

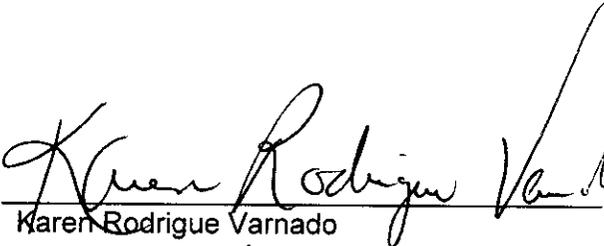
Standard Operating Procedure
for
Accreditation of Out-Of-State Laboratories

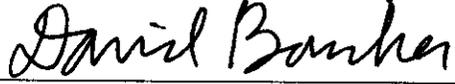
Revision 4

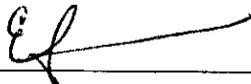
Laboratory Services Division

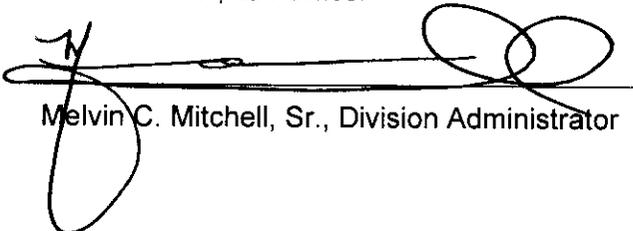
Office of Environmental Assessment

Louisiana Department of Environmental Quality

Development Team:  Date: 5/8/07
Karen Rodrigue Varnado

Lead Developer:  Date: 5-8-7
David Boucher , LELAP Supervisor

Approved by:  Date: 5/10/07
Elaine Sorbet, QA Officer

Approved by:  Date: 05-10-07
Melvin C. Mitchell, Sr., Division Administrator

Please Note: The official version of this document is maintained on the LDEQ Intranet. Copies, whether in electronic or printed form, are not official and should be verified for currency against the official document on the Intranet. The Control Header of the SOP will be used for comparison to the official document.

Document Review and Revision Record

Note: Actions older than 5 years may be removed from this record

Approval Date	Revision No.	Record of Activity
2/08/01	0	Initial document approved.
Unknown	1	Approval date is not available.
03/15/05	2	New Administrator
04/13/06	3	Changed to new format
05/11/2007	4	Name change for the LELAP Supervisor and technical corrections for NELAC and TNI

Table of Contents

1.0	Purpose	4
2.0	Scope	4
3.0	Outline of Procedure.....	4
4.0	Procedure to Accredite Applicants Possessing NELAP Accreditation	7
5.0	Procedures to Evaluate and Accredite Laboratories Via Recognition.....	8
6.0	Evaluation of Laboratories Not Covered Through Recognition.....	10

Standard Operating Procedures for ACCREDITATION OF OUT-OF STATE LABORATORIES

SOP #LELAP T-007

1.0 Purpose

This standard operating procedure (SOP) establishes the requirements for the procedure to be followed by the Louisiana Environmental Laboratory Accreditation Program (LELAP) for the recognition of out-of-state laboratories.

2.0 Scope

This procedure shall be used by LELAP to review and respond to initial accreditation applications from laboratories not located in Louisiana that wish to apply for accreditation. The procedure provides accreditation by recognition to laboratories that are accredited by a National Environmental Laboratory Accreditation Program (NELAP)-recognized primary accrediting authority.¹ This procedure addresses the protocol used by LELAP to accredit laboratories that are not accredited by a NELAP primary accrediting authority. The protocol allows for the review of existing accreditations² that are held by the applicant and other supporting documentation. The review may result in accreditation through recognition if warranted by the review findings. Otherwise, out-of-state laboratories applying for accreditation that are not accredited by a NELAP primary accrediting authority or a LELAP recognized State laboratory accrediting authority shall be evaluated under the provisions of LELAP SOP #LELAP T-001 to T-006.

3.0 Outline of Procedure

The evaluation of all accreditation applications from out-of-state laboratories begins with the review of their application package. Table 1 shows all items that must be submitted as part of the application. In addition, the applicant must supply copies of the most recent report covering on-site assessments by either: 1) a NELAP primary accrediting authority or 2) the state accrediting authority with jurisdiction in the state where the laboratory is located.

¹ A NELAP primary accrediting authority (AA) is one that ensures directly that the laboratory is in conformance with the National Environmental Laboratory Accreditation Conference (NELAC) standards. The AA may be any federal department, federal agency, or state agency that requires laboratory testing in conformance with at least one of the EPA programs within the scope of NELAC.

² A Louisiana-recognized accrediting authority may any federal department, federal agency, or state agency that requires laboratory testing in conformance with LAC Title 33, Part I, Subpart 3, chapters 47 through 57. Conformance is established by the evaluation and approval of the out-of-state accrediting authority by the Administrator of LELAP.

Table 1
Application Requirements

Item	Specific Requirement	Citation³
1	Purpose of Application	Application, Section A
2	Type of Accreditation	Application, Section B
3	Laboratory Name	Application, Section C
4	Mailing Address	Application, Section D
5	Shipping Address	Application, Section E
6	Billing Name and Address	Application, Section F
7	Laboratory Telephone Number	Application, Section G
8	Laboratory Fax Number	Application, Section H
9	Laboratory Internet E-Mail Address (if applicable)	Application, Section I
10	Type of Laboratory	Application, Section J
11	Name of Laboratory Representative (include Org. Chart)	Application, Section K, LAC 33:I.4901.A.1
12	Existing Certifications and PT Results (out-of-state laboratories only)	Application, Section L
13	Laboratory Technical Director (include resume)	Application, Section M
14	Key Laboratory Personnel (include resumes)	Application, Section N
15	Test Categories, Fields of Testing, and Fee Calculation	Application, Section O
16	Specific Method Accreditation(s) Being Sought	Application, Sections P-V
17	Quality Control Information (include a copy of QA manual and a list of Standard Operating Procedures ⁴)	Application, Section W, LAC 33:I.4705.A
18	Statement of Validation	Application, Section X
19	Designation of Laboratory Representative	Application, Section Y
20	Proficiency Test Results (minimum of one round, two required prior to full accreditation)	LAC 33:I.4703.B
21	Analytical Data Packages for Test Categories and or Methods with No Approved PT Samples available	LAC 33:I.4703.B
22	Application Fee and Accreditation Fee Payment (based on 15 above)	LAC 33:I.4707.D

3.1 Applicants that have not been the recipient of an on-site assessment by a recognized AA do not meet the requirement of LAC 33:I.4715.A.2. These laboratories must be evaluated using SOP #LELAP T-004.

³ The citation identifies where the requirement for the specific information is established.

⁴ Identify each laboratory SOP by a title and unique number. Cross-reference the SOP's to the specific methods (by number shown in the application form) for which accreditation is being sought.

- 3.2 Under the provisions of LAC 33:I.4717, LELAP shall apply the procedure cited in the NELAC Constitution, Bylaws, and Standards, July 1999 for the recognition of accreditation of out-of-state laboratories that are accredited by a NELAP-primary accrediting authority. The basic steps of this procedure are shown in Figure 3-1. The procedure is composed of six steps. They are:
 - 3.3 Review of application and fees.
Comparison of Scope of Services requested in the application to Louisiana and listed on the primary accrediting authority accreditation certificate.
Issue accreditation for all fields of testing recognized by the primary accrediting authority.
 - 3.4 Laboratories applying for accreditation may be located in states that are not NELAP AA's. In these cases, LELAP will review the application and other supporting material to determine if accreditation should be granted. Laboratories may request accreditation from LELAP for fields of testing not covered by their NELAP primary accrediting authority. Note if the NELAP primary accrediting authority offers accreditation in all the fields of testing covered by the Louisiana application, LELAP shall require the applicant to apply for recognition by their NELAP primary accrediting authority. LELAP shall not grant accreditation in fields of testing where the NELAP primary AA denied accreditation.
 - 3.5 LELAP shall determine if the current state accrediting authority program that has jurisdiction over the applicant meets the requirements of LAC 33:I.4715. A.2 . LELAP shall evaluate the application and other supporting materials to determine if the analyses covered by the scope can be approved for LDEQ accreditation.
 - 3.6 LELAP shall accept direct applications from out-of-state laboratories that are not accredited by an accrediting authority recognized by LELAP as authorized under LAC 33:I.4715.A.1. The accreditation process required by LELAP SOP #LAP005 shall be used to evaluate the application.
 - 3.7 Applicants that already possess an accreditation certificate from a NELAP primary AA who are applying for Louisiana accreditation in fields of testing that are not covered by their NELAP accreditation shall be evaluated by LELAP SOP #LAP005 only for those fields of testing. In these instances, LELAP will become the NELAP primary AA but only for those fields of testing not covered by the original NELAP primary AA.

4.0 Procedure to Accredite Applicants Possessing NELAP Accreditation

- 4.1 For NELAP -accredited out-of-state laboratories, LELAP is considered a secondary accrediting authority⁵. LELAP shall grant recognition of accreditation to laboratories accredited by any NELAP-recognized primary accrediting authority after review of the laboratory's application. Such recognition of NELAP accreditation shall be granted on a laboratory-by-laboratory basis. LELAP shall consider only the current Certificate of Accreditation issued by the NELAP-recognized primary accrediting authority and the information submitted with the application to Louisiana.
- 4.2 When granting recognition of accreditation to a laboratory, LELAP shall:
- 1) grant accreditation for the fields of testing, methods and analytes for which the laboratory holds current primary NELAP accreditation, and grant accreditation and issue a certificate to an applicant laboratory within thirty (30) calendar days of receipt of the laboratory's application accompanied by the scope of certification from the NELAP primary accrediting authority.
- 4.3 Laboratories as required by LELAP shall pay all fees. Laboratories seeking LDEQ accreditation shall not be required to meet any additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of testing for which the laboratory holds a primary NELAP accreditation.
- 4.4 If LELAP notes any nonconformance with the NELAC standards by a laboratory during the initial application process for recognition of accreditation, or for a laboratory that already has been granted NELAP accreditation through reciprocity, LELAP shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. The laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated. The notification must cite the applicable sections within the NELAC standards and LAC requirements for which nonconformance by the laboratory has been noted:
- 1) If the alleged nonconformance is noted during the initial application process for recognition of NELAP accreditation, final action on the application for recognition of NELAP accreditation shall not be taken until the alleged nonconformance issue has been resolved, or
 - 2) If the alleged nonconformance is noted after recognition of NELAP accreditation has been granted, the laboratory shall maintain its current NELAP accreditation status until the alleged nonconformance issue has been resolved.

⁵ A NELAP-secondary accrediting authority is any territorial, state, or federal agency that grants NELAP accreditation to laboratories based upon their accreditation by a NELAP-recognized primary accrediting authority.

- 4.5 Upon receipt of the notification from LELAP, the NELAP-recognized primary accrediting authority shall:
- 1) Review and investigate the alleged nonconformance,
 - 2) Take appropriate action on the laboratory as set forth by the NELAC standards, including the addition of any change of accreditation status in the National Environmental Laboratory Accreditation Database. All such actions shall be taken in accordance with the laboratory's right to due process as set forth in the NELAC standards, Chapter Four, Accreditation Process, and
 - 3) Respond to LELAP, in writing, with a copy to the NELAP Director, within twenty (20) calendar days of receipt of the LELAP notification providing:
 - a. an initial report of the findings;
 - b. a description of the actions to be taken; and,
 - c. a schedule for implementation of further corrective action on the alleged nonconformance, if necessary.
- 4.6 If, in the opinion of LELAP, the primary accrediting authority does not take timely and appropriate action on the complaint, LELAP shall notify the NELAP Director of the dispute between the two accrediting authorities regarding proper disposition of the complaint. Within 20 calendar days of receipt of such notification, the NELAP Director shall review the alleged nonconformance and take appropriate action according to the NELAP standards. The decision of the NELAP Director shall be binding on LELAP.
- 4.7 LELAP shall issue an accreditation certificate for all fields of testing where the applicant has successfully completed this process.
- 4.8 If the applicant has applied for accreditation in fields of testing not offered by their NELAP primary accrediting authority, LELAP can apply LELAP SOP T-001 to T-006 to grant NELAP accreditation for those fields of testing.

5.0 Procedures to Evaluate and Accredite Laboratories Via Recognition

At the discretion of the Administrator of LELAP, out-of-state (non-NELAP) accreditation programs can be granted recognition for the purposes of Louisiana accreditation if they meet the requirements of LAC 33:I.4715.A.2. The Administrator shall establish if the out-of-state accreditation program meets the aforementioned requirements by the following steps.

- 5.1 The Administrator shall examine the regulatory basis of the out-of-state accreditation program. The important characteristics that the program must possess are the following.
- 1) Established by law.
 - 2) Required of all laboratories submitting data to state environmental programs.
 - 3) Implemented by qualified state employees who are governed by conflict of interest provisions.

- 4) Based upon analytical methods of the US EPA or other recognized bodies (see LAC 33:I.4503, *EPA-approved methods*).
- 5) Renewed annually
- 6) Contains provisions for revocation of accreditation.

5.2 The out-of-state accreditation program must be no less stringent than the LAC regulations covering laboratory accreditation (LAC 33:I.4503). The Administrator, or his designee, must certify that the out-of-state program is equivalent to or more stringent than LAC in the following areas:

- 1) Proficiency testing twice a year for **all** applied fields of testing. Acceptable scores must be required for all analyte/matrix pairs in at least two of three successive PT studies. See LAC 33:I.4711.
- 2) Qualifications of staff members. See LAC 33:I.4901.
- 3) Requirement for on-site inspection. See LAC 33:I.5101.
- 4) Facilities that are suitable for the scope of services covered by the accreditation. See LAC 33:I.5103.
- 5) Required use of state-approved test methods. See LAC 33:I.5105 and LAC 33:I.5307
- 6) Required response to deficiencies noted during on-site inspections (both internal and external) and proficiency testing results. See LAC 33:I.5107 and LAC 33:I.4711.F.
- 7) Required use of an approved quality assurance/quality control plan. See LAC 33:I.5301.
- 8) Requirements for equipment and supplies. See LAC 33:I.5303.
- 9) Calibration requirements. See LAC 33:I.5305.
- 10) Special requirements for radiochemistry and microbiology. See LAC 33:I.5309 and LAC 33:I.5311.
- 11) Reporting requirements. See LAC 33:I.5313.
- 12) Record keeping requirements. See LAC 33:I.5315.
- 13) Requirement for notification of incorrect/improper/expired sample analysis. See LAC 33:I.5501.
- 14) Reporting of changes in laboratory operations. See LAC 33:I.5707.

5.3 Applicant laboratories whose state accreditation programs have been recognized by the Administrator of LELAP as described above shall be evaluated by the following procedure.

- 1) The laboratory application must meet all the requirements given in LELAP SOP T-006.
- 2) In lieu of an on-site assessment, LELAP, or its designee, shall conduct a desk audit on the following material:
 - a. Laboratory quality assurance/quality control plan,
 - b. Administrative SOP's including but not limited to document control, corrective actions, reporting, and records retention and archival storage,
 - c. Analytical method SOP's selected from the scope of services described in the application. At least two methods must be examined from each field of testing covered by the application. If the analytical method requires a

special sample preparation technique, the preparative method must be reviewed also

- d. A minimum of the two most current PT studies for fields of testing covered by the application. This includes the report of any corrective actions undertaken by the laboratory, and
 - e. The assessment report from the last on-site inspection conducted by the current accrediting authority. This includes all laboratory responses to the findings.
- 3) The results of the latest PT studies shall be reviewed to determine if the applicant has achieved acceptable results for all analyte/matrix pairs covered by the scope of the application. See Section 6 of LELAP SOP #LAP005 for details of the procedure.
 - 4) LELAP shall send notification by certified mail of accreditation or denial of accreditation.

5.4 At the discretion of LELAP, an on-site assessment of the out-of-state applicant may be conducted. In this case, all provisions of LELAP SOP T-004 shall apply.

5.5 LELAP shall issue an accreditation certificate for all fields of testing where the applicant has successfully completed this process.

6.0 Evaluation of Laboratories Not Covered Through Recognition

Applicant Laboratories from states that do not have a NELAP-approved accrediting authority or a program approved by the Administrator of LELAP must be accredited using LELAP SOP T-004. The on-site inspection is mandatory. This applies to applicants requesting Louisiana recognition for fields of testing not offered by their NELAP-approved AA.

7.0 Role of Primary Accrediting Authority in Handling Potential Nonconformances Reported by Other Accrediting Authorities

7.1 If a NELAP-recognized secondary accrediting authority notes any potential nonconformance with the NELAC standards by a laboratory during the initial application process for reciprocal accreditation, or for a laboratory that already has been granted NELAP accreditation through reciprocity, the NELAP-recognized secondary accrediting authority shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. However, the laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated. The notification must cite the applicable sections within the NELAC standards for which nonconformance by the laboratory has been noted.

7.1.1 If the alleged nonconformance is noted during the initial application process for reciprocal NELAP accreditation, final action on the application for reciprocal NELAP accreditation shall not be taken until the alleged nonconformance issue has been resolved, or

7.1.2 If the alleged nonconformance is noted after reciprocal NELAP accreditation has been granted, the laboratory shall maintain its current NELAP accreditation status until the alleged nonconformance issue has been resolved.

7.2 Upon receipt of the notification of potential non-conformance, the NELAP-recognized primary accrediting authority shall:

7.2.1 review and investigate the alleged nonconformance,

7.2.2 take appropriate action on the laboratory as set forth by the NELAC standards, including the addition of any change of accreditation status in the National Environmental Laboratory Accreditation Database. All such actions shall be taken in accordance with the laboratory's right to due process as set forth in the NELAC standards, Chapter 4, Accreditation Process,

7.2.3 respond to the NELAP-recognized secondary accrediting authority, in writing, with a copy to the NELAP Director, within 20 calendar days of receipt of the notification providing:

- i) an initial report of the findings;
- ii) a description of the actions to be taken; and,
- iii) a schedule for implementation of further action on the alleged nonconformance, if necessary.

If, in the opinion of the secondary accrediting authority, the primary accrediting authority does not take timely and appropriate action on the complaint, the secondary accrediting authority should notify the NELAP Director of the dispute between the two accrediting authorities regarding proper disposition of the complaint. Within 20 calendar days of receipt of such notification, the NELAP Director shall review the alleged nonconformance and take appropriate action according to the standards set forth in this chapter.