

**Standard Operating Procedure
For
Procedures for Records Management**

Revision 4

Laboratory Services Division

Office of Environmental Assessment

Louisiana Department of Environmental Quality

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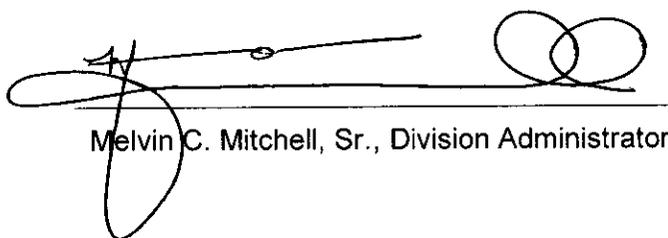
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Date: 5-8-07

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.

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Standard Operating Procedure for Procedures for Records Management

SOP #LELAP A-001

1.0 Purpose

This document establishes the requirements for the standard operating procedure (SOP) followed by the Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) for maintenance of all documents, records and database.

2.0 Scope

This procedure shall be used by LELAP to establish and maintain all documents, records and database for the program.

3.0 Mail

3.1 The Program Analyst shall receive and process all mail delivered to the program within 48 hours of receipt.

3.2 Upon receipt, all mail shall be date stamped and correspondence relevant to the program shall be entered into the lab accreditation database within 48 hours of receipt. The documents shall have a LELAP route slip stapled to them. The route slip will have the assigned assessor marked and contain the date assigned and the LELAP number for the laboratory. A brief description of the document shall be contained in the "reference section" of the route slip. Applications, Corrective Action Plans, appeals, proficiency test results and general correspondence from the applicant laboratories shall be handled in this manner.

3.3 The Program Analyst shall assign and note the LELAP identification number for the laboratory. This number shall be placed in the upper right hand corner of all applications, corrective action plans, appeals, proficiency test results and any general correspondence relevant to the program.

3.4 The Program Analyst shall attach a route slip to each piece of mail relevant to LELAP. The route slip shall note the assigned LELAP person. The mail is then forwarded to that individual.

4.0 Applications

4.1 The Program Analyst shall assign a unique LELAP identification number to each new application received by the program. The Program Analyst shall then create a facility file within 48 hours of receiving the application. All facility files shall be housed in a centralized location.

4.2 All information contained in the application shall be entered into the Accrediting Authority Management System (AAMS) database maintained by the Program Analyst and each LELAP Assessor.

4.3 The LELAP Program Analyst shall request an agency interest identification number for each new facility through the TEMPO system. TEMPO is the Department's database. The following information shall be submitted to the TEMPO Manager when requesting an agency interest number:

- Facility Name
- Mailing, billing and shipping addresses
- LELAP identification number
- Facility representative name and phone number
- Facility fax number
- Representative e-mail address

4.4 The TEMPO Manager shall send the agency interest identification numbers via e-mail to the LELAP Program Analyst. The Program Analyst shall enter the agency interest identification number into the AAMS database. The number is entered into the "Alternate ID" field.

4.5 The Program analyst shall attach the LELAP route slip to the new facility files and forward to the LELAP Supervisor for assignment to a LELAP Assessor within 48 hours of receipt of the application.

4.6 The LELAP Supervisor shall notify the Program Analyst of new LELAP Assessor assignments within 24 hours of receiving the file from the Program Analyst. The Program Analyst shall enter the new assignment into the AAMS Database the same day the applicant laboratory is assigned to a LELAP Assessor. The Program Analyst shall then forward the new application file to the assigned LELAP Assessor for review and processing.

4.8 The assigned LELAP Assessor shall review the AAMS database entries for accuracy against the original application and make any necessary corrections. Once the assigned LELAP Assessor has conducted completeness and technical review of the file, it shall be returned to the Program Analyst and shall be placed into the filing system.

5.0 Assessments

5.1 The Program Analyst shall track all assessments that are conducted and assessment reports written in the AAMS database.

5.2 The Program Analyst shall enter the date of the audit, the assigned LELAP Assessor or third party assessor, and the date of the assessment report into the AAMS database when notified by the LELAP Assessor.

5.3 The Program Analyst or the designated LELAP Representative shall mail assessment reports to the Laboratories. All assessment reports shall be mailed certified return receipt requested, with a notation "AR" on the return receipt.

5.4 The date the facility received the assessment report is determined from the date of receipt on the returned green card and that date shall be entered into the AAMS database as the date received.

6.0 Corrective Action Responses

6.1 The Program Analyst shall date stamp the date received of all corrective action responses, attach a route slip and enter the date the responses are received into the AAMS database.

6.2 The Corrective Action Response shall be forwarded to the assigned LELAP Assessor for review and processing. After the Assessor has completed the review and responded to the corrective action plan, the records shall be returned to the Program Analyst to be placed into the file system.

7.0 Proficiency Test Results

7.1 The Program Analyst shall date stamp proficiency test results when received and attach a route slip to the document. The route slip shall indicate the assigned LELAP assessor.

7.2 The Program Analyst shall forward the PT results and attached route slip to the appropriate LELAP Assessor. Once the Assessor has reviewed the PT results, the documents will be returned to the Analyst for filing.

8.0 Files

8.1 The Program Analyst shall be responsible for maintaining the filing system for LELAP.

8.2 An in/out log shall be signed when a file is checked in or out. It is the assigned LELAP Assessor's responsibility to ensure that his/her particular laboratory files are maintained in proper order.

8.3 All records shall be kept in reverse chronological order within the file system. Records will be filed by year in each facility folder. This will allow the Program Analyst to archive records easily. It shall be the responsibility of each LELAP Assessor to ensure that all records are kept in the accurate format.

8.4 If a document is too large to fit into the file folder, then the document shall be placed in the oversize file area. A photocopy of the cover page of the oversize document shall be placed in the file folder, with directions as to where the complete document is located.

8.5 All documents must be bound before they can be placed in the laboratory records. Documents may be stapled, placed in comb binders, three ring binders or any other acceptable means of binding. Paper clips or binder clips are not to be used for binding documents in file folders. Documents in three ring binders too large for the file cabinets must be placed on the bookshelves in the LELAP File room.

9.0 Certificates

9.1 LELAP Assessor

9.1.1 The Assessor shall print a draft Scope of Accreditation for each assigned facility that has successfully completed the certification process based on information that has been entered into the AAMS database.

9.1.2 For each laboratory completing the accreditation process, the assigned LELAP Assessor shall review the information in the AAMS database, and make any necessary corrections. .

9.1.3 The LELAP Assessor shall conduct a laboratory application evaluation using the correct form (Attachment A) for each assigned laboratory to determine compliance with the LELAP regulations and/or NELAP standards or as appropriate The NELAC Institute (TNI) standards.

9.1.4 The LELAP Assessors shall complete and print the appropriate Certificate of Accreditation (Attachment). The LELAP certificate is to be used for any facility that receives accreditation from the State program and the NELAP certificate is to be used for any laboratory that receives certification for the national accreditation program.

9.1.5 The LELAP Assessors shall draft a memorandum recommending the applicant laboratory for accreditation. The LELAP Assessor shall then compile an accreditation package and shall forward the package to the LELAP Supervisor for review if the

accreditation package is complete the Supervisor will forward it to the Accreditation Officer for signature.

9.1.6 The accreditation package shall contain the following documents: cover letter, Certificate of Accreditation, Scope of Accreditation, Laboratory Application Evaluation Form, memorandum recommending (Attachment A) the applicant laboratory for accreditation, and accreditation package checklist completed by the Assessor and initialed by the LELAP Supervisor.

9.2 Laboratory Services Division Administrator

9.2.1. The Laboratory Services Division Administrator shall be the Accrediting Authority. In the event of prolonged absence the Department shall delegate the authority to a member of the executive staff.

9.2.2. The Accreditation Authority shall review the Certificate of Accreditation package as submitted by the assigned LELAP Assessor. If the Accreditation Authority deems the package complete, then he shall sign the Certificate of Accreditation and return the accreditation package to the assigned LELAP Assessor for disposition.

10.0 Invoices

10.1 LELAP shall bill facilities in July of the current fiscal year for annual fees. Application fees shall be billed every three years.

10.2 LELAP assessor shall prepare an excel spreadsheet that contains at a minimum the following information: LELAP Certificate Number, Facility Name, Address, State, Zip and the number of test categories that the applicant or continuing laboratory is seeking accreditation. This information shall be sent by e-mail to fiscal services where the invoices will be printed. Draft copies of the invoices are e-mailed to the LELAP Supervisor for review. If approved, Fiscal Services will send the Invoices to the appropriate laboratory. A copy of the invoices will be sent to LELAP to be placed into the facility records. Fees are based on the information provided on page iii of the LELAP application.

10.3 All invoices shall be mailed certified return receipt requested. All payments are due within 30 days of receipt of the invoice. It is noted on the return receipt card that an invoice is being mailed. The date the facility receives the invoice is determined from the returned card and entered into the AAMS database.

10.4 Fiscal Services tracks receipt of fees and shall send a second notice to any laboratory that has not paid their fees within 30 days. If payment is not received within 60 days, then Fiscal Services will notify the LELAP Supervisor. A letter notifying the laboratory that accreditation has been suspended will be sent via certified mail. Suspension will start with the date of the letter. If payment is not received with 30 days

of receipt of the suspension notice, the laboratory will be disaccredited. Notification of disaccreditation shall be sent via certified mail.

11.0 Database Updates

The LELAP Program Analyst shall update the AAMS database on an as needed basis. The Program Analyst shall notify the LELAP staff any time that there have been changes made to the databases. All incoming and outgoing mail must be entered into the document receipt area of the database.

12.0 LELAP Web Site

A LELAP Assessor will act as one of two Laboratory Services' Webmaster. These two individuals are responsible for updating the Laboratory Services and LELAP web pages. The LELAP Supervisor or his designee will prepare the list of accredited laboratories. The list of accredited laboratories is prepared as a text or excel file and sent via e-mail to the Webmaster. The list is updated when applicants are accredited; any facility information has changed, i.e. address, phone number, representative name; a facility has withdrawn; or a facility's accreditation status has changed.

13.0 Document Control and Retention

13.1 All official LELAP records shall be stored in the LELAP file room or archived in Room BS01. Admittance to the file areas is controlled through the building's security system. Entrance to the LELAP file room is through the Administrative area of the building and requires a magnetic card pass and key to access the door. Entrance to room BS01 requires a magnetic card pass to access the hallway and key to access the door. The LELAP Supervisor and Analyst have keys for these rooms.

13.2 Visitors wishing to review LELAP documents and files are required to sign-in with the receptionist. Visitors will be ushered to the conference room. LELAP personnel will pull the requested records and remain with the visitor in the conference room while the records are reviewed. Any visitor requesting copies of documents will be asked to complete the appropriate request form and must pay the appropriate fee. The Department's records manager will be contacted for the form and the cost of copies.

13.3 Documents that have been deemed "Confidential" by the Secretary will be filed in locked filing cabinet located in the LELAP file room. Access to "Confidential" records shall be restricted to the Secretary, Legal, LELAP Supervisor, and the LELAP Assessor assigned to the facility.

13.4 The LELAP program shall maintain all records for a period of ten years. Records for the current three years shall be maintained in the LELAP file room. Records exceeding three years shall be removed and archived in Room BS01. Effective April 2004, all LELAP records shall be filed according to Certificate number. Records will be

filed in reverse chronology and by year. The Program Analyst will remove records and archive as appropriate and with assistance from the assigned LELAP assessor shall review all facility files and remove any documents that have exceeded the 10-year period. Prior to destroying of purged records, the LELAP QA Coordinator shall review the records to determine whether they should be destroyed.

13.5 Records sent to archive shall be boxed and the box labeled with the LELAP accreditation number and box number. The Program Analyst will maintain a list of records sent to archive and the box number where the records are stored.

13.3 Records for facilities that withdraw for LELAP or close shall be archived in Room BS01. These records shall be boxed and the box labeled with the LELAP Accreditation Number, WITHDRAWN, and a box number. The Program Analyst will keep a list of withdrawn facilities and the box number that contains those records.

13.6 The LELAP QA officer/Supervisor shall maintain all official versions of any form necessary for LELAP to ensure compliance with the Louisiana Environmental Laboratory Accreditation Program regulations and NELAP Standards or TNI Standards as appropriate. The official version of any form shall be maintained electronically.

13.7 The official LELAP Quality Assurance Plan and Standard Operating Procedures shall be maintained on the LDEQ intranet. Copies, whether in electronic or printed form, should be verified for currency against the official document on the Intranet. The control header of the SOP shall be used for comparison to the official document.

13.8 The Quality Assurance Officer for LELAP shall have available on site a printed copy of the Quality Assurance Plan and Standard Operating Procedures for this program.

14.0 Meetings

14.1 All meetings scheduled with regards to accreditation shall be scheduled by the appropriate LELAP Assessor or by the LELAP Supervisor or his designee. LELAP Assessors shall document all meetings by using the LELAP Sign-In form.

14.2 The LELAP Assessor shall be responsible for providing a copy of the Sign-In form to each of the participants in the meeting. The original sign-in form shall be filed in the applicant laboratories files.

15.0 Forms

15.1 The LELAP QA Coordinator shall maintain electronically and in hard copy all forms required by the program for its day-to-day operations.

15.2 The Program QA Coordinator shall review and revise as necessary all forms annually.

ATTACHMENT A
FORMS

Forms

Laboratory File Check-Out/Check-In Form

Scope of Accreditation Form

Laboratory Application Evaluation Form

Memorandum of Recommendation Form

Cover-letter for Certificate Form

Certificate of Accreditation Form

Meetings Sign-In Form

Scope of Accreditation Form

Scopes of Accreditation for both NELAP and LELAP certificates are generated from the AAMS database.

Laboratory Application Evaluation Form
Laboratory Application Evaluation

Lab Name:

Evaluator:

Date:

Concurrence:

Date:

Requirement	Complete ¹	Pass/Fail ²	Incomplete ³	Missing Material ⁴
Application ⁵		Does not Apply	NA	
PT Studies ⁶	List Dates:	If no, list analyte(s)		ID Failed Elements
On-site Assessment Response CAP) ⁷	List Date:	NA	Yes or No	If Yes, List Missing Deficiencies Numbers
On-site assessment response (CCAD) ⁸	List Dates: CAP-- CCAD--	NA	Yes or No	If, Yes, List Missing Items in CAP and/or CCAD

¹ Answers are yes or no.

² Have results passed all LDEQ requirements?

³ Does not apply if the application is complete. Answer is "Yes" in material is missing or not evaluated as of this date.

⁴ Identify the missing material that must be provided by the lab. CCAD materials must be in the submissions from the lab, otherwise it is "incomplete". Material that has been submitted but has been determined to be inadequate is classified as unacceptable (e.g. SOP's that have been submitted but don't meet LDEQ standards should be identified as SOP's- "unacceptable"

⁵ Are the fields of testing and methods clearly identified in the application?

⁶ All PT studies (at least two per year) must be on file with LELAP.

⁷ Was a CAP submitted that covered all deficiencies? If incomplete/unacceptable, identify missing material by deficiency number?

⁸ Were CCAD submitted with the CAP/a separate submission? ? If incomplete/unacceptable, identify missing material by deficiency number?

**Memorandum of Recommendation Form
(Sent on LDEQ Letterhead)**

Date

MEMORANDUM

TO: Melvin C. Mitchell, Accrediting Authority
Louisiana Environmental Laboratory Accreditation Program

FROM: **Assessor's Name, Assessor**
Louisiana Environmental Laboratory Accreditation Program

RE: Accreditation

The Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) and/or its third party contractor have completed an on-site assessment of the laboratory listed below.

Laboratory Name
Physical Address
City, State Zip Code

A review of all documents submitted to the department has been completed. Requirements for accreditation as found in LAC 33, Part I, Subpart 3 have been successfully fulfilled by the laboratory. Therefore, I am recommending this laboratory for accreditation. The accreditation is for their mobile laboratory operating Louisiana.

Should you have any questions, please contact me.

KV

**Cover-letter for NELAP Certificate Form – First page
(Sent on LDEQ Letterhead)**

**CERTIFIED MAIL #«Certmail_Prefix» «Certmail»
Return Receipt Requested**

Date

AI #«LABALTERNATEID»

LELAP Certificate #«Lab_ID»

«PRIMARYCONTACTSALUTATION» «PRIMARYCONTACTFNAME»
«PRIMARYCONTACTLNAME»
«ORG»
«MAILLINE1» «MAILLINE2»
«MAILCITY», «MAILSTATE» «MAILZIP» «MAILCOUNTRY»

RE: Laboratory Accreditation

Dear «PRIMARYCONTACTSALUTATION» «ABBREVLASTNAME»:

In accordance with Louisiana Administrative Code, Title 33, Part I, Subpart 3, Laboratory Accreditation, the State of Louisiana formally recognizes that this laboratory has successfully completed the accreditation process and is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment. Accreditation does not constitute an endorsement of the suitability of the listed methods for any specific purpose. Parameters or analytes that the laboratory has applied for accreditation not included in the scope of accreditation attachment are not accredited.

NELAP accreditation is granted **only** for those methods/analytes for which “NELAP” is indicated as the type of accreditation. “STATE” is indicated as the type of accreditation for those methods/analytes for which NELAP accreditation is not available. Accreditation is dependent on the laboratory’s successful ongoing compliance with regulations as outlined in the Louisiana Administrative Code, Title 33, Part I, Subpart 3, Laboratory Accreditation.

The enclosed accreditation certificate is property of the State of Louisiana. Should a change in accreditation status occur, the Department may recall the original accreditation certificate and attachments. The recalled certificate and attachments should be returned to: Office of Environmental Assessment, Louisiana Environmental Laboratory Accreditation Program, P.O. Box 4314, Baton Rouge, LA 70821-4314, Attention: Mr. David Boucher.

LAC 33:I.5313.A requires that the laboratory report must include all relevant information. Therefore, the certificate number shall be placed in the upper right corner of all laboratory

reports. If the test report includes results of any test for which the laboratory is not accredited, the unaccredited results must be clearly identified as such.

Please be advised that it is your responsibility to examine the scope of accreditation attachment for accuracy and completeness. If you find that an analyte for which you expected to be accredited is not listed, please examine your records to ensure that:

1. You have met the requirements for successful participation in proficiency test studies as outlined in LAC 33:I.4711 and in the NELAC Standard 2.7.2.
2. In the case of accreditation by recognition, the requested analyte must be listed for the requested method and matrix on both the certificate issued by the Primary AA **and** on the Louisiana application form.

If you have any questions, please contact the Louisiana Environmental Laboratory Accreditation Program at (225) 219-9800.

Sincerely,

David Boucher, Supervisor
Louisiana Environmental Laboratory Accreditation Program

kv:db

Enclosure

NELAP Certificate

