Standard Operating Procedure
for
Review of Accreditation Applications

Revision 6

Laboratory Services Division

Office of Environmental Assessment

Louisiana Department of Environmental Quality

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Table of Contents

1.0 Purpose 4

2.0 Scope 4

3.0 Outline of Procedure 4

4.0 LELAP Response to the Initial Application Submittal 6

5.0 Response to Continuing Findings in the Laboratory's Application 10

6.0 LELAP Review of Corrective Action Plan or Completed Corrective Action Documentation Submitted in Response to Laboratory Assessments 10

7.0 LELAP Review of Completed Corrective Action Documentation (CCAD) Submitted in Response to Laboratory Performance Testing Results 11

Standard Operating Procedure for

Review of Accreditation Applications

SOP #LELAP T-002

1.0 Purpose

This standard operating procedure (SOP) establishes the requirements followed by the Louisiana Environmental Laboratory Accreditation Program (LELAP) when responding to laboratories (applicants) submitting an accreditation application.

2.0 Scope

This procedure shall be used by LELAP to review and respond to initial accreditation applications, renewal applications or corrective action plans (CAPs) submitted by laboratories that are applying for initial accreditation, continuing accreditation, or as part of their proficiency testing (PT) program.

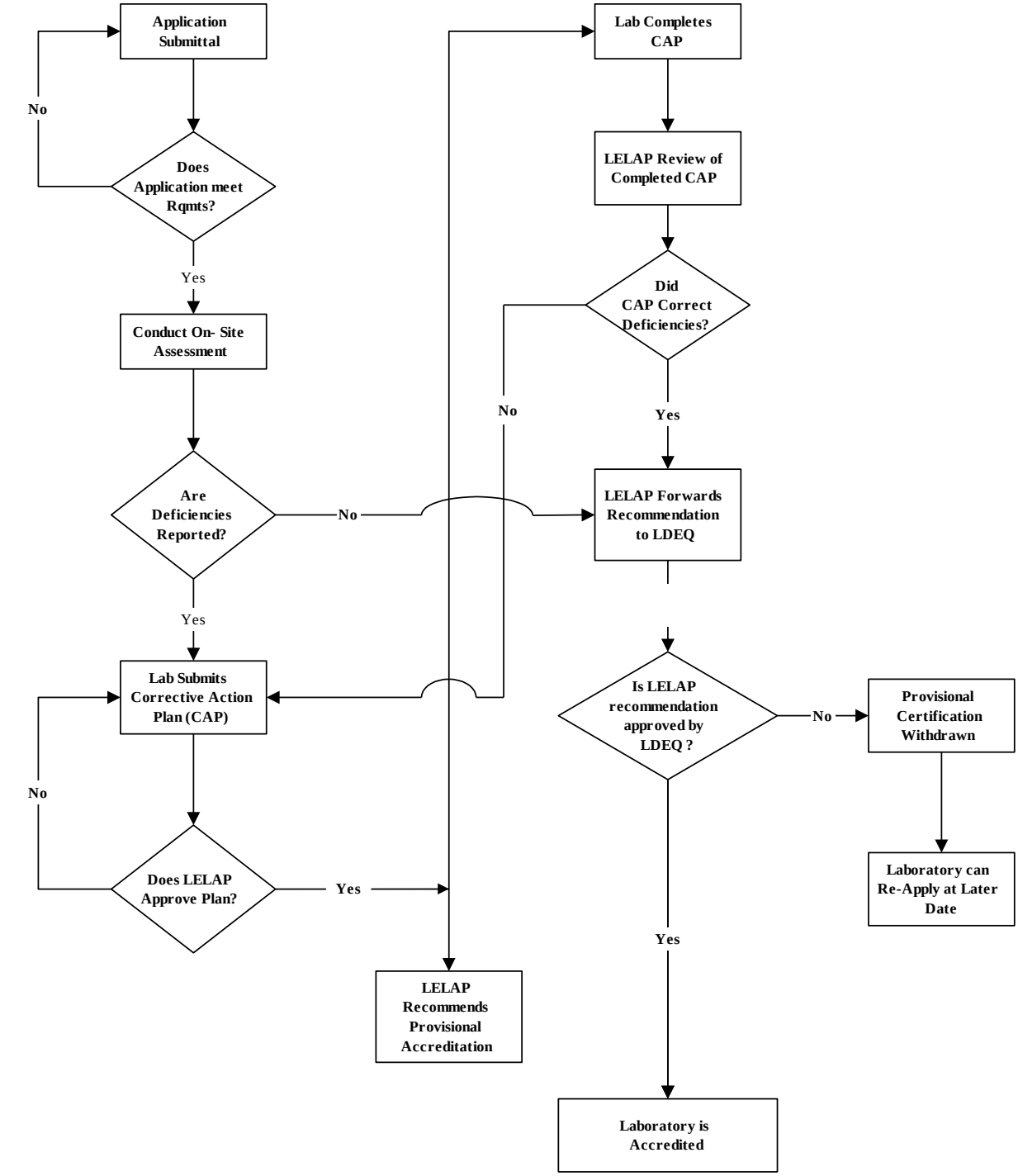
3.0 Outline of Procedure

3.1 The responsibility to respond to findings found during the accreditation process for both initial and continuing accreditation lies with the laboratories. Figure 3-1 illustrates the overall process. Findings can be found at any stage of the accreditation process. The stages are:

- Application for accreditation that includes payment of applicable fees,
- LELAP assessment for compliance with Louisiana Administrative Code (LAC), Title 33, Part 1, Subpart 3, and
- Participation in a semi-annual proficiency testing program.

3.2 To complete the review of the submitted applications, LELAP shall determine if the application contains findings related to the required information or has failed to submit the correct payment for the accreditation being sought. Section 4 of this SOP describes the process used to review applications and notify the laboratory of any findings related to the application.

3.3 The LELAP accreditation assessment process normally utilizes an on-site inspection of the facility, its quality system, and analytical procedures, as well as interviews with management and staff. The on-site assessment shall be preceded by an off-site review of selected laboratory documentation and PT performance records. An assessment report (AR) is provided to the laboratory identifying conditions that are not compliant with LAC requirements.



LPA005 Figure 3-1 -final draft.vsd
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Figure 1

LDEQ Laboratory Accreditation Process

3.4 Sufficient information shall be provided in the assessment report to document the non-compliance. This includes the citations to the LAC and NELAC requirements that apply to findings. The laboratory has thirty (30) calendar days to submit a corrective action plan (CAP) that specifies the steps to be taken, including a date of completion or timeline, to correct the findings noted in the report. The laboratory may choose to implement a corrective action within the thirty-day period. All corrective actions must be completed within six months of the date-of-receipt of the formal AR. Section 6 of this SOP describes how LELAP Assessors shall review and respond to the proposed corrective actions associated with assessment reports.

3.5 This SOP also describes how LELAP shall respond to the corrective actions proposed/completed by the laboratory to correct unacceptable performance in their PT program. LELAP must receive each PT report from the PT provider concurrently with the laboratory. The laboratory has thirty (30) working days to investigate and correct the cause of any PT failures and to demonstrate satisfactory performance. Section 7 of this SOP describes how LELAP shall evaluate the laboratory's corrective actions associated with their PT program.

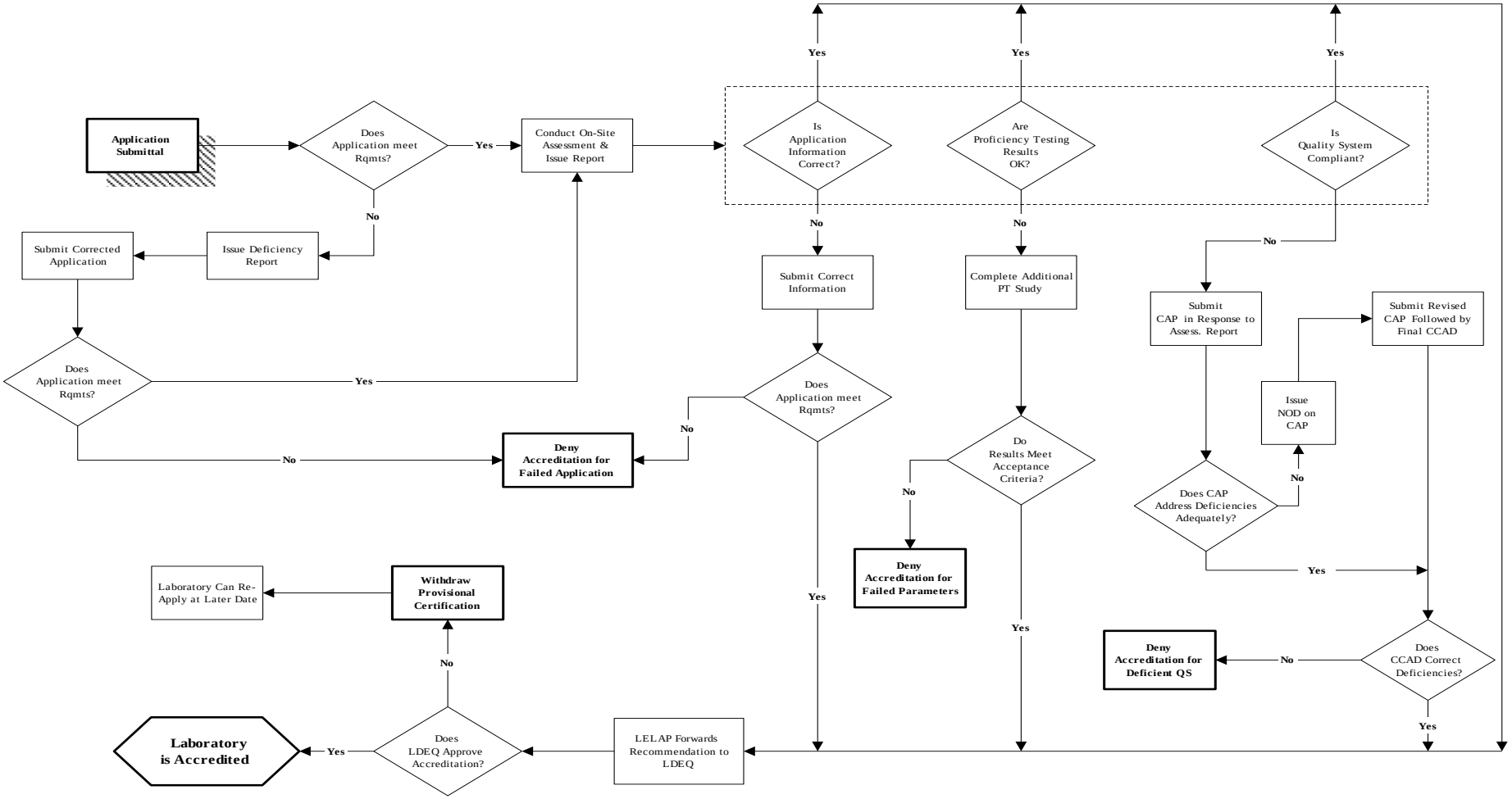
3.6 The process assures that LELAP has reviewed and approved the laboratory's operations to assure compliance with all LAC or NELAC requirements. Figure 2 shows the details of the review, comment, and corrective action cycle.

4.0 LELAP Response to the Initial Application Submittal

4.1 The assigned LELAP Assessor shall notify the applicant of receipt of the application and indicate that the application is currently under review within ten working days of receipt of the application by the Assessor.

4.2 LELAP shall review each application to determine if the required information has been submitted. LELAP shall initiate action on each application in the order it was received. The items required in the application process are shown in Table 4-1. Any findings in the application shall be documented and the laboratory's designated representative notified by registered or certified mail. The laboratory has thirty (30) calendar days from the receipt of the notice of deficiency (NOD) letter to submit the required information and/or fees. LELAP shall not proceed with further consideration (e.g. technical review of the quality system documents, on-site assessment) of the laboratory until the application (including fees) is deemed complete.

4.3 There is no corrective action plan associated with a laboratory's response to findings associated with their application and submittal of fees. The applications must be complete and correct.



LELAP Review/Response Process
for Laboratories Seeking Accreditation

Figure 2

Table 4-1
Application Requirements

Item	Specific Requirement	Citation[1]
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
	Hours of Operations	
10	Type of Laboratory	Application, Section J
	VIN Number or serial number of the laboratory if it is a mobile laboratory	
11	Name of Laboratory Representative	Application, Section K
12	Existing Certifications and Performance Testing Results (out-of-state laboratories only)	Application, Section L
13	Laboratory Technical Director (include resume)	Application, Section M
	Laboratory Quality Assurance Officer (include resume)	
14	Key Laboratory Personnel (include resumes)	Application, Section N
15	Test Categories, Fields of Testing, and Fee Calculation	Application, Section O
16	Specific Method Accreditations Being Applied For	Application, Sections P-V
17	Quality Control Information (include a copy of QA manual and a list of Standard Operating Procedures[2])	Application, Section W, LAC 33:I.4705.A
18	Statement of Validation	Application, Section X
19	Designation of a Laboratory Representative	Application, Section Y
20	Proficiency Test Results (minimum of passing one round of	LAC 33:I.4703.B

[1] The citation identifies where the requirement for the specific information is established.
[2] 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.

	two tests required prior to full accreditation)	
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

4.4 The laboratory is required under LAC 33:I.5707 to keep all information in the application up to date. Any changes in name, ownership, location, key personnel, facilities, methodology or any other factors significantly affecting the performance of analysis must be reported to LELAP within thirty (30) days. Failure to do so shall result in a NOD letter being issued to the laboratory when LELAP discovers the conditions have changed since the application was filed and may lead to suspension or revocation of status.

4.5 The Program Analyst or the assigned Assessor shall update the application file with the new information when the response to the NOD letter is received.
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4.6 At its discretion, a laboratory may request to withdraw its accreditation. The written notification to withdraw must be received by the accreditation body (AB).

5.0 Response to Continuing Findings in the Laboratory's Application

5.1 If the completed corrective actions of the laboratory are still deficient, the laboratory shall be notified by certified or registered mail that its accreditation is suspended under LAC 33:I.5705. The notification shall state that accreditation will be denied if a fully compliant response is not delivered to LELAP within ten (10) working days of receipt of the notice. All fees related to the accreditation application shall be forfeited to the State if the required information is not submitted on time. Re-application can be made by the laboratory under the terms of LAC 33:I.5709.

5.2 On-site assessments shall not be authorized by LELAP until all items in the approved application are compliant with LAC requirements. The conditions described in the application will be confirmed during the on-site assessment. One or more findings shall be reported if any change in laboratory operations as defined by LAC 33:I.5707 is found.

6.0 LELAP Review of Corrective Action Plan Submitted in Response to Laboratory Assessments

6.1 The Assessor shall review the corrective action plan (CAP) submitted by each laboratory in response to the findings noted in the AR resulting from the LELAP assessment.

6.2 The review process shall confirm that all findings noted in the AR are addressed in the CAP and if the response satisfactorily addresses the finding(s).

6.3 LELAP Response to Laboratory Corrective Actions – Initial Submittals

LELAP shall find the laboratory responses to the AR to be in one of three categories:

6.3.1 *Approved* – Corrective action responses in this category meet all requirements of LAC when successfully implemented and documented

6.3.2 *Incomplete* – Corrective action responses in this category are incomplete and require that the laboratory submit a more detailed description of the proposed action before LELAP can

determine if the response is acceptable. LELAP shall identify the information that must be submitted to allow a final determination to be made.

6.3.3 *Not Approved* – Corrective action responses in this category are insufficient to meet LAC requirements. LELAP shall cite the provisions of LAC or NELAC that are not met by the proposed action.

6.4 LELAP Assessors shall submit their review findings to the laboratory's designated representative within thirty (30) working days of receipt of the corrective action plan or completed corrective action documentation.

6.5 The laboratory must submit revised corrective action responses for ***Incomplete*** or ***Not Approved*** responses no later than thirty (30) working days from the documented date of receipt of the LELAP response. LELAP shall review and respond to these submissions within thirty (30) working days of receipt.

6.6 The accreditation process will terminate if the laboratory fails to respond by submission of proposed or completed corrective actions within the allowed thirty (30) working days because of the continuing status of the findings (LAC 33:I.5107.B). If, after submission of the required CAP and receipt of the LELAP review comments, the corrective actions of the laboratory are still deficient at the end of the six-month timeframe (LAC 33:I.5107.B), the laboratory's designated representative shall be notified by certified or registered mail that their accreditation is suspended or revoked under LAC 33:I.5107.B for non-compliance.

7.0 LELAP Review of Corrective Action Documentation Submitted in Response to Laboratory Performance Testing Results

7.1 The laboratory is required by LAC 33:I.4711.F to submit documentation for corrective actions undertaken to correct failed PT results.

7.2 The results from laboratory proficiency testing (PT) programs shall be reported directly to LELAP by the proficiency testing service provider at the same time the results are forwarded to the laboratory. The accredited laboratory shall notify their PT sample provider to identify LELAP as the accrediting agency to receive results of the PT study(ies) to implement the requirements of LAC 33:I.4711.F.

7.3 Upon receipt of the laboratory's results from the PT service provider, LELAP shall review the report. All unacceptable results shall be tracked by LELAP to assure that the laboratory responds in the timeframe required. The laboratory must submit CCAD to LELAP within thirty (30) calendar days of receiving notification of unacceptable results (LAC 33:I.4711.F). If a response is not received from the laboratory within thirty (30) calendar days, LELAP shall issue a NOD within five (5) working days. The NOD shall list findings for the unacceptable results by analyte/method as reported by the PT service provider and a finding for failure to submit corrective actions to the unacceptable PT results in the required timeframe. The laboratory shall be given five (5) working days after receipt of the notice of finding in which to make the required submittals.

7.3.1 LELAP may not issue a response to the laboratory in cases where all the corrective actions are deemed acceptable. However, if the review of the corrective actions results in a finding of *Not Approved,* LELAP shall notify the laboratory in writing within ten (10) working days. The notification shall describe the reasons for the *Not Approved* finding. The laboratory has ten (10) working days to correct the outstanding PT finding and report the completed action to LELAP.

7.3.2 Laboratory failure to correct known findings shall be cause for discreditation or suspension under LAC 33:I.5705.F.4. Laboratories that have applied for and received accreditation as a NELAP certified laboratory (LAC 33:I.4715) are also subject to suspension under NELAC Standard 4.4.2.b.2. The LELAP representative responsible for reviewing a laboratory's PT compliance shall begin the process of reviewing the laboratory's accreditation status according the approved procedures as required by LAC 33:I.5705.F. The laboratory shall be notified of this review action by registered or certified mail.