

Steps to Successfully Achieving National Accreditation

Working with Laboratories, Accrediting Bodies and
The NELAC Institute

Presented By:
Jack Farrell
Analytical Excellence, Inc.
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Discussion Objectives

- The Importance of having a National Consensus Standard
- Myths, Perception and Reality regarding implementing the TNI Standards
- TNI tools and assistance to laboratories seeking accreditation
- Some suggestions and tips in preparing for implementation of the TNI Standards



The Importance of a National Standard – Essential Elements

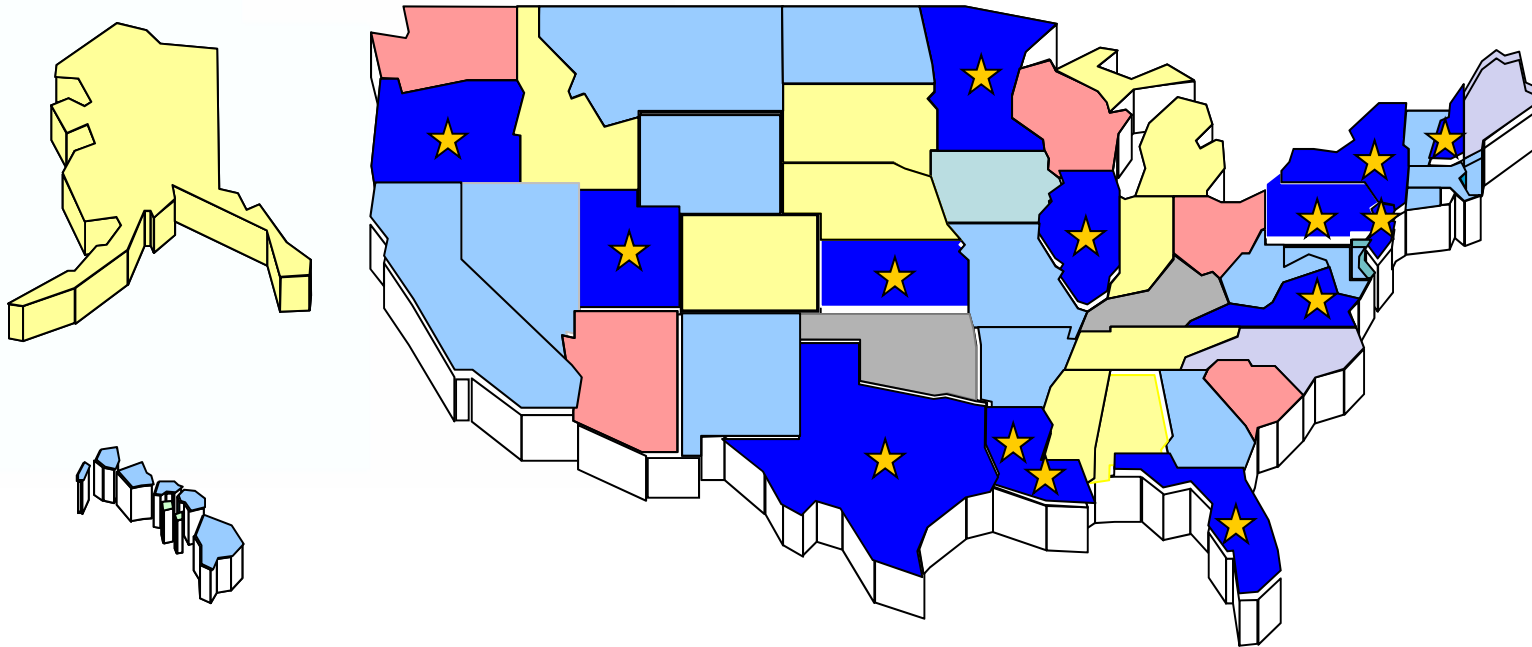
- Consensus development
- Based on national and international standards
- Data of known and documented quality
- Historical reconstruction – measurement traceability
- Protecting the public health and environment
- Over 10 years of concerted effort from inception to refinement into a mature standard
- Defensible, implementable and auditable









Environmental Laboratory Standards that are Accepted Nationally



The National Program Today



-  NELAP Accreditation Body
-  Working on Application
-  Accept NELAP
-  Incorporate NELAP elements
-  State program with significant differences
-  Drinking water only



Why Does Data Get Challenged?



Why Challenge Data?

- The events of the day – Flint, Michigan, etc.
- Protection of health and environment
- Data not sufficiently documented
- Can't recreate what was done (historical reconstruction)
- Questionable analytical practices
- Defensibility
 - Scrutiny of laboratory data
 - Enforcement actions
 - Reliability



A Quality Systems Standard to Support the Technical Aspects of Testing

- Adds to the protection of the end user, the laboratory, public health and the environment
- Because the result is not the only thing that is important
- Strengthens consistency and comparability of information
- Traceability of measurements – reconstruction
- Adds integrity to the testing results
- Provides the *“Ability to sleep better at night”*

Myths, Perception and Reality

There are at least three ways of looking at everything



Do You Do These Activities?

- Keep training records
- Demonstrations of competency and proficiency
- Standard Operating Procedures
- Control and traceability of reagents and standards
- Calibration of equipment and instruments
- Control of documents and records
- Internal audits
- Corrective actions
- Data integrity training
- Control samples and receipt
- Training to SOPs vs. tribal serial training
- Write down what you do
- Meet method requirements
- Have external audits
- Control purchasing of supplies
- What else?

What Do You Think?

Myth, Perception or Just Reality

- I don't need all this documentation. My clients just want the numbers and don't care about anything else.

I don't know, maybe just perception, but compliance data requires historical reconstruction.

- I will have to create a whole new bureaucracy to incorporate this Standard.

Myth, very small to small labs implement as a part of their current quality assurance system.

- I know what I am doing...what else is necessary?

Fact, but if you can't back up from documents and records what was done, it is not acceptable for compliance data.

- I will have to hire more staff....no budget.

I don't know, but labs with small budgets and no additional staff make it work.



What Do You Think?

Myth, Perception or Just Reality

- It's all documents and records.
Largely factual, but it is also a change in paradigm thinking and managing operations to assure data of known and documented quality.
- It's all for the auditors.
Myth, the purpose is not to please auditors or make their job easier. As long as the information is readily available, it is up to the lab to decide how to organize and manage.
- I really don't understand the Standard. It's too complicated.
Fact, that is why the States and TNI have a variety of resources, tools and training to assist all sized labs.
- Small municipal labs are going to be closing because of all this extra work.
Perception, but not related to the TNI Standard. It may be in how the management implements, the economy, need or some other reason.

What Do You Think?

Myth, Perception or Just Reality

- I already do this stuff; why do I have to prove that I do it?
Perception, because it is the world we operate in.
- NELAP accreditation is only required for commercial laboratories.
Myth, data is data; why would lab requirements differ?
- This stuff is only needed by large laboratories.
Perception, a quality system may help a large lab's efficiency more. Quality management is applicable to all sizes of labs.
- Assessments are just arbitrary and inconsistent opinions.
Perception, you just made the case for a consensus nationally accepted standard of performance.



The Facts of the Matter

Almost all environmental compliance and management decisions are based on measurement data.

Credible measurements of *known and documented quality* are absolutely critical in making accurate, cost effective decisions by regulators and industry in protecting our environment and the public health.

What Have States Done to Help Labs Comply?

- Training
- Helplines
- Checklists and guidance
- Assessor training
- Active regional laboratory organizations
- Tools, templates, checklists, networking

What Tools and Resources TNI Provides

Taken from presentations developed by the TNI
Advocacy Committee and Executive Director

TNI Resources

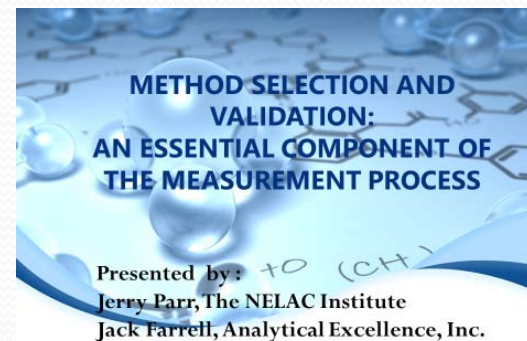
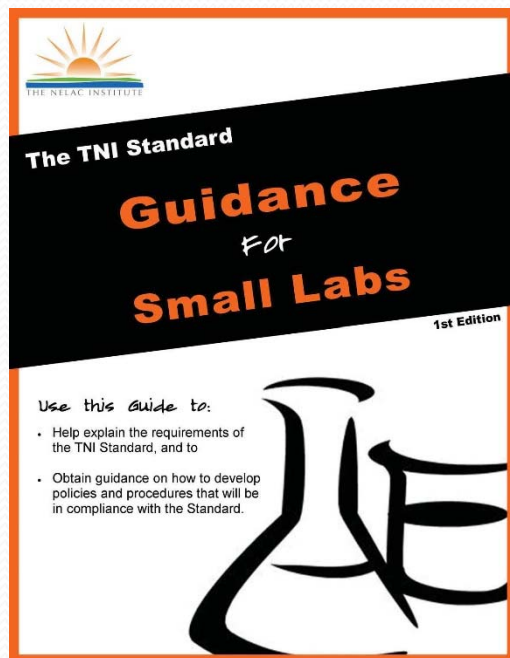
Course 2-1013: Implementing the 2009 TNI Standard

The objective of this course is to help laboratory management understand the requirements of the 2009 TNI Standard. The material will "demystify" terminology, provide assistance in understanding the requirements, and provide guidance on how to incorporate the requirements of the Standard into laboratory operations without disrupting current practices.



Internal Audits for Small Municipal Laboratories

Tiffini Adams
Quality Assurance Officer
Central Valley Water Reclamation Facility
Salt Lake City, UT



LAMS: Find
Labs, Methods and
Analytes



Accreditation/
Certification
Program Profiles



TNI
Documents and
Presentations



Education and
Training
Opportunities

Technical Assistance

- Small Laboratory Handbook
 - Tips and hints for implementing the TNI Standard
- Quality Manual Template
 - Fill in the blank template
- TNI Standard Webcast
 - 16-hour comprehensive training on the TNI Standard
- TNI Quality Systems Webcast Lectures
 - A series of 10 lectures on various topics (e.g., data integrity, corrective actions, LOD/LOQ)



Technical Assistance

- Listing of consultants to help laboratories
- How to get accredited flow chart
- Quality Systems checklist
- Standards Interpretations
- Small Laboratory Advocacy Group bulletin board
- Assessment Forum and Mentor Sessions
- Fields of Proficiency Testing Tables
- LAMS



Assessment Forum and Mentor Sessions

- Making Internal Audits Effective
- Internal Audits for Small Municipal Laboratories
- Practicing Root Cause and Corrective Action
- Microbiology QA/QC Requirements
- Meeting TNI Standard Requirements for Microbiology
- Writing Findings
- What a QA Officer Really Does...
- Following the Yellow Brick Road to Managing Quality
- Top 10 Suggestions on Being a Better QA Officer
- ...and many more

<http://www.nelac-institute.org/content/tnidocs.php>

Laboratory Accreditation Management System (LAMS)

- Searchable database of accredited laboratories
- Method Table
 - 4,116 methods
 - Includes approvals in 136 and 141
 - Includes links to methods
- Analyte Table
 - 3,219 analytes



Downloadable Webcasts

- Corrective Action Process and Root Cause Analysis
- Theoretical and Practical Consideration for Establishing Sensitivity of Measurements
- Internal Audits and Management Review
- Ethics Training for the Environmental Professional
- Establishing a Data Integrity Plan
- Defining Organizational Responsibilities
- Method Selection and Validation
- Etc...





Webinars Planned for 2016

- The TNI Radiochemistry Standard
- 2016 TNI Standard
- How to Select Instrumentation
- ????
 - Send us your suggestions for training
 - Send us a proposal to provide training



Other Member Benefits

- Access the TNI Methods Compendium, an on-line portal to copies of over 3,000 environmental testing methods.
- Networking capabilities and access to colleagues and experts nationwide.
- No charge to use the TNI Generic Laboratory Application.
- Access the Stationary Source Audit Sample Statistics for no charge.

Preparing to Successfully Apply For and Gain Accreditation



It's a Journey - Not a Race

- Read the Standard
- Understand what is required
- Look critically at your current operation and identify potential “gaps” that need to be addressed
- Plan the development and implementation
- DO NOT OVERTHINK THE PROCESS
- Develop the accreditation system for your laboratory - not the auditors
- If you have the flexibility, start small and grow



It's a Journey - Not a Race

- Don't think you have to know everything
- Get help from experts, colleagues and the Accrediting Body staff
- Take advantage of training opportunities
- Use the tools on the TNI website and other websites
- Implement the elements of the quality management system in pieces (*cut the elephant up into small pieces*)



Tough Challenges

- Mind set and commitment (change in the paradigm)
- Getting over the past
- Dealing in facts, not perceptions
- Adequate record keeping and documentation
- Measurement and standards traceability
- Recognize that it is going to take time and effort (at least initially)



Steps to Consider

- Read and understand the Standard – not the easiest task (how many times?)
- Document, document, document
- Let go of the past – *it ain't that way no more*
- Get help – network, workshops, lab associations, consultants, etc.
- Go visit a lab or two that has implemented the Standard
- Think through your accreditation needs – which fields of testing do you really need
- Establish a written development and implementation plan with time tables (six months to two years)



Steps to Consider

- Read and understand the Standard
- Don't reinvent the wheel – learn from others
- Have detailed standard operating procedures
- Remember the quality management system only needs to be as detailed and complex as your operation requires
- Address all of the applicable provisions of the Standard



Closing Comments

- Accreditation to the TNI Standard is not for everyone.
- If you are providing compliance data, a mature quality management system has many benefits.
- It takes focus, time and effort.
- It helps assure data of known and documented quality.
- It takes a lot of effort and years to develop an acceptable accreditation system.
- Why reinvent the wheel?
- Small and very small labs can and do successfully implement the TNI Standard



Thank you for your attention and opinions.

Any questions or last words?

Analytical Excellence, Inc.



Quality Systems

Compliance Mgmt.

Profitability

AEX@ix.netcom.com

(407)331-5040 (voice)

(407) 331-4025 (Fax)

812 Po... Place, Altamonte Springs, FL 32701