



# Accreditation Body Application and Evaluation

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NELAP Board Chair

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## Overview

- NELAP Board
- Accreditation Body Application
- Evaluation Team
- Onsite Evaluation
- Observation of Laboratory Assessment
- Reports and Responses
- Final Recommendation
- Vote by NELAP Board

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## NELAP Board

### Mission Statement:

To implement a national program for the uniform and consistent accreditation of environmental laboratories

□ Replaces NELAP director cited in NELAC 2003 Standards.





## NELAP Board

The purpose of the National Environmental Laboratory Accreditation Program (NELAP) is to establish and implement a program for the accreditation of environmental laboratories.

The primary components of this program are:

- The recognition of accreditation bodies,
- The adoption of acceptance limits for proficiency testing developed in the Proficiency Testing (PT) Program, and
- The adoption of the laboratory accreditation system developed in the Laboratory Accreditation System Program (LASP).





## NELAP Board

- One representative and one alternate from each NELAP-recognized Accreditation Body.
- Each representative and alternate is officially appointed by the Accreditation Body to represent their state program.
- A chairperson is selected by the members of the NELAP Board.
- Program administrator to help with administrative functions.
- Meets on 1<sup>st</sup> and 3<sup>rd</sup> Monday at 1:30 Eastern.





## NELAP Board

- Agrees to grant accreditation to any laboratory with NELAP primary accreditation from another NELAP-recognized Accreditation Body.
  - Laboratory must apply for secondary accreditation.
  - AB must grant all Fields of Accreditation from primary certificate applied for and included in the secondary AB's recognition.
  - May not ask for additional documentation or require laboratories to meet additional standards.
- Provides representative for AB evaluation.





## NELAP Board

- Discussion topics include:
  - Consistency of assessment
  - Implementation issues
  - Evaluation process and SOP
  - Vote on recognition recommendation
  - Self-sufficiency and fees





## Process Overview

- Submit Application Package
- Completeness Review
- Technical Review
- Onsite Evaluation
- Onsite Report and Recommendation
- Lab assessment observation (delayed)
- Final Report
- Evaluation Team recommendation to the NELAP Board

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## AB Application

- Download documents located on NELAP Board page on the TNI website:
  - TNI Accreditation Body Application
  - TNI Fields of Recognition Spreadsheet
  - Recognition Flowchart
  - TNI SOP for the Evaluation of Accreditation Bodies
  - TNI Application Completeness Checklist
  - TNI Checklist to Determine Accreditation Body Compliance





## AB Application

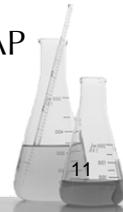
- Check the appropriate application type.
- Enter the Accreditation Body name as you want it displayed on the recognition certificate.
- Enter the Accreditation Body mailing address.
- Enter Accreditation Body Phone, FAX and general Email.
- Identify the Accreditation Body program manager and provide contact information.
- Identify the Accreditation Body Quality Assurance Officer and provide contact information.
- List the Accreditation Body staff, their area of responsibility, education, experience, and most recent NELAP training.





## AB Application

- Provide names and contact information for contractors to be used by the program.
- The list of Laboratories is only used for renewal applications. You can skip this page.
- Identify all individuals authorized to sign Laboratory Accreditation Certificates.
- List normal business hours.
- Be sure that the person responsible for laboratory accreditation signs document.
- Attach spreadsheet denoting requested areas of NELAP recognition. (Technology/Matrix).

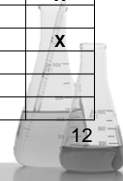




# Fields of Recognition

Technology Description	Drinking Water	Non-Potable Water	Solids and Chemical	Air	Tissue
Amperometric Titration					
Alpha Spectrometry	X	X	X		
Alpha Scintillation Cell Counter					
Anodic Stripping Voltammetry					
Auto Analyzer	X	X	X		X
Beta Spectrometry	X	X	X		
Beta/Gamma Coincidence Scintillation Counter					
Toxicity Testing		X	X		
Chromofluorogenic-Qualitative	X	X			
Chromofluorogenic-Quantitative	X	X			
Conductance	X	X	X		X
Coulometric Titration	X	X	X		X
Chromogenic/MPN-Quantitative	X	X			
Chromogenic/Quantitray	X	X			
Atomic Absorption-Cold Vapor Spectrometry	X	X	X	X	X
Atomic Fluorescence - Cold Vapor Spectrometry	X	X	X	X	X
Atomic Emission - Direct Current Plasma Spectrometry	X	X	X	X	X
Differential Pulse Polarography					
Atomic Absorption - Flame Spectrometry	X	X	X	X	X
Atomic Emission - Flame Spectrometry		X	X	X	
Fermentation Broth(A-1)-Quantitative	X	X	X		
Fermentation Broth+Fluorogenic-Qualitative	X	X			

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## AB Application

- Copies of the statutes and regulations establishing and governing the accreditation body's environmental laboratory accreditation program.
- Copies of the policies, guidance documents, and SOPs governing the operation of the accreditation body's environmental laboratory accreditation program.
- Provide documentation on how the AB restricts the use of its accreditation by accredited laboratories.
- Copy of the Quality Systems Manual
- The procedures for selecting, training, contracting and appointing assessors.
- A description of the AB's conflict of interest disclosure program.





## AB Application

- Complete Checklist to Determine Accreditation Body Compliance.
  - Answer all 326 questions on 27 pages by checking Y, N, or N/A.
    - + There should be very few N/A
    - + Every “N” will likely be identified as a deficiency during the technical review.
  - For every “Y” indicate the document supporting your answer and identify exact location in the document.
  - List multiple documents if necessary
- Send this completed checklist as part of the Application Package.





# AB Application

- Send application with receipt confirmation to:

Jerry Parr, Executive Director  
The NELAC Institute  
P. O. Box 2439  
Weatherford, TX 76086

- Letter acknowledging receipt sent to AB
- Application forwarded to Evaluation Coordinator.
- Any questions about process should be sent to Carol Batterton,  
Program Administrator:

[[carbat@beecreek.net](mailto:carbat@beecreek.net)]

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## Evaluation Coordinator (EC)

- Assists the evaluation team by assuring all communications between the evaluation team and the AB, and between the evaluation team and the NELAP Board occurs in a timely manner.
- Tracks and documents that all aspects of AB evaluations are performed in a timely manner in conformance with the SOP for Evaluations of Accreditation Bodies.
- Reviews the AB application for completeness, with concurrence of Lead Evaluator (LE).
- Reviews the evaluation reports for completeness and consistency according to the Evaluation SOP and NELAC Standards.







## Evaluation Team

- At least one member from the EPA region in which the AB is located.
- State Accreditation Body representative
- Quality Assurance Officer
- All members work under the direction of the lead evaluator
  
- Note: lead evaluator duties may be assumed by EPA staff or state AB representative.





## Evaluation Team

- All evaluation team members must meet minimum requirements for training and professional qualifications.
- The lead evaluator (and preferably all team members) must successfully complete the NELAP accreditation body evaluator training course.
- All members of the evaluation team must sign the conflict of interest certification.
- All evaluation team members must comply with the policies of the TNI NELAP Board and the following criteria as specified in NELAC 2003 Standard 6.9.1(d) which states:





## Evaluation Team

*The NELAP evaluation team shall:*

- *have at least one member of the NELAP evaluation team who meets the education, experience and training requirements for laboratory assessors specified in the NELAC standards, Chapter 3, On-site Assessment; and*
- *have at least one other member with experience that includes at least one of the following:*
  - *certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;*
  - *one year of experience implementing federal or state laboratory accreditation rulemaking; or*
  - *one year experience developing or participating at a managerial level in laboratory accreditation programs.*
- *Have documentation that verifies freedom from any conflict of interest that would compromise acting in an impartial nondiscriminatory manner.*
- *All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NELAP evaluation team member.*





## Lead Evaluator (LE)

- Generally responsible for planning activities
  - Team coordination
  - Scheduling
- Provides direction to the evaluation team throughout the evaluation process
- The LE is responsible for obtaining consensus of the evaluation team for the final recommendation of AB recognition status to the NELAP Board.
- The LE reviews and approves all reports sent to the AB.

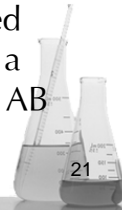




## Quality Assurance Officer (QAO)

- The QAO assures all AB evaluations are performed in a consistent manner in conformance with the Standard Operating Procedure for the Evaluation of Accreditation Bodies.
- The QAO reviews the following aspects of the AB evaluation process:
  - technical review of the AB application;
  - on-site evaluation of the AB;
  - review of the AB's corrective action plans;
- The QAO informs the NELAP Board of any unresolved consistency problems as they occur and will provide a report to the NELAP Board at the completion of each AB evaluation.

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## Completeness Review

- Application is transferred to the Evaluation Coordinator, who then has 20 days to complete the Checklist for Application Completeness.
- If the EC identifies missing information, an Application Completeness Deficiency report is sent to the AB.
- The AB has 20 days to submit missing documentation, though they can request a 20 day extension.
- The Lead Evaluator is notified if the application completeness status.





## Technical Review

- The Evaluation Team must complete a technical review of the application package and issue technical review report within 30 days.
- The AB must respond with a corrective action plan addressing all deficiencies within 30 days of receipt.
- The Evaluation Team must complete review of the corrective action plan and issue review report within 30 days of receipt.
- If deficiencies remain, the AB has 20 days to address these remaining deficiencies.
- The Evaluation Team must review the 2<sup>nd</sup> corrective action plan and send report within 20 days of receipt.





## Technical Review

- If no deficiencies were identified during the technical review or if all the deficiencies have been appropriately addressed in corrective action plan(s), the LE will schedule the onsite evaluation.
- If application deficiencies remain after the 2<sup>nd</sup> corrective action plan, the Evaluation Team will recommend to the NELAP Board that the application for recognition be denied.







## Onsite Evaluation

- An onsite management review (ISO 17011) is required initially and every three years.
- Once the evaluation team determines that the documentation is satisfactory and the application is accepted, the AB will be notified within 30 calendar days to schedule the on-site evaluation. An on-site evaluation will be conducted within 60 days of completion of the application technical review, at the mutual convenience of the evaluation team and the AB.





## Onsite Evaluation

- The LE sends written confirmation to the AB of the logistics required to conduct the evaluation including:
  - onsite evaluation date and agenda or schedule of activities,
  - copies of the standardized evaluation checklists,
  - the names, titles, affiliations, and on-site responsibilities of the NELAP evaluation team members, and
  - the names and titles of AB staff that need to be available during the on-site evaluation.





## Onsite Evaluation

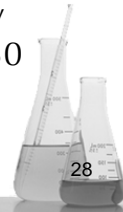
- The evaluation team conducts a comprehensive evaluation of the AB's accreditation program to determine the accuracy of information contained in the AB application and the AB's conformance to the NELAC Standards. The evaluation team will do this by:
  - interviewing management and technical staff (AB lab assessors) and reviewing documentation to determine if corrective actions were taken to address deficiencies noted in the technical review.
  - reviewing the training records and conducting interviews of AB staff designated as qualified assessors to evaluate their training.





## Onsite Evaluation

- The evaluation team has 30 days to prepare and send findings of the on-site evaluation to the AB.
  - (Note - The AB evaluation is not considered complete until the on-site evaluation and laboratory assessment observation are complete.)
- The AB must respond to the onsite report with a plan of corrective action within 30 days.
- The Evaluation Team must review and respond to the corrective action report within 20 days.
- The AB must respond to that corrective action review report with another plan of corrective action within 30 days.





## Onsite Evaluation

- If the AB addresses all the deficiencies, the LE will recommend to the NELAP Board that the AB be granted NELAP recognition.
- The NELAP Board then reviews the evaluation report and associated documentation and votes on recognition status.
- NELAP Board issues the certificate of Recognition, including fields of recognition, valid for three years.
- The AB or Evaluation Team has the right to appeal the final decision.





# Onsite Evaluation

Certificate No. \_\_\_\_\_

**CERTIFICATE OF  
NELAP RECOGNITION**

*The National Environmental Laboratory Accreditation Program  
recognizes the:*

  
*as being compliant with the accreditation body requirements of  
the NELAC Standard, and is hereby recognized  
to accredit environmental laboratories in accordance with these standards.*

Effective Date: \_\_\_\_\_ Valid through: \_\_\_\_\_

\_\_\_\_\_  
*TNI NELAP Board Chair*

Fields of Accreditation are delineated  
in the attached table

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## BECOMING A NELAP-RECOGNIZED ACCREDITATION BODY

What do you need to do?

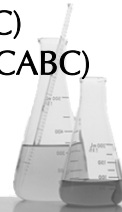
Kenneth W. Jackson  
NY State Dept. of Health  
Wadsworth Center, Albany NY





## Today's Discussion

1. The management and quality systems the potential Accreditation Body (AB) must have in place
2. Will discuss the "what", not the "how"
3. Will refer to:
  - The Application Completeness Checklist (ACC)
  - The Checklist to Determine AB Compliance (CABC)







# Essential Requirements

1. Statute and enabling regulations (ACC 2)
  - The AB must have statutory authority to grant, deny, suspend and revoke accreditation
  - Must have regulations to comply with the NELAC standards and enforce them
  - Regulations must authorize the AB to grant secondary accreditation based on the primary accreditation granted by any other NELAP AB





## Essential Requirements

1. Statute and enabling regulations (ACC 2)
2. Fully documented management and quality systems (ACC 3, 10, 15, 16)
  - All SOPs and guidance documents for program operation (ACC 3).
  - Quality Systems Manual (ACC 10). (include: policy statement; document control; organizational chart; etc.)
  - Policies and Procedures for maintaining well documented and orderly lab files (ACC 15)
  - Internal audit reports and corrective actions (ACC 16)





# Essential Requirements

1. Statute and enabling regulations (ACC 2)
2. Fully documented management and quality systems (ACC 3, 10, 15, 16)
3. Personnel (ACC 7, 8, 12)
  - Program manager
  - Quality Systems Officer
  - Trained assessors (assessor files must have quals, internal and external training; *Note: recent NELAP ruling that basic and technical training requirements must be met within one year*)





## Assuring all Requirements are in Place

The NELAC standards include requirements for Laboratories, PT Providers, PT Provider Accreditors and Accreditation Bodies (ABs).

Requirements for ABs are found in the following Chapters:

- Chapter 2, Proficiency Testing
- Chapter 3, On-Site Assessment
- Chapter 4, Accreditation Process
- Chapter 5, Quality Systems
- Chapter 6, Accrediting Authority (now Accreditation Body)

The AB requirements (326 of them!) are conveniently collected together in the “Checklist to Determine Accreditation Body Compliance” (CABC).





## The AB Requirements

The 326 items in the CABC can be placed into groups

- A. AB Management System (CABC 34-43; 46-58; 115-126; 139; 180-218; 226-239; 254-320)
- B. Accrediting labs: the lab application (CABC 27-30; 140-142; 150-178; 240-253)
- C. Accrediting labs: the on-site assessment (CABC 26; 31; 32; 39; 59-61; 63-114; 127-139; 143-149)
- D. Accrediting labs: granting accreditation (CABC 219-225; 321-326)
- E. Accrediting labs: tracking proficiency testing (CABC 1-25; 44; 45)





## The AB Management System

### 1. Documentation (CABC 34-43; 226-239; 254-270)

- Authority to grant accreditation; lab accreditation process; requirements for granting, denying, suspending, revoking accreditation.
- Lab rights and duties; laboratory requirements
- List of assessors/tech support personnel; assessor training program
- Fees
- Annual document review





## The AB Management System

1. Documentation
2. Resources (CABC 270)
  - AB must demonstrate it has the resources needed to do the job in a timely manner





## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements

- Qualifications and professional standards (CABC 46; 115-126)
- Internal and external training (CABC 47-51)
- Documentation that training assures: familiarity with regs; accreditation requirements; assessment methods; lab technologies/test methods (CABC 52-58)
- Evaluation of assessor performance (CABC 279)







## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements
4. Internal Audits (CABC 287, 308)
  - Documented procedure must include effectiveness of the program's quality system





## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements
4. Internal Audits
5. Proficiency Testing (CABC 290)
  - AB must show it requires labs to meet the NELAC PT requirements





## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements
4. Internal Audits
5. Proficiency Testing
6. Records (CABC 139, 271-285, 293, 294)
  - Assessors
  - Comprehensive and complete records for each lab
  - Retain records for 10 years  
(5 yrs for on-site assessment reports)





## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements
4. Internal Audits
5. Proficiency Testing
6. Records
7. Denial, Suspension, Revocation (CABC 180-217; 289)





## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements
4. Internal Audits
5. Proficiency Testing
6. Records
7. Denial, Suspension, Revocation
8. Contracting (CABC 297-302)





## The AB Management System

1. Documentation
2. Resources
3. Assessor Requirements
4. Internal Audits
5. Proficiency Testing
6. Records
7. Denial, Suspension, Revocation
8. Contracting
9. Notifying Changes to NELAP (CABC 315-320)
  - Authority; regs; guidance docs; SOPs; address; org structure; key personnel; contracting





## Accrediting Labs: The Lab Application

1. Application package (CABC 140-142, 150-177)
2. Technical Directors (CABC 27-30, 157)
  - Must verify qualifications





## Accrediting Labs: The Lab Application

1. Application package
2. Technical Directors
3. Lab Quality Manual, if required (CABC 171)
  - May not be required for renewal or secondary accreditation







## Accrediting Labs: The Lab Application

1. Application package
2. Technical Directors
3. Lab Quality Manual required
4. Recognition (CABC 240-246).
  - Secondary accreditation must be based only on the certificate(s) issued by the Primary AB





# Accrediting Labs: The On-Site Assessment

## 1. Timelines

- Assessment; deficiency report; corrective action report (CABC 59, 31-32)





## Accrediting Labs: The On-Site Assessment

1. Timelines
2. Structure of the assessment  
(CABC 79-91, 94)





## Accrediting Labs: The On-Site Assessment

1. Timelines
2. Structure of the assessment
3. Conducting the assessment (CABC 26; 39, 60-78, 91, 99-114, 127)
  - Records; quality system; test methods; use of NELAC checklist
  - Follow-up assessments





## Accrediting Labs: The On-Site Assessment

1. Timelines
2. Structure of the assessment
3. Conducting the assessment
4. Deficiency report (CABC 97, 98, 128-136, 144)





## Accrediting Labs: The On-Site Assessment

1. Timelines
2. Structure of the assessment
3. Conducting the assessment
4. Deficiency report (CABC 97, 98, 128-136, 144)
5. Lab's corrective action report (CABC 143, 145, 148)





# Accrediting Labs: Granting Accreditation

## 1. Interim Accreditation (CABC 219-220)

- Use of interim accreditation is optional
- May be used for initial applications or for labs that have not been subject to on-site assessment within 2.5 years





## Accrediting Labs: Granting Accreditation

1. Interim Accreditation
2. Certificates of accreditation (CABC 221-225)







## Accrediting Labs: Granting Accreditation

1. Interim Accreditation
2. Certificates of accreditation
3. Advertising; use of NELAP accreditation (CABC 321-326)





## Accrediting Labs: Tracking Proficiency Testing

1. Laboratory Requirements (CABC 1-24; 44)
2. AB Responsibilities (2; 25; 45)





# Summary

## 1. The AB must have a Quality Manual, Policies and Procedures addressing the following:

- Document control
- Organizational Structure
- Records control
- Contracting
- Complaints
- Lab Application Review
- Assessor Training and Oversight
- On-Site Assessment
- On-Site Assessment Deficiency Review
- On-Site Assessment Corrective Action Review
- On-Site Assessment Follow-up and Administrative Action
- Internal Quality Audit

- and more! If you do it, it must be documented





# Summary

2. The AB must have a fully documented file (electronic and/or hardcopy) on each accredited laboratory
  - Application forms
  - Documentation that Technical Director qualifications have been verified (primary accreditation)
  - PT data
  - On-site assessment checklists
  - Corrective action reports
  - Correspondence
  - Copies of certificates of accreditation
  - etc.





# Summary

## 3. The Technical Review:

“Tell me”. Does the AB have all essential documentation in place?





# Summary

## 4. The On-Site Evaluation

“Show me”. Is the AB doing in practice what its documentation says it must do?

(It is recognized that many functions will not be implemented until the AB starts accrediting labs)

*Note: the AB will be held to following its SOPs even if they exceed the NELAC requirements.*





# Next Steps

This presentation described WHAT the AB must do

Next, NELAP will be offering mentoring; i.e., HOW to do it.

A mentoring session will be provided at the  
January 2009 Forum on Laboratory  
Accreditation.





NELAP wants YOU as an AB, and we are here to help.

The ABs collectively have about 70-80 years experience in running NELAP accreditation programs, and most of us have gone through the application process 4 times. We are here to help and share our experiences (mistakes and successes).







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



**Thank You**

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