



SOP TITLE	Issuance of Provisional Recognition to NELAP Accreditation Bodies
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Issuance of Provisional Recognition to NELAP Accreditation Bodies

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1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) describes the procedures used by The NELAC Institute (TNI) National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council (AC) to establish an alternative to continuing recognition for existing NELAP Accreditation Bodies (ABs). It sets forth the circumstances and conditions for Provisional Recognition of Accreditation Bodies (ABs) under the National Environmental Laboratory Accreditation Program (NELAP), as a result of an evaluation conducted under the SOP 3-102, Evaluation of Accreditation Bodies.

This Standard Operating Procedure is applicable to continuing evaluations of Accreditation Bodies conducted by NELAP Evaluators. It is based on the policies of the TNI NELAP AC and the 2009 TNI Standard. Unless otherwise noted, the applicable standard for this document is the 2009 TNI Standard for the Environmental Laboratory Sector, Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories". This will be referred to as "the Standard" in this document.

This SOP shall be applicable as an alternative to not renewing recognition when an AB has demonstrated that it will be unable to complete, within the timeframes set forth in SOP 3-102, Evaluation of Accreditation Bodies, corrective actions to findings that threaten the integrity of the accreditation process, but when the NELAP AC determines that not renewing the AB's recognition would not be in the best interest of NELAP.

It is a means to allow continued operation without jeopardizing other parts of NELAP, while permitting the AB additional time to bring its activities into full conformance with the Standard, for a strictly defined time period.

2.0 Summary

This document includes the procedures used to provide a suitable recommendation for Provisional Recognition of an AB to the TNI NELAP AC, when neither full recognition nor non-renewal of recognition are acceptable options. Provisional Recognition has been determined to be a reasonable alternative to non-renewal of recognition, in that it has minimal punitive effect on laboratories receiving primary or secondary accreditation from the AB, as well as minimal effect on the NELAP community of ABs, yet it is expected to provide strong incentive to the designated AB to implement the needed corrective actions as rapidly as possible.

Provisional Recognition shall be considered only when uncorrected findings from an evaluation actually jeopardize the integrity of the assessment process. However, this does not mean that laboratories accredited by the AB in question are automatically suspected to be deficient. It is anticipated that most items triggering Provisional Recognition will be ones that require additional resources or the involvement of organizations outside of the AB itself to rectify.

3.0 Related Documents

TNI Standard 2009, Volume 2, Module 1
POL 1-104, Management of Records
SOP 1-104, Management of TNI Documents
POL 3-102, Relationship of Recognitions and Evaluations
SOP 1-104, Document Management
SOP 3-104, Dispute Resolution
SOP-3-105, Standards Interpretation Request Management
SOP 3-102, Evaluation of Accreditation Bodies

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4.0 Definitions

NOTE: Terms not defined in this section may be found in Volume 2 of the 2009 or the 2016 TNI Standard: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, or the normative references for those standards

Application of Standards: implementation of the accreditation standards by the AB and the Evaluation Teams during an evaluation of an Accreditation Body.

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

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.

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

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

EPA Liaison: a staff person designated by EPA to serve as liaison to the NELAP Accreditation Council.

Evaluation Team (ET): a team comprised of the Lead Evaluator (LE), other State AB and/or EPA representatives, and any other technical evaluators or alternates approved by the NELAP Accreditation Council to conduct a review of an AB for the purposes of granting or renewing NELAP recognition to the AB.

Evaluator: one who performs on-site evaluation of accreditation bodies' capability and capacity for meeting the requirements of the standard, by examining records and other evidence.

Finding: an assessment conclusion referenced to the 2009 or the 2016 TNI Standard and supported by objective evidence.

Lead Evaluator (LE): an individual contracted to TNI who provides direction for the evaluation team and is responsible for the final recommendation regarding AB recognition, based on input from the entire team.

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

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 NELAP accreditation for a specified field of testing.

Recognition: The NELAP Accreditation Council's term for including a state AB in the arrangement whereby other ABs will accept accreditations issued by the "recognized" AB.

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

Technical Review: A detailed review of the materials required to be submitted by an AB as its application package for NELAP recognition. This review determines whether the documentation and policies are acceptable according to the 2009 TNI Standard, and is typically performed with the help of a detailed checklist.

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5.0 Procedures

- 5.1 When approaching the end of the evaluation process for AB renewals according to the evaluation SOP, the ET shall consider and determine whether renewal or non-renewal of recognition is appropriate, as stated in section 6.14. If there remain outstanding findings that are not corrected after the second opportunity for the AB to provide satisfactory corrective actions (section 6.13), provisional recognition may be considered as an alternative.
- 5.2 If there exist any circumstances making non-renewal an unsuitable action, yet the outstanding finding threatens the integrity of the accreditation process, then Provisional Recognition should be considered, to allow additional time and support for the AB to implement suitable corrective action.
- 5.3 Examples of uncorrected findings from an evaluation that might actually jeopardize the integrity of the assessment process are items of a serious nature that cannot be rectified within the timelines of the evaluation SOP, such as but not limited to:
 - a single individual or assessor who is suspected of inappropriate activity
 - systematic failure to track PTs
 - a drastic shortage of assessors to handle the evident workload
- 5.4 Provisional recognition may be granted on a case-by-case basis with an appropriate timeline set for renewing full recognition. This timeline shall be within the evaluation cycle and shall not alter that evaluation cycle.
 - 5.4.1 This timeline shall be as short as possible and agreed upon as reasonable to accomplish the needed actions by the AB's management and the LE (with agreement of the ET.)
 - 5.4.2 It is not anticipated that any time extensions will be granted under this provisional recognition step. It is a final stage before the final ET recommendation not to renew the AB's recognition takes place and is to be implemented only in extreme circumstances.
 - 5.4.3 Provisional recognition may be limited to certain fields of accreditation. The fields of accreditation impacted and the rationale for limiting provisional recognition to those fields shall be clearly explained to the AB as well as to the NELAP Accreditation Council.
- 5.5 The nature of the evidence that will demonstrate satisfactory correction of the finding(s) shall be determined and documented as part of the Provisional Recognition recommendation. If an additional site visit is required, the number of evaluators shall be established and the trip costs estimated and agreed upon at the time provisional recognition is granted.
- 5.6 There shall be some provision for other ABs to obtain additional information about labs accredited by the provisionally recognized AB, whether from the AB or the labs themselves, in order to assure that continued mutual recognition is appropriate. If the AB is likely to be unable to sustain this additional workload, that will be noted in the recommendation letter to the NELAP AC.
[NOTE: *All recognize that adding an additional workload to either the provisionally approved AB or the laboratories accredited by that AB is sub-optimal, yet this is necessary for the overall program.*]
- 5.7 Implicit in the recommendation for Provisional Recognition is the fact that the laboratories accredited by the AB are not necessarily sub-standard; there may exist a lack of documentation instead of actual deficient performance for all or at least the majority of the AB's laboratories.
- 5.8 A sample recommendation letter to the NELAP AC is provided in Appendix A.

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- 5.9 Provided the NELAP AC approves the recommendation for provisional recognition, the renewal letter shall include the additional items relevant to provisional recognition. A sample letter is in Appendix B.
- 5.10 When an AB is Provisionally Recognized, that change in status shall be noted on the TNI webpage where state ABs are listed. In addition, each AB member of the NELAP AC shall be obligated to inform its staff of the Provisionally Recognized status of the AB.
- 5.11 At the end of the established time for which provisional recognition is granted, the AB shall submit, and the ET review, the materials identified as required [per section 5.5, above] to determine if the corrective action is satisfactory. If an on-site visit is necessary, it should be scheduled to coincide with the expiration of the timeline established for the provisional recognition.
- 5.12 No time extensions shall be permitted. The AB is presumed to have agreed to the timeline when it was established.
- 5.13 The NELAP AC may offer assistance to the provisionally recognized AB, to facilitate its return to full recognition.
- 5.14 The ET shall have 30 days to review the submitted materials and reach a conclusion about whether the corrective action satisfactorily addresses the finding. The conclusions of the ET about the appropriateness and effectiveness of the corrective action(s) of the AB shall be transmitted in a report to the AB. The ET shall tender its final recommendation about whether to remove provisional recognition status and renew the AB's recognition or to decline to renew that recognition to the NELAP AC. This communication shall be in the same fashion and using the same example letters as contained in SOP 3-102, Evaluation of Accreditation Bodies.
- 5.15 Provisional recognition is the final opportunity. There shall be no "second chance" submission, as with corrective actions for findings from the initial on-site report.
- 5.16 The decision of the NELAP AC concerning the ET's recommendation will be either to remove the AB's provisional status, or to terminate the AB's status as a NELAP AB and withdraw its recognition. Such action will be final, without appeal, although the AB will not be prohibited from future re-application to be recognized as a NELAP AB.

6.0 **Criteria, Standards**

- 6.1 The criteria for considering provisional recognition are that the entire NELAP program would be negatively impacted by revocation of the AB's recognition and that the ongoing uncorrected findings jeopardize the integrity of the overall assessment process.
- 6.2 Provisional recognition shall be granted on a case-by-case basis with the appropriate timeline for renewing full recognition set as a condition of the provisional recognition.
- 6.3 All evaluators must ensure that they are using the correct version of the 2009 or 2016 TNI Standard and associated checklists. The reference documents may be found on the NELAP AC web page.

7.0 **Records Management**

- 7.1 Records associated with the evaluation of the ABs shall be handled in accordance with TNI Policy POL-104 Management of Records. All AB evaluation records shall be electronic, preferably in portable document format (pdf).

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- 7.2 Any recommendation letter that includes Provisional Recognition shall become part of the AB evaluation records specified in SOP 3-102, Evaluation of Accreditation Bodies.
- 7.3 When provisional recognition is accepted by the AC, a new certificate shall be issued to the AB with the wording that the AB is “provisionally recognized” That certificate will remain in effect until provisional recognition is replaced with full recognition or the AB withdraws from NELAP. Upon implementation of acceptable corrective actions, a new certificate shall be issued to the AB with the word “provisionally” removed. The actions in this section shall occur as described without respect to the NELAP Policy on the Relationship of Recognitions and Evaluations, POL 3-102.
- 7.4 Records associated with AB evaluations are considered as being “deliberative” and not subject to release on request under TNI’s open records policy until such time as final decision(s) are reached, in accordance with the TNI Document Management SOP 1-104.

8.0 Quality System, Quality Control

- 8.1 This SOP will be reviewed every three years or whenever the TNI Standard is updated, whichever is more frequent. This review will be triggered by the Laboratory Accreditation System Executive Committee (LASEC).
- 8.2 This review will be documented and any changes deemed necessary will be made with the NELAP AC’s approval.
- 8.3 Whenever this document is revised, the revisions will be distributed to the NELAP evaluators and the NELAP AC and will be posted on the TNI website.

9.0 SOP Approved Changes

Revision No.	Effective Date	Description of Change
0	6/14/2011	New Document.
0.1	8/22/2014	Change to address Policy Committee comments. References clarified.
0.2	6/2/2019	Five year review, minor technical edits only.

APPENDIX A – Example of Recommendation Letter to the NELAP Accreditation Council

Recommendation for Provisional Recognition of XXXXX as a NELAP Accreditation Body

[insert name and title]
Chair,

National Environmental Laboratory Accreditation Program Accreditation Council (NELAP AC)

The National Environmental Laboratory Accreditation Program (NELAP) evaluation team assigned to the XXXXX has completed its evaluation of this Accreditation Body. In accordance with the TNI 2009 (or 2016) Standard, 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 part of the evaluation is discussed below.

Team members (appointed by the NELAP AC):

- [insert Evaluation Team members]

Technical Review

The evaluation team completed its technical review and issued a report detailing findings on xx/xx/xxxx. In a response dated xx/xx/xxxx 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 [or some items were deferred for further consideration during the on-site visit.]

On-Site Evaluation

The team conducted an on-site evaluation of the XXXXX laboratory accreditation program on xx/xx/xxxx. The team interviewed ## XXXXX staff members, reviewed laboratory files, training files, complaint files, and PT records. The team documented ## instances in which XXXXX was determined to be in non-conformance with the TNI 2009/2016 Standard, Volume 2. A report was prepared and sent to XXXXX on xx/xx/xxxx. XXXXX provided a corrective action plan for the ## findings on xx/xx/xxxx. The evaluation team has reviewed these corrective action responses and finds them to be acceptable, with the exception of the item noted below:

***list unresolved finding here*

Observation (optional and unlikely to be included)

The Lead Evaluator performed an observation of XXXXX's on-site assessment of XYZ Laboratories (city, state) on Month/Days/Year. The conduct of this assessment was found to be in compliance with the 2009/2016 TNI Standard. The significant deviation observed has not yet received an acceptable corrective action

*** deviation observed that has not yet been corrected*

Recommendation

The evaluation team recommends that the NELAP AC provisionally recognize XXXXX's Accreditation Program for all the fields of accreditation in the attached list. [or specify which fields of accreditation are impacted/not impacted.] The Evaluation Team recommends the following conditions for this provisional recognition.

Timeline for completion of corrective action(s)

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Evidence to be submitted verifying that the corrective action is complete shall be:
List of items here

The evaluation team recommends [does not recommend] that a repeat site visit be conducted to verify that XXXXX's corrective action(s) for this finding are satisfactory.

For your consideration and for the permanent record, 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 (xxx) zzz-yyyy.

Respectfully,

/signed by Lead Evaluator/

Attachments

cc: XXXXX, XXXXX

APPENDIX B – Example of Renewal Letter to AB, with Provisional Recognition

January 4, 201x

Manager of the AB
State of XXXXXX
[Address]

Re: Evaluation Result for Renewal Application for Recognition of the XXXXX as a NELAP Accreditation Body

Dear [Manager]:

I am writing on behalf of the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council (AC) to inform you and your staff that the NELAP Accreditation Council has voted to grant provisional recognition to the XXXXX, as a NELAP recognized Accreditation Body.

In accordance with the 2009/2016 TNI Standard and the procedures and checklists adopted by the NELAP AC for implementing that standard, the evaluation of XXXXX 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 laboratory accreditation program, and 3) an observation of XXXXX conducting an on-site laboratory assessment.

Based on the evaluation team findings and XXXXX's response, there remains [one] finding from that evaluation that is uncorrected. This finding is stated below, along with the evidence that will be accepted to establish that corrective action is complete. This finding is the basis for provisional recognition, which is granted for [period of time] and ending on [end date], to allow XXXXX to complete corrective actions for this finding.

** finding

**evidence or list of documents that will be acceptable for determining that corrective actions are complete

As part of this provisional recognition process, you are required to perform the following actions:

- implement whatever steps are necessary to correct the finding by [date]
-
- submit the stated evidence to [LE/ET/EC] by [end date of provisional recognition.]

Once the required evidence is submitted, the ET will review it [and conduct an on-site visit, if determined] within 30 days to establish whether the finding is satisfactorily corrected. At that time, a final decision will be made about XXXXX's application for renewal of recognition as a NELAP AB.

I must also inform you that failure to submit the required evidence by [the date] will result in automatic revocation of XXXXX's recognition as a NELAP Accreditation Body. No time extensions are permitted. In order to regain recognition after revocation, XXXXX will need to re-apply as a new AB.

The NELAP AC appreciates the effort and assistance that you and your staff provided to the evaluation team and your continued support of NELAP.

If you have any comments or questions, please contact me at 888-555-1111.

Sincerely,

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Chair
NELAP Accreditation Council

cc: AB staff
LE for ET
Evaluation Coordinator