



# National Environmental Laboratory Accreditation Program (NELAP)

## Accreditation Body Evaluator Training

2003 NELAC Standards  
January 30-31, 2008 - Web Conference

# Logistics



- Video Conference
- Please NO NAMES!! -
  - ♦ Past experiences are to remain anonymous
- Agenda - See Outline
  - ♦ Start time tomorrow
  - ♦ End time each day

# Module 1

## Background Information

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3

## Course Outline

- Module 1: Background
- Module 2: The Recognition Process
- Module 3: The Evaluation Team
- Module 4: Application Completeness &  
• Technical Review
- Module 5: On-site Evaluation of Accreditation Body
- Module 6: Observation of Laboratory Assessment
- Module 7: Results of the Evaluation
- Module 8: Outcome of Process

## Purpose of Training

- Outline duties of an accreditation body evaluator
- Teach participants to:
  - ✦ Perform application completeness & technical reviews
  - ✦ Conduct on-site evaluations
  - ✦ Observe laboratory assessments
  - ✦ Prepare evaluation reports
  - ✦ Report on findings and observations from above

## Training References

- Based on
  - ✦ 2003 NELAC Revised - Chapter 6 (Gray Version)
  - ✦ 2003 Cleaned up Version - No EPA number - not adopted!
  - ✦ 2003 NELAC Standard Chapters 1, 2, 3, 4 and 5
  - ✦ The NELAC Institute Accreditation Body Application (Rev 112007)
  - ✦ Application Completeness Checklist (Rev 112907)
  - ✦ SOP for the Evaluation of Accreditation Bodies (Rev 8.5, 11/06/07)
  - ✦ Checklist to Determine Accreditation Body Compliance (Rev 12/13/07)
  - ✦ Observation Checklist for Laboratory Observations (Rev 1.0 2/26/07, document posted 12/13/07)
  - ✦ Evaluation Report Format (Version Draft 1/4/08)
  - ✦ Interpretation SOP (Draft for LASC adoption Dec 07)
  - ✦ Dispute Resolution SOP (Draft to LASC, NELAP Board)

## Definitions

- NELAC Chapter 1, Appendix A
- SOP - Evaluation of ABs
  - ✦ Review Section 5.0
- New Terms:
  - ✦ Accreditation Body (formerly Accrediting Authority)
  - ✦ Evaluation Coordinator (EC)
  - ✦ Quality Assurance Officer (QAO)
  - ✦ Field of Accreditation
  - ✦ Technology
  - ✦ NELAP Recognition

## Background: A Brief History

- **1970 - 1980's** – Variety of environmental laboratory certification programs
- **1992** – National accreditation for environmental laboratories recommended
- **Early 1990's** – Framework established by EPA and the States for a national system

## Background

- **1995** – National Environmental Laboratory Accreditation Conference (NELAC) established to develop and adopt standards
- **1997** – First standards adopted
- **1999** – First Accrediting Authorities recognized
- **2001** – First laboratories accredited
- **2003** – NELAC develops/adopts last set of standards and restricts its role to standards adoption - (INELA formed 2002. Closed 2006)
- **2005** – Self sufficiency task group (SSTG) created

## The NELAC- Institute (TNI)

- Formed November 2006
  - ✦ NELAC Board and TNI sign MOU
  - ✦ Program activities continue
- Non-profit organization with members
  - ✦ Managed by Board of Directors
  - ✦ Organized into Programs
  - ✦ Administrative Services support the programs

*[www.nelac-institute.org/](http://www.nelac-institute.org/)*

## NELAP Board Members

Dan Hickman, Oregon DEQ (Chair)

- Bill Hall, New Hampshire ELAP
- George Kulasingham, California DHS-ELAP
- Dave Mendenhall, Utah DOH
- Aaren Alger, Pennsylvania DEP
- Steve Stubbs, Texas CEQ
- Louis Wales, Louisiana DHH
- Steve Arms, Florida DOH
- Ken Jackson, New York State DOH
- Jack McKenzie, Kansas DHE
- Mike Miller, New Jersey DEP, (Jan 2008 - Joe Aiello)
- Scott Siders, Illinois EPA
- Paul Bergeron Louisiana DEQ

## Other Contacts

- EPA Regional Evaluators
  - ✦ Appendix A
- Accreditation Body Evaluators
  - ✦ Appendix B

*Evaluation SOP*

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12

## National Environmental Laboratory Accreditation Program (NELAP)

- The purpose is to establish and implement a program for the accreditation of environmental laboratories
- NELAP Board Primary Components:
  - ✦ Recognition of Accrediting Authorities,
  - ✦ Adoption of acceptance limits for proficiency testing developed by the PT Board
  - ✦ Adoption of the laboratory accreditation system developed by the Laboratory Accreditation Committee (LAC)

*TNI Website December 2007*

## NELAP Board Expectation

- To ensure that the program is implemented effectively and to address the needs of the stakeholder community, the NELAP Board is expected to work in cooperation with other key committees within TNI. Specifically, the NELAP Board:
  - ✦ Will work with the LAC in the development of the laboratory accreditation system,
  - ✦ Will work with the Consensus Standards Development Program to ensure that accreditation standards developed for use for this program are suitable for use, and
  - ✦ Will work with the PT Board to ensure that the PT acceptance limits developed by the PT Board are suitable for use

## An Accreditation Body

- What is it?
  - ✦ The Territorial, State, or federal agency, previously named Accrediting Authority, having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (NELAC 1.4.2.3)
- What is its role?
  - ✦ Accredits environmental laboratories that comply with NELAC standards

*(NELAC Chapter 6.2)*

# Tracking Checklist

- Appendix D - Evaluation SOP
  - ✦ All elements identified
  - ✦ Days allowed from NELAC standard
  - ✦ Tracking to determine if process completed in timely manner

## Questions ???

- Evaluator should know some of the history of
  - ✦ NELAC
  - ✦ NELAP
  - ✦ TNI
- Evaluators should know where to find the information
- Evaluators should understand the goal for national environmental laboratory accreditation

# NOTES

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## Module 2

# The Recognition Process

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19

## NELAP Recognition: Overview

- Recognition:
  - ✦ the determination by the NELAP Board that an Accreditation Body meets the requirements of the NELAP and is recognized to grant NELAP accreditation to laboratories.

- Recognition – NELAP’s approval of an Accrediting Authority’s implementation of NELAC Standards.
- Based on successful evaluation of accrediting authority’s program and recommendations by NELAP team and ?NELAP Director?.
- There are states and agencies that accept NELAC accreditation by other recognized NELAP AAs.

# Recognition Steps

- Accreditation Body Application Submittal
  - ✦ Initial or Renewal
- Evaluation
  - ✦ Application Completeness Review
  - ✦ Application Technical Review
  - ✦ On-site Evaluation
  - ✦ Laboratory Assessment Observation
  - ✦ Recommendation Report to TNI NELAP Board
- Decision by the NELAP Board
  - ✦ Recognition to Grant, Maintain or Revoke in full or in part (NELAC 6.6.b.1)

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21

Application is made by the potential Accrediting Authority.

Completeness Review done by Evaluation Team Leader.

Evaluation is done by the Evaluation team - there will be more discussion of how this team is formed latter in this course - this course is to help you know what to do as a team member. The evaluation team is responsible for:

Technical Review of Application - This includes 2 rounds opportunities to correct deficiencies noted by the Team.

On-site evaluation .

Team Report and Recommendation the recommendation can be for granting or continuing recognition or denying or revoking recognition This is at 6.4.3.g.

Decision is by the ?NELAP Director? or authorized successor and can be to accept the teams recommendation

The Applicant can appeal the decision - this is at 6.10 in the Standard.

## Application Process

- New applicants obtain applications from NELAP Board via TNI website
  - Renewal applicants receive their applications with a renewal letter from NELAP Board via TNI website
  - Applicant fills out application for desired fields of accreditation
  - Applicant fills out technical checklist
  - Applicant fills out checklist for application completeness
  - Applicant obtains signature of its senior manager
  - Applicant submits package to NELAP Board
- (NELAC Chapter 6.3)

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22

• Required components of application are in 6.3.1.b and for example Fields of Accreditation are in 6.3.1.b.6.

• 6.3.1.c requires the signature of highest ranking official in department responsible for laboratory accreditation.

## The Application

- Application requires information such as:
  - ✦ General organization and contact information
  - ✦ Copies of applicable statutes, rules, regulations, SOPs, policies, and guidance
  - ✦ Areas of recognition that applicant is seeking
- Four copies must be submitted
  - ✦ EC, QAO, Lead Evaluator (LE) and AB representative
- Initial Application (Evaluation SOP Section 7.2.1)
- Renewal Application (Evaluation SOP Section 7.2.2)
- LE notifies AB of receipt of application (to be added to Evaluation SOP)

*(NELAC Chapter 6.3.1)*

## Typical Examples Fields of Accreditation

<b>Matrix</b>	<b>Technology/ Method</b>	<b>Analyte/ Analyte Group</b>
Drinking Water	HPLC-UV/EPA 555	Pentachlorophenol
Non-Potable Water	GC-MS/EPA 625	PAHs
Solid and Chemical Materials	ICPAES/EPA 6010	Arsenic
Drinking Water	GC-ECD/EPA 505	Atrazine
Non-Potable Water	CVAA (w/EPA 1631 extraction) /PBMS	Mercury
Air and Emissions	GCMS TO15	VOCs

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24

- These are the examples from the 2001 Standard.
- They are in Section 1.8.1 of Chapter 1 where the Tiered Approach to Fields of Accreditation is defined.

## Evaluation Purpose

- Examination of systems, processes and procedures of AB to:  
*Evaluation SOP Section 4.0*
  - ✦ Provide a determination of;
    - AB's compliance with the policies of the TNI NELAP Board
    - Capabilities to perform laboratory assessments in a consistent, uniform manner
- Verify Compliance with the requirements of the NELAC standards  
*Evaluation SOP Section 6.4.2*
  - ✦ Accuracy of information in ABs application and documents
  - ✦ Implementation of program as defined in application and supporting documents

## Evaluation Process

- Application Completeness Review
- Application Technical Review
- On-site Evaluation
- Observation of Laboratory Assessment
- Evaluation Report
- Review Corrective Action Plan
- Recommendation Report to TNI NELAP Board

## Decision

- NELAP Board
  - ✦ Report from Evaluation Team
- After Corrective Action Completed
- Model Letter - Appendix G
  - ✦ SOP for Evaluation of AB's
- Certificate of Recognition
  - ✦ Issued by NELAP Board
  - ✦ Transferred to AB
  - ✦ Signed by NELAP Board Chair

## Questions ???

- The evaluation team should understand the steps in the recognition process
- The NELAP Board and Chair perform many of the functions defined in 2003 NELAC Chapter 6 for the NELAC Director
- The recognition process must be able to determine if the AB is performing and meeting the NELAP requirements

# NOTES

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## Module 3

# The Evaluation Team

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30

## The NELAP Evaluation Team



**OR**



## Purpose of Team

- To evaluate applicant or renewal AB for purposes of granting NELAP recognition
  - ✦ Every 3 years
  - ✦ Announced (NELAC Chapter 6.4.b)
    - Announced or unannounced subsequent evaluations
  - ✦ Arrange and conduct evaluation
    - Administrative and technical review
    - On-site evaluation
    - Observe laboratory assessment
    - Report on Evaluation
    - Recommendation for recognition

*(NELAC Chapter 6.4)*

## About the Team

- Appointed by NELAP Board
- Perform completeness and technical review of the application
- Conducts on-site evaluation
- Observes laboratory on-site assessment
- Includes a Lead Evaluator (LE)
  - ✦ All members of team work under the direction of the LE
  - ✦ Contact point for the EC

- Team experience and training requirements at 6.9.1.

## Team Assistance

*New to the process*

- Evaluation Coordinator (EC)
  - ✦ Assists evaluation team with all communications
    - Between evaluation team and AB
    - Between evaluation team and NELAP Board
  - ✦ Assures timely evaluations
    - Following SOP for Evaluation of ABs
    - Tracks and documents all aspects of AB evaluations
  - ✦ Reviews AB application for completeness
    - Concurrence with LE
  - ✦ Reviews evaluation report for completeness and consistency
    - Evaluation SOP
    - NELAC standard

*Evaluation SOP Section 6.6*

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34

**The first bullet point reflects current standard but may need to be revised under the reorganization**

## Team Assistance

### *New to the process*

- QA Officer (QAO)
  - ✦ Assures AB evaluations performed in consistent manner
    - Evaluation team following SOP for Evaluation of ABs
  - ✦ Informs LE during assessment if inconsistency is observed
    - Discreetly (add to SOP)
  - ✦ Participates on all AB evaluations (definitions)
    - Performs quality assurance function
    - Reports to NELAP Board
  - ✦ Reviews following aspects:
    - Technical review of AB application
    - On-site evaluation of the AB
    - Review of AB's corrective action plans
  - ✦ Informs NELAP Board
    - Unresolved consistency problems as they occur
    - Provide a report at the completion of each AB evaluation

### *Evaluation SOP Section 6.7*

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35

**The first bullet point reflects current standard but may need to be revised under the reorganization**

## Team Assistance

### *New to the process*

- TNI Program Administrator
  - ✦ Assists the EC with communication (*Evaluation SOP Section 6.6.1*)
  - ✦ Assists the EC with tracking and documenting AB evaluations (*Evaluation SOP Section 6.6.2*)

*Addendum to SOP for the Evaluation of ABs*

*AB recognition Renewals 2007-2008*

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36

**The first bullet point reflects current standard but may need to be revised under the reorganization**

## Other Roles

- NELAP Chair
  - ✦ Accepts communication on behalf of the Board
  - ✦ Issues letters from NELAP Board and recognition Certificate
- NELAP Board
  - ✦ Policy and procedure decision
  - ✦ Decision on recognition

**The first bullet point reflects current standard but may need to be revised under the reorganization**

## Duties of NELAP Evaluators

- Read and know the NELAC Standards well
  - ✦ No changes made to the NELAC Standards since 2003
    - Policy and interpretations made by AA committee or NELAP Board must be known by the evaluators
  - ✦ Applicants evaluated against the standards in effect at the time of application (Date of receipt by EC)
  - ✦ Future evaluations based on standards in place at that time
- **Keep current with the standards and procedures!**
- Interview AB staff and assessors to evaluate implementation consistency with
  - ✦ AB's procedures
  - ✦ NELAP Board policy and procedures
  - ✦ NELAC Standard 2003



## Evaluation Team Members

- NELAP Board selects team
  - ✦ EPA region where AB is located
    - Other EPA team members may be proposed to NELAP Board
  - ✦ Representative of another AB
  - ✦ Technical evaluators
- Team selects the LE
- NELAP Board makes final determination of team members

*(NELAC Chapter 6.9.1)*

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39

- Certification as a management systems lead evaluator from an internationally recognized auditor certification body.
- One year of experience implementing federal or state laboratory accreditation rulemaking
- Laboratory accreditation management.
- One year experience developing or participating in laboratory accreditation programs.
- All experience must be acquired within 5 year period immediately preceding appointment.
- Standard does use term “management systems lead evaluator” the certification is for “management systems lead assessor” -may have been some problems with globally replacing evaluator with assessor.

## Lead Evaluator (LE)

- Responsible for planning activities
- Provides direction to the evaluation team
- Reviews and approves all reports sent to AB
- Works with EC and others:
  - ✦ communication with AB
  - ✦ processing of all records and reports
- Notifies NELAP Board of any conflict of interest by team members
- LE obtains records
  - ✦ All records retained by Secretary NELAP Board
  - ✦ Copies to QAO, EC of applicable document(s)

## Team Members

- One member meets education, experience and training requirements for lab assessors specified in the NELAC standards Chapter 3
- One other member with experience in one of the following: (may be same person and not different person)
  - ♦ Certification as a management systems lead assessor
  - ♦ One year implementing federal or state lab accreditation rulemaking
  - ♦ One year developing or participating at a managerial level in lab accreditation program
- Sign conflict of interest
- Acquired experience within last 5 year period

Who keeps these records?

## Qualification and Responsibility

- Training and Professional Qualification
- Complete Evaluator Training
  - ✦ LE must complete
  - ✦ Others may complete
- Sign conflict of interest form
  - ✦ Appendix C - Evaluation SOP
- Comply with TNI NELAP Board Policies

## Team Members

- Interview AB staff
- Review records of AB
- Document records reviewed
- Document findings
- Provide input to team to support recognition recommendation

# Interview Exercise

## Class Work

- How do you interview?
  - ✦ Lets review....
    - Each person must present one example of a good interviewing technique
  - ✦ What is most important when interviewing AB staff?
    1. Listening
    2. Telling the AB about the new NELAP Board
    3. Looking at documents and records
    4. Watching the QAO's expression to see if you are asking the right question as the evaluator

## Questions ??

- Each team member must know their role in the team
- The QAO is in an observation role during the on-site visit. The QAO provides input to the evaluation team only
- The EC communicates and compiles documentation
  - ✦ Does not write materials
  - ✦ Checks to see if all documents are complete and submitted
- The LE directs the evaluation process and writes the report

# NOTES

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46

Any Questions, If not we will continue with a discussion of the Technical Review.

## Module 4

# Application Completeness & Technical Review

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47

## Initial Application Process

- Application Form from NELAP Board
  - ♦ See TNI website
- Signed by highest ranking individual within the department or agency responsible for laboratory accreditation
  - ♦ Attestation to the validity of submittal
- Form and supporting documents submitted to NELAP Board chair or designee
- Letter from NELAP Board Chair or designee acknowledging receipt and the evaluation process is started

*(NELAC Chapter 6.3.1)*

## Renewal Application Process

- NELAP Chair sends letter to AB with directions to download Application Form
  - ✦ 270 days prior to expiration of current NELAP recognition
  - ✦ Copies to EC within 30 days of application letter
  - ✦ Evaluation team members identified in letter
  - ✦ Notification to submit 4 copies of application and supporting documentation
  - ✦ Return receipt acknowledgement required
    - (not required to be certified US Mail as stated in NELAC Standard )

*(NELAC Chapter 6.3.1)*

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49

## Application Submittal

- AB submits 4 copies of all materials
- Submit within 30 days of application letter
- Board notification - lack of submittal
- AB must submit within 20 days     **No extensions after March 1**
  - ✦ Recognition expires with the current NELAP certificate
- All copies of materials to EC
  - ✦ Subsequent communication between LE and AB
  - ✦ Copies provided to EC
  - ✦ LE responds to communications, as necessary
  - ✦ QAO to receive all materials (add to SOP)

***Evaluation SOP Section 7.2.2.2 and 7.2.2.3***

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50

## Completeness Review of Application

- Use Application Completeness Checklist
- Review to ensure all requested information has been submitted
- Not for judging adequacy of submitted materials
- Performed by EC
- Completed within 20 days of receipt



*(Evaluation SOP Section 7.4.1)*

*(NELAC Chapter 6.3.2)*

## Completeness Review Outcome

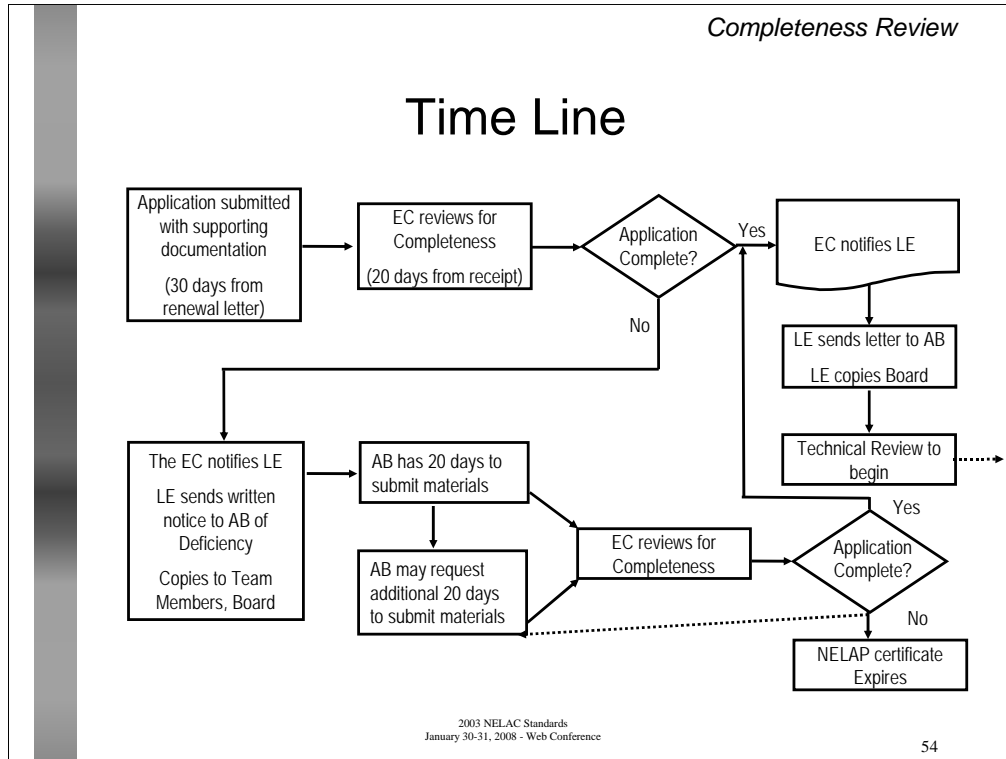
- EC Completeness Review Report to LE
  - ✦ EC uses “Checklist for Application Completeness”
  - ✦ LE may also review for completeness
- LE notifies AB and NELAP Board of acceptable Application Completeness
- If not complete - LE must:
  - ✦ Send letter to AB with Deficiency Report
    - Model Letter in Appendix E Evaluation SOP
  - ✦ Send copies to:
    - NELAP Board
    - Evaluation Team Members



*(NELAC Chapter 6.3.2)*

## Completeness Review Response

- AB has 20 days to respond
- AB must submit missing materials
- Extensions up to 20 days may be granted per NELAC Standard 6.3.2.c(3)



- We have dealt here mostly with the Application and Completeness review portions of the NELAC process and this slide shows the Completeness Review steps in the NELAC recognition Process

- This a good way to summarize steps in this part of process.

## Technical Review of Application

- Evaluation Team conducts review
  - ✦ Verify all required elements addressed
- Applicant's completed NELAP Application Checklist used as guide
- Document your review on "Checklist To Determine Accreditation Body Compliance"
- Meets requirements of 2003 NELAC Standard
  - ✦ Chapter 2, Chapter 3, Chapter 4, Chapter 5, Chapter 6
- Letter to AB
  - ✦ 30 days from date application was determined complete

### *Evaluation SOP Section 7.4.2*

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55

Technical review conducted by same team that performs on-site evaluation, since these are done during the same evaluation cycle, this is an absolute requirement - different from the possibility of team changes between a 4-year evaluation - the evaluation with an on-site and a 2-year evaluation without an on-site.

**TNI should verify that the Web Site is still current**

## Required Technical Elements

- Legally identifiable, governmental entity
- Authority, rights, and responsibilities to carry out an environmental laboratory accreditation program
- Liability and Worker's Compensation Claims

Gray items identified by NELAP Board

(NELAC Chapter 6.3.2.1)

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56

## Required Technical Elements (cont.)

- Financial stability and physical and human resources for operation
  - ✦ Able to complete timely action on a laboratory's application
  - ✦ Verify nine months from lab application to complete action
  - ✦ Turnaround times are carried out as required by NELAC standard
- Appoint and maintain records on its assessors
  - ✦ Education, experience, training - NELAC Chapter 3
  - ✦ Records must include seven items in NELAC 6.3.2.1.f

*(NELAC Chapter 6.3.2.1)*

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57

•6.3.2.1.e sets a benchmark for completion of an a laboratory's application within 9 months, so Timely = 9 months.

•6.3.2.1.h - Individual responsible for day-to-day management must:

- be an employee of the applicant authority
- plan and manage the program
- coordinate program with other territory, state, and federal accrediting authorities
- coordinate development of environmental laboratory accreditation regulations
- evaluate the technical competence and performance of contractors

## Required Technical Elements (cont.)

- Have a process for assessing its assessor's performance
    - ✦ Organizational employee evaluation program
    - ✦ NELAC Chapter 3 compliance
  - Specify an individual responsible for daily management
    - ✦ Employee of AB
    - ✦ Technical expertise
      - Plan and manage lab accreditation program
      - Coordinate lab accreditation program
      - Coordinate development of lab accreditation regulations
      - Evaluate technical competence and performance of contractors or employees
- (NELAC Chapter 6.3.2.1)*

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58

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•6.3.2.1.h - Individual responsible for day-to-day management must:

- be an employee of the applicant authority
- plan and manage the program
- coordinate program with other territory, state, and federal accrediting authorities
- coordinate development of environmental laboratory accreditation regulations
- evaluate the technical competence and performance of contractors

## Required Technical Elements (cont.)

- Management and technical staff free from
  - ✦ Commercial, financial or other pressures that influence results of accreditation process
  - ✦ Conflicts of interest
- Documented procedure
  - ✦ Annual systematic internal audit
    - Verification of compliance with NELAC standard
    - Effectiveness of quality systems - NELAC Chapter 6.3.2.1.3
    - Same procedure as other units in AB
- The Applicant must have a designated individual who manages the quality system and maintains documentation required in NELAC 6.3.2.1.3

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*(NELAC Chapter 6.3.2.1)*

59

•Applicant must also ensure that contractors do not offer consultancy or services that could compromise objectivity.

•6.2.2g deals with grandfathering NELAP accredited laboratories when the lab's home state becomes a newly recognized NELAP Accrediting Authority.

## Required Technical Elements (cont.)

- SOPs for dealing with appeals, complaints, and disputes
  - ✦ Laboratory denial, suspension, revocation
  - ✦ Users of services
  - ✦ Other matters
- Proficiency testing programs required that meet NELAC Chapter 2, Appendix A
  - ✦ PT providers approved by PTOB/PTBA

*(NELAC Chapter 6.3.2.1)*

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60

•Applicant must also ensure that contractors do not offer consultancy or services that could compromise objectivity.

•6.2.2g deals with grandfathering NELAP accredited laboratories when the lab's home state becomes a newly recognized NELAP Accrediting Authority.

## Required Technical Elements (cont.)

- Must not offer consultancy or services that could compromise objectivity or impartiality of accreditation process and decisions
  - ✦ Contractors and employees
- Documented procedure to address NELAC Standard 6.2.2.g
  - ✦ Handling of renewals for labs where home state becomes an AB

*(NELAC Chapter 6.3.2.1)*

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61

•Applicant must also ensure that contractors do not offer consultancy or services that could compromise objectivity.

•6.2.2g deals with grandfathering NELAP accredited laboratories when the lab's home state becomes a newly recognized NELAP Accrediting Authority.

## Documentation Maintained

- Documentation describing the program must be maintained in:
  - ✦ Hardcopy or
  - ✦ Electronic media or
  - ✦ Other means
- Authority to grant accreditation and whether lab accreditation is mandatory or voluntary
- Requirements for laboratory to become accredited
- Assessor training and ongoing internal audit program

*(NELAC Chapter 6.2.3)*

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62

–These are the requirements at 6.2.3.a.1 in the standard (i, ii, iii, iv).

–AA shall maintain in hard copy, electronic media, or other means a document or documents describing its environmental laboratory accreditation program including the bullets in the slide..

## Documentation Maintained (cont.)

- List of names of qualified assessors and technical support personnel (See 3.4.1.2)
  - ✦ Areas of responsibility, education and experience
- Requirements for granting, maintaining, withdrawing, suspending, or revoking lab accreditation
- Lab accreditation process
- Fees charged
- Rights and duties of accredited labs
- List of NELAP accredited labs and the NELAP accreditation granted

*(NELAC Chapter 6.2.3)*

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63

And these continue the requirements at 6.2.3.a.1 in the standard (v, vi, vii, viii, ix).

## Documentation Maintained (cont.)

- Documents reviewed annually
  - ✦ Record of review available for inspection
  - ✦ Changes to program must be updated in documents within 30 days of review
- Document(s) readily available on request
- Arrangements to safeguard confidential information
  - ✦ NELAC Chapter 3

*(NELAC Chapter 6.2.3)*

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64

- The document(s) described shall be made readily available on request.
- AA shall have arrangements to safeguard information claimed by the labs as confidential (consistent with Ch 3).
  - In accordance with 40 CFR Part 2 Subpart B.
- These are from 6.2.3 b,c,d.

## Proficiency Testing Review

- Require laboratories to participate in a Proficiency Testing (PT) program
- Accept results from an approved Proficiency Testing provider
- Current Fields of Proficiency Testing are on the TNI Website
- See “Checklist To Determine Accreditation Body Compliance” items 1 to 25, 44, 45

(NELAC Chapter 6.3.2.1)

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65

•This is from 6.3.2.1.m and Chapter 2.

•Chapter 2 of the NELAC Standard deals with Proficiency Testing and the Oversight of Proficiency Testing sample provider.

•Discusses the requirements of a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA).

•2.0 states “States that for fields of accreditation for which proficiency testing (PT) samples are not available from an accredited PT Provider, a Primary Accrediting Authority may accept PT results from non-accredited PT Providers. In these cases, the Secondary Accrediting Authority shall accept the decision of the Primary Accrediting Authority.

•**TNI should verify that the Web Site is still current.**

## Records Requirements

- AB must have arrangements to establish and maintain records for each accredited lab
- Policy and procedure for retaining NELAP accreditation records
  - ✦ Minimum 10 years retention
  - ✦ Longer if required by law, regulation or contractual obligation
- Policy and procedure for access control to records defined by state entity

*(NELAC Chapter 6.3.2.1.1)*

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66

- Laboratory records may be required to be maintained for more than 10 years because of State statute or contractual obligations.
- Updates to the NELAP national database:
  - must occur no less than every 2 weeks.
  - reports must be submitted even if there are no changes to the database.

## Records Requirements (cont.)

- Policy and procedure for updating the NELAP national database
  - ✦ NELAP required information for each accredited
    - Primary and secondary
  - ✦ Every two weeks (minimum)
  - ✦ Report submitted even if no changes

*(NELAC Chapter 6.3.2.1.1)*

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67

- Laboratory records may be required to be maintained for more than 10 years because of State statute or contractual obligations.
- Updates to the NELAP national database:
  - must occur no less than every 2 weeks.
  - reports must be submitted even if there are no changes to the database.

## Use of Contractors

- Signed, binding contract ensuring all functions carried out are in compliance with the NELAC standard
- AB has full responsibility for contracted work
- Applicant will ensure that the contractor
  - ♦ Is competent and complies with provisions in NELAC standard
  - ♦ Complies with confidentiality requirements of AB and NELAC standard

*(NELAC Chapter 6.3.2.1.2)*

## Use of Contractors (cont.)

- The AB must ensure that the contractor is not directly involved with:
  - ✦ Laboratory seeking NELAC accreditation
  - ✦ Any other affiliation which would compromise impartiality in the NELAP accreditation process

*(NELAC Chapter 6.3.2.1.2)*

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## Quality System

- Suitable and effective for the type, range, and volume of work to be performed
- Documented in a quality system manual and associated written quality procedures
  - ♦ Shall be available for use by staff

*(NELAC Chapter 6.3.2.1.3)*

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# Quality Manual

- Quality policy statement
  - ✦ Objectives, commitments
  - ✦ Signed by manager
- Organizational structure of program and responsibilities of personnel assigned
- Policies and procedures for acquiring, training, supervising, and evaluating performance of employees/ contractors carrying out AB program functions
- Arrangements for annual internal audits
  - ✦ Quality system review

*(NELAC Chapter 6.3.2.1.3)*

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## Quality Manual (cont.)

- System for providing feedback to personnel responsible for audited area
  - ✦ Timely and appropriate corrective action
- Procedures for addressing conflict of interest
- Policies and procedures for
  - ✦ Maintaining document control
  - ✦ Implementing accreditation program
  - ✦ Addressing appeals, complaints, and disputes
  - ✦ Dealing with reports of questionable laboratory practices

*(NELAC Chapter 6.3.2.1.3)*

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## Mutual Assistance Agreements

- Primary AB may have arrangement for other AB to perform lab accreditation functions
  - ✦ Determine if mutual assistance agreement exists
  - ✦ Document in report
  - ✦ Agreement may be verbal or in writing

Not frequently adopted by ABs

*(NELAC Chapter 6.3.2.1.4)*

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73

## Technical Review Complete

- No Deficiencies identified
  - ✦ Notify AB within 30-days of acceptable technical review
    - schedule on-site evaluation
  - ✦ On-site evaluation to be conducted within 60-days following approval of the application
  - ✦ The on-site evaluation scheduled with mutual convenience of the AB and the evaluation team.



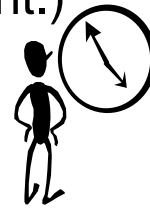
*(NELAC Chapter 6.3.2.2)*

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74

See SOP section 6.6

## Technical Review Complete (cont.)



- Deficiencies identified
    - ✦ Team will send a report that:
      - Model Letter Appendix F
      - Identifies specific deficiencies
      - Includes references to specific NELAC standards
      - May provide suggested corrective action (report not deficiency)
    - ✦ AB must respond
      - with written corrective actions in 30 days from receipt
      - Or withdraw all or part of NELAP recognition request
    - ✦ Evaluation team reviews corrective actions
      - 30 days to review
    - ✦ AB must respond in 20 days
- Corrective action plan presented  
(add to SOP)
- (NELAC Chapter 6.3.2.2)*

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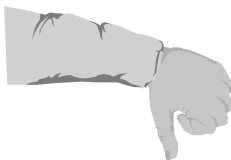
75

•Applicant may withdraw some or all of its recognition request.

•6.3.2.2.c defines when a team will not accept an application but remember that the standard at 6.5 allows an applicant to apply for a two year extension to comply with the standard if the Applicant has an operating accreditation program and needs new or revised regulations or legislation.

## Corrective Action Submittal

- If After Two Submittals - Unsatisfactory Response
  - ✦ Evaluation team documents remaining deficiencies
  - ✦ Recommend to NELAP Board
    - Initial application be denied
    - Renewal application - AB recognition be revoked

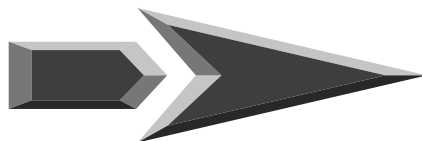


*(NELAC Chapter 6.3.2.2)*

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## Technical Review Outcome

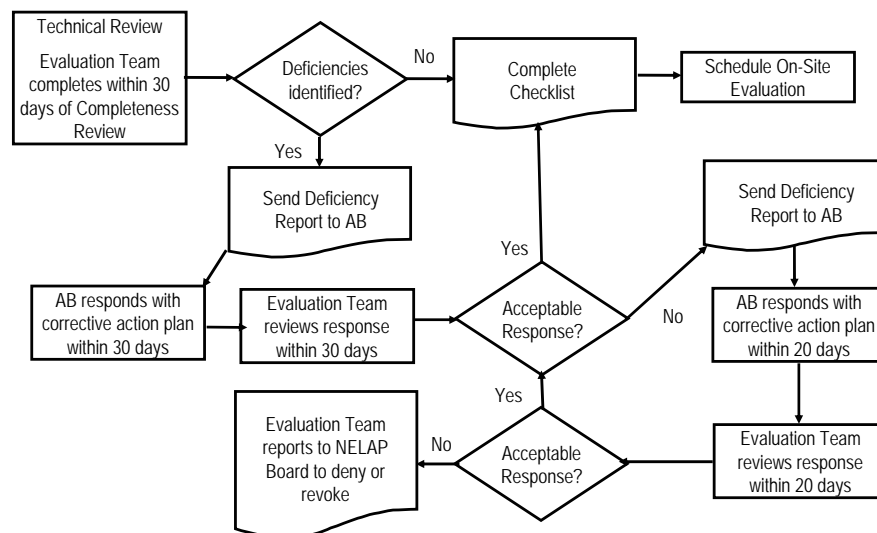
- Deficiencies corrected –
  - ✦ The Application is accepted
  - ✦ Notify AB that technical review acceptable
  - ✦ Team plans and schedules on-site evaluation



**PROCEED  
TO GO!  
COLLECT  
\$200**

*(NELAC Chapter 6.3.2.2.e)*

## Time Line

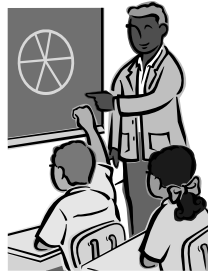


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- Recap the process.
- Refer to Figure 1 in Standards for more details.

## Completeness/Technical Review Exercise Group Work

- Writing Deficiencies
  - ✦ Review attached portion of Application
  - ✦ Write out deficiency (s), if any
  - ✦ Lets review content



## Questions ??

- The EC performs the completeness review
  - ✦ LE may assist
- The LE performs the technical review
- The QAO ensures monitors process
- The AB must submit complete information and technical information for review
  - ✦ The AB must respond promptly to any deficiencies in the information submitted
  - ✦ The on-site is not scheduled until this is complete

# NOTES

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## Module 5

# On-Site Evaluation of Accreditation Body

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82

## Purpose of the On-Site Evaluation

- Verify compliance with the requirements of the NELAC standards:
  - ✦ The accuracy of information contained in the application and supplemental documents
  - ✦ Whether implementation of program conforms with the information and data supplied by the AB

*(NELAC Chapter 6.4.2.a)*
- Comprehensive evaluation of AB program
  - ✦ AB application materials
  - ✦ AB conformance to NELAC Standards

*Evaluation SOP Section 7.6.2*

## On-site Evaluation

- Initially and every 3-years thereafter
- Announced, in most cases
  - ✦ Unannounced evaluations are permitted in some cases for determining compliance
- At least one NELAP evaluator must observe a laboratory assessment conducted by AB assessor
  - ✦ Evaluator does not participate in the assessment
  - ✦ Evaluator is observer only!

*(NELAC Chapter 6.4)*

## The On-site Process

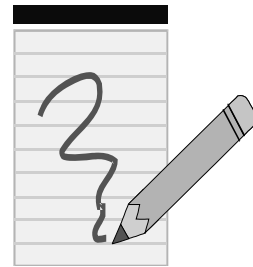
- On-site process consists of the following:
  - ✦ Opening meeting
  - ✦ Comprehensive on-site evaluation
  - ✦ Exit interview to discuss all noted deficiencies
- Team must conduct evaluation in accordance with TNI SOP for Evaluation of Accreditation Bodies (*NELAC Chapter 6.4.2.g*)
  - ✦ Section 7.5 (Scheduling)
  - ✦ Section 7.6 (Conducting)

*(NELAC Chapter 6.4.2)*

## Scheduling the On-site Evaluation

- Who, when, where, and how?
  - ✦ Team must travel to site
  - ✦ Critical AB personnel must be in attendance

*Evaluation SOP Section 7.5*



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## Initiation of On-site Process

- Within 30 days of application acceptance, lead evaluator contacts applicant to schedule
- Lead evaluator provides applicant with written confirmation of logistics required to conduct the on-site evaluation
  - ♦ **Specific Contents of Confirmation NELAC**  
**6.4.1.b** - See Evaluation SOP Section 7.5.2
- On-site evaluation conducted within 60 days of application acceptance

*(NELAC Chapter 6.4.1)*

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87

All days calendar days.

## Written Confirmation

- Sent by LE to:
  - ✦ Evaluation Team, AB, QAO and EC
- Logistics with following:
  - ✦ Onsite evaluation date, agenda or schedule of activities
  - ✦ Copies of standardized evaluation checklists
  - ✦ Names, titles, affiliations and on-site responsibilities of the team members
  - ✦ Names, titles of AB staff to be available during evaluation

*Evaluation SOP Section 7.5.2*

## Planning Considerations

- Identify personnel/program functions who need to be interviewed
- Develop specific questions based on technical review and responses from applicant to deficiencies found
- Identify facilities, systems, processes, or operations for examination
- In general, planning activities will be the responsibility of the Lead Evaluator but all team members should be involved.

•Personnel for interviews:

- Managers
- Technical Staff
- Assessors

## Who Do We Interview?

- Selection of AB staff for interviewing:
  - ✦ Program Manager (however named)
  - ✦ Quality Manager (however named)
  - ✦ PT Coordinator (however named)
  - ✦ Training or Human Resources Personnel
    - Record maintenance of training and qualifications
  - ✦ Sampling of assessors or all assessors
    - Sampling may be random using a probabilistic technique
    - Select at least newest staff member and most experienced
    - Select assessor with no findings in most reports
    - Select assessor with poor evaluation ratings
    - Remote interviews may be used to interview staff
    - Other criteria you recommend?

## Logistical Considerations

- Travel arrangements
  - ✦ Secure travel funds
  - ✦ Team members traveling from different locations
  - ✦ Coordination of arrivals and lodging arrangements
  - ✦ Pre-assessment meeting and communications
- On-site needs
  - ✦ Working space, including private interview room(s)
  - ✦ Access to files
  - ✦ Access to telephones, copiers, and/or computers

## Federal Agency

- Special needs:
  - ✦ Security clearances
  - ✦ Appropriate badge
  - ✦ Security briefing
- Request advance information
  - ✦ National security controls and reason for controls
  - ✦ Information that is not for public release

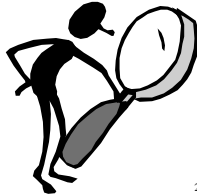
*(NELAC Chapter 6.4.2.d)*

## The Opening Meeting

- Meeting with AB's management
  - ✦ Other personnel may be included
- Suggested meeting contents:
  - ✦ Description of:
    - What will be done
    - How it will be done
    - What will be done with the results
  - ✦ Emphasis on:
    - "Fact-finding and process understanding" approach
    - Based on applicant's own program/information
    - Use of "no surprises" style

## Steps in the On-site Process

- Review applicant's on-site recordkeeping and documentation practices
- Conduct interviews with management and technical staff (SOP 7.6.2.1)
- Review selected laboratory accreditation cases
  - ✦ Review at least 3 NELAP accredited labs (SOP 7.6.2.2)
  - ✦ More files may be necessary if significant findings warrant



*(NELAC Chapter 6.4.2.b)*

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## Steps in the On-site Process (cont.)

- Review training records and conduct interviews of the staff designated as qualified assessors (SOP 7.6.2.)
  - ✦ Training
  - ✦ Knowledge of laboratory assessment techniques
  - ✦ Knowledge of the NELAC standards
- Review records of complaints, disputes, and appeals (SOP 7.6.2.4)
- Review quality assurance and internal audit procedures
  - ✦ Determine if corrective actions were taken to address internal audit deficiencies (SOP 7.6.2.1)  
(NELAC Chapter 6.4.2.b)

## Steps in the On-site Process (cont.)

- Review evaluation forms submitted by laboratories (SOP 7.6.2.3)
  - ✦ May be used to further select assessors for interview
- Observing the AB during an on-site lab assessment (SOP 7.6.2.6)
  - ✦ Lab must hold sufficient fields of accreditation to allow team to observe comprehensive on-site
  - ✦ A second lab may be necessary if a full service lab is not due for AB assessment
- Review last NELAP evaluation report (SOP 7.6.2.7)
- Assess AB to ensure that all EPA program requirements are met including drinking water, wastewater and air programs (SOP 7.6.3)

## Access to Records

- Team has access only to records that are:
  - ✦ Part of the accreditation program
  - ✦ Necessary to determine compliance
  - ✦ EPA to determine how to handle dual programs
    - Outside the scope of the evaluation.
- Applicant not required to provide access to:
  - ✦ Sensitive or confidential documents
  - ✦ Documents that are part of an on-going legal proceeding

*(NELAC Chapter 6.4.2.c)*

## Selecting Laboratory Files

- Varying fields of accreditation
- Varying assessors
- Select from the following labs:
  - ✦ Lodged a complaint, if applicable
  - ✦ Subject to administrative action due to severe deficiencies in the quality system, if applicable

*Evaluation SOP Section 7.6.4*

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98

Also suggest review any on-line resources

## Laboratory File Information

- Application
- Conflict of Interest Verification
- NELAC Chapter 5 Checklist (NELAC Chapter 3.6.3)
- Proficiency Testing Results for Compliance With Methodological and EPA Program Requirements
- Deficiency Report(s)
- Corrective Action Report(s)
- Correspondence
- Final Report
- Certificate, If Granted



*Evaluation SOP Section 7.6.4*

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Also suggest review any on-line resources

## Access to Personnel

- Team will have opportunity to interview privately:
  - ✦ All management, technical staff and assessors
  - ✦ Any NELAP-accredited laboratory receiving accreditation from the AB
  - ✦ Only used if there is a problem -
  - ✦ What might be considered a problem that would require the evaluator to interview privately?

Private interviews for documented cause

*(NELAC Chapter 6.4.2.e)*

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100

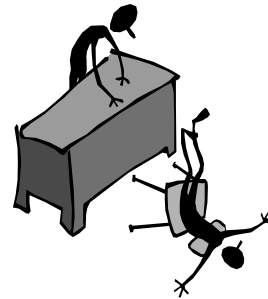
From the standard at 6.4.2.e) “The NELAP evaluation team shall have the opportunity to interview privately: 1) all management, technical staff and evaluators of the accrediting authority’s environmental laboratory accreditation program; and 2) any NELAP-accredited laboratory receiving its accreditation from the applicant accrediting authority.”

This does not say that the standard requires the team to evaluate everyone

.

## A Special Note

- Team's role – to understand the details of the program
- Despite any adverse findings, team members must remain professional and not:
  - ♦ Overreact
  - ♦ Imply the AB should not seek recognition



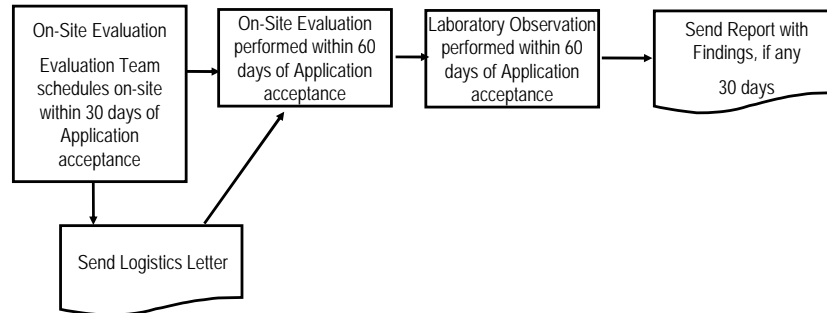
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## Closing Meeting Exit Interview

- Discuss all noted deficiencies
- Suggested meeting contents:
  - ♦ Describe:
    - What was done during evaluation on-site visit
    - Preliminary findings that emerged
    - What will be done with the results
  - ♦ Identify:
    - Strengths and weaknesses in applicant's program
    - Major deficiencies that must be resolved
    - Corrective action process and its timing

*(NELAC Chapter 6.4.2.f)*

## Time Line



## On-Site Evaluation Exercise Group Work

- Lets practice
  - ✦ Lets review the AB records for quality systems
  - ✦ What is correct?
  - ✦ What is not in compliance with the NELAC standard?
  - ✦ Document your findings



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## Questions ??

- The Evaluation Team reviews a sampling of the records of the AB
- The records for the laboratory assessment to be observed is reviewed by the Evaluation Team Member performing the observation
- The report of the Evaluation Team is written
- Deficiencies in the program, if any, are documented

# NOTES

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106

# Module 6

## Observation of Laboratory Assessment

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107

## Lab Assessment Observation

- ♦ As part of the initial and three (3) year AA renewal process, at least one of the NELAP evaluator(s) shall observe a laboratory assessor conducting an on-site assessment of a laboratory seeking initial or renewal NELAP accreditation.
- ♦ The NELAP evaluator(s) shall not participate in the laboratory's assessment.

*(NELAC Chapter 6.4.d)*

## Scheduling the Observation

- One member of Evaluation Team (at least)
- QAO may be present
- LE requests schedule of upcoming lab assessments
- LE selects lab from this schedule
  - ✦ May be performer prior to technical review
  - ✦ Recommended that observation take place after technical review and site visit is complete
- LE may send more than one team member
  - ✦ Scope of lab assessment
  - ✦ Number of AB assessors
  - ✦ Availability of team members

*Evaluation SOP Section 7.8*

## Conducting the Observation

- The evaluation team must only observe the AB's laboratory assessment team
- The evaluation team members are not active participants in the laboratory assessment
  - ✦ Handling introductions, outcome of onsite and observation
- Items that should be evaluated during the observation are provided in 2003 NELAC Standards Section 3.5
- The evaluation team should observe as many aspects of the AB's assessment as possible.
- Concentrate on areas where the technical review may have revealed weaknesses in the AB's program.  
*Evaluation SOP Section 7.9*

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## DO NOT INTERFERE!!!

- The Evaluator must NOT interfere in the lab assessment under any circumstances!!
- Wait until after the lab assessment to identify your points and findings.
  - ✦ Done outside the laboratory building
- Document your observations in detail
- Identify any deficiencies in your report
  - ✦ Enact the interpretation clause or get other information if a standard interpretation is a problem
  - ✦ Note that state legal requirements may cause the difference - document in your report!!

## Documentation of Findings from the Lab Assessment Observation

- ♦ The LE collects notes from all team members who participated in the observation.
- ♦ The LE incorporates findings from these notes into the on-site evaluation report

## Laboratory Observation Exercise Group Work

- Lets practice
  - ✦ How to observe a lab observation
    - All students are the observer
  - ✦ Watch the instructor conduct a lab assessment
    - Need volunteer to be the laboratory
  - ✦ What goes right?
  - ✦ What is not in compliance with the NELAC standard?
  - ✦ Document your findings

## Questions ??

- One laboratory assessment is observed by a member of the Evaluation Team
- Records of the observation are collected by the LE
- LE adds findings and observations to the final report
- The one rule - DO NOT INTERFERE
- Laboratory observation is a system review

# NOTES

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115

# Module 7

## Results of the Evaluation

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116

## On-Site Evaluation Report

- Prepared within 30 days of evaluation completion – includes:
  - ✦ Date of evaluation
  - ✦ The names of the persons responsible for report
  - ✦ Fields of accreditation
  - ✦ Team comments on compliance
- Sent with receipt confirmation

*(NELAC Chapter 6.4.3.a)*



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117

All days calendar days

### 6.4.3 On-site Evaluation Reports

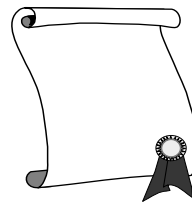
- a) The NELAP evaluation team will send by certified mail to the accrediting authority an on-site evaluation report within 30 calendar days of completion of the on-site evaluation. The report shall include, but is not limited to:
- 1) the date(s) of evaluation;
  - 2) the name(s) of the person(s) responsible for the report;
  - 3) the NELAP recognition fields of accreditation for which initial recognition or renewal is sought; and
  - 4) the comments of the NELAP evaluation team on the accrediting authority's compliance with the requirements of the NELAC standards.
- b) If the on-site evaluation does not reveal any deficiencies, the NELAP evaluation team shall recommend to the ?NELAP Director? that the AA be granted or maintain NELAP recognition.

# Evaluation Report Format

- **Standardized Format**
  - ✦ January 2008 draft version
    - may be modified as long as elements presented
- **Table of Contents**
  - ✦ Team Composition
  - ✦ Members of [Organization] interviewed
  - ✦ Dates of On-Site Evaluation
  - ✦ Background
  - ✦ Findings
  - ✦ Summary
  - ✦ Attachment: Observation of On-site Laboratory Assessment
  - ✦ Appendices if warranted, should be included

## Next Step – No Deficiencies

- Team recommends to NELAP Board
  - ✦ Initial application – grant recognition
  - ✦ Renewal application – maintain/renew recognition
- NELAP Board issues certificate of NELAP recognition



*(NELAC Chapter 6.4.3.b)*

## Next Step – Deficiencies Cited

- Develop report that will:
  - ✦ Identify specific deficiencies
  - ✦ Include references to specific NELAC standards
  - ✦ Provide suggested corrective action

*(NELAC Chapter 6.4.3.c)*

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120

6.4.3.c

## AB's Response

- 30 days from receipt of report
  - ✦ AB must submit a corrective action plan
- Corrective action plan must:
  - ✦ Detail specific actions that will be taken
  - ✦ Identify the schedule for timely completion
  - ✦ Require implementation within 65 days of receipt of on-site report
    - Except those requiring new or revised regulations or legislation
      - Maximum time 2 years (NELAC Chapter 6.5)

*(NELAC Chapter 6.4.3.d)*

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121

•Implementation of regulatory corrective actions may take more than 65 days but only if involves deficiencies in Section 6.5, those where an operating program requires new or revised regulations or legislation.

•All days calendar days.

•65 days from 6.4.3.d.3.

## AB's - No Response

- No response in 30 days
  - ✦ Evaluation team recommends to NELAP Board
    - Denial (New applicants)
    - Revocation (Renewal Abs)

*(NELAC Chapter 6.4.3.e)*

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122

•Implementation of regulatory corrective actions may take more than 65 days but only if involves deficiencies in Section 6.5, those where an operating program requires new or revised regulations or legislation.

•All days calendar days.

•65 days from 6.4.3.d.3.

## Response to Corrective Action Plan

- Team – 20 days to review corrective action plan and provide comments
- Applicant – 20 days to respond to comments
- Team – 20 days to review second submittal
- Deficiencies must be resolved by the second submittal

*(NELAC Chapter 6.4.3.f)*

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123

- 6.4.3.f, 6.4.3.g
- If deficiencies remain, Team notifies applicant by certified mail.
- If applicant does not submit responses within the required timeframes.
  - Team recommends denial or revocation.
- If deficiencies that affect only certain fields or accreditation are not corrected, the team can recommend recognition for all but those FOAs.
- If deficiencies affect the entire program, the team must recommend denial or revocation of the entire program G.4.3.g.1&2.

## Revocation or Denial Recommendations

- Full or Partial Revocation or Denial may be recommended
- Negative recommendations can be caused by:
  - ✦ Failure to submit a corrective action plan within the time limits
  - ✦ Failure to resolve all deficiencies
  - ✦ Falsification of information

*(NELAC Chapter 6.4.3.g)*

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124

•This deals primarily with evaluation of corrective action plans submitted by applicants.

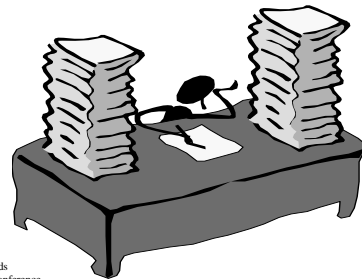
6.4.3 g team recommendation for denial or revocation

6.4.3 falsification of information

6.6.e applicant appeal rights on revocation or denial decision

## Recommendations to the NELAP Board

- All recommendations or requests to the NELAP Board are made in writing
  - ✦ Send copy to QAO
  - ✦ Document rationale and outstanding deficiencies



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125

- Both the Evaluation teams recommendations and the applicant's request for an extension to comply with the standards must be in writing.
- The applicant's request must go through the evaluation team.
- And again: the requirements of Section 6.5 are an operating program and the need for new or revised regulations or legislation.

## Recommendations to NELAP Board (cont.)

- Deficiencies resolved successfully within two tries
  - ✦ Team recommends recognition
- Deficiencies not resolved within two tries, or determination of falsification
  - ✦ Team recommends that applicant's recognition be revoked or denied

*(NELAC Chapter 6.4.3)*

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126

•Section 6.6.b.1 requires the team to make “a recommendation to grant, maintain or revoke NELAP recognition in full or in part.”

•If all deficiencies are not corrected and they affect the entire accreditation program, the Team shall recommend that the Authority's recognition be revoked or denied.

## Recommendations to NELAP Board (cont.)

- Deficiencies affect only certain fields of accreditation
  - ✦ Team may recommend approval for unaffected fields
- Deficiencies involve new legislation or rulemaking
  - ✦ AB can request an extension of time to comply with standards
  - ✦ Team shall recommend approval  
(NELAC Chapter 6.4.3)

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127

- If remaining deficiencies affect only certain fields of accreditation, the NELAP Assessment Team may recommend approval for only those fields of accreditation without deficiencies. This is in Section 6.4.3.g.1.
- If remaining deficiencies can be resolved only by new legislation or rulemaking, The applicant can request an extension to comply if they have an operating accreditation program. This request is made through the evaluation team to the ?NELAP Director? as specified in Section 6.5 the team can recommend accreditation as stated in 6.4.3.g.3.

## Requests for Extensions

- 2-year extension may be granted if:
  - ✦ Authority operates an accreditation program
  - ✦ Implementation of corrective actions requires regulatory or legislative action
- If deficiencies continue - more than 2 years
  - ✦ Requires NELAP Board review and acceptance
  - ✦ May require AB to demonstrate progress on improvements

*(NELAC Chapter 6.5)*

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128

- Requests submitted in writing through the evaluation team to the Director.
- AARB is the Accrediting Authority Review Board and the requirement for the recommendation is in Section 6.5.b.1.
- The accrediting authority must also provide documentation to demonstrate that it has made significant progress towards completing its regulatory or legislative process as required by Section 6.5.b.3.
- Timetable required by 6.5.c

## Final Recommendation from Team

- Where applicable, includes
  - ✦ Recommendation to grant, maintain, or revoke accreditation in full or in part
  - ✦ Summary of supporting reasons
  - ✦ Copies of all application and on-site review letters and corrective action responses
  - ✦ Copy of requests for an extension of time
- AB supplied with a copy of the Team's final report to the NELAP Board
  - ✦ Also QAO
  - ✦ Electronic copies (add to SOP)
- The NELAP Board notifies the AB of acceptance or rejection of the Team's recommendation within 30-days  
(NELAC Chapter 6.6)



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129

- Recommendation from Team to ?NELAP Director?.
- Review Letters and corrective action plans include:
  - Application review letters sent to the AA
  - Corrective action response letters submitted by the AA
  - On-site evaluation review letters sent to the AA
  - All the on-site evaluation response letters submitted by the AA
  - Section 6.6 of standard

## Appeals

- AB or applicant has the right to appeal the NELAP Board's initial decision by notifying the NELAP Board within 20 days of receipt of the initial decision
- Dispute Resolution - Based On SOP
  - ✦ To be finalized during this meeting

*(NELAC Chapter 6.11)*



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130

- Within 20 days of receipt of the Team's recommendation, ?NELAP Director? provides notification of acceptance or rejection.
- The AA has the option to appeal a revocation or denial decision regarding NELAP recognition by the ?NELAP Director? as set forth in 6.11 The AARB is as we've said the Accrediting Authority Review Board.
  - 6.6.e references Section 6.10. This section deals with appealing findings based upon differences in Standards interpretations, it is Section 6.11 that deals with appealing denial or revocation decisions.

## Certificate of NELAP Recognition

- NELAP Board issues certificate of NELAP recognition
- Recognition effective for three years



*(NELAC Chapter 6.7)*

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## Closure of Recognition Process

- Within 30 days of final decision, Team submits to NELAP Board
  - ✦ All original documents, letters, evaluation notes, checklists, etc.
  - ✦ The EC under direction of LE submits all records to NELAP Board
  - ✦ The LE may retain a complete file
  - ✦ Final storage to be determined



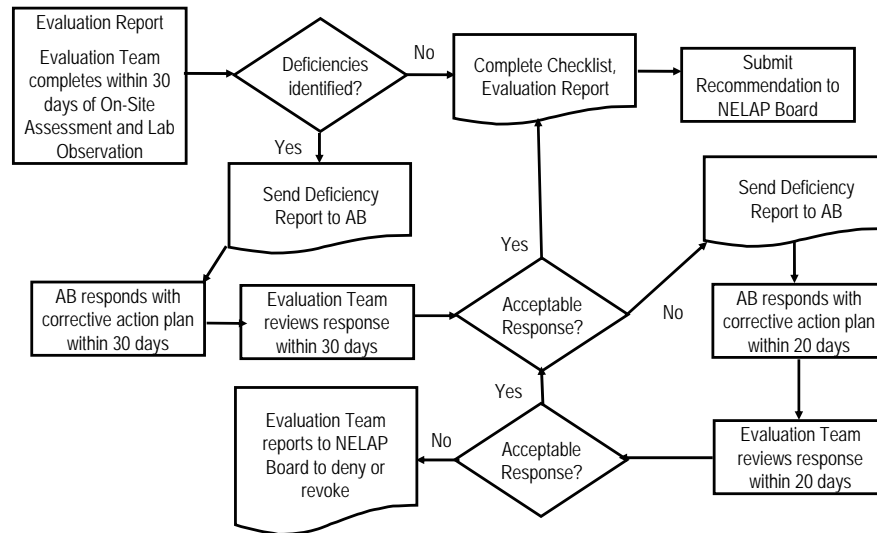
*(NELAC Chapter 6.9)*

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132

- Within 30 days of:
  - Director's final decision, or
  - AA Review Board's final recommendation.
- 6.9.a

## Time Line



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133

•We've provided two time line charts for this part of the process., but please remember that the most detailed and accurate flow chart is Figure 1 in Chapter 6 of the Standard

•Any Questions?

## Questions ??

- The AB must submit acceptable corrective actions with a time frame
- The Team reviews corrective action and submits recommendations
- The NELAP Board issues a certificate of recognition
- The NELAP Board issues a letter of denial or revocation if corrective action is not acceptable

# NOTES

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135

This concludes the evaluator portion of the course, tomorrow, we will deal with Interviewing and as time permits have a question and answer forum where all can participate. We have representation from Chapter 6 - Louis Johnson, NELAP - Ed Kantor. I know a little bit about Chapter 5 - quality systems and I'm learning about Chapter 3 - On Site ASSESSMENT.

# Module 8

## Outcome of Process

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136

## SOPs are on the Way

- Dealing with conflict
- Interpretation of NELAC standard
- Dispute resolution SOP
- Lead Evaluator
  - ✦ Stick to the facts - just the facts!
  - ✦ Report all Interpretations and Disputes to NELAP Board or as directed by SOP(s)
  - ✦ Get Help - You are not Alone!

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137

During the Atlanta workshop meeting (January 2002), participants rated interviewing as one of the most important tools for detecting improper practices. They developed this list: “The 7 Principles of Effective Interviewing”.

# Interpretation SOP

- Applicable to questions or interpretations
  - ✦ 2003 NELAC Standard
  - ✦ Approved TNI Standard
- Not applicable to test method and techniques
- Not used to create new standards, changes to standards
- Does not interfere with AB's authority to grant, deny, suspend or revoke accreditation
  - ✦ Must use Appeals process to handle disputes between AB and Laboratory

## Interpretation

- TNI receives questions and forwards to LASC
- LASC reviews to appropriate actions
- LASC forwards draft recommendations to NELAP Board
- NELAP Board approves or returns recommended interpretations - Notifies LASC
- LASC presents to TNI Board
- TNI posts interpretation to website

*LASC = Laboratory Accreditation System Committee*

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139

## Interpretation Considerations

- NELAP Board must ensure each interpretation
  - ✦ Provides sound and well-reasoned interpretation that is consistent with the standards
  - ✦ Must be within the scope of the SOP
  - ✦ Does not create new standards or change existing standards

# Dispute Resolution SOP

- Disputes between
  - ✦ AB
  - ✦ Evaluation Team
  - ✦ NELAP Board
- Convene a Review Panel, if necessary
  - ✦ If the Appeal to the NELAP Board is denied
  - ✦ Requested by AB or Evaluation Team (disputing party)
  - ✦ Request must be made within 30 calendar days of official notification of NELAP Board outcome of the appeal

Time line may change with final SOP(s)

# Review Panel

- Composition
  - ✦ 3 members - TNI stakeholder group
    - AB or other governmental agency operating accreditation programs
    - Laboratory
    - All Others
  - ✦ One of the 3 members is a TNI Board member
    - Chair of review panel
- Free of bias or relationship with review
- Interview AB, NELAP Board, others
- Complete work in 90 days

## Dispute Outcome

- NELAP Board makes final decision
- NELAP Board notifies AB of outcome
- One appeal allowed per application cycle
- Recognition status remains in effect during appeal
- Records of dispute and resolution
  - ✦ TNI website

## Conflict Handling Exercise Class Work

- Handling Interpretations and Conflict
  - ✦ Process review via examples
  - ✦ How do you handle method or standard interpretations?
    - Differences with Lab
    - Differences with Evaluation Team
  - ✦ How do you handle Conflicts between Evaluation Team and AB?

## Questions ??

- Appeals and dispute process are used to resolve conflict
- Interpretation of standard recommended by LASC and approved by NELAP Board
- Dispute resolution process establishes an independent review panel. Recommendation from review panel to NELAP Board.
- NELAP Board makes final decision on recognition

# NOTES

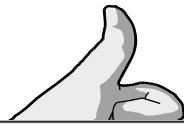
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146

This concludes Module 4. Do you have any questions?

# Thank You

After viewing the links to additional resources,  
please complete our online feedback form.



**Thank You**

[Links to Additional Resources](#)

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For those wishing to receive a hard-copy training certificate, please send an email  
to Carol Batteron at [carbat@beecreek.net](mailto:carbat@beecreek.net) with your complete mailing address.

2003 NELAC Standards  
January 30-31, 2008 - Web Conference

147

147