ENVIRONMENTAL LABORATORY SECTOR

Basic Assessor Training Course Curriculum

TNI Guidance Document

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BASIC ASSESSOR TRAINING COURSE CURRICULUM
A TNI GUIDANCE DOCUMENT

INTRODUCTION

Volume 2 of the TNI Environmental Laboratory Sector Standard requires that all accreditation body assessors take and pass a course in conducting on-site assessments using the TNI standards. This is a guidance document that gives a recommended course outline and examination design.

Part of the purpose of the TNI standards is to ensure consistency of the on-site assessment. The spirit of TNI fosters the sharing of expertise. So, while the Committee acknowledges that many assessors have a lot of experience in performing assessments; all assessors still need to fulfill the training requirements. There is no provision for "testing out" of the course. Some specific topics may be covered by homework assignments and/or handouts supplemented by discussion as needed to fit the material into the time allotted.

This is a living document and as all stakeholders participate in the training process the Committee hopes to receive feedback on the content and effectiveness of the guidance document.

The instructor may use whatever content delivery format they desire as long as the course provides the opportunity for ample interaction between instructors and participants and includes exercises designed to be completed by teams of participants. The material may be covered in whatever order the instructor finds most beneficial. The standards have been grouped by topics. The Committee has indicated portions of the outlines that it thinks should be emphasized by putting them in blue type.

The instructor may decide the length of the course but must allow adequate time to cover all portions of the outline. While the standards primarily determine what should be covered, the instructor should be mindful of teaching the assessors how to ensure the standard's requirements are met. Instructors need to demonstrate how all the elements of the standards are a tool to determining patterns and trends, good and bad, in the laboratory. We recommend the course be at least two days.

Accrediting bodies are responsible for ensuring that their assessors are properly trained. Therefore, it would be in the best interest of instructors to maintain credentials and qualification statements and make them available upon request. Instructors should provide participants with proof that they have attended and passed the course.

Instructors should provide a mechanism for feedback on the course. These course evaluations should be made available to the accrediting bodies and TNI.

- History of TNI and the standard development process
- Accrediting Body General Requirements (V2M1)
- Quality System General Requirements (V1M2)
- Quality System Technical Disciplines (V1M3-7)
- On-site Assessment (V2M3)
- Proficiency Testing

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History of TNI and the Standards Development Process

1. **History of TNI**
   - 1.1. Regulatory status of Environmental Community in 1990s
     - 1.1.1. Patchwork of widely varying state and federal agency program requirements and certifications
     - 1.1.2. Unwitting and unwilling *de facto* laboratory certification for large commercial laboratories by EPA Contract Laboratory Program
     - 1.1.3. Little focus on quality systems or management systems approach
   - 1.2. Group of Stakeholders
     - 1.2.1. State Certification agencies
     - 1.2.2. EPA
     - 1.2.3. Other federal programs-DOD, DOE, etc.
     - 1.2.4. Tribes
     - 1.2.5. Labs: commercial and government
     - 1.2.6. Other: standards manufacturers, consultants, etc.
   - 1.3. CNAEL
     - 1.3.1. Chartered in 1991
     - 1.3.2. Federal Advisory Committee Act (FACA) to explore the possibilities of a national program and provide recommendations to EPA concerning the alternatives for a national program
     - 1.3.3. Members represented the stakeholder community (federal, state accrediting programs, commercial laboratories, etc.)
   - 1.4. NELAC
     - 1.4.1. Officially established in 1995
     - 1.4.2. Standards setting organization
     - 1.4.3. NELAP established in 1999
   - 1.5. NELAC/INELA-Standards development split from standards adoption and implementation
   - 1.6. TNI
     - 1.6.1. Established in 2006
     - 1.6.2. Non-governmental entity to manage standards development, adoption implementation, and ancillary functions.

2. **ISO Accreditation Model**
   - 2.1. Quality System Registration vs. Accreditation
   - 2.2. ISO 17025
   - 2.3. ISO 17011

3. **Goals of the TNI Accreditation Program**
   - 3.1. Known and Documented Quality
   - 3.2. Consistent Nationwide Standard with Reciprocity
   - 3.3. Incorporation of ISO Principles-Focus on Quality System
   - 3.4. Adapted Specifically for Environmental Laboratories
   - 3.5. Inclusion of All Stakeholders

3.6. Flexibility in Meeting Requirements
3.7. Appropriate for all Laboratory Sizes
3.8. Able to be Assessed

4. Standards Development Process
4.1. Expert Committees
4.2. Voluntary Consensus Standards Body
4.2.1. Openness
4.2.2. Balance of interest
4.2.3. Due process
4.2.4. Appeals process
4.2.5. Consensus
4.3. Standard flow
4.3.1. Working Draft Standard
4.3.2. Voting Draft Standard
4.3.3. TNI Standard
4.4. Voting Process

5. Structure of TNI
5.1. Standards Development
5.2. Make-up of Committees
5.2.1. Voting Members
5.2.2. Associate Members
5.3. Standards Adoption
5.4. Structure of Standard-Module format
5.5. Standards Implementation
5.5.1. LASC
5.5.1.1.Membership and Structure
5.5.1.2.Responsibilities
5.5.2. NELAP
5.5.2.1.Membership (State ABs) and Structure
5.5.2.2.Responsibilities
5.6. Other
5.6.1. Proficiency Testing Program
5.6.1.1.PT Board
5.6.1.2.Providers
5.6.1.3.Accreditation
5.6.2. Advocacy Program
5.6.3. Technical Assistance
5.6.4. Forum on Laboratory Accreditation
5.6.5. Conference Planning
5.6.6. Policy
5.6.7. Website

Management and Technical Requirements for Laboratories Performing Environmental Analysis

Accreditation Body Requirements
General Requirements
Volume 2, Module 1

1. **Legal Responsibility and Structure (section 4.1)**
   - 1.1. An Accreditation Body must be a legally defined entity with no conflicts of interests with any governmental Conformance Assessment Body. (CAB)
   - 1.2. Always a government agency
   - 1.3. Structure must give confidence in its accreditations.

2. **Authority**
   - 2.1. Must have complete authority over its accreditations although able to subcontract portions of the process

3. **Effects of secondary accreditation on the approval process and the onsite inspection**

4. **Rules, duties, and procedures of the AB must be written.**
   - 4.1. Impartial in its activities to all interested parties. Give examples of types of relationships involved

5. **Consultancy, AB's activities, limited fields of accreditation.**
   - 5.1. Confidentiality (section 4.4)
   - 5.2. Liability and financing sources must be defined (section 4.5)
   - 5.3. Accreditation Activity must be defined, including process for extending activities. (section 4.6)
6. **Development of guidance documents.**

7. **Management (section 5.0)**
   - 7.1. Draw parallels to the management system and tools required to be maintained by the CABs
     - 7.1.1. Management system has measurable goals and a QA officer
     - 7.1.2. Document Control
     - 7.1.3. Record keeping
     - 7.1.4. Nonconformities and corrective actions system
     - 7.1.5. Preventive Actions
     - 7.1.6. Internal audit requirements and frequency
     - 7.1.7. Management reviews and required inputs
     - 7.1.8. Complaints, appeals and disputes policies must be written.

8. **Human Resources (section 6.0)**
   - 8.1. Type of human resources needed, oversight of personnel, and records.

8.1.1. Relationship of personnel qualifications to area of responsibility
8.1.2. Demonstrated competence of assessors, training, and monitoring of assessment and assessor performance

9. Accreditation Process (section 7.0)

9.1. Application Criteria and relevant AB information must be publicized
9.2. Application for Accreditation must include methods used and Quality Systems Manual
9.3. Resource review to ensure timely action
9.4. Subcontracting the assessment including the meaning and limitations of subcontracting and oversight of assessor organization
9.5. Decision making and granting accreditation
9.5.1. Timelines
9.5.2. Consultancy prohibition
9.5.3. Conflict of interest possibilities
9.5.4. Reasons to deny an application or certificate
9.5.5. Items to be included on the CAB certificate.
9.6. Appeals Process
9.7. Reassessment and surveillance.
9.7.1. Types and purpose for each
9.7.2. Other surveillance activities permitted.
9.8. Extending Accreditation
9.9. Suspending, Withdrawing or Reducing Accreditation.
9.9.1. Reasons for action and consequences.
9.10. Required Record keeping on CABs
9.11. Proficiency Testing and Other comparisons for CABs

10. **Responsibilities of the AB and the CAB** (section 8.0)

10.1. Obligations of the CAB to maintain current information and cooperate with the AB
10.2. Obligations of the AB
10.2.1. Publicizing accreditation status
10.2.2. Notifying CABs of changes in requirements.
10.3. Accreditation and use of symbols.
10.3.1. Misuse of symbols
10.3.2. Improper accreditation claims - include checking CAB websites

Quality Systems General Requirements
Volume 1 Module 2

1. Quality System Checklist

1.1. Purpose

1.2. Proper use

1.2.1. How and when to complete the checklist

1.2.2. Techniques for using checklist for good assessments

1.2.3. Using to document findings

2. Management Requirements

2.1.1. Organization's key personnel and duties (Sections 4.1, 4.2 and 5.2.6.1)

2.1.2. Data Integrity System Components (section 4.2.8)

2.1.2.1. Documents to look for and how to evaluate

2.1.2.2. Management's role in the process

2.1.2.3. Data Integrity Investigations

2.1.2.4. Data integrity training (section 5.2.7)

2.1.3. The quality manual (section 4.2.8.3 and 4.2.8.4)

2.1.4. Standard Operating Procedures (SOP) (section 4.8.5)

2.1.5. Document and Record Control Systems (section 4.3)

2.1.5.1. Existence of System

2.1.5.2. Adequacy of systems

2.1.6. Subcontracting (section 4.5)

2.1.7. Corrective Action (section 4.11)

2.1.8. Preventive Action (section 4.12)

2.1.8.1. Cause Analysis

2.1.8.2. Selection and implementation of corrective action

2.1.8.3. Monitoring corrective action

2.1.8.4. Additional assessments

2.1.9. Internal Audits (section 4.14)

2.1.9.1. What documents to look for

2.1.9.2. Reviewing internal audits

2.1.9.3. Using internal audits to determine some areas for in-depth review and determine if similar issues exist in other areas of the lab

2.1.9.4. How to determine if corrective actions have been taken and are effective

2.1.10. Management Reviews (section 4.15)

3. Technical Requirements

3.1.1. Environmental Test Methods (section 5.4)

3.1.1.1. Method Selection

3.1.1.2. Method modifications

3.1.1.3. Laboratory Developed Methods

3.1.2. Support Equipment Calibration Requirements (section 5.5.13.1)

3.1.3. Measurement Traceability (section 5.6)

3.1.3.1. Reference standards and materials
3.1.3.2. Documentation and Labeling of Standards, Reagents and Reference Materials
3.1.4. Sample Collection and Handling
3.1.4.1. Sample acceptance policy
3.1.4.2. Documentation and tracking
3.1.4.3. Sample Storage
3.1.5. Essential Quality Control Procedures (section 5.9)
3.1.6. Reporting Results (section 5.10)

Quality Systems Technical Disciplines
Volume 1 Modules 3-7

1. **Introduction and Scope (sections 1.1 and 1.2)**

2. **Terms and Definitions (section 1.3)**

3. **Method Selection and Validation (sections 1.4 and 1.5)**

4. **Demonstration of Capability (DOC)**
   - 4.1. Initial satisfactory DOC (section 1.6.2)
   - 4.2. Ongoing DOC (section 1.6.3)

5. **Technical requirements (section 1.7)**

Note: training in specific disciplines is included in the Technical Assessor Training. This section is to provide an overview of the issues common to most or all of the disciplines for determining if there are systemic problems in the laboratory.

- 5.1. Initial and Continuing Calibration
  - 5.1.1. Asbestos (sections 1.7.1 and 1.7.5)
  - 5.1.2. Chemical (sections 1.7.1 and 1.17.2)
  - 5.1.3. Toxicity (section 1.7.)
  - 5.1.4. Radiochemistry (section 1.7.1)
  - 5.1.5. Microbiological (section 1.7.1 and 1.7.2)
- 5.2. Quality Control
  - 5.2.1. Asbestos (sections 1.7.2, 1.7.3, 1.7.4 and 1.7.6)
  - 5.2.2. Chemical (section 1.7.3)
  - 5.2.3. Toxicity (section 1.7.1)
  - 5.2.4. Radiochemistry (section 1.7.2)
  - 5.2.5. Microbiological (section 1.7.3)
- 5.3. Data Acceptance/Rejection Criteria
  - 5.3.1. Asbestos (section 1.7.7)
  - 5.3.2. Chemical (section 1.7.4)
  - 5.3.3. Toxicity (section 1.7.2)
  - 5.3.4. Radiochemistry (section 1.7.3)
  - 5.3.5. Microbiological (section 1.7.4)
- 5.4. Sample handling
  - 5.4.1. Asbestos (section 1.7.8)
  - 5.4.2. Chemical (section 1.7.5)
  - 5.4.3. Toxicity (section 1.7.3)
  - 5.4.4. Radiochemistry (section 1.7.4)
  - 5.4.5. Microbiological (section 1.7.5)

On-Site Assessment
Volume 2, Module 3

1. **Human Resources – The Assessor**
   - 1.1. Education and Training Requirements for Assessors (section 4.2)
   - 1.2. Records on Assessors (section 4.3)
   - 1.3. Conflicts of Interest (section 4.3.4)
   - 1.4. Standards of Professional Conduct for Assessors
     - 1.4.1. Section 4.4 of standard
     - 1.4.2. What constitutes professional and unprofessional behavior
     - 1.4.3. Conflict resolution
     - 1.4.4. Limitations of their authority while on-site.

2. **Frequency of On-site Assessments (section 5.0)**

3. **The On-site Assessment Process**
   - 3.1. Preparation for Assessment (section 6.3)
   - 3.2. Document and Record Review (section 6.4)
     - 3.2.1. What documents to be reviewed
     - 3.2.2. How to review the documents against TNI standards.
     - 3.2.3. Also see PT and Quality Systems outlines.
   - 3.3. Documents Provided to CAB (section 6.5)
     - 3.3.1. This section allows the AB to request documents for review before the assessment. This gives the AB the flexibility to review documents off-site. This can potentially decrease the time and expense of the assessment.
   - 3.4. Confidential Business Information (section 6.6)
   - 3.5. Length of Assessment and Time Management (section 6.7)
   - 3.6. Opening Conference (section 6.8)
   - 3.7. Assessment Activities (section 6.9)
     - 3.7.1. See outlines for Volume 1
     - 3.7.2. Interviewing Techniques
       - 3.7.2.1. Good interviewing techniques and the personal dynamics of the on-site assessment.
       - 3.7.2.2. Effective questioning techniques and methods for objective information gathering.
       - 3.7.2.3. How to assess analyst performance during interviewing i.e. observation of practical skills
       - 3.7.2.4. Options: participants get to conduct interviews using techniques learned or use examples of interviews i.e. video, interview transcript
   - 3.8. Offering Suggestions
     - 3.8.1. Types of appropriate suggestions
     - 3.8.2. How to offer suggestions
   - 3.9. Handling the Unexpected or Non Routine
     - 3.9.1. Key personnel not available

3.9.2. Changes in the scope of accreditation while on-site (section 7.0 of standard)
3.9.3. Missing documents and stalling
3.9.4. Inappropriate data manipulations and suspected fraud.
3.10. Closing Conference (section 6.11)

4. Reporting Procedures

4.1. Analysis of Findings and Assessment Report (Section 6.10)
4.2. Writing the report
4.2.1. How to clearly state the finding and which area of the lab in which it was found
4.2.2. Indicate that the lab should determine if this type of deficiency is in other areas of the lab
4.2.3. Giving the evidence for the finding
4.2.4. Supporting the finding with a requirement from the standard and/or method.
4.2.5. Using the quality system checklist – making sufficient accurate notes
4.3. Timelines for reporting and appropriate release of the report. (section 6.12)
4.3.1. When the rare exception to the timeline is unavoidable, it is the responsibility of the offending party to contact the other party and give an explanation for deviation to the established procedure and to determine a new mutually agreeable schedule.

5. Reassessments and Surveillance (section 6.13)

5.1. Accreditation Body (AB) options for the types of assessments
5.2. Purpose of each type of assessment

Proficiency Testing
Volume 1, Module 1; Volume 2, Module 2 and Volume 3

1. **Accreditation Body (AB) Requirements**
   - 1.1. Primary AB (V2,M2 section 4.1)
   - 1.2. Secondary AB (V2, M2 section 4.2)

2. **Requirements for Accreditation**
   - 2.1. Initial Accreditation
   - 2.1.1. Number of PT samples (V1,M1 section 4.1.1 and V2,M2 section 5.1.1)
   - 2.1.2. Time frame for PT samples (V1,M1 section 4.1.3 and V2,M2 sections 5.1.3 and 5.1.4)
   - 2.2. Continuing accreditation
   - 2.2.1. Frequency and Success Rate (V1,M1 sections 4.2.1 and V2,M2 sections 5.2.1)
   - 2.2.2. PT availability issues (V2, M2 section 5.2.2)
   - 2.2.3. Experimental FoPT's (V1,M1 section 4.2.2 and V2, M2 5.2.3)

3. **Requirements for PT Sample Analysis**
   - 3.1. Analyzed in the same manner as routine samples (V1,M1 section 5.1.1 and V2,M2 section 6.1) Explain how to determine this standard has been met.
   - 3.2. Inappropriate Actions (V1, M1 section 5.1.3 and V2, M2 section 6.2) Explain how to determine if inappropriate actions have occurred.

4. **Sample Reporting and Evaluation**
   - 4.1. Laboratory reporting requirements (V1, M1 section 5.2)
   - 4.2. Laboratory record retention requirements (V1, M1 section 5.3)
   - 4.3. Timeframe for AB assessment of results (V2, M2 section 7.1)
   - 4.4. Acceptance or rejection of the analytical results for a FoPT (V1, M2 sections 7.2 and 7.3)

5. **Corrective Action for Unacceptable FoPT** (V1, M1 section 6.1 and V2, M2 section 8.2)

6. **Complaint Resolution**
   - 6.1. Handling questions about PT samples or performance evaluations made by the PTP (V1, M1 section 7.1 and V2, M2 section 9.1)
   - 6.2. Resolution of a laboratory's questions about the validity of not acceptable evaluations (V1, M1 section 7.2 and V2, M2 section 9.2) Include examples.

7. **Suspension or Revocation of Accreditation**
   - 7.1. When to suspend or revoke laboratory accreditation for an unacceptable FoPT (V2, M2 sections 10.1 and 10.3)

7.2. Reinstating accreditation after FoPT suspension or revocation (V1, M1 section 8.0 and V2, M2 sections 10.2 and 10.4)

8. Requirements for a PT Provider

8.1 Requirements for Accreditation (V3 section 4.0)

8.1.1 Participation in audits (V3 section 4.3)
8.1.2 Data submission (V3 section 4.4)
8.1.3 Confidentially (V3 section 4.4.2)
8.1.4 PT sample verification (V3 section 4.5)
8.1.5 Participation in conflict resolution (V3 section 4.6)

8.2 Management Requirements (V3 section 5.0)

8.2.1 Quality Systems including ISO 9001, ISO Guide 34, ILAC G-13 and ISO 17025 (V3 section 5.1)
8.2.2 Records retention (V3 section 5.1.6)
8.2.3 Conflicts of interest and confidentially (V3 section 5.2)
8.2.4 Facilities and Personnel (V3 section 5.3)
8.2.5 Complaints handling (V3, section 5.4)
8.2.6 Notification of Sample Integrity (V3, section 5.5)

8.3 PT Sample Design (V3, section 6.0)

8.3.1 Design Review (V3, section 6.1)
8.3.2 Sample Matrices (V3, section 6.2)
8.3.3 Numbers of Sample Analytes (V3, section 6.3)
8.3.3.1 TNI FOPT Tables
8.3.3.2 Multi Analyte Categories
8.3.3.3 Random Selection of Analytes
8.3.4 Assigned Values (V3, section 6.4)
8.3.4.1 Chemical, True Values, Significant Figures
8.3.4.2 Microbiological, Solid and Chemical Matrix Samples.
8.3.4.3 Qualitative Analytes

8.4 PT Sample Testing (V3, section 7.0)

8.4.1 Verification of Assigned Values (V3, section 7.1)
8.4.2 Homogeneity Testing (V3, section 7.2)
8.4.3 Stability testing (V3, section 7.3)
8.4.3 Reporting (V3, section 7.4)

8.5 Provision of PT Samples (V3, section 8.0)

8.5.1 Study Duration (V3, section 8.1)
8.5.2 Study Instructions and Study Prohibitions (V3, section 8.2)
8.5.3 Regular Scheduled PT Studies (V3, section 8.3)
8.5.4 Supplemental PT Studies (V3, section 8.4)

8.6 System for Reporting by Participants (V3, section 9.0)

8.7 PT Study Data Analysis (V3, section 10.0)
- 8.7.1 Data Review (V3, section 10.1)
- 8.7.2 Acceptance Limit Determination (V3, section 10.2)
- 8.7.3 Evaluation of Individual Participant Results (V3, section 10.3)

8.8 Generation of Study Reports (Volume 3, section 11.0)
- 8.8.1 Schedule (V3, section 11.1)
- 8.8.2 Final Evaluation Report (V3, section 11.2)
- 8.8.3 Study Failure Rate Report (V3, section 11.3)

8.9 Overview of The Guidance Procedure for Testing the Homogeneity and and Stability of Pt Samples (V3, Appendix A)

EXAMINATION GUIDANCE

The purpose of the Basic Assessor Course examination is to determine that an assessor has adequate knowledge of applicable TNI standards and the skill to perform assessments that evaluates if the laboratory is producing data of known and documented quality as prescribed in the TNI standards. To that end, it is strongly recommended that the following guidance is used in the preparation and administering of the exam.

Exam Characteristics

The exam should have at least 50 questions. The questions can be multiple choice, true/false and/or fill in the blank. No more than 20% of the questions should be true/false. At least 10% of the questions should be fill-in-the blank. However, the questions should be objective.

Assessors should be encouraged to refer to the standard and methods in their capacity as assessors, therefore the exam should be an open book exam. Students should be allowed two hours to complete the exam.

A score of 70% is considered passing. A participant will be allowed one retest upon failure of the exam. The retest must be significantly different from the original test.