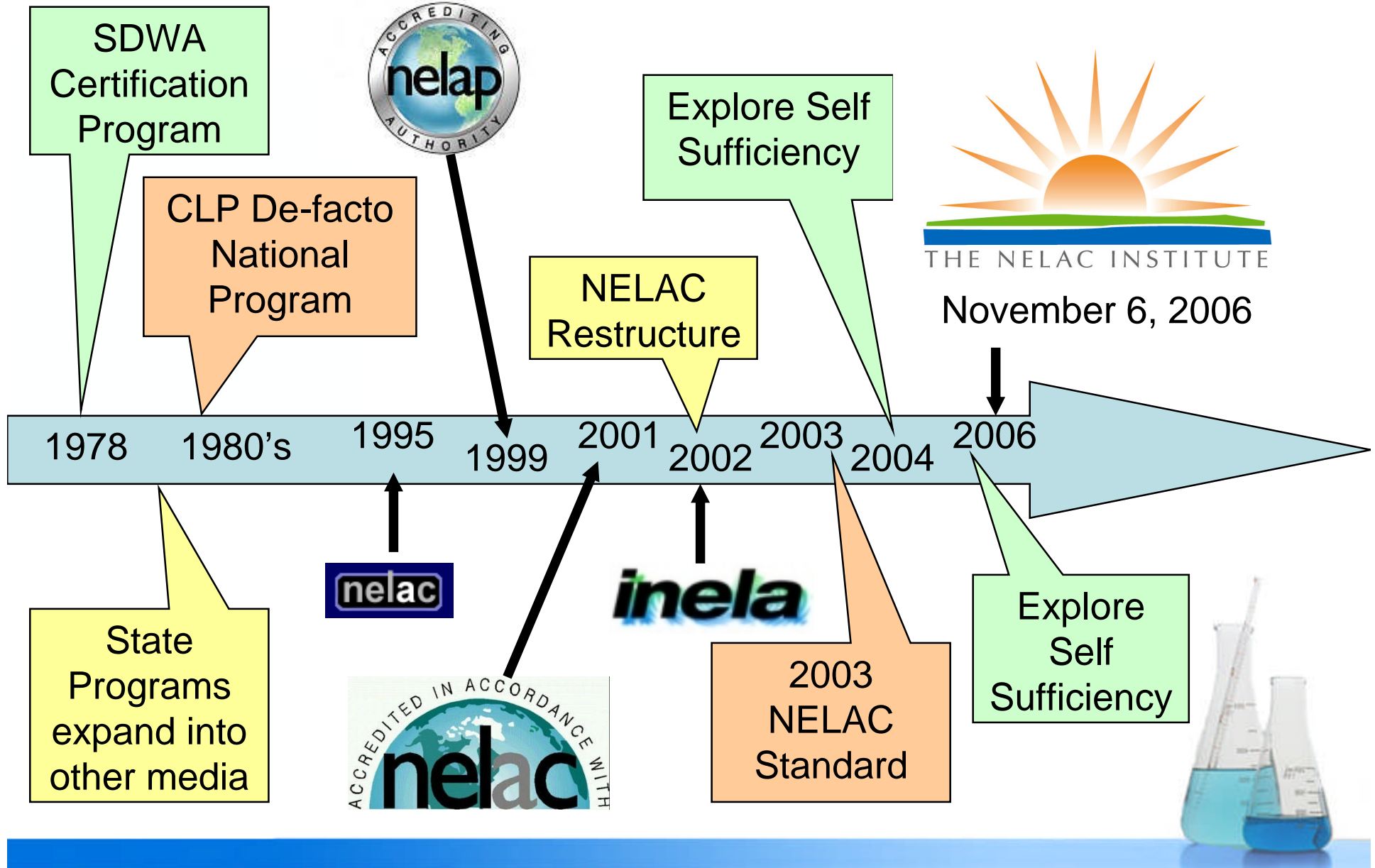
WHO IS TNI?

- ❑ 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).





OUR HERITAGE





MISSION AND VISION

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.

All entities generating environmental data in the United States will be accredited to consensus national standards.





TNI STRUCTURE

Board of Directors

Self-Governing Programs

- Consensus Standards Development
- National Environmental Laboratory Accreditation
- Laboratory Accreditation System
- Technical Assistance
- Proficiency Testing
- Advocacy
- Stationary Source Audit Sample

Staff

Administrative Committees

- Policy
- Advocacy
- Website
- Conference Planning
- Finance

Individual Members





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 the public





ACCREDITATION OF ENVIRONMENTAL LABORATORIES

TNI's National Environmental Laboratory Accreditation Program (NELAP)





PURPOSE OF ACCREDITATION

Accreditation is designed to ensure that laboratories are technically competent and are able to generate technically valid results.

Corollary: An accredited laboratory will more likely generate data of appropriate quality for a particular analysis because of its quality system.





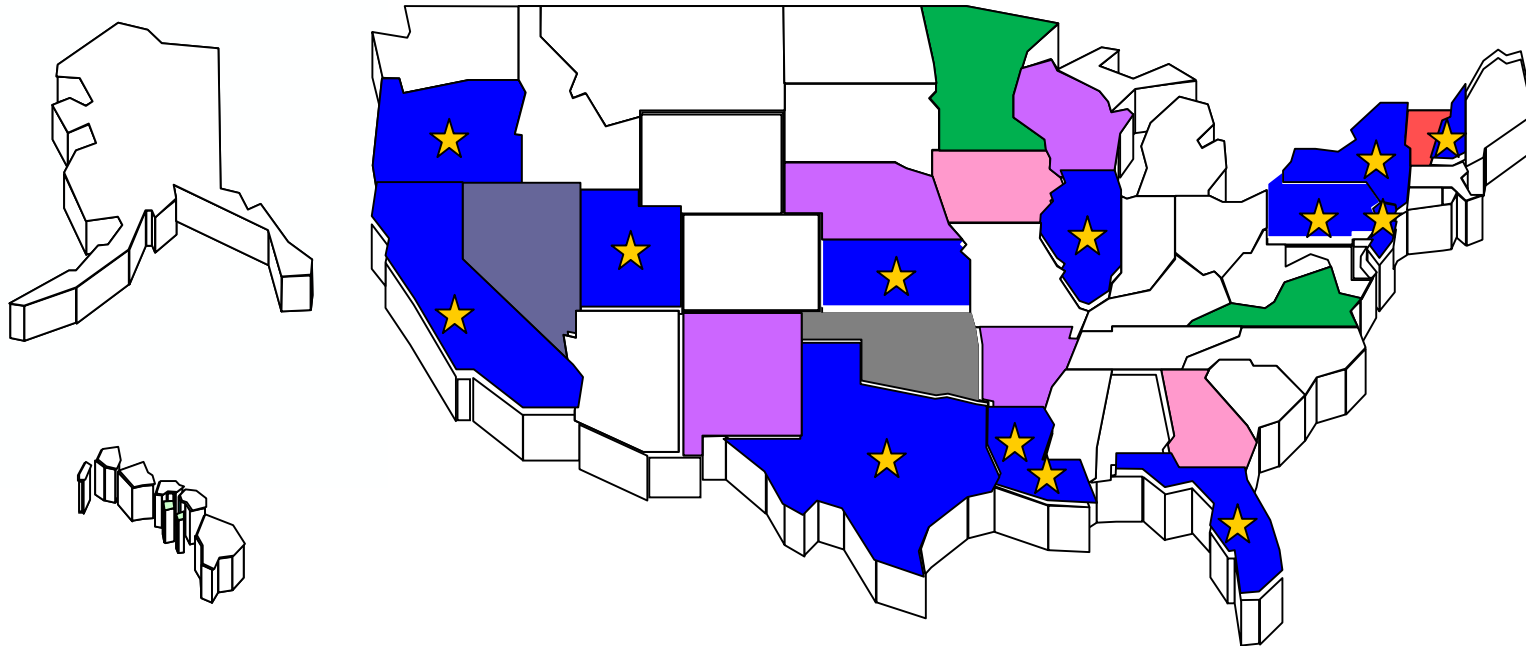
FUNDAMENTAL CONCEPTS







- 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.
- Laboratories can voluntarily apply to any approved NELAP AB, if their home state does not participate.





NELAP ABs



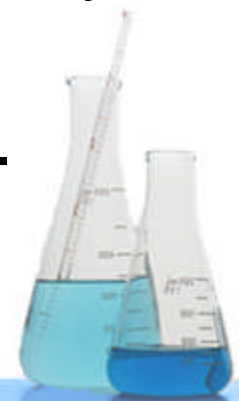
-  NELAP Accreditation Body
-  Application Being Processed
-  Working on Program/Application
-  Require Program
-  Recognize Program
-  Incorporated Program Components





NELAP CHARACTERISTICS

- Implemented by state government agencies formally recognized by TNI as Accreditation Bodies (ABs);
- Based on internationally recognized standards adapted by TNI for environmental testing;
- Implemented with respect to a specific scope of testing;
- Includes periodic inspection of the laboratory by qualified assessors; and
- Involves review of proficiency testing results.





NELAP STANDARDS

- Developed using a consensus process that included the perspectives of multiple stakeholders.
- Used recognized international standard for the competency of laboratories (ISO 17025) as the basis.
- Added additional specificity to address specific issues associated with environmental testing.
- Focus is on generation of authentic data (*i.e., data of known and documented quality generated according to accepted professional practices of the industry*).





CHOICES: 1997 - 2003

- EPA Drinking Water Program
- ISO 17025 only
- Various home-grown state programs
- Some combination of the above





GUIDING PRINCIPLES

- **Flexible:** Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel approaches. specify the *What* and avoid where possible the *How To*.
- **Auditable:** Sufficient detail included so that the assessors can evaluate laboratories consistently.
- **Practical and Essential:** Necessary policies and procedures that should not place an unreasonable burden upon laboratories.
- **Widely Applicable:** Applicable to laboratories regardless of size and complexity.
- **Appropriate:** Ensure that data is of known quality and that the quality is adequate for the intended use.





COMPARISON TO DW PROGRAM

Drinking Water Certification

- DW Certification Manual
 - Technical Requirements
 - Records
 - QA Plan
 - Personnel
 - Guidance and 95% Should
 - 205 pages
- Successfully analyze PT sample each year
- Audit every 3 years

NELAP Accreditation

- NELAC Standard
 - Technical Requirements
 - Records
 - QA Manual
 - Personnel
 - Regulation and 100% Must
 - 289 pages
- Analyze 2 PT samples per year and pass 2 out of 3
- Assessment every 2 years





DOCUMENT COMPARISON

Drinking Water Manual

- Mainly guidance
- Requirements focused on:
 - Method compliance
 - Time & temperature
 - Reagents/media
 - Lab ware
 - Enumeration

NELAC Standard

- 100% Requirements
- Requirements focused on:
 - Quality System
- Changes in language
 - Should to must
 - Specific to general
 - Increased requirements





SHOULD TO MUST

Drinking Water Manual

- The date, contents, sterilization time and temperature, total time for each cycle, and analyst's initials should be recorded each time the autoclave is used.

NELAC Standard

- Records of autoclave operations shall be maintained for every cycle. Records shall include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out), and analyst's initials.





SPECIFIC TO GENERAL

Drinking Water Manual

- Thermometers must be graduated in 0.5 C increments (0.2 C increments for tests which are incubated at 44.5 C) or less.

NELAC Standard

- The graduation of the temperature measuring devices must be appropriate for the required accuracy of measurement.





INCREASED REQUIREMENTS

Drinking Water Manual

- Balances should be calibrated monthly using ASTM type 1, 2, or 3 weights (minimum of three traceable weights which bracket laboratory weighing needs).

NELAC Standard

- Prior to use on each working day, balances shall be checked in the expected use range, with NIST traceable references where commercially available.





COMPARISON TO ISO 17025

- ISO 17025
 - Management Requirements
 - Technical Requirements
 - 35 pages
 - Includes Calibration Laboratories
- NELAC Chapter 5
 - Management Requirements
 - Technical Requirements
 - 121 pages





DOCUMENT COMPARISON

ISO 17025

- Generic Requirements
 - Testing Laboratories
 - Calibration Laboratories

NELAC Standard

- 17025 Testing Laboratory Requirements

PLUS

- Specific Requirements for Environmental Laboratories

AND

- Data Integrity
- QC Appendices





EXAMPLE: INSTRUMENT CALIBRATION

ISO 17025

- Before being placed into service, equipment shall be calibrated to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.

NELAC Standard

- 3 pages of specific details related to initial calibration and calibration verification.





THE 2003 NELAC STANDARD

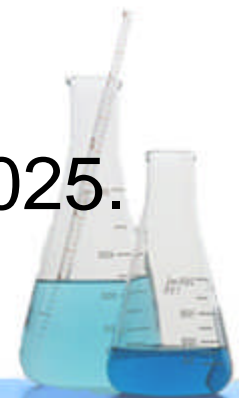
- Strengths:
 - Uses ISO 17025 quality system approach,
 - Adds specificity to improve clarity and help with consistency for environmental testing,
 - Allow flexibility in meeting requirements,
 - Represents best professional practice, and
 - Allows for multiple Accreditation Bodies to implement consistently.
- Summary:
 - **NELAC 2003 is the best accreditation program for environmental laboratories currently in use.**





THE 2003 NELAC STANDARD

- Weaknesses:
 - 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.





A NEW APPROACH

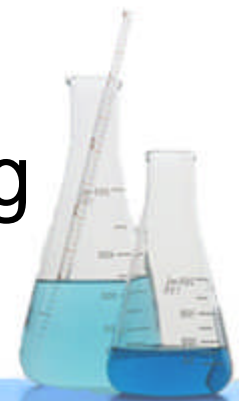
- Start with the purpose of an accreditation program
- Ensure key elements are retained
- Consider the following goals:
 - Easy to use and understand
 - Easy to grow and expand
 - Easy to revise and implement
 - Applicable to all laboratories





BASIS OF NEW STANDARDS

- International Standards
 - ISO 17025
 - ISO 17011
 - ISO Guide 43
- Work of NELAC from 1994 - 2003
- Significant input from TNI membership during consensus voting process
- Reorganized to facilitate understanding





THE NEW TNI LABORATORY STANDARD

- 138 pages (*versus 289 for 2003 NELAC Standard*)
- Uses current version of ISO 17025
- Increased clarity.
- Everything in one place:
 - Proficiency testing,
 - Quality systems, and
 - Personnel.
- Discipline specific quality control modules greatly improved.
- Very few new requirements.
- Greater flexibility





BENEFITS OF NEW LABORATORY STANDARDS

- ❑ Removal of outdated NELAC language
- ❑ Incorporation of ISO 17011
- ❑ Incorporation of current version of ISO 17025
- ❑ Volume/Modular approach simplifies understanding
- ❑ Improved clarity on Technical Requirements
- ❑ True consensus standard!!!





PLAN FOR IMPLEMENTING LABORATORY STANDARDS

- August 2009 Adoption by NELAP Board;
- January 2010 Changes in state regulations;
- Spring 2010 Training and outreach;
- August 2010 Replace NELAC 2003.





THE NELAC INSTITUTE

<http://www.NELAC-Institute.org>

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