

The NELAC Institute
National Environmental Laboratory Accreditation Program

Standard Operating Procedure
For the
Evaluation of Accreditation Bodies

Revision 8.4
October 22, 2007

Prepared by TNI NELAP Board Date _____

Reviewed by _____ Date _____

Concurred by _____ Date _____

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51.0 At least one other member of the team shall have the experience stated in NELAC Standard 6.9.1(d)(2):..... 18

52.0 See section 5.0..... 18

53.0 The NELAP Board makes the final determination of evaluation team members..... 18

54.0 Each member of the evaluation team is required to fill out and submit the Conflict of Interest form provided in Appendix B to the LE after the NELAP Board designates the evaluation team members and before commencing the technical review. The LE will inform the NELAP Board if any team member(s) has a conflict..... 18

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59.0 The AB shall have no more than 20 days from receipt of the Completeness Deficiency Report to supply any missing information. If the missing material is not submitted, renewal will not proceed. Once the EC determines that the application is complete, he/she shall notify the LE, who shall in turn notify the AB and the NELAP Board of this determination. [NELAC Standard 6.3.2]..... 18

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63.0 The NELAP Evaluation Team shall review the application and supporting documents to evaluate whether the AB’s accreditation program requires its laboratories to meet the NELAC Standard; Chapter 2 Proficiency testing, Chapter 3, On-site Assessment, Chapter 4, Accreditation Process and Chapter 5 Quality Systems..... 18

64.0 Also, the technical review shall follow the requirements of the NELAC Standard Section 6.3.2.1..... 18

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66.0 The AB will have 30 days to respond to any deficiencies with written corrective actions. The evaluation team shall review and respond to the AB’s corrective actions within 30 days of receipt..... 19

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68.0 The evaluation team shall review the AB’s second corrective action response within 20 calendar days of receipt. If application deficiencies remain after the second attempt to resolve them, the team shall document the unresolved deficiencies and recommend to the NELAP Board that: 19

69.0 If the initial application as submitted contained no deficiencies or if the deficiencies were corrected as provided in subsection 6.3.2.2(d) of the NELAC Standard, except those deficiencies requiring legislation or rulemaking action as set forth in Section 6.5 of the NELAC Standard, the NELAP evaluation team shall schedule the on- site evaluation. 19

70.0 If the AB’s renewal application contained no deficiencies or if deficiencies were corrected in accordance with the NELAC Standards, the application is accepted and the evaluation team shall schedule the on-site evaluation. [NELAC Standard 6.3.2.2.e]..... 19

71.0 If an AB elects to appeal denial or revocation of NELAP recognition resulting from the application technical review process, an AB must follow the procedure set forth in the Section 6.10 of the NELAC Standard..... 19

72.0 Scheduling the On-Site Program Evaluation..... 19

73.0 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 shall be conducted within 60 days of completion of the application technical review, at the mutual convenience of the evaluation team and the AB. 19

74.0 The LE, on behalf of the evaluation team, will send written confirmation to the AB of the logistics required to conduct the evaluation, and to all of the evaluation team members. The written confirmation shall include, but is not limited to:..... 19

75.0 onsite evaluation date and agenda or schedule of activities,..... 20

76.0 copies of the standardized evaluation checklists,..... 20

77.0	the names, titles, affiliations, and on-site responsibilities of the NELAP evaluation team members, and.....	20
78.0	The names and titles of AB staff that need to be available during the on-site evaluation.	20
79.0	Conducting the On-Site AB Evaluation.....	20
80.0	The evaluation team shall conduct an opening meeting prior to the start of the evaluation.	20
81.0	The evaluation team shall conduct 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:	20
82.0	interviewing management and technical staff (AB lab assessors); (2) reviewing internal AB audits to determine if corrective actions were taken to address noted deficiencies;	20
83.0	reviewing a minimum of three files from the list of NELAP accredited laboratories (more files should be reviewed if significant findings warrant);	20
84.0	reviewing evaluation forms submitted by laboratories;	20
85.0	reviewing records of laboratory complaints, disputes and appeals;	20
86.0	reviewing the training records and conduct interviews of AB staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques and the NELAC Standard; and	20
87.0	observing the AB during its on-site assessment of a laboratory. The laboratory selected should hold sufficient fields of accreditation to allow the team to observe a comprehensive on-site assessment by the AB. A second laboratory assessment observation may be necessary if a full service laboratory is not due for an AB assessment.	20
88.0	The evaluation team will assess the AB to ensure that all EPA program requirements are met, including drinking water, wastewater and air programs.....	20
89.0	When selecting laboratory files to review, the evaluation team will select those with varying fields of accreditation and different assessors. The evaluation team will also include files from (i) a laboratory that has lodged a complaint, if applicable; and (ii) a laboratory that was subject to administrative action through severe quality system deficiencies if applicable. At a minimum, the team will review the following information in each laboratory file:.....	20
90.0	The team will conduct an exit debriefing to discuss all noted deficiencies.	21
91.0	Documentation of Findings from the On-Site Program Evaluation.....	21
92.0	In accordance with Section 6.4.3 of the NELAC Standards, documentation of the findings shall be delineated in the final report, along with any significant findings from the observation of the accreditation body's on-site assessment of a laboratory. (See SOP Section 6.10.)	21
93.0	The evaluation team has 30 days to prepare and send findings of the on-site evaluation to the AB by any method providing receipt confirmation. (Note - The AB evaluation is not	

considered complete until the on-site evaluation and laboratory assessment observation are complete.).....21

94.0Scheduling of the Observation of the Laboratory Assessment.....21

95.0 In accordance with Section 6.4(d) of the NELAC Standards, at least one member of the NELAP evaluation team must observe the AB conducting an actual on-site laboratory assessment. The QAO may also be present at the on-site laboratory. At the time the on-site evaluation is being scheduled, the LE should request from the AB a schedule of upcoming laboratory assessments. The LE will use this schedule to select the lab assessment which will be observed during the on-site evaluation or other mutually agreed time. (Note: Although the observation can be conducted prior to the on-site AB evaluation, it probably should not take place until after the technical review issues have been resolved).....21

96.0 The LE may elect to send more than one member of the evaluation team to observe the assessment. This decision should be based on: (1) the scope of the laboratory assessment and the number of AB assessors involved, and (2) the availability of members of the evaluation team. .21

97.0Conduct of the Laboratory Assessment Observation.....21

98.0 During the observation of the laboratory assessment, the evaluation team member’s role is to observe the AB’s laboratory assessment team. The evaluation team members are not active participants in the laboratory assessment. The evaluation team member(s) should make every effort to observe as many aspects of the AB’s assessment as possible and should make sure to concentrate on areas where the technical review may have revealed weaknesses in the AB’s program..... 21

99.0 A copy of the current version of the checklist, “NELAP Evaluation of AB Assessors”, shall be completed.....22

100.0Documentation of Findings from the Laboratory Assessment Observation.....22

101.0 Each member of the AB evaluation team that participates in the laboratory assessment observation must transmit his/her observations to the EC for inclusion in the on-site evaluation report. These findings must be transmitted to the EC in a timely manner. The exact due date shall be determined by consensus of the evaluation team members to make sure that no deadlines are missed.22

102.0 Following approval by the LE, the NELAP evaluation team on-site assessment report shall be sent to the AB by any method providing receipt confirmation within 30 calendar days of completion of the on-site assessment.....22

103.0Response to the AB Corrective Action Report (CAR)..... 22

104.0 Each member of the evaluation team must also review the AB’s response to the on-site evaluation report, including its proposed corrective actions, and transmit their review to the LE in a timely manner. The LE shall respond to the AB in writing, within 20 calendar days of receipt of the AB CAR.....22

105.0 If the AB CAR does not address all deficiencies, the LE shall notify the AB by any method providing receipt confirmation that it must submit another CAR for the remaining deficiencies not covered by Section 6.5 of the NELAC Standard within 20 calendar days of receipt of this notification..... 22

106.0 If the AB corrects all the deficiencies, The LE shall recommend to the NELAP Board that the AB be granted NELAP recognition..... 22

107.0 The LE must consider the AB’s responses in preparing written recommendations to the NELAP Board (as discussed in Sec. 6.12)..... 22

108.0 Recommendations to the NELAP Board..... 22

109.0 All recommendations to the NELAP Board regarding NELAP recognition will be made in accordance with Section 6.6 of the NELAC Standards. The LE shall be responsible for preparing the written recommendation with input from, and on behalf of, the entire evaluation team. The report will be compiled by the EC, under the direction of the LE. Appendix F provides a model recommendation letter. 22

110.0 The renewal or dismissal letter and the certificate, if one is awarded, will then be issued and mailed by the NELAP Board..... 22

111.0 Issuance of Certificate of Recognition to the AB..... 23

112.0 Handling of Unexpected Circumstances..... 23

[8.0 Criteria, Checklists, Standards 23](#)

113.0 All evaluators must ensure that they are using the correct version of the NELAC standards and checklists. 23

114.0 The complete 2003 NELAC Standard will be available with sections highlighted to identify language that were moved to policy and procedures..... 23

115.0 Current editions will be available on The NELAC Institute (TNI) website at:..... 23

[9.0 Records Management 23](#)

116.0 Records associated with the evaluation of the ABs shall be handled in accordance with the requirements found in Section 6.9 of the NELAC Standards. 23

117.0 The EC, under the direction of the LE, is responsible for submitting all documents, letters, evaluation notes, checklists, etc., to the NELAP Board within 30 days of the team’s final recommendation. 23

118.0 The LE, at his/her discretion, may retain a complete file of the AB evaluation. 23

119.0 Final storage location for records is yet to be determined..... 23

[10.0 Quality Control..... 23](#)

120.0 This SOP will be reviewed annually by the NELAP evaluators. 23

121.0	This review will be documented and any changes deemed necessary will be made with the NELAP Board’s approval.	23
122.0	If the document is revised, the revisions will be distributed to the NELAP Assessors and the NELAP Board.....	23
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1.0 Modifications

Date:	Change:
10/22/07	Updated personnel list for Appendix A and B.
10/22/07	Editorial and formatting

2.0 Purpose

This document describes the procedures used by The NELAC Institute (TNI) National Environmental Laboratory Accreditation Program (NELAP) Board to evaluate NELAP Accreditation Bodies (AB) for initial or continuing recognition.

3.0 Applicability

This Standard Operating Procedure is applicable to initial or continuing reviews of Federal, State or Tribal Accreditation Bodies conducted by NELAP Evaluators. It is based on the policies of the TNI NELAP Board and the 2003 NELAC Standards.

4.0 Summary/Scope

This document includes the procedures used to:

- Perform a completeness check of an AB's application and its attachments.
- Perform a technical review of these materials.
- Perform an on-site evaluation of an AB.
- Perform an observation of the AB's assessor(s) performing a laboratory assessment.
- Complete the on-site evaluation report.
- Perform the review of and response to the AB's corrective action plans.
- Provide recommendations of the evaluation team to the TNI NELAP Board.

The examination of the systems, processes and procedures of the AB must provide a determination of the AB's compliance with the policies of the TNI NELAP Board and its capabilities to perform laboratory assessments in a consistent, uniform manner.

5.0 Definitions

Accreditation: the process by which an agency or organization evaluates and determines that a laboratory meets certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accreditation Body (AB): 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]

Applicant Laboratory or Applicant: the laboratory or organization applying for NELAP accreditation. (NELAC)

Assessment: the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of NELAC). (NELAC)

Assessment Criteria: the measures established by NELAC and applied in establishing the extent to which an applicant is in conformance with NELAC requirements. (NELAC)

Assessment Team: the group of people authorized to perform the on-site inspection of a laboratory and evaluate proficiency testing data required to establish whether an applicant meets the criteria for NELAP accreditation. (NELAC)

Assessor: one who performs on-site assessments of accreditation bodies and laboratories' capability and capacity for meeting NELAC requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested. (NELAC)

Audit: a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

Critical Finding: a finding or a combination of findings that results in a significant negative effect on data quality or defensibility, if not corrected. (NELAC)

Deficiency: See Finding and Critical Finding

Denial: to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application. (NELAC)[4.4.1]

Evaluation: the process used to measure or establish the performance, effectiveness, and conformance of an organization as a NELAP Accreditation Body

Evaluation Coordinator (EC): An individual, selected by the NELAP Board, who coordinates all communications between the Evaluation Team and the AB, and assures all steps of the evaluation are completed in a timely manner. The Evaluation Coordinator (EC) reports directly to the NELAP Board.

Evaluation Team: A team comprised of the EC, LE, QAO, other State AB and/or EPA representatives, and any other technical evaluators approved by the TNI NELAP Board to conduct a review of an AB for the purposes of granting NELAP recognition to the AB.

Field of Accreditation: (previously Field of Testing) NELAC's approach to accrediting laboratories by matrix, technology/method and analyte/analyte group. Laboratories requesting accreditation for a matrix-technology/method-analyte/analyte group combination or for an updated/improved method are required to submit only that portion of the accreditation process not previously addressed. (NELAC)

Field of Proficiency Testing: NELAC's approach to offering proficiency testing by matrix, technology, and analyte/analyte group.

Finding: an assessment conclusion, referenced to a NELAC Standard and supported by objective evidence that identifies a deviation from a NELAC requirement.

Lead Evaluator (LE): a state or EPA member of the evaluation team who provides direction for the evaluation team and is responsible for the final recommendation regarding AB recognition, based on input from the entire team.

NELAC Standards: the plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Environmental Laboratory Accreditation Conference. (NELAC)

NELAP 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. (NELAC)

Primary Accreditation Body: the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing. (NELAC)

Quality Assurance Officer: An individual, selected by the NELAP Board who participates on all AB assessments during an assessment cycle, performing a quality assurance function, and acting as a liaison between the NELAP Board and the evaluation team. The QAO reports directly to the NELAP Board

Secondary Accreditation Body: the Territorial, State or federal agency that grants NELAC accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accreditation Body. See also Recognition and Primary Accreditation Body. (NELAC)

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Technology: a specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

United States Environmental Protection Agency (EPA): the federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

6.0 Personnel Qualifications and Responsibility

- 1.0 All evaluation team members must meet minimum requirements for training and professional qualifications.
- 2.0 The lead evaluator (and preferably all team members) must successfully complete the NELAP accreditation body evaluator training course.

- 3.0 All members of the evaluation team must sign the conflict of interest certification. See Appendix B for the Conflict of Interest form.
- 4.0 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 which states:
- 5.0 The NELAP evaluation team shall:
 - 6.0 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
 - 7.0 have at least one other member with experience that includes at least one of the following:
 - 8.0 certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;
 - 9.0 one year of experience implementing federal or state laboratory accreditation rulemaking; or
 - 10.0 one year experience developing or participating at a managerial level in laboratory accreditation programs.
 - 11.0 Have documentation that verifies freedom from any conflict of interest that would compromise acting in an impartial nondiscriminatory manner.
 - 12.0 All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NELAP evaluation team member.
 - 13.0 The Lead Evaluator is generally responsible for planning activities. All members of the evaluation team should be involved to ensure that the evaluation is well planned and consistent with the evaluations of other ABs.
 - 14.0 The LE provides direction to the evaluation team throughout the evaluation process.
 - 15.0 The LE is responsible for obtaining consensus of the evaluation team for the final recommendation of AB recognition status to the NELAP Board.
 - 16.0 The LE reviews and approves all reports sent to the AB by the Evaluation Coordinator
 - 17.0 The Evaluation Coordinator has the following duties:
 - 18.0 Assists the evaluation team by having responsibility for all direct communication between the evaluation team and the AB, and between the evaluation team and the NELAP Board.
 - 19.0 Assures all aspects of AB evaluations are performed in a timely manner in conformance with the Standard Operating Procedure for the Evaluation of Accreditation Bodies
 - 20.0 Reviews the AB application for completeness, with concurrence of the LE.
 - 21.0 Compiles the evaluation reports under the direction of the LE

22.0 The Quality Assurance Officer has the following duties:

23.0 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.

24.0 The QAO participates in the following aspects of the AB evaluation process:

25.0 technical review of the AB application;

26.0 on-site evaluation of the AB;

27.0 and review of the AB's corrective action plans;

28.0 The QAO will inform 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.

7.0 Procedures

29.0 Frequency and Scope of Evaluation

30.0 The 2003 NELAC standards require Accreditation Bodies to be evaluated initially and at a minimum of once every 3 years thereafter. This evaluation will include:

31.0 Completeness and technical reviews of the application package,

32.0 An on-site evaluation,

33.0 Observation of the AB conducting an on-site laboratory assessment,

34.0 On-site evaluation report(s) with findings for both the on-site evaluation and the observation, and

35.0 Recommendations to the TNI NELAP Board regarding recognition or denial of recognition.

Once the evaluation team makes a recommendation to the NELAP Board for granting or denying recognition, all subsequent communications shall be between the TNI NELAP Board and the AB, with copies given to the LE and the EC.

36.0 Application Process

37.0 Initial Application

38.0 Initial Application forms for NELAP recognition can be obtained from the NELAP Board.

39.0 The application must be signed and dated by the highest ranking individual within the department or agency responsible for laboratory accreditation activities for which NELAP recognition is being sought. (This is the person that has the ultimate authority and responsibility for accreditation decisions.) By signature on the application, this individual must attest to the validity of the information contained within the application and its

supporting documents.[NELAC Standard 6.3.1(c)]

40.0The completed application and supporting documents shall be submitted to the NELAP Board chairperson or designee.

41.0Upon receipt of the application and supporting documents the NELAP Board chairperson or designee shall send an acknowledgement to the AB and establish an evaluation team, with the approval of the NELAP Board. The review process shall begin. (This SOP Section 6.5) [NELAC Standard 6.3.2(c)]

42.0Renewal Applications

43.0Notification

The NELAP Board chairperson or designee will send a letter with an attached application to the AB at least 270 (October 1, 2007) calendar days prior to the expiration of the AB's current NELAP recognition with copies sent to the EC and appropriate LE. In the letter, the NELAP Board will indicate that four copies of the completed application and any supporting documentation shall be submitted to the EC. All team members will be identified in the letter. The letter shall be sent by any method providing receipt confirmation.

44.0Application Submittal

45.0The AB must submit four copies of the completed application and supporting documents to the EC within 30 days of receipt of the application. [NELAC Standard 6.3.1(d)(3)]

46.0If the AB does not submit a renewal application within 30 days, the AB will receive final notification from the NELAP Board by any method providing receipt confirmation that, if an application is not submitted within another 20 days, the AB's recognition will expire with the current NELAP certificate recognition. [NELAC Standard 6.3.2 (b)]

47.0Application Communications

Once the application is given to the EC, all subsequent communications shall be between the EC and the AB, with copies provided to the LE. The LE will respond to these communications as necessary.

48.0Selection of the Evaluation Team

49.0The NELAP Board appoints the team. The team will usually include one member from the EPA Region in which the AB is located (See Appendix A for EPA staff). The EPA Region can propose additional EPA team members to the NELAP Board. The evaluation team will also include a representative of another AB and the QAO. The evaluation team shall agree on one of their members being designated LE, and shall submit that person's name to the NELAP Board for approval. All team members will work under the direction of the LE. [NELAC Standard 6.9.1]

- 50.0 At least one member of the team shall have completed the evaluator training course.
- 51.0 At least one other member of the team shall have the experience stated in NELAC Standard 6.9.1(d)(2):
- 52.0 See section 5.0
- 53.0 The NELAP Board makes the final determination of evaluation team members.
- 54.0 Each member of the evaluation team is required to fill out and submit the Conflict of Interest form provided in Appendix B to the LE after the NELAP Board designates the evaluation team members and before commencing the technical review. The LE will inform the NELAP Board if any team member(s) has a conflict.

55.0 Review of Application and Supporting Documents

56.0 Application Completeness Review

- 57.0 Following receipt of the application, the EC shall review it for completeness within 20 days, using the “Checklist for Application Completeness”, and will report to the LE
- 58.0 If the application is not complete, the LE will send the AB an Application Completeness Deficiency Report (Appendix E includes a possible example of a deficiency report letter) in writing. The NELAP Board and evaluation team members will receive a copy of this Deficiency Report.
- 59.0 The AB shall have no more than 20 days from receipt of the Completeness Deficiency Report to supply any missing information. If the missing material is not submitted, renewal will not proceed. Once the EC determines that the application is complete, he/she shall notify the LE, who shall in turn notify the AB and the NELAP Board of this determination. [NELAC Standard 6.3.2]
- 60.0 Extensions up to 20 days may be granted in accordance with NELAC Standard 6.3.2 c (3).

61.0 Application Technical Review

- 62.0 The evaluation team shall then conduct a technical review to verify that all required items have been addressed. The applicant’s completed NELAP Application Checklist will be used as a guide to determine accreditation body compliance with the NELAC Standard. The review shall be performed by the same NELAP Evaluation Team assigned to the on-site evaluation.
- 63.0 The NELAP Evaluation Team shall review the application and supporting documents to evaluate whether the AB’s accreditation program requires its laboratories to meet the NELAC Standard; Chapter 2 Proficiency testing, Chapter 3, On-site Assessment, Chapter 4, Accreditation Process and Chapter 5 Quality Systems.
- 64.0 Also, the technical review shall follow the requirements of the NELAC Standard Section

6.3.2.1.

65.0 The evaluation team has 30 days to conduct this review after the application is determined complete and respond in writing to the AB. The evaluation team will send by any method providing receipt confirmation an application technical review deficiency report to the AB. [NELAC Standard Section 6.3.2.2.d]

66.0 The AB will have 30 days to respond to any deficiencies with written corrective actions. The evaluation team shall review and respond to the AB's corrective actions within 30 days of receipt.

67.0 If the accreditation body's plan of corrective actions does not address all deficiencies, the NELAP evaluation team will notify the accreditation body by any method providing receipt confirmation that it must submit another plan of corrective actions for the remaining deficiencies within 20 calendar days of the accreditation body's receipt of this notification.

68.0 The evaluation team shall review the AB's second corrective action response within 20 calendar days of receipt. If application deficiencies remain after the second attempt to resolve them, the team shall document the unresolved deficiencies and recommend to the NELAP Board that:

- the AB's application for initial recognition be denied, or
- the AB's recognition be revoked.

69.0 If the initial application as submitted contained no deficiencies or if the deficiencies were corrected as provided in subsection 6.3.2.2(d) of the NELAC Standard, except those deficiencies requiring legislation or rulemaking action as set forth in Section 6.5 of the NELAC Standard, the NELAP evaluation team shall schedule the on-site evaluation.

70.0 If the AB's renewal application contained no deficiencies or if deficiencies were corrected in accordance with the NELAC Standards, the application is accepted and the evaluation team shall schedule the on-site evaluation. [NELAC Standard 6.3.2.2.e]

71.0 If an AB elects to appeal denial or revocation of NELAP recognition resulting from the application technical review process, an AB must follow the procedure set forth in the Section 6.10 of the NELAC Standard.

72.0 Scheduling the On-Site Program Evaluation

73.0 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 shall be conducted within 60 days of completion of the application technical review, at the mutual convenience of the evaluation team and the AB.

74.0 The LE, on behalf of the evaluation team, will send written confirmation to the AB of the

logistics required to conduct the evaluation, and to all of the evaluation team members. The written confirmation shall include, but is not limited to:

75.0 onsite evaluation date and agenda or schedule of activities,

76.0 copies of the standardized evaluation checklists,

77.0 the names, titles, affiliations, and on-site responsibilities of the NELAP evaluation team members, and

78.0 The names and titles of AB staff that need to be available during the on-site evaluation.

79.0 Conducting the On-Site AB Evaluation

80.0 The evaluation team shall conduct an opening meeting prior to the start of the evaluation.

81.0 The evaluation team shall conduct 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:

82.0 interviewing management and technical staff (AB lab assessors); (2) reviewing internal AB audits to determine if corrective actions were taken to address noted deficiencies;

83.0 reviewing a minimum of three files from the list of NELAP accredited laboratories (more files should be reviewed if significant findings warrant);

84.0 reviewing evaluation forms submitted by laboratories;

85.0 reviewing records of laboratory complaints, disputes and appeals;

86.0 reviewing the training records and conduct interviews of AB staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques and the NELAC Standard; and

87.0 observing the AB during its on-site assessment of a laboratory. The laboratory selected should hold sufficient fields of accreditation to allow the team to observe a comprehensive on-site assessment by the AB. A second laboratory assessment observation may be necessary if a full service laboratory is not due for an AB assessment.

88.0 The evaluation team will assess the AB to ensure that all EPA program requirements are met, including drinking water, wastewater and air programs.

89.0 When selecting laboratory files to review, the evaluation team will select those with varying fields of accreditation and different assessors. The evaluation team will also include files from (i) a laboratory that has lodged a complaint, if applicable; and (ii) a laboratory that was subject to administrative action through severe quality system deficiencies if applicable. At a minimum, the team will review the following information in each laboratory file:

- Application
- Conflict of interest verification

- NELAP checklist
- Proficiency testing (PT) results for compliance with methodological and EPA program requirements
- Deficiency report(s)
- Corrective action report(s)
- Correspondence
- Final report
- Certificate if granted

90.0The team will conduct an exit debriefing to discuss all noted deficiencies.

91.0Documentation of Findings from the On-Site Program Evaluation

92.0In accordance with Section 6.4.3 of the NELAC Standards, documentation of the findings shall be delineated in the final report, along with any significant findings from the observation of the accreditation body's on-site assessment of a laboratory. (See SOP Section 6.10.)

93.0The evaluation team has 30 days to prepare and send findings of the on-site evaluation to the AB by any method providing receipt confirmation. (Note - The AB evaluation is not considered complete until the on-site evaluation and laboratory assessment observation are complete.)

94.0Scheduling of the Observation of the Laboratory Assessment

95.0In accordance with Section 6.4(d) of the NELAC Standards, at least one member of the NELAP evaluation team must observe the AB conducting an actual on-site laboratory assessment. The QAO may also be present at the on-site laboratory. At the time the on-site evaluation is being scheduled, the LE should request from the AB a schedule of upcoming laboratory assessments. The LE will use this schedule to select the lab assessment which will be observed during the on-site evaluation or other mutually agreed time. (Note: Although the observation can be conducted prior to the on-site AB evaluation, it probably should not take place until after the technical review issues have been resolved).

96.0The LE may elect to send more than one member of the evaluation team to observe the assessment. This decision should be based on: (1) the scope of the laboratory assessment and the number of AB assessors involved, and (2) the availability of members of the evaluation team.

97.0Conduct of the Laboratory Assessment Observation

98.0During the observation of the laboratory assessment, the evaluation team member's role is to observe the AB's laboratory assessment team. The evaluation team members are not active

participants in the laboratory assessment. The evaluation team member(s) should make every effort to observe as many aspects of the AB's assessment as possible and should make sure to concentrate on areas where the technical review may have revealed weaknesses in the AB's program.

99.0A copy of the current version of the checklist, "NELAP Evaluation of AB Assessors", shall be completed.

100.0 Documentation of Findings from the Laboratory Assessment Observation

101.0 Each member of the AB evaluation team that participates in the laboratory assessment observation must transmit his/her observations to the EC for inclusion in the on-site evaluation report. These findings must be transmitted to the EC in a timely manner. The exact due date shall be determined by consensus of the evaluation team members to make sure that no deadlines are missed.

102.0 Following approval by the LE, the NELAP evaluation team on-site assessment report shall be sent to the AB by any method providing receipt confirmation within 30 calendar days of completion of the on-site assessment.

103.0 Response to the AB Corrective Action Report (CAR)

104.0 Each member of the evaluation team must also review the AB's response to the on-site evaluation report, including its proposed corrective actions, and transmit their review to the LE in a timely manner. The LE shall respond to the AB in writing, within 20 calendar days of receipt of the AB CAR.

105.0 If the AB CAR does not address all deficiencies, the LE shall notify the AB by any method providing receipt confirmation that it must submit another CAR for the remaining deficiencies not covered by Section 6.5 of the NELAC Standard within 20 calendar days of receipt of this notification.

106.0 If the AB corrects all the deficiencies, The LE shall recommend to the NELAP Board that the AB be granted NELAP recognition.

107.0 The LE must consider the AB's responses in preparing written recommendations to the NELAP Board (as discussed in Sec. 6.12).

108.0 Recommendations to the NELAP Board

109.0 All recommendations to the NELAP Board regarding NELAP recognition will be made in accordance with Section 6.6 of the NELAC Standards. The LE shall be responsible for preparing the written recommendation with input from, and on behalf of, the entire evaluation team. The report will be compiled by the EC, under the direction of the LE. Appendix F provides a model recommendation letter.

110.0 The renewal or dismissal letter and the certificate, if one is awarded, will then be issued and

mailed by the NELAP Board.

111.0 Issuance of Certificate of Recognition to the AB

The issuance of Certificates of Recognition shall be the responsibility of the NELAP Board and shall be done in accordance with the requirements found in Section 6.7 of the NELAC Standards.

112.0 Handling of Unexpected Circumstances

In the event that the team encounters an unexpected or unusual circumstance, the LE should seek guidance from the QAO and the NELAP Board. This will help insure consistency in how such circumstances are handled. For example, what should the team do if the AB has no on-site laboratory assessments scheduled during the review period?

8.0 Criteria, Checklists, Standards

113.0 All evaluators must ensure that they are using the correct version of the NELAC standards and checklists.

114.0 The complete 2003 NELAC Standard will be available with sections highlighted to identify language that were moved to policy and procedures

115.0 Current editions will be available on The NELAC Institute (TNI) website at:

www.nelac-institute.org

9.0 Records Management

116.0 Records associated with the evaluation of the ABs shall be handled in accordance with the requirements found in Section 6.9 of the NELAC Standards.

117.0 The EC, under the direction of the LE, is responsible for submitting all documents, letters, evaluation notes, checklists, etc., to the NELAP Board within 30 days of the team's final recommendation.

118.0 The LE, at his/her discretion, may retain a complete file of the AB evaluation.

119.0 Final storage location for records is yet to be determined.

10.0 Quality Control

120.0 This SOP will be reviewed annually by the NELAP evaluators.

121.0 This review will be documented and any changes deemed necessary will be made with the NELAP Board's approval.

122.0 If the document is revised, the revisions will be distributed to the NELAP Assessors and the NELAP Board

11.0References

National Environmental Laboratory Accreditation Conference, Constitution, Bylaws and Standards, 2003.

Kubik, Kevin, et al, "Standard Operating Procedure for the Evaluation of Accrediting Authorities".

APPENDIX A - List of EPA Regional Evaluators for 2007 - 2008

Region 1	Ann Jeffries Arthur Clark
Region 2	Donna Ringle Kevin Kubik
Region 3	Joseph Slayton
Region 4	Marilyn Maycock Wayne Turnbull Charlie Appleby
Region 5	Cheng-wen Tsai Patrick Churilla
Region 6	Marvelyn Humphrey Raymond Flores
Region 7	Robert Nichols Lawrence Marchin
Region 8	Tony Medrano
Region 9	Mark Kutnink Ken Hendrix Jack Berges
Region 10	Roy Araki

APPENDIX B - List of AB Evaluators for 2007 - 2008

California	Fred Choske Alt: Jane Jensen
Florida	Carl Kircher Alt: Steve Arms
Illinois	TBD
Kansas	Aurora Shields
Louisiana DEQ	Karen Varnedo
Louisiana DHH	Louis Wales
New Hampshire	Bill Hall
New Jersey	Burny Wilk
New York	Ken Jackson
Oregon	Dan Hickman
Pennsylvania	Aaren Alger
Texas	Steve Stubbs Alt: Steve Gibson
Utah	Kristin Brown

APPENDIX C - Evaluation Team Conflict of Interest Form

Name _____

Agency _____

Date of NELAP Evaluator Training Course _____

Name of Accreditation Body Being Reviewed _____

I certify that I have no known relationship with the above Accreditation Body that would impair my objectivity in the performance of my responsibilities as described in the NELAC Standards.

Signature _____

Date _____

APPENDIX D - Application Review Tracking Checklist

AB Applicant _____ Regional Lead Evaluator _____

Item	NELAC Standard	Days Allowed	Date Completed
Assignment of Evaluation Team			
Region proposes additional technical evaluators to NELAP Board			
Application Renewal Notification			
NELAP Board sends out renewal letter		--	
AB returns complete application		30	
NELAP Board notifies AB of late application		20	
Conflict of Interest forms submitted to LE		7	
LE informs NELAP Board of COI (Y/N)		3	
Application Completeness Review		--	
Evaluation team conducts review		20	
LE notifies AB of deficiencies			
AB response to deficiencies		20	
Application Technical Review		--	
Evaluation team conducts review		30	
LE notifies AB of deficiencies			
AB response to deficiencies		30	
Evaluation team reviews response			
LE 2nd notice of deficiencies to AB			
AB 2nd response to deficiencies		20	
Evaluation team reviews 2nd response			
Schedule On-Site AB Evaluation		--	
LE notifies AB of on-site review logistics			
Conduct on-site review			

Item	NELAC Standard	Days Allowed	Date Completed
Conduct Observation of AB Lab Assessment			
Prepare Final Report			
Send Final Report to AB		30 days from end of total on-site	
AB response to Final Report		30 days from receipt of Rpt.	
Evaluation team reviews response		20 days	

APPENDIX E - Model Letter for Application Completeness Review Deficiencies

EXAMPLE

Dr. Xxxxx N. Yyyyyyy
Xxy State Dept. of Health
P.O. Box XXX
Xxxx, Xxx 45690

Dear Dr. Yyyyyyy,

The National Environmental Laboratory Accreditation Program (NELAP) Evaluation Team (ET) assigned to the Xxxx Accreditation Body has completed its review of the renewal application dated November 21, 2003. As you are aware, a completeness review is conducted by the ET in order to determine whether or not the information and supporting documentation required in subsection 6.3.1(b) of the NELAC Standards has been included in the application.

The ET believes that the Xxxx application is incomplete because:

[List deficiencies and reference NELAC Standard for each deficiency]

According to the NELAC Standards section 6.3.2.c (3), you have 20 days from receipt of this letter in which to provide the requested information. Thank you for your prompt attention to this matter. If you have any questions, please feel free to contact me at (xxx) yyy-zzzz.

Sincerely,

Yyyy Y. Zxxzz
NELAP Lead Evaluator
EPA, Region X
cc: NELAP Board

APPENDIX F – Model Letter for Technical Review Deficiencies

EXAMPLE

Dr. Xxxxx N. Yyyyyyy
Xxy State Dept. of Health
P.O. Box XXX
Xxxx, Xxx 45690

Dear Dr. Yyyyyyy,

The National Environmental Laboratory Accreditation Program (NELAP) Evaluation Team (ET) assigned to the [insert state] Accreditation Body (AB) has completed its technical review of the renewal application dated November 21, 2003. As you are aware, a technical review is conducted by the ET in order to determine whether or not the accreditation body's environmental laboratory accreditation program requires its accredited laboratories to meet the standards set forth in the NELAC Standards. The ET review is based on the 2003 National Environmental Laboratory Accreditation Conference (NELAC) Standards for Chapters 2, 3, 4, and 5. The 2003 NELAC Standard for Chapter 6 was followed to conduct the review.

The ET has identified a number of findings on Attachment 2, "Checklist to Determine Accreditation body Compliance." Items on the checklist which have been checked "No" are deficiencies. Specific comments relative to each deficiency have been provided in the "Document Location/Comments" column. In addition to the items which have been checked "No," there are some items where we have included a "?" in either the Yes or No column. In these instances the ET could not determine if the requirement had been met or not. Additional information to clarify what has been provided is needed by the ET in order to make a final determination. This additional clarifying information should be provided in your response to this report. Please note that while some items have been checked "Yes," the actual implementation of these requirements cannot be assessed until the actual on-site assessment of the XYX AB program takes place later this month.

Per NELAC requirements, you have 30 days in which to provide a corrective action response to this technical report. Please attach to your response any new or updated documents cited in your corrective action response.

If you have any questions or require clarification regarding any of our findings, please feel free to contact me at (xxx) xxx-xxxx.

Sincerely,

Yyyy Y. Zxxxx

NELAP Regional Lead Evaluator

EPA, Region y

Attachments

cc: NELAP Board

[Insert Evaluation Team members]

APPENDIX G - Model Recommendation Letter to the TNI NELAP Board

EXAMPLE

Recommendation for Renewal of Recognition of XXXXX as a NELAP Accreditation Body

[insert name and title]

Division of Environmental Science and Assessment (2DESA)

National Environmental Laboratory Accreditation Program Board (NELAP Board)

The National Environmental Laboratory Accreditation Program (NELAP) evaluation team assigned to the XXXXX has completed its evaluation of this Accreditation body. In accordance with Chapter 6 of the 2003 National Environmental Laboratory Accreditation Conference (NELAC) Standards, the evaluation consisted of the following: 1) a technical review of the XXXXX application for renewal and its supporting documentation 2) an on-site evaluation of the XXXXX lab accreditation program, and 3) an observation of XXXXX conduct of an on-site laboratory assessment. Each of these parts of the evaluation are discussed below.

Team members (appointed by the NELAP Board):

- [insert Evaluation Team members]

Technical Review

The evaluation team completed its technical review and issued a report detailing findings on April 12, 2004. In a response dated April 28, 2004 XXXXX provided a list of corrective actions taken to address the deficiencies noted. The team reviewed these corrective actions and determined that they adequately addressed the findings noted.

On-Site Evaluation

The team conducted an on-site evaluation of the XXXXX laboratory accreditation program on April 19 - 21, 2004. The team interviewed 19 XXXXX staff members, reviewed laboratory files, training files, complaint files, and PT records. The team documented 11 instances in which XXXXX was determined to be in non-conformance with the NELAC standards. A report was prepared and sent to XXXXX on May 27, 2004. XXXXX provided a corrective action plan for the 11 findings on June 23, 2004. The evaluation team has reviewed these corrective action responses and finds them to be acceptable.

Observation

The Regional Lead Evaluator performed an observation of XXXXX's on-site assessment of XYZ Laboratories (Edison, NJ) on May 18-20, 2004. The conduct of this assessment was found to be in compliance with the NELAC standards. No significant deviations were observed.

Recommendation

The evaluation team recommends that NELAP recognition of XXXXX's Accreditation Program be continued for all the fields of accreditation in the attached list.

As required by NELAC 6.6(b)3, attached please find copies of the following documents:

1) evaluation team's technical report, 2) XXXXX technical report corrective action response, 3) evaluation team's on-site evaluation report, and 4) XXXXX on-site evaluation corrective action plan.

If you have any comments or questions, please contact me at (xzx) zzz-yyyy.

Attachments

cc: XXXXX, XXXXX