



Bureau of Laboratories

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Laboratory Improvement Through Accreditation

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Overview

- 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?

The Why - 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.

▶ Guiding Principles of TNI Standard-Getting Started

- **Flexible:** Allow labs freedom to use experience and expertise in performing 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

TNI 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.

TNI 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.

▶ Continued Compliance - Improvements

- 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 for Lab Improvements

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

▶ Process for Lab Improvement

- Proactive Improvement Measures
 - Laboratory Initiated
 - Preventive
- Reactive Improvement Measures
 - Response to Assessment/Deficiency Report
 - Customer Complaints
 - Mandated by Accreditation Body

Proactive Improvement Measures

- 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

▶ Assessment/Audit Process for Lab Improvement

- Assessment of Laboratory Operations
 - Interviews and thorough data review
 - SOPs, PT performance, training, recordkeeping, sample receipt and handling procedures, equipment, etc.
- Assessment of Laboratory Personnel
 - Laboratory Supervisor qualifications and capability, analyst training and competence
- Complaint Investigations
 - Complaints from other laboratories, customers, employees, DEP Programs, NELAP accreditation bodies, etc.

Identify Areas of Improvement

- Absentee/Ineffective Laboratory Management
- Failure to Report Accurate Results
- Data Approval by Untrained/Unqualified Analysts
- Improper Manual Integrations
- Improper Sample Analysis
- Use of Malfunctioning Equipment
- Analyst Failures
- Improper Handling of PT Samples
- Drinking Water Reporting Problems
- Dry-Labbing/Falsification of Data Records

▶ Return to Compliance and Lab Improvement

- Corrective Action Report
 - Root Cause Determinations
 - Corrective Actions
 - Follow-up on Effectiveness of Corrective Actions
- Self-Reporting/Notification to DEP
- Re-training of Analysts
- Upgrade/Purchase New Instrumentation
- Hire New Staff
- Termination of Staff
- Notice to Clients

▶ Return to Compliance and Lab Improvement

- Consider contracting with a third party auditor for training, practice audits or consulting to assist with corrective actions
- Internal Audits of some or all of past data, reissue amended test reports
- Rotate Analysts/Cross-Training Opportunities
- Participate in training offerings from instrument manufacturers
- Attend TNI Meetings, participate in standard development

Lab Improvements Limit Resolution of Liability

- Lab Accreditation Act provides for remedies available by law
- DEP can order corrective actions
 - Designed to stop harm caused by violations
 - Administratively or in court
 - Unilaterally or with consent
- Civil Penalties
 - Deter; remove economic benefits of noncompliance
 - Unilateral or with consent
- Criminal enforcement – PA Attorney General, EPA

Potential Consequences of Non-Compliance Not Addressed

- Consent Order and Agreement
- Consent Assessment of Penalties
- Disqualification of a Lab Supervisor
- Denial, Suspension, Revocation of Accreditation
- Civil Enforcement in courts
- Criminal Investigation, Prosecution, etc.

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



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