



**Development of a Consensus
Standard for Quality Systems
in Environmental Testing
Laboratories.**

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Quality Systems
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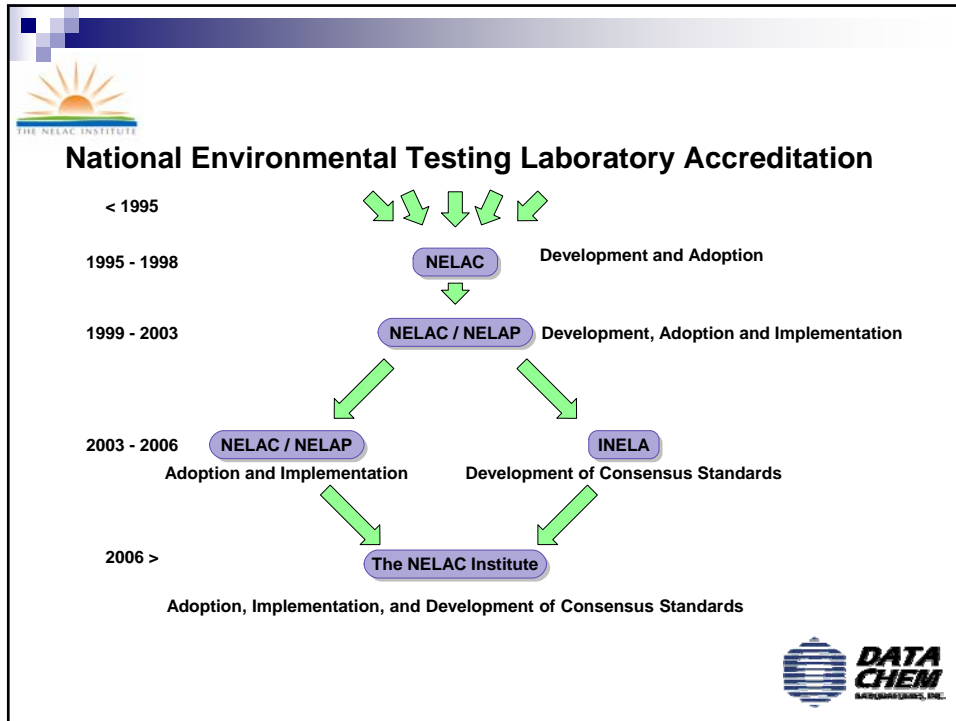
What is NELAC?

What is NELAP?

What is INELA?

What is TNI?






What is Consensus?



What is a Standard?

DATA CHEM
ANALYTICAL SERVICES, INC.


The slide contains the NELAC Institute logo in the top left corner, two large bolded questions in the center, and the DATA CHEM logo in the bottom right corner.




Consensus is a decision-making process that not only seeks the agreement of most participants, but also to resolve or mitigate the objections of the minority to achieve the most agreeable decision.



A **standard** is an established norm or requirement. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes and practices.







ANSI Requirements of a Consensus Standards Development Body


- Openness
- Balance of interest
- Consensus
- Due Process
- Appeals Process

Having met all requirements, the TNI Consensus Standards Development Program was approved by ANSI, effective December 18, 2007.



The NELAC Institute (TNI) Standards Development Process

Monthly Meetings	Expert Committee submits Working Draft Standard for public comment	
Monthly Meetings	Working Draft Standard is modified from public comment	Public Meeting
Monthly Meetings	Modified WDS is voted to Draft Interim Standard	
	All Stakeholders vote and comment on Draft Interim Standard	Public Meeting
Monthly Meetings	Draft Interim Standard is modified by persuasive comments and all comments are addressed.	
Monthly Meetings	Committee votes Draft Interim Standard to Final Standard	Public Meeting






How did we get here?

Working Draft Standards

- Dallas, Jan 2004
- Charleston, Aug 2004
- Philadelphia, Jan 2005
- Austin, April 2005*
- Raleigh, Aug 2005
- Chicago, Jan 2006
- Kansas, Aug 2006
- Tallahassee, Oct 2006*
- Denver, Jan 2007




How did we get here?

Draft Interim Standards

- Cambridge, Aug 2007
- Lancaster, Oct, 2007*

Final Standards

- Newport Beach, Jan 2008





Where are we today?

Final Standards have been reviewed for consistency.

Final Standards will be published to Website. May 2008

Appeals Process will begin when published. 6 Weeks

Appeals process through TNI Board of Directors. ?

Final Standards will be submitted to TNI NELAP Board. Aug 2008




TNI Quality Systems Expert Committee

Accreditation Bodies
Aaren Alger, State of Pennsylvania
Laurie Carhart, State of New York
Michelle Potter, State of New Jersey

Accredited Laboratories
Robin Cook, City of Daytona Beach
Robert Di Rienzo, DataChem Laboratories
Wilson Hershey, Lancaster Laboratories
Paul Junio, Test America

Other
Silky Labie, State of Florida
Fred McLean, DoD
Randy Querry, A2LA







The TNI Standards are based on the concept of sectors, volumes, and modules.

Environmental Laboratory Sector


- Volume 1 – Laboratory Requirements**
- Volume 2 – Accreditation Body Requirements**
- Volume 3 – Proficiency Testing Provider Requirements**
- Volume 4 – Proficiency Testing Oversight Requirements**




The TNI Standards are based on the concept of sectors, volumes, and modules.



Field Services and Measurement Organization Sector

- Volume 1 – FSMO Requirements**
- Volume 2 – FSMO Accreditation Body Requirements**





**How does a laboratory know
what to do?**





**The TNI Standards are based on the
concept of sectors, volumes, and modules.**

Environmental Laboratory 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 – Toxicity Testing**







**The TNI Standards are based on the
concept of sectors, volumes, and modules.**

Environmental Laboratory Sector

Volume 1 – Laboratory Requirements

**Module 1 – Proficiency Testing
PT Testing Requirements for Laboratories**





**The TNI Standards are based on the
concept of sectors, volumes, and modules.**

Environmental Laboratory Sector

Volume 1 – Laboratory Requirements

**Module 2 – Quality Systems: General Requirements
A Quality System for all laboratories**







The TNI Standards are based on the concept of sectors, volumes, and modules.

Environmental Laboratory Sector

Volume 1 – Laboratory Requirements

Module 3 – Asbestos Testing
Module 4 – Chemical Testing
Module 5 – Microbiological Testing
Module 6 – Radiochemical Testing
Module 7 – Toxicity Testing

Technical Modules





Volume 1

Environmental Laboratory Sector

Laboratories Requirements

- Includes all standards for laboratories
- Uses ISO/IEC 17025:2005 for Quality Systems
- Flexible and Consistent
- Technical Modules can be added as needed
- Available for purchase with ISO Language
www.nelac-institute.org







Volume 1

Environmental Laboratory Sector Laboratories Requirements


Module 2 - Quality Systems: General Requirements


- **Format consistent with ISO 17025:2005**
- **Additional NELAC requirements follow applicable ISO sections**
- **Redundant language has been removed**
- **All technical requirements moved to Modules 3 to 7**



Module 2 - Quality Systems: General Requirements



- 1.0 INTRODUCTION, SCOPE AND APPLICABILITY**
Introduction and Scope
- 2.0 NORMATIVE REFERENCES**
- 3.0 TERMS AND DEFINITIONS**
Additional Terms and Definitions, Definition Sources, and Exclusions and Exceptions
- 4.0 MANAGEMENT REQUIREMENTS**
Organization, Management, Document Control, Review of Request, Tenders and Contracts, Subcontracting of Environmental Tests, Purchasing Services and Supplies, Service to the Client, Complaints, Control of Nonconforming Environmental Testing Work, Improvement, Corrective Action, Preventive Action, Control of Records, Internal Audits, Management Review, and Data Integrity Surveillance





Module 2 - Quality Systems: General Requirements

5.0 TECHNICAL REQUIREMENTS
General, Personnel, Accommodation and Environmental Conditions, Environmental Test Methods and Method Validation, Calibration Requirements, Measurement Traceability, Collection of Samples, Handling Samples and Test Items, Quality Assurance for Environmental Testing, and Reporting the Results




Module 2 - Quality Systems: General Requirements


Example Section from Module 2 – Non ISO version

4.14 Internal Audits (ISO/IEC 17025:2005(E), Clause 4.14)
ISO text 4.14.1 to 4.14.4 here

4.14.5 Additional Items

- a) The laboratory shall have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results.
- b) The laboratory management shall ensure that these actions are discharged within the agreed time frame.
- c) The Internal audit schedule shall be completed annually.







Volume 1
Environmental Laboratory Sector
Laboratories Requirements

Modules 3 to 7 - Technical Modules for Asbestos, Chemistry, Microbiology, Radiochemistry, and Toxicity Testing


- **No ISO language**
- **Specific to Testing Activity**
- **Consistent Format and Structure in all Technical Modules**




Modules 3 to 7 - Technical Modules for Testing

TESTING

- 1.1 Introduction
- 1.2 Scope
- 1.3 Terms and Definitions
- 1.4 Method Selection
- 1.5 Method Validation
 - Validation of Methods, Limit of Detection and Limit of Quantitation, Evaluation of Precisions and Bias, and Evaluation of Selectivity







Modules 3 to 7 - Technical Modules for Testing

TESTING

- 1.6 Demonstration of Capability (DOC)
 - General, Initial DOC, and Ongoing DOC
- 1.7 Technical Requirements
 - Initial Calibration, Continuing Calibration, Quality Control for Chemistry, Data Reduction, Reagent Quality, Water Quality and Checks, Data Acceptance/Rejection Criteria, and Sample Handling





Modules 3 to 7 - Technical Modules for Testing

Example Section

- 1.6 Demonstration of Capability (DOC)**
 - 1.6.1 General**

Prior to acceptance and institution of any method for which data will be reported, a satisfactory initial DOC is required (see Section 1.6.2).
Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) is required.
In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the ongoing DOC shall be acceptable.







Modules 3 to 7 - Technical Modules for Testing Example Section

1.6 Demonstration of Capability (DOC)
1.6.1 General (Continued)

The laboratory shall have records on file to demonstrate that a DOC is not required. For the initial DOC, appropriate records as discussed in Section 1.6.2 shall be completed. An initial DOC shall be completed each time there is a change in instrument type, personnel, or method. All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.



Questions?

