NELAC Laboratory Training Curriculum

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Section 1 - Introduction

1.1 Purpose of NELAC
1.2 What is NELAC? What is NELAP?
1.3 NELAC and ISO

Similarities
Differences
NELAC always takes precedence

Section 2 - Management Requirements

2.1 Organization Responsibility

Suggested Topics:

Responsibility to meet the NELAC Standard
Management System includes all associated facilities

2.2 Organization Requirements

Suggested Topics:

Management and Technical Personnel with authority and resources
Identifying Changes in the Quality Systems
Freedom from undue pressures and influences
Policies and Procedures for clients confidentiality
Policies and Procedures that do not diminish confidence in capabilities
Defining the organization and management structure
Documentation of personnel responsibility
Adequate Supervision
Technical Management Responsibility
Documentation of Technical personnel capabilities, training, and certification
Appointment of Quality Manager and Authority
    Oversight
    Function Independent from Laboratory Operations
    Evaluating Data Objectively without influence
    Documentation training and experience
    General Knowledge of Analytical Test Methods
    Internal Audits
    Notification of Deficiencies
    Documentation of Corrective Actions
Appointment of Deputies
Participation in a Proficiency Test Program

Section 3 – Quality System

3.1 Establishing, Implementing, and Maintaining a Quality System

3.2 Documenting Policies and Objectives in a Quality Manual

Suggested Topics:

Commitment to good laboratory practice and quality
Management's statement for standard of service
Objectives of the Quality System
Requirement of personnel familiarization with the quality documentation
Documentation of implementation of policies and procedures in the quality documentation
Laboratory Management commitment to compliance

3.3 Items to include in the Quality Manual

Suggested Topics:

Outline the Structure of documentation used in quality system
Reference to Supporting and Technical Procedures
Contents of the Title Page
Quality Policy Statement, Objectives, and Commitments
Organization Structure, Management Structure, and Organizational Charts
Procedures to ensure that all records required are retaining
Procedures for control and maintenance of documentation
Job Descriptions Documentation
Identification of the laboratory's approved signatories
Procedures for achieving traceability of measurements
List of test methods
Review of all new work
Documentation of calibration and verification test procedures used
Procedures for handling submitted samples
Documentation of Major Equipment, Measurement Standards, Facilities, and Services
Documentation of maintenance on equipment
Documentation of Verification Practices
Procedures for Feedback and Corrective Action
Procedures for dealing with complaints
Procedures for protecting confidentiality
Procedures for Audits and Data Review
Documentation for reporting analytical results
Table of Contents, References, Glossaries, and Appendices
Roles of Responsibility
Establishing and Maintaining Data Integrity Procedures
Providing a mechanism for confidential reporting of data integrity issues
Ethical Concerns and Issues

Section 4 - Document Control

4.1 - Establishing and Maintaining Procedures to control all documents

4.2 - Document Approval and Issue

Suggested Topics:

Distribution of Authorized Editions
Periodic Review
Removal of Invalid and Obsolete Documents
Archival of Obsolete Documents
Unique Identification of Documentation
Document Changes

Section 5 - Review of Requests, Tenders and Contracts

Suggested Topics:

Ensuring adequate definition, documentation, and understanding
Review of Capability
Review of Appropriate Test Methods for meeting client requirements
Records of Review
Documentation of Subcontracting
Informing the Client of any deviations
Amendments to the Contract

Section 6 – Subcontracting of Environmental Tests

Suggested Topics:

Laboratory's Responsibilities and Requirements for Subcontracting
Documentation of Subcontracting

Section 7 – Purchasing Services and Supplies

Suggested Topics:

Policies and Procedures for purchasing of services and supplies
Inspection and Verification of purchased supplies, reagents, and consumable materials
Evaluation of suppliers of Critical Consumables, Supplies, and Services

Section 8 – Client Services

Suggested Topics:

Clarification of client requests
Monitoring of Performance
Confidentiality
Policy and Procedures for the resolution of complaints
Documentation of complaints, corrective actions, and internal investigations

Section 9 – Non-Conformance Control

Suggested Topics:

Designation of Responsibilities and Authorities
Identifying Corrective Actions
Tracking of Resolutions
Client Notification when Data Quality is effected
Authorization for resumption of work

Section 10 – Corrective Action Control

Suggested Topics:

Policy and Procedures for Implementing Corrective Actions
Documentation of the Root Cause
Monitoring of Corrective Actions
Additional Audits
Information to document in Technical Corrective Actions
Corrective Actions and Reporting of Data

Section 11 – Preventive Action Control

Suggested Topics:

Identifying opportunities for Improvement
Identifying potential sources for Non-Confomances
Procedures for Initiation and Effectiveness

Section 12 – Record Control

Suggested Topics:

Documenting all laboratory activities
Information to include in Record Control
Documentation of Sample Handling
Establishing Procedures for Identification, Collection, Indexing, Access, Filing, Storage, Maintenance, and Disposal of quality and technical records
Proper storage and readily retrievable
Security, Protection, Confidentiality, and Back-up
Ability for historical reconstruction
Establishing an Audit Trail
Information within the Audit Trail
Signatures and Initials
Records Management and Storage
Laboratory Sample Tracking and Handling
Laboratory Support Activities
Analytical Records
Administrative Records

Section 13 – Internal Audits

Suggested Topics:

- Scheduling Periodic Audits
- Procedure for Audit findings that cast doubt
- Follow-up on Corrective Actions due to Audit Findings

Section 14 – Management Review

Suggested Topics:

- Scheduling Periodic Management Reviews
  - Review suitability of policies and procedures
  - Review reports from managerial and supervisory personnel
  - Review outcome of recent internal audits
  - Review corrective and preventative actions
  - Review assessments by external bodies
  - Review results of inter-laboratory comparisons or proficiency tests
  - Review changes in volume and type of work
  - Review client feedback
  - Review complaints
  - Review quality control activities
  - Review resources
  - Review staff training
- Procedure for tracking Management Review Actions
- Follow-up on Actions due to Management Review

Section 15 – Technical Requirements

Suggested Topics:

- Determining total uncertainty of measurement
- Ensuring competence of technical personnel
- Formulating goals for education, training, and skills of laboratory personnel
- Supervision and competence of contracted personnel
- Maintenance of current job descriptions
- Data Integrity Training

Section 16 – Accommodation and Environmental Conditions

Suggested Topics:

- Laboratory facility
- Monitoring, Controlling, and Recording Environmental Conditions
- Prevention of cross-contamination
- Access control
- Unencumbered work areas

Section 17 – Environmental Test Methods and Method Verifications

Suggested Topics:

- Maintaining current SOPs
- Maintaining current in-house methods manual
- Information to include for each method within the in-house methods manual

Section 18 – Selection of Methods

Suggested Topics:

- References
- Documentation of Methods used
- Communication with client
- Demonstration of Capability
- Documentation of Demonstration of Capability
- Laboratory-Developed Methods
- Non-Standard Methods
- Validation of Methods
- Estimation of Uncertainty of Measurement

Section 19 – Control of Data, Equipment, and Support Equipment

Suggested Topics:

- SOPs for Software Verification and Validation
- Establishing Security and Maintenance
- Equipment capability assessments
- Standards for Support Equipment
- Instrument Calibrations Standards
- Tracking of Equipment Service
- Documentation of unacceptable performance
- Verification and Validation of Equipment

Section 20 – Measurement Traceability

Suggested Topics:

- Procedures for Measurement Traceability and Calibration
- Procedures for Scheduled Continual Calibration
- Traceability of Reference Standards and Reference Materials
- Scheduling Intermediate Checks of Standards and Reference Material
- Transport and Storage of Standards and Reference Material
- Documentation and Labeling of Standards, Reagents, and Reference Material

Section 21 – Sampling

Suggested Topics:

- Establishing a Sampling Plan
- Documentation in deviations, additions, and exclusions from the documented Procedures
- Recording Relevant Data and Operations

Procedures for Handling of Samples
Sample Receipt Protocols
Information required for Sample Receipt
Sample Acceptance Policy

Section 22 – Assuring the Quality of Environmental Test and Calibration Results

Suggested Topics:

Establishing Quality Control Procedures for Monitoring the Validity of Environmental Tests
Essential Quality Control Procedures

Section 23 – Reporting the Results

Suggested Topics:

Requirements and Responsibilities for Reporting
Information and data to include in Test Reporting
Supplemental Information for Test Reports
Opinions and Interpretations
Subcontracting Requirements
Electronic Deliverable and Transmission Requirements
Report Formats
Amendments to Test Reports