



Laboratory Challenges with TNI Implementation and Laboratory Audits

December 14, 2017

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California's Challenge with Implementing New Regulations Based on TNI

- In 1988, the California Environmental Laboratory Improvement Act established the State's **Environmental Laboratory Accreditation Program (ELAP)** to provide evaluation and accreditation of environmental testing laboratories
- ELAP accredits nearly 600 in-state and 100 out-of-state labs
- In 2016 ELAP decided to adopt regulations based on the 2016 TNI Standard, Volume 1
- In August 2017 ELAP released Preliminary Draft Regulations (PDR) that were reviewed by labs
 - Labs submitted comments to ELAP on PDR; still under review
 - Revised regulations may not be adopted until mid to late 2018
 - In the meantime, labs must proceed with adopting TNI



Challenges with ELAP/TNI Audits

- In past years, audits were conducted by ELAP staff
- Recently, ELAP hired new staff and contracted with third party assessors to provide “TNI gap analysis” to help labs meet proposed draft regulations
- This fall ELAP conducted “practice assessments” at a few labs in Central Valley region using third party assessors





APHL QI Forum Call Objectives

Laboratories in California are concerned about adopting TNI given uncertainties about the final regulations and changes in auditing process

Objectives

- **Gain further knowledge about TNI implementation and audits**
 - **Lessons learned from labs in California recently inspected by third party auditors**
 - **Guidance from TNI expert lab, Pennsylvania Department of Environmental Protection Laboratories**



Challenges for Monterey County Health Department Laboratory

- **Quality Systems Manual – need guidance on language, format, amount of detail required**
- **Daily QCs logs - are ‘written procedures’ required?**
 - **Daily temperature, and pH and conductivity checks on reagent water**
 - **Lack procedures, except SOPs for actual sample analysis**
 - **Only recording daily values on log sheet**
- **Perform pipette calibration checks quarterly instead of annually**
 - **Takes one analyst about 10 hours to check all pipettes**
- **Test reports to include start time of sample analysis for tests with holding times 72 hours or less. Required for 12 of our 23 methods.**
 - **We do not have an interface from our LIMS system to our analytical computers. This is done by manually when entering results.**



California Labs Audit Experience

Merced and Kings Counties Public Health Laboratories

- **Background**
 - **Both labs share the same laboratory director and were recently inspected by third party (non-ELAP) auditors**
- **Audit**
 - **Audit based on TNI standards**
 - **Both labs performed well in meeting TNI technical requirements but need to work on management requirements**
 - **Audits were much longer and more rigorous than past ELAP inspections**
 - **Positive experience overall**



California Labs Audit Experience cont.

Lessons Learned

- **Prepare “audit packets” to demonstrate traceability**
 - **Similar to CLIA Quality Systems Review**
 - **Document traceability of 10 samples (per year)**
 - **For each sample, make copies of requisition, worksheet, QC of all equipment, temp charts, etc used during sample analysis and reporting. Record serial & lot #s on worksheets, including lot # of disposable pipets**
- **If possible, create a single document/database containing all QA/QC data**
- **Staff should prepare to be interviewed**
- **If your lab uses IDEXX for bacteria testing but are not performing membrane filtration (MF), you need to document that you do NOT perform MF. Be aware that Colilert 18 and 24 have different storage temperature requirements.**
- **TNI certification is not affordable/economical for labs with revenues below \$10,000/year**



California Labs Audit Experience cont.

San Joaquin County Public Health Laboratory

- **Positive experience with third party auditor**
- **Length of audit longer than previous ELAP inspections**
- **Lab was judged based on mostly ELAP requirements, not TNI**
- **No TNI gap analysis performed**
- **Lab staff were interviewed**



Pasadena Water and Power

California's TNI Experience

Presented by
David Kimbrough, Ph.D., Water Quality Manager

Presented to
Association of Public Health Laboratories

Thursday, December 14, 2017



Accreditation





How is Getting Accredited is like Getting on the Matterhorn?

Pasadena Water and Power



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There are Two Requirements

Pasadena Water and Power

Requirement

- Pay a Fee
- Be 117 cm Tall

Standard



Purpose

Stay in Business



Safety

**You Either Have a Ticket or You Do Not
You are Either 117 cm Tall or You are Not
It is a Requirement with Clear Standards and**

PASADENA



How Do You Get Accredited by ELAP?

Pasadena Water and Power

Environmental Laboratory Accreditation Program



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There are Four Requirements

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Requirement

- Fill Out a Form
- Pay a Fee
- Pass a PT
- Pass an On-Site Assessment

Standard



Purpose

Know the Lab

Stay in Business

Know Ability

Know Capabilities

These Are Requirements with Clear Standards and Purposes

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USEPA Method 150.1 Equipment

Pasadena Water and Power

- Requirement - Section 5

- Standard

Purpose

A Lab Needs a pH Meter and Equipment to Determine pH

5.0 Apparatus

- 5.1 pH Meter-laboratory or field model. A wide variety of instruments are commercially available with various specifications and optional equipment.
- 5.2 Glass electrode.
- 5.3 Reference electrode-a calomel, silver-silver chloride or other reference electrode of constant potential may be used.
NOTE 1: Combination electrodes incorporating both measuring and reference functions are convenient to use and are available with solid, gel type filling materials that require minimal maintenance.
- 5.4 Magnetic stirrer and Teflon-coated stirring bar.
- 5.5 Thermometer or temperature sensor for automatic compensation.



A Laboratory Either Has a pH meter, stirrer, sensors or it does not.

It is a Requirement with Clear Standards and Purpose

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USEPA Method 150.1 Buffers

Pasadena Water and Power

- Requirement - Section 6

- Standard

- Purpose

A Lab Needs a Calibration Buffers to Determine pH

6.0 Reagents

- 6.1 Primary standard buffer salts are available from the National Bureau of Standards and should be used in situations where extreme accuracy is necessary.
 - 6.1.1 Preparation of reference solutions from these salts require some special precautions and handling⁽¹⁾ such as low conductivity dilution water, drying ovens, and carbon dioxide free purge gas. These solutions should be replaced at least once each month.
- 6.2 Secondary standard buffers may be prepared from NBS salts or purchase as a solution from commercial vendors. Use of these commercially available solutions, that have been validated by comparison to NBS standards, are recommended for routine use.



A Laboratory Either Has a pH Calibration Buffers or it does not.

It is a Requirement with Clear Standards and Purpose



USEPA Method 150.1 Calibration

Pasadena Water and Power

- Requirement - Section 7

- Standard

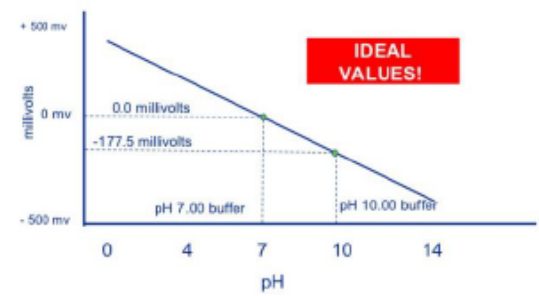
- Purpose

A Lab Needs to Calibrate the Meter to Determine pH

7.0 Calibration

- 7.1 Because of the wide variety of pH meters and accessories, detailed operating procedures cannot be incorporated into this method. Each analyst must be acquainted with the operation of each system and familiar with all instrument functions. Special attention to care of the electrodes is recommended.
- 7.2 Each instrument/electrode system must be calibrated at a minimum of two points that bracket the expected pH of the samples and are approximately three pH units or more apart.
 - 7.2.1 Various instrument designs may involve use of a "balance" or "standardize" dial and/or a slope adjustment as outlined in the manufacturer's instructions. Repeat adjustments on successive portions of the two buffer solutions as outlined in procedure 8.2 until readings are within 0.05 pH units of the buffer solution value.

pH Electrode Calibration Curve



A Laboratory Either Calibrates its pH meter or it does not.

It is a Requirement with Clear Standards and Purpose



USEPA Method 150.1 Procedure

Pasadena Water and Power

- **Requirement - Section 8**

8.0 Procedure

8.1 Standardize the meter and electrode system as outlined in Section 7.

8.2 Place the sample or buffer solution in a clean glass beaker using a sufficient volume to cover the sensing elements of the electrodes and to give adequate clearance for the magnetic stirring bar.

8.2.1 If field measurements are being made the electrodes may be immersed directly in the sample stream to an adequate depth and moved in a manner to insure sufficient sample movement across the electrode sensing element as indicated by drift free (< 0.1 pH) readings.

8.3 If the sample temperature differs by more than 2°C from the buffer solution the measured pH values must be corrected. Instruments are equipped with automatic or manual compensators that electronically adjust for temperature differences. Refer to manufacturer's instructions.

8.4 After rinsing and gently wiping the electrodes, if necessary, immerse them into the sample beaker or sample stream and stir at a constant rate to provide homogeneity and suspension of solids. Rate of stirring should minimize the air transfer rate at the air-water interface of the sample. Note and record sample pH and temperature. Repeat measurement on successive volumes of sample until values differ by less than 0.1 pH units. Two or three volume changes are usually sufficient.

8.5 For acid rain samples it is most important that the magnetic stirrer is not used. Instead, swirl the sample gently for a few seconds after the introduction of the electrode(s). Allow the electrode(s) to equilibrate. The air-water interface should not be disturbed while measurement is being made. If the sample is not in equilibrium with the atmosphere, pH values will change as the dissolved gases are either absorbed or desorbed. Record sample pH and temperature.

- **Standard**



- **Purpose**

A Lab

Needs to
Operate the
Meter

Correctly to
Determine
pH

A Laboratory Either Operates its pH meter according to the Method or it does not. It is a Requirement with Clear Standards and Purpose

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TNI





Hundreds of Requirements

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Section	Text 1
4.0	Management Requirements
4.1	Organization
4.1.1	The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.
4.1.2	It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities
4.1.3	The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration are:
4.1.5	The laboratory shall:
4.1.5 a	have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the
4.1.5 b	have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;
4.1.5 c	have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
4.1.5 d	have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;
4.1.5 e	define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;
4.1.5 f	specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;
4.1.5 g	provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;
4.1.5 h	have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;
4.1.5 i	appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is
4.1.5 j	appoint deputies for key managerial personnel
4.1.5 k	ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.
4.1.6	Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management
4.1.7	Additional Requirements for Laboratories
4.1.7.1	Where staffing is limited, the technical manager and the quality manager may be the same person.
4.1.7.1 a	The laboratory's quality manager and/or his/her designee(s) shall:
4.1.7.1 a	serve as the focal point for QNQC and be responsible for the oversight and/or review of QC data;
4.1.7.1 b	have functions independent from laboratory operations for which they have QA oversight;
4.1.7.1 c	be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;
4.1.7.1 d	have documented training and/or experience in QA/QC procedures and the laboratory's quality system;
4.1.7.1 e	have a general knowledge of the analytical methods for which data review is performed;
4.1.7.1 f	arrange for or conduct internal audits as per Section 4.14 annually;
4.1.7.1 g	notify laboratory management of deficiencies in the quality system; and
4.1.7.1 h	monitor corrective actions.
4.1.7.2	The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:
4.1.7.2 a	be a member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results;
4.1.7.2 b	be experienced in the fields of accreditation for which the laboratory is seeking accreditation;
4.1.7.2 c	have duties that include:
4.1.7.2 c i	monitoring standards of performance in QC and QA, and
4.1.7.2 c ii	monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.
4.1.7.2 d	not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body
4.1.7.2 d+a	Circumstances to be considered in the decision to grant such authorization shall include:
4.1.7.2 d i	the extent to which operating hours of the laboratories to be directed overlap,
4.1.7.2 d ii	adequacy of supervision in each laboratory, and
4.1.7.2 d iii	the availability of environmental laboratory services in the area served.
4.1.7.2 e	if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the technical manager(s) to temporarily perform this function.
4.1.7.2 e+a	If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing, and



Purchasing

Pasadena Water and Power

4.6 Purchasing Services and Supplies (ISO/IEC 17025:2005, Clause 4.6)

4.6.1 *The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.*

4.6.2 *The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.*

4.6.3 *Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.*

NOTE: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

4.6.4 *The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.*



Purchasing Requirements

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- **Requirement 4.6.2 – 3 - 4**

Does the laboratory ensure that supplies & services comply with specified requirements?



- **Standard**

What specified requirements?

How does ELAP assess this?

- **Purpose**

How Does

This Protect Public Health

It is a Standardless Requirement

It Serves No Purpose

It is Vague and Subjective

PASADENA



Purchasing Requirements

Pasadena Water and Power

Quality Manual for PWP WQL

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10.0 Purchasing Services and Supplies (TNI Volume 1, Module 2, Section 4.6)

10.1 Background

It is the policy of the WQL to use the purchasing and procurement program required by the Purchasing Procedures Manual of the City of Pasadena's Finance Department, Purchasing Division (<http://ww5.cityofpasadena.net/city-manager/wp-content/uploads/sites/37/2017/05/Exhibit-48.pdf>).

10.2 Purchasing

It is the policy of the WQL to only accept delivery of those products that were ordered by WQL staff.

10.3 Quality

It is the policy of the WQL to only use products that do not negatively impact the quality of the laboratory results. If any product is found to negatively impact the quality of the laboratory results, it will no longer be used or ordered.

10.4 Documents

All documents part of the purchasing process are retained in a manner consistent with the Purchasing Procedure's Manual.

For This Lab to Be Accredited for pH TNI Adds



Module 1: 72 Items
Module 2-4: 281 Items
Module 2-5: 352 Items
Module 4: 329 Items
Total: 1,034



California Experience So Far

Pasadena Water and Power

California ELAP is Currently Contracting with NV5 to do TNI-like Assessments On Drinking Water Accredited Laboratories

- The Goal was:
 - Training of ELAP Staff
 - Providing Labs with sort of Gap Analysis
 - Reduce ELAP's OSA Backlog
- The Laboratories were not Expected to be TNI Compliant
- **The On-Site Assessment takes Two to Three Times as Long**
- The Actual Technical Assessment is largely the same.

Conclusions





pennsylvania

DEPARTMENT OF ENVIRONMENTAL PROTECTION



Bureau of Laboratories

Quality Improvement through TNI Standard Implementation and Audits A State's Story

PA DEP Perspective
December 14, 2017

Tom Wolf, Governor

Patrick McDonnell, Executive
Secretary

Quality Improvement Stories

- Why PA implemented the TNI Standard and Quality (Management) System Approach? Similar to other states?
- Getting started to implement the TNI Standard
- What happens when we have FINDINGS in the audit process?
- How do we afford accreditation fees?

▶ Purpose of Laboratory Accreditation

- The laboratory accreditation program (LAP) was established to protect the public health, safety, welfare, and the environment by ensuring the accuracy, precision, and reliability of data generated by environmental laboratories.
- An accredited laboratory will more likely generate data of appropriate quality for a particular analysis because of its quality system.

Source: 25 Pa Code § 252.2 Scope

Quality (Management) System Approach

- Developed using a consensus process that included the perspectives of multiple stakeholders including EPA, laboratories and state agencies.
- Used a recognized international standard for the competency of laboratories (ISO/IEC 17025) as the basis.
- Added additional specificity to address 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*).

Why the TNI Standard

A 501(c)3 non-profit organization.

A member organization managed by a Board of Directors.

Over 1000 members

A voluntary consensus standards development organization accredited by the American National Standards Institute (ANSI).

Why the TNI Standard

- The authority to administer an accreditation program comes from each participating state's statutes and regulations.
- PA Laboratory Accreditation Act 2002
- CA State Water Resources Control Board (State Water Board) ELAP Regulations July 2017 Preliminary draft
- EPA continues to have a key oversight function for drinking water.
- TNI provides the infrastructure to facilitate communication and consistency.

Guiding Principles of TNI Standard

- **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 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, complexity and scope of services.
- **Appropriate:** Ensure that data is of known quality and that the quality is adequate for the intended use.

TNI Standard

TNI Standard

- Requirements
 - Management
 - Technical
 - Records
 - QA Manual
 - Personnel
 - QC
- Analyze 2 PT samples per year and pass 2 out of 3
- Assessment every 2 years

2009 2016 TNI STANDARD

- Uses ISO/IEC 17025 quality system approach,
- Adds specificity to improve clarity and help with consistency for environmental testing,
- Allows flexibility in meeting requirements,
- Represents best professional practice, and
- Allows for multiple Accreditation Bodies to implement consistently.
- Includes data integrity component missing from ISO 17025
 - Internal Audit requirements for frequency, timeliness, and notification to affected clients (V1M2:4.15.5)
 - Data Integrity Investigations must be confidential and documented (V1M2: 4.16)
 - Data Integrity Training requirements for all employees (V1M2: 5.2.7)

Organization of TNI Laboratory Std

- 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

Quality System Module

Section 4: Management Requirements

- Implementation of a quality system
- Management requirements
- Documents and records
- Internal assessments
- System controls and improvements

Comparable to ISO 9000, these requirements are good management practices to ensure analyses are performed in an orderly and structured way.

Quality System Module

Section 5: Technical Requirements

- Technical competence of staff
- Validity and appropriateness of test methods
- Traceability of measurements
- Instrument calibration
- Testing environment
- Sampling, handling and transportation of samples
- Quality assurance of test data
- Reporting

These requirements focus on ensuring reliable and accurate data.

Advantages of TNI NELAP

- Uses a consensus standard that is widely recognized as the gold standard for environmental laboratory accreditation.
- Relies on peer oversight to ensure all participating ABs are competent to operate accreditation programs.
- Utilizes TNI resources (assessor training, national database, Fields of Proficiency Testing, webinars, etc.) to leverage state resources.
- Membership gets to fully participate in the process and help guide the future.

What Does a Standard Look Like

4.14 Internal Audits (ISO/IEC 17025:2005(E), Clause 4.14)

4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit shall address all elements of the management system, including the testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

TNI Resources

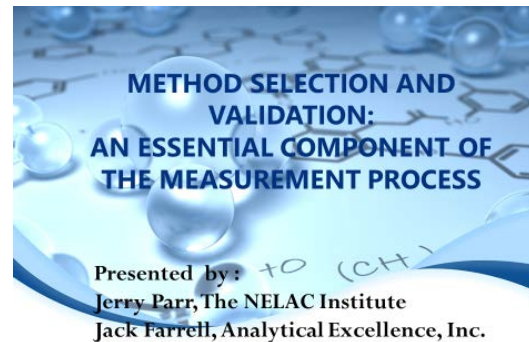
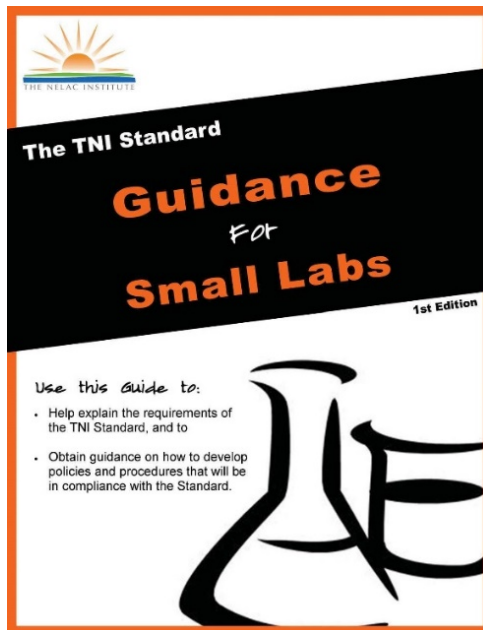
Course 2-1013: Implementing the 2009 TNI Standard

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



Technical Assistance for Laboratories

- Small Laboratory Handbook
 - Tips and Hints for implementing the standard
- Quality Manual Template
 - Fill-in-the-blank template ready to tailor to any lab
- TNI Standard webcast
 - 16-hour comprehensive training on the TNI Standard
- Listing of consultants to help laboratories
- “How to get accredited” flow chart
- Quality Systems checklist
- Standards Interpretations
- Small Laboratory Advocacy Group
- Fields of Proficiency Testing Tables
- List of Third-party Lab Assessors

Assessment Forum and Mentor Sessions

☐ Held in Conjunction with TNI Meetings

- 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>

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...



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

Audit Processes

- Assessment of Laboratory Operations
 - On-site and through data review
 - SOPs, data, PT performance, training, recordkeeping, sample receipt and handling procedures, equipment, etc.
- Assessment of Laboratory Personnel
 - Laboratory Supervisor qualifications and capability, analyst training and competence
- Assessment of Laboratory Management System
 - SOPs and Quality Manual, internal audits, management reviews, preventive actions, corrective actions, complaint investigations and resolution procedures, etc.

Most Common Findings From Assessments

- Not following SOP
- Data integrity training
- Internal audits
- Records

Examples of Data Integrity Training

- Improper Manual Integrations:
 - Adding or removing peak area to have QC appear to pass
 - Arbitrarily separating co-eluting peaks into separate compounds based on retention times
 - Selecting the wrong peak so that the reported result is ND or <QL
 - Arbitrarily selecting peak area that cannot be distinguished from instrument noise

How do you Implement the TNI Std

- Management Commitment to Quality –
 - beyond compliance
 - corporate culture
- Defined Chain of Command and Reporting Responsibilities
- Ethics Training
- Continual Re-Assessment of Analytical Capability/Laboratory Capacity
- Management Reviews
- Continuous Monitoring and Training
- External Audits/Consultants
- Preventive Instrument Maintenance
- Standard Operating Procedures

Continued Compliance

- Corrective Action Report
 - Root Cause Determinations
 - Corrective Actions
 - Follow-up on Effectiveness of Corrective Actions
- Self-Monitoring
- Re-training of Analysts
- Upgrade/Purchase New Instrumentation
- Manage staff, objectives, train, follow up

Tips from PA BOL

Leadership

Practice On-sites – Lab Improvement

Findings for one section may be applicable to lab

Recommendations – may be simplified

Auditors are not the enemy

There is no such thing as a perfect score

In Summary

- Accreditation reflects capability
- Accountability and compliance is the laboratory's responsibility
- Management is the first line of defense
- Focus on Preventive Action and Root Cause Investigations
- Findings are for laboratory improvement
- Reliable and defensible data means safer and healthier environments and citizens



QUESTIONS?

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