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July 10, 2006

Ms. Joan Cassedy
Independent Laboratory Institute
1629 K Street NW Suite 400
Washington DC 20006

Re: EPA Cooperative Agreement

Dear Ms. Cassedy,

The Environmental Laboratory Advisory Board (ELAB), which serves a s a Federal Advisory Committee to the Environmental Protection Agency (EPA), has learned of the award to the Independent Laboratory Institute (ILI) for purposes of general training that specifically includes requirements under the National Environmental Laboratory Conference (NELAC). ELAB has been tasked with investigating this training "issue" as well.

Our Board members have developed and approved the attached NELAC Laboratory Training Curriculum Outline that we would like to share with the ILI. It is our hope that this curriculum can be utilized within your program under the EPA cooperative agreement.

The attached is a detailed work product that we would be pleased to discuss with you at your convenience.

We feel that it would be in the mutual best interests of ILI and ELAB, as well as all NELAC Stakeholders, if such a curriculum could be incorporated into training activities of the ILI.

Please contact me if you have any questions or would to establish a meeting to discuss further. Thank you for your time and consideration.

Respectfully submitted,

Robert K. Wyeth
Chairman
Environmental Laboratory Advisory Board

cc: Dr. Earl Hansen
ELAB members
Ms. Lara Autry

NELAC Laboratory Training Curriculum

Background:

The Environmental Laboratory Advisory Board has been obtaining feedback from the National Environmental Laboratory Accreditation Conference (NELAC) through open forums and face-to-face meetings regarding the need to provide training for laboratories that are pursuing national laboratory accreditation. The goals of this Curriculum are to:

1. Provide tools in order for any environmental laboratory to become successful in the National Environmental Laboratory Accreditation Program,
2. Provide the criteria for establishing a Quality System. The Quality System is a key component of the accreditation process,
3. Provide guidance for good laboratory practices, and
4. Provide the technical tools to establish a system for creating data with known certainty and documented quality.

NELAC Laboratory Training General Curriculum Outline

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 process
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