

REQUEST FOR PROPOSALS

“Laboratory Auditing”

LOUISIANA DEPARTMENT OF ENVIRONMENTAL QUALITY



RFP No: 3000006528

Proposal Due Date/Time: December 2, 2016/3:00 p.m. CST

Issue Date: November 2, 2016

REQUEST FOR PROPOSALS

“Laboratory Auditing” Louisiana Department of Environmental Quality

TABLE OF CONTENTS

	Page
PART I. ADMINISTRATIVE INFORMATION	1
1.1 Request for Proposals (RFP).....	1
1.2 Contract Term and Compensation	1
1.3 Proposal Preparation	1
1.4 Questions and Answers.....	1
1.5 Submission of Proposals.....	2
1.6 Changes, Addendum, or Withdrawal of Proposals.....	3
1.7 Blackout Period.....	3
1.8 RFP Schedule Summary	4
1.9 Definitions.....	4
PART II. GENERAL INFORMATION.....	6
2.1 Corporation Requirements	6
2.2 Code of Ethics for State Employees	6
2.3 Insurance Requirements.....	6
2.4 Proposal Costs.....	6
2.5 Veteran-Owned and Service-Connected Small Entrepreneurships (Veteran Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) Programs	6
PART III. PROPOSAL PREPARATION INSTRUCTIONS	9
3.1 Proposal Content.....	9
3.2 Elements for Technical Proposal (Volume I)	9
3.2.1 Proposal Cover Sheet	9
3.2.2 Table of Contents	9
3.2.3 Scope of Services	9
3.2.4 Personnel Qualifications and Experience.....	11
3.2.5 Company Qualifications and Experience	11
3.2.6 Subcontractors.....	12
3.2.7 Price Proposal (Schedule of Prices)	12
3.3 Elements for Financial Information (Volume II).....	13
3.4 Proposal Format	14
3.5 Use and Disclosure of Confidential Information	14

PART IV. PROPOSAL EVALUATION AND SELECTION	15
4.1 Evaluation Process	15
4.2 Evaluation Criteria	15
4.3 Price Evaluation Calculation.....	16
4.4 Veteran-Owned and Service-Connected Small Entrepreneurships (Veteran Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) Programs Participation	17
4.5 Clarifications and Oral Presentations.....	17
4.6 Determination of Responsibility	17
4.7 Contract Award and Debriefings	18
4.8 Protest of the Solicitation or Award.....	18
4.9 Right to Prohibit Award.....	19

Appendices to this RFP:

Appendix A.....	Proposal Cover Sheet
Appendix B	Experience Table
Appendix C	Sample Contract
Appendix D.....	Veterans/Hudson Initiative Proposal Table

Attachments to this RFP:

Attachment 1	Statement of Work
Enclosure A.....	SOP No. 1787 Laboratory Assessment and Assessment Reporting
Enclosure B.....	SOP No. 1786 LELAP Proficiency Testing Evaluation
Enclosure C.....	QAPP No. 3021 LELAP Quality Assurance Plan
Exhibit 1	QMP No. 1000 Quality Management Plan
Enclosure D.....	SOP No. 1788 Review and Response to Laboratory Corrective Action Plans
Attachment 2	Schedule of Prices Form
Attachment 3	Forms
Form A	LaVet-SE-HI Invoice Reporting

REQUEST FOR PROPOSALS

“Laboratory Auditing” Louisiana Department of Environmental Quality

PART I. ADMINISTRATIVE INFORMATION

1.1 Request for Proposals (RFP)

The Louisiana Department of Environmental Quality, hereinafter referred to as the “Department”, requires the services of a well-qualified contractor to conduct laboratory audits. . The goal is to ensure the accuracy, precision, and reliability of laboratory data generated, as well as the use of Department-approved methods in the generation of that data. The Department invites all qualified parties (companies and individuals) to submit proposals for providing these services. The Department anticipates making up to five (5) awards to the highest scoring firms or companies, with the assignment of audits to each firm or company solely at the discretion of the Department.

1.2 Contract Term and Compensation

The term of the contract resulting from this RFP will be thirty-six (36) months, beginning approximately January 1, 2017 and ending approximately December 31, 2019. Compensation for contract services will be based on the Schedule of Prices (see RFP Section 3.2.7) and the unit rates resulting from the RFP process to be incorporated into the contract. The purpose of this contract is to establish terms, conditions and rates to be paid by audited laboratories. This contract and any amendments require the approval of the Department.

1.3 Proposal Preparation

Instructions for preparing proposals are provided in Part III of this Request for Proposal. Proposals submitted for consideration should follow the specified order of presentation and format.

1.4 Questions and Answers

It is not intended that a pre-proposal conference be held. **Any and all questions regarding this Request for Proposals must be submitted in writing to the Department’s Financial Services Division contact person listed below. Written questions must be received no later than 3:00 p.m. CST on or before November 16, 2016. Do not contact other Department personnel with questions regarding this RFP.** The Department reserves the right to modify the RFP should a change be identified that is in the best interest of the Department.

Questions may be mailed to:

Sharon Schexnayder
Financial Services Division
Louisiana Department of Environmental Quality
P. O. Box 4303
Baton Rouge, LA 70821-4303

or submitted by e-mail to: DEQ-Sect-Procurement@la.gov

Questions will also be accepted by FAX at (225) 219-3868.

Questions submitted in any other manner or to any other address, email, or telephone number will not be answered.

Only Sharon Schexnayder or her designee has the authority to officially respond to proposer's questions on behalf of the Department. Any communications from any other individuals are not binding on the Department.

Official responses to all questions by potential proposers will be posted on LaPAC at <https://wwwcfprd.doa.louisiana.gov/osp/lapac/pubMain.cfm> or on the Department's website at www.deq.louisiana.gov/RFP. Responses will be posted on November 17, 2016. It is the responsibility of potential Proposers to check the web site prior to submitting their proposal to verify that they have the most recent updates (i.e. questions and answers, addenda, additional information, etc.). Proposals that do not use the most recent updates will be scored accordingly.

1.5 Submission of Proposals

The Department requests that five (5) copies of the technical proposal and one (1) copy of the financial information be submitted to the address specified below no later than 3:00 pm CST on or before December 2, 2016. **At least one copy of the technical proposal shall contain original signatures of those company officials or agents duly authorized to sign proposals or contracts on behalf of the organization.** A certified copy of a board resolution granting such authority should be submitted if proposer is a corporation. The copy of the technical proposal with original signatures will be retained for incorporation in any contract resulting from this RFP.

Proposals, amendments, and any other information received after the date and time identified above will not be considered.

All proposals should be delivered to:

Sharon Schexnayder, Financial Services Division
Louisiana Department of Environmental Quality
Galvez Building
602 N. Fifth Street
Baton Rouge, Louisiana 70802

The U. S. Postal Services does not deliver mail directly to the Department's Headquarters at the address above. Therefore, Proposers must hand deliver or send their proposals by some means other than the U.S. Mail. Proposers are further advised not to wait until the last day to dispatch their proposals. Maximum competition is encouraged but time extensions for messenger delays, traffic, fogbound airplanes, or other causes will not be granted. Proposals will not be accepted by facsimile (FAX) or electronic mail (e-mail).

Proposers are solely responsible for the timely delivery of their proposals. The Department will not acknowledge by mail or telephone timely receipt of proposals.

1.6 Changes, Addendum, or Withdrawal of Proposals

The Department shall reserve the right to change the schedule of events or revise any part of the RFP by issuing an addendum to the RFP at any time. Addenda, if any, will be posted at <https://wwwcfprd.doa.louisiana.gov/osp/lapac/pubMain.cfm> or www.deq.louisiana.gov/RFP. It shall be the responsibility of the proposer to check the website for addenda to the RFP, if any.

Any changes or addendum to a proposal must be submitted in writing, signed by an authorized representative of the Proposer, cross-referenced clearly to the relevant proposal section, and received by the Department prior to the proposal due date and time. All changes and addenda must meet all requirements for the proposal. Any Proposer choosing to withdraw its proposal must submit a written withdrawal request to the Department prior to the deadline to submit proposals.

1.7 Blackout Period

The Blackout Period is a specified period of time during a competitive sealed procurement process in which any proposer, bidder, or its agent or representative, is prohibited from communicating with any state employee or contractor of the State involved in any step in the procurement process about the affected procurement. The Blackout Period applies not only to state employees, but also to any contractor of the State. "Involvement" in the procurement process includes but may not be limited to project management, design, development, implementation, procurement management, development of specifications, and evaluation of proposals for a particular procurement. All solicitations for competitive sealed procurements will identify a designated contact person, as per Section 1.4 of this RFP. All communications to and from potential proposers, bidders, vendors and/or their representatives during the Blackout Period must be in accordance with this solicitation's defined method of communication with the designated contact person. The Blackout Period will begin upon posting of the solicitation. The Blackout Period will end when the contract is awarded.

In those instances in which a prospective proposer is also an incumbent contractor, the State and the incumbent contractor may contact each other with respect to the existing contract only. Under no circumstances may the State and the incumbent contractor and/or its representative(s) discuss the blacked-out procurement.

Any bidder, proposer, or state contractor who violates the Blackout Period may be liable to the State in damages and/or subject to any other remedy allowed by law.

Any costs associated with cancellation or termination will be the responsibility of the proposer or bidder.

Notwithstanding the foregoing, the Blackout Period shall not apply to:

1. A protest to a solicitation submitted pursuant to La. R.S. 39:1671;
2. Duly noticed site visits and/or conferences for bidders or proposers;
3. Oral presentations during the evaluation process;
4. Communications regarding a particular solicitation between any person and staff of the procuring agency provided the communication is limited strictly to matters of procedure. Procedural matters include deadlines for decisions or submission of proposals and the proper means of communicating regarding the procurement, but shall not include any substantive matter related to the particular procurement or requirements of the RFP.

1.8 RFP Schedule Summary

The events and dates summarized in Table 1 represent milestones in the Department's RFP process; however, the Department reserves the right to deviate from this schedule.

Table 1. RFP Schedule Summary

Event	Date	Local Time
Begin Advertisement of RFP	November 2, 2016	
Deadline for the Department receipt of written questions from prospective Proposers	November 16, 2016	3:00 p.m. CST
Post responses to written inquires	November 17, 2016	
Proposal due date and time	December 2, 2016	3:00 p.m. CST
Oral presentations by Proposers (if required)	December 23, 2016	
Estimated award date	Approximately January 4, 2017	
Estimated initiation of the contract period	Approximately January 1, 2017	

1.9 Definitions

Contractor – Any person or firm having a contract with a governmental body; the selected proposer

DOA - Division of Administration

OSP – Office of State Procurement

Proposer – A firm or individual who responds to this RFP

RFP – Request for Proposals

Shall, Will, Must - Denotes a mandatory requirement

Should, Can, May - Denote a preference, not a mandatory requirement

State - The State of Louisiana

The Department – Louisiana Department of Environmental Quality

PART II. GENERAL INFORMATION

2.1 Corporation Requirements

If the Proposer is a corporation not incorporated under the laws of the State of Louisiana, the Contractor shall obtain a Certificate of Authority pursuant to La. R.S. 12:301-302 from the Louisiana Secretary of State, Corporations Division, 3851 Essen Lane, Baton Rouge, Louisiana, 70809, (225) 925-4704. The Certificate of Authority must be provided prior to contracting with the Department.

If the Proposer is a for-profit corporation whose stock is not publicly traded, the Proposer shall file a Disclosure of Ownership form with the Louisiana Secretary of State's office before contracting with state government. The Disclosure of Ownership Affidavit must be provided prior to contracting with the Department.

2.2 Code of Ethics for State Employees

Proposers are hereby advised that contractors may, in certain circumstances, be deemed "public employees" as interpreted by the Louisiana Board of Ethics. Proposers are responsible for determining that there will be no conflict or violation of the Ethics Code if their company is awarded the contract. (See Appendix C, Sample Contract, Article 25).

2.3 Insurance Requirements

Proposers are encouraged to carefully examine the insurance coverages that will be required by the contract. (See Appendix C, Sample Contract, Article 27). Certificates of insurance, signed by a person authorized by that insurer to bind coverage on its behalf, must be provided by the successful contractor and approved by the Department before work begins. Furthermore, the successful contractor must include all subcontractors as insured under its policies or shall be responsible for verifying and maintaining the Certificates provided each subcontractor before work begins.

2.4 Proposal Costs

Proposers are responsible for all costs incurred for the preparation of their proposals. Proposals received in response to this RFP are subject to the Louisiana Public Records Law, R.S. 44:1 and become the property of the Department and will not be returned.

2.5 Veteran-Owned and Service-Connected Small Entrepreneurships (Veteran Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) Programs

The State of Louisiana Veteran and Hudson Initiatives are designed to provide additional

opportunities for Louisiana-based small entrepreneurships (sometimes referred to as LaVet's and SE's respectively) to participate in contracting and procurement with the state. A certified Veteran-Owned and Service-Connected Disabled Veteran-Owned small entrepreneurship (LaVet) and a Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) small entrepreneurship are businesses that have been certified by the Louisiana Department of Economic Development. All eligible vendors are encouraged to become certified. Qualification requirements and online certification are available at <http://smallbiz.louisianaeconomicdevelopment.com>.

Ten percent (10%) of the total evaluation points on this RFP are reserved for Proposers who are themselves a certified Veteran or Hudson Initiative small entrepreneurship or who will engage the participation of one or more certified Veteran or Hudson Initiatives small entrepreneurships as subcontractors.

Reserved points shall be added to the applicable Proposers' evaluation score as follows:

Proposer Status and Reserved Points

- Proposer is a certified small entrepreneurship: Full amount of the reserved points
- Proposer is not a certified small entrepreneurship but has engaged one or more certified small entrepreneurships to participate as subcontractors or distributors. Points will be allocated based on the following criteria:
 - the number of certified small entrepreneurships to be utilized
 - the experience and qualifications of the certified small entrepreneurship(s)
 - the anticipated earnings to accrue to the certified small entrepreneurship(s)

If a Proposer is not a certified small entrepreneurship as described herein, but plans to use certified small entrepreneurship(s), the Proposer shall complete and include in their proposal, Appendix D, Veteran-Owned and Service-Connected Small Entrepreneurships (Veterans Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) Programs Table. Reserved points will be allocated according to the information provided by the proposer, not by what could be inferred.

During the term of the contract and at expiration, the Contractor will also be required to report Veteran-Owned and Service-Connected Disabled Veteran-Owned and Hudson Initiative small entrepreneurship subcontractor or distributor participation and the dollar amount of each. See Attachment 3, Form A

The statutes (R.S 39:2171 *et. seq.*) concerning the Veteran Initiative may be viewed at <http://legis.la.gov/39:2171>; and the statutes (R.S 39:2001 *et. seq.*) concerning the Hudson Initiative may be viewed <http://legis.la.gov/Legis/Law.aspx?d=96265>. The rules for the Veteran Initiative (LAC 19:VII. Chapters 11 and 15) and for the Hudson Initiative (LAC 19:VIII Chapters 11 and 13) may be viewed at <http://www.doa.la.gov/Pages/osp/SE/se.aspx>.

A current list of certified Veteran-Owned and Service-Connected Disabled Veteran-Owned and Hudson Initiative small entrepreneurships may be obtained from the Louisiana Economic Development Certification System at <http://smallbiz.louisianaeconomicdevelopment.com>. Additionally, a list of Hudson and Veteran Initiative small entrepreneurships, which have been certified by the Louisiana Department of Economic Development and who have opted to register in the State of Louisiana LaGov Supplier Portal https://lagoverpvendor.doa.louisiana.gov/irj/portal/anonymouse?guest_user=self_reg may be

accessed from the State of Louisiana Procurement and Contract (LaPAC) Network <https://wwwcfprd.doa.louisiana.gov/osp/lapac/pubMain.cfm>. When using this site, determine the search criteria (i.e. alphabetized list of all certified vendors, by commodities, etc.) and select SmallE, VSE, or DVSE.

PART III. PROPOSAL PREPARATION INSTRUCTIONS

3.1 Proposal Content

Proposals submitted in response to this RFP should include as much detail as practical to provide a straightforward, clear, and concise description of the Proposer's ability to meet the requirements of the RFP. The Proposer should demonstrate his understanding of the Department's requirements. Each Proposer is solely responsible for the accuracy and completeness of his proposal.

3.2 Elements for Technical Proposal (Volume I)

Each Proposer should address the elements described by this section in his Technical Proposal in the order listed.

3.2.1 Proposal Cover Sheet

Each Proposer must complete Appendix A, Proposal Cover Sheet. **Proposals lacking a signed cover sheet shall be disqualified.**

3.2.2 Table of Contents

Each Proposer should include a paginated Table of Contents to facilitate locating proposal information.

3.2.3 Scope of Services

Each Proposer should submit a Scope of Services that clearly and concisely describes his technical and management approach to completing the requirements described in Attachment 1, Statement of Work (SOW). The Proposer's Scope of Services should be presented in as much detail as judged necessary by the Proposer. An unsupported statement that the Proposer will comply with all the requirements of this solicitation shall not be acceptable.

Each Proposer's Scope of Services should include a brief introduction followed by a discussion of the following technical elements, in the order listed.

(1) Project Management

The Proposer should describe the proposed approach to project management including, the following information:

(a) Overall company organization

Describe the overall organization of the company. Include a company organizational chart. If multiple offices are involved in the project, describe how the home office and branch offices will interact with each other and with the Department. Include a description of the involvement of any proposed subcontractors in this project (See Item 3.2.6, Subcontractors).

(b) Project organization

The Proposer should provide the following information

Provide a project-specific organizational chart identifying the **Proposer's key personnel and key subcontractor personnel** proposed for work on this project as identified in Attachment 1, SOW, Section 5.0 Minimum Qualifications of the Contractor's Personnel. This chart should specifically include, but need not be limited to, Project Manager and Project Manager Backup, Auditor(s) and Stack Test Auditor(s). Show the lines of authority and lines of communication among all participants, including management, supervisory, and technical staff, and points of contact for the Department, and any subcontractor relationships. The chart should be realistic and practical. The organizational chart should be accompanied by a narrative identifying the function and responsibilities of each position identified in the organizational chart and the names of specific personnel proposed for assignment to these positions (include dual assignments, multiple individuals assigned to one position, and subcontractors).

(c) Management approach

The Proposer should describe the proposed approach to project management. Project management shall include, but is not limited to, supervision of the Contractor's personnel, communication between the Contractor and the Department, meetings and training sessions, contract administration, and preparation and submission of submittals and deliverables in general.

(2) Performance of Project Tasks

The Proposer should describe the proposed approach to the performance of the technical tasks described in Attachment 1, SOW. The Proposer should include a description of deliverables to be received by the Department as end products of the services rendered. The Proposer should include a statement of intent indicating compliance with the LDEQ's Standard Operating Procedures (SOP). The statement of intent shall be required prior to award.

- Enclosure A - SOP 1787 Laboratory Assessment and Assessment Reporting
- Enclosure B - SOP 1786 LELAP Proficiency Test Evaluation
- Enclosure C - QAPP 3021 LELAP Quality Assurance Plan

- Enclosure D - SOP 1788 Review and Response to Laboratory Corrective Action Plans

3.2.4 Personnel Qualifications and Experience

The Proposer should provide evidence that its proposed staff meets or exceeds the minimum education and experience requirements described in Attachment 1, SOW, Section 5.0 Minimum Qualifications of the Contractor's Personnel. The Department will consider only experience that is relevant to the tasks listed in Attachment 1, SOW.

The Proposer should describe the qualifications and experience of **all key personnel** designated in the project-specific organizational chart (provided under Section 3.2.3, Item 1b. above) as assigned to this project. The Proposer should include résumés (**key personnel only**) showing each assigned individual's education, registrations, accomplishments, and experience.

The Proposer should provide a list of technologies assessed or included in technical training showing they have a thorough knowledge of all relevant analytical methods in the categories they will be conducting assessments.

The Proposer should include a statement that Proposer's staff are:

- familiar with the 2009 TNI standard and Department accreditation regulations, procedures and requirements
- familiar with quality assurance documents and standard operating procedures and any other document(s) necessary for a comprehensive records review

3.2.5 Company Qualifications and Experience

The Proposer should describe the company's qualifications and experience that are relevant to the proposed tasks listed in Attachment 1, SOW. Experience will be considered relevant if prior projects major features include laboratory auditing and stack test auditing. Both government and privately-sponsored work may be included. Experience gained through previous contracts with the Department may be considered by the Department for proposal evaluation, whether or not listed by the Proposer.

Each Proposer should describe projects undertaken by his company during the past three (3) years from the proposal submittal date. Experience gained through joint ventures by the company may be included. In the event that the company has not done business under its present organizational name and status for three (3) years, other corporate experience brought to the company through mergers or similar corporate creations may be added.

The Proposer's experience information should be submitted in the tabular format provided in Appendix B, Experience Table. The table may be enlarged or duplicated as

necessary to provide all required information. For each listed project, the Proposer should provide:

- (1) the name and address of the client (sponsoring agency or company);
- (2) the name, telephone number, and email address of the client's contact person;
- (3) the project title and contract number;
- (4) the starting and ending dates of the project (contract term);
- (5) the total dollar amount of the project; and
- (6) a brief description of the project.

Each Proposer may include as many entries as he desires, however, only complete entries will be considered. Because the Department may contact a representative sample of the listed clients as references during the evaluation process, Proposers should verify that all client contact information and telephone numbers are current.

3.2.6 Subcontractors

All subcontractors proposed for use by the Proposer for this project should be identified on Appendix A, Proposal Cover Sheet. The Proposer should provide a signed letter of agreement or a copy of a signed contract from any intended subcontractor. This commitment must demonstrate the subcontractor's willingness to undertake his portion of the proposed project.

If any of the subcontractors proposed by the Proposer is a certified small entrepreneurship, the proposer shall complete and include in their proposal all documentation as described in Section 2.5 of this RFP.

3.2.7 Price Proposal (Schedule of Prices)

Each Proposer must submit a price proposal using the Department's pricing structure provided in Attachment 2, Schedule of Prices. No other format shall be acceptable. **Proposals not including a Schedule of Prices shall be disqualified.** Additionally, all blanks on the Schedule of Prices must be completed. For items with no charge, "\$0" must be entered. If a Proposer identifies deficiencies or errors in this format, he should bring this information to the attention of the Department prior to proposal submission. The Department will review the information, and, if necessary, will issue any correction as an addendum to the RFP.

Only Attachment 2, Schedule of Prices will be considered in evaluating the price proposal. The Proposer is advised to not include any additional terms and conditions, company fee schedules, etc., as they will not be considered.

3.3 Elements for Financial Information (Volume II)

Financial information is used for determination of responsibility (See Section 4.6), and not as evaluation criteria. In a separate volume, proposals should include evidence demonstrating the Proposer's financial capability to carry out this project. Evidence can include, but is not limited to:

- (Preferred) Financial Statements compiled by a Certified Public Accountant (CPA) for the past 3 years. This includes:
 - Notes to the Financial Statements, and
 - The CPA's Compiled Report for each year
- Letter of intent to obtain a 100% Performance Bond

If a performance bond is chosen by the Proposer as evidence of financial capability, the successful Proposer shall be required to provide a performance (surety) bond in the amount of 100% of the contract to insure the successful performance under the terms and conditions of the contract negotiated between the successful Proposer and the State. Any performance bond furnished shall be written by a surety or insurance company currently on the U.S. Department of the Treasury Financial Management Service list of approved bonding companies which is published annually in the *Federal Register*, or by a Louisiana domiciled insurance company with at least an A-rating in the latest printing of the A.M. Best's Key Rating Guide to write individual bonds up to 10 percent of policyholders' surplus as shown in the A.M. Best's Key Rating Guide or by an insurance company that is either domiciled in Louisiana or owned by Louisiana residents and is licensed to write surety bonds.

No surety or insurance company shall write a performance bond which is in excess of the amount indicated as approved by the U.S. Department of the Treasury Financial Management Service list or by a Louisiana domiciled insurance company with an A-rating by A.M. Best up to a limit of 10 percent of policyholders' surplus as shown by A.M. Best; companies authorized by this Paragraph who are not on the treasury list shall not write a performance bond when the penalty exceeds 15 percent of its capital and surplus, such capital and surplus being the amount by which the company's assets exceed its liabilities as reflected by the most recent financial statements filed by the company with the Department of Insurance.

If the performance bond is chosen by the Proposer as evidence to demonstrate financial capability, the Performance Bond is to be provided within ten (10) working days from request. Failure to provide within the time specified may cause your offer to be rejected.

In addition, any performance bond furnished shall be written by a surety or insurance company that is currently licensed to do business in the state of Louisiana.

The selected Proposer may be required to provide additional information as requested by the Department.

3.4 Proposal Format

Proposals submitted for consideration should follow the format and order of presentation provided in Part III, Sections 3.1 and 3.2. Each volume of the proposal should be typed and securely bound in a three ring binder. Pages of the technical proposal should be numbered consecutively and each section should be marked by a labeled page divider. Proposals should be prepared simply, legibly, and economically. Elaborate binders, color pictures, and promotional material are neither necessary nor desired.

3.5 Use and Disclosure of Confidential Information

Pursuant to LSA-R.S. 30:2030 and R.S. 44:1, et seq., documents submitted by Proposers in response to this RFP shall be available to the public. If a Proposer wishes to secure nondisclosure of information contained in his proposal, the Proposer must submit a written request to the Secretary of the Department in accordance with LAC 33:I. Chapter 5 and applicable laws. Upon review of the written request, the Secretary of the Department will determine if the information requires confidentiality.

PART IV. PROPOSAL EVALUATION AND SELECTION

4.1 Evaluation Process

A Selection Committee composed of the Department personnel will evaluate and rank the proposals according to the criteria listed in Section 4.2. Any proposal that does not provide the following mandatory items shall be disqualified by the Department and shall not be evaluated by the Selection Committee:

- (1) an original signed Proposal Cover Sheet (Part III, Section 3.2.1); and
- (2) a Schedule of Prices (Part III, Section 3.2.7)

Proposals will be evaluated in light of the material and the substantiating evidence presented in the proposal, not on the basis of what can be inferred. Additionally, the Department may contact a representative sample of the clients provided to describe the company's experience as references during the evaluation process. (See Section 3.2.5 above.)

The scores will be compiled using Table 2. Evaluation Criteria. The responsible and qualified Proposer(s) with the highest rated proposal will be recommended for tentative selection. Multiple awards may be made. The Selection Committee will report its comments and recommendations to the Department Secretary or his designee. The tentative selection is subject to the approval of the Secretary of the Department or his designee and the Division of Administration, Office of State Procurement. The Secretary of the Department or his designee is the only individual who can legally commit the Department to the expenditure of funds in connection with this proposed procurement. Any other commitment, either explicit or implied, is invalid. The contract will not be valid until approved by the Division of Administration, Office of State Procurement.

4.2 Evaluation Criteria

The Evaluation Team will evaluate and score the proposals using the criteria and scoring as follows:

Table 2. Evaluation Criteria

CRITERIA	MAXIMUM SCORE
1. Merit of the Proposer's Scope of Services (Part III, Section 3.2.3) and overall quality of the proposal (Part III, Sections 3.1 through 3.4).	10
2. Qualifications and relevant experience of the Proposer's key personnel assigned to the project (including subcontracted personnel as allowed) (Part III, Sections 3.2.4 and 3.2.6).	25
3. Qualifications and relevant experience of the Proposer in providing laboratory auditing and stack test auditing (Part III, Sections 3.2.5 and 3.2.6).	30
4. Price (Part III, Section 3.2.7).	25
5. Hudson/Veteran Small Entrepreneurship Program (Part IV, Section 4.4)	10
TOTAL SCORE	100

4.3 Price Evaluation Calculation

To compare Proposers' unit prices, the Department will calculate a total evaluation price for each proposal by using the Evaluation Calculations below.

Table 3. Evaluation Calculation Table

Item	Unit	Evaluation Weighting Factor	Proposer Rate	Line Total
Laboratory Auditing: Physical Audit and Corrective Action Plan (CAP) Work	Hour	480	\$	
Travel Time	Hour	160	\$	
Audit Preparation and Report Writing	Hour	300	\$	
Total Evaluation Price				

The proposal with the lowest total price from Attachment 2, Schedule of Prices, will receive the maximum possible points. All other proposals will be rated using the following formula:

$$25 \quad \times \quad \frac{\text{Evaluation Price of lowest proposal}}{\text{Evaluation Price of proposal being rated}} = \text{Proposal price points}$$

4.4 Veteran-Owned and Service-Connected Small Entrepreneurships (Veteran Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) Programs Participation

Ten percent (10%) of the total evaluation points on this RFP are reserved for Proposers who are themselves a certified Veteran or Hudson Initiative small entrepreneurship or who will engage the participation of one or more certified Veteran or Hudson Initiatives small entrepreneurships as subcontractors.

Reserved points shall be added to the applicable Proposers' evaluation score as follows:

Proposer Status and Reserved Points:

- Proposer is a certified small entrepreneurship: Full amount of the reserved points
- Proposer is not a certified small entrepreneurship but has engaged one or more certified small entrepreneurships to participate as subcontractors or distributors. Points will be allocated based on the following criteria:
 - the number of certified small entrepreneurships to be utilized
 - the experience and qualifications of the certified small entrepreneurship(s)
 - the anticipated earnings to accrue to the certified small entrepreneurship(s)

4.5 Clarifications and Oral Presentations

Written or oral clarifications may be requested for the purpose of enhancing the Department's understanding of a proposal element, eliminating minor irregularities, or correcting apparent clerical mistakes in a proposal. Written or oral discussions may be conducted with Proposers who submit proposals determined to be reasonably susceptible of being selected for award. Any commitments or representations made during discussions, if conducted, may become formally recorded in the final contract. However, proposals may be accepted without such clarifications or discussions and award may be made on the basis of initial offers received. Therefore, proposals should be complete as submitted and reflect the most favorable terms available.

Proposers may be requested to make oral presentations of their proposals to enhance the Department understanding prior to the final selection of the Contractor. Proposers selected for oral presentations will be those susceptible of receiving an award. These Proposers will be notified by the Department's Financial Service's Division on or before December 16, 2016. Presentations will be made by the selected Proposers on December 23, 2016, at a time assigned by the Department.

If oral presentations are required, the original scores may be adjusted to reflect information received in the presentation using the same evaluation criteria in Section 4.2 except that the cost score will remain unchanged.

4.6 Determination of Responsibility

Determination of the Proposer's responsibility relating to this procurement shall be made according to the standards set forth in LAC 34:2536.2. The Department is prohibited from

awarding any contract for consulting services for \$50,000 or more to any person or firm unless the Department has first determined that such person or firm is responsible according to the standards described in this section. The Department must find that the selected Proposer:

- (1) has adequate financial resources for performance, or has the ability to obtain such resources as required during performance;
 - (i) Upon completion of the Evaluation and Ranking Report, the highest rated proposal shall receive further review through preparation of a Financial Statement Analysis of the documentation provided in response to Section 3.3 of the RFP. The Department reserves the right to request additional information to satisfy financial status review requirements.
- (2) has the necessary experience, organization, technical qualifications, skills, and facilities, or has the ability to obtain them; and
- (3) is able to comply with the proposed or required time of delivery or performance schedule; and
- (4) has a satisfactory record of integrity, judgment, and performance (A Proposer which is seriously delinquent in current contract performance, considering the number of contracts and the extent of delinquencies of each, shall in the absence of evidence to the contrary or compelling circumstances, be presumed to be unable to fulfill this requirement.); and
- (5) is otherwise qualified and eligible to receive an award under applicable laws and regulations.

Proposers should ensure that their proposals contain sufficient information for the Department to make its determination by presenting acceptable evidence of financial resources, experience, organization, technical qualifications, skills, personnel, and facilities, to perform the services called for by the contract.

4.7 Contract Award and Debriefings

Unless it is determined that it is in the best interest of the State of Louisiana to reject all proposals or cancel the RFP, the Department estimates that the contract will be awarded by approximately January 4, 2017, and will issue a “Notification of Award” letter to the successful Proposer. Unsuccessful Proposers will also be notified of the Department’s decision in writing, and may request a post-award debriefing by contacting Sharon Schexnayder at (225) 219-3812, or by e-mail at sharon.schexnayder@la.gov.

4.8 Protest of the Solicitation or Award

Any Proposer aggrieved by the proposed award has the right to submit a protest in writing to the head of the agency issuing the proposal within fourteen (14) calendar days after the award has been announced by the agency.

4.9 Right to Prohibit Award

In accordance with the provisions of R.S. 39:2192, any public entity is authorized to reject a proposal or bid from, or not award the contract to, a business in which any individual with an ownership interest of five percent or more, has been convicted of, or has entered a plea of guilty or nolo contendere to any state felony or equivalent federal felony crime committed in the solicitation or execution of a contract or bid awarded under the laws governing public contracts under the provisions of Chapter 10 of Title 38 of the Louisiana Revised Statutes of 1950 and all contracts under Title 39, Chapter 17 of the Louisiana Procurement Code, including contracts for professional, personal, consulting, and social services.

**APPENDIX A
PROPOSAL COVER SHEET**

Project Title: “Laboratory Auditing”

Proposer: Company Name: _____

Company Address: _____

Are you a certified Veteran or Hudson Initiative small entrepreneurship? (Y/N) ____

If “Yes”, is your Veteran / Hudson Initiative certification attached? (Y/N) ____

Proposer’s Contact Person:

Official Contact Name: _____

Title: _____

Mailing Address: _____

Physical Address (if different): _____

Email Address: _____

Telephone No. (_____) _____

FAX No. (_____) _____

The Proposer designates the above-named person as the person to receive all documents relative to the proposal and contract. Proposer certifies that the above information is true and grants permission to LDEQ to contact the above named person or otherwise verify the information provided.

Subcontractors (add lines as necessary):

Name	Written commitment attached (Y/N)	Veteran/Hudson Initiative* certification attached (Y/N)

***See Section 2.5 of the RFP for more information on what must be submitted with your proposal**

I hereby certify that:

1. The information contained in its response to this RFP is accurate.
2. Proposer complies with each of the mandatory requirements listed in the RFP and will meet or exceed the functional and technical requirements specified therein;
3. Proposer accepts the procedures, evaluation criteria, mandatory contract terms and conditions and all other administrative requirements set forth in this RFP.
4. This proposal will remain in effect for at least ninety (90) calendar days from the proposal due date.
5. Proposer possesses an established system of accounting and financial controls adequate to permit the effective administration of this contract or willingness to modify the present system to meet State of Louisiana requirements.
6. Proposer will be ready and able to begin work within fifteen (15) business days after contract award.

7. Proposer accepts the mandatory Department of Environmental Quality contract provisions (Appendix C).
8. The undersigned is authorized to represent _____ and can commit the organization to all provisions of this proposal.
9. Proposer understands that if selected as the successful Proposer, he/she will have fifteen (15) business days from the date of delivery of final contract in which to complete contract negotiations, if any, and execute the final contract document.
10. Proposer certifies, by signing and submitting a proposal for \$25,000 or more, that their company, any subcontractors, or principals are not suspended or debarred by the General Services Administration (GSA) in accordance with the requirements in OMB Circular A-133 (A list of parties who have been suspended or debarred can be viewed via the internet at www.epls.gov).

Signature

Date

**APPENDIX B
EXPERIENCE TABLE**

"Laboratory Auditing" RFP
(Enlarge or duplicate table as necessary)

Client Name and Address	Contact Person, Telephone Number and email address	Project Title and Contract Number	Dates of Project/ Dollar Amount of Contract	Description of Project

APPENDIX C
SAMPLE CONSULTING SERVICES CONTRACT

THIS CONTRACT, made and entered into this _____ day of _____, 2016, by and between the Department of Environmental Quality of the State of Louisiana, hereinafter referred to as "the Department", and **Contractor Name**, **Contractor Address**, **Tax ID No.** _____ hereinafter referred to as the "Contractor".

The Department hereby contracts and retains the Contractor who agrees to proceed, after proper notice and receipt of written authorization by the Department with all services necessary to the performance, in proper sequence and in the time specified, of the items of work for the project as hereinafter set forth.

1. PROJECT IDENTITY

This contract shall be identified as **“Laboratory Auditing”** with the LaGov Number assigned as set forth above. All invoices and other correspondence submitted to the Department in connection with this contract shall be identified by this LaGov Number.

2. CONTRACT TERM

The term for the fulfillment of services to be performed pursuant to this contract shall be from January 1, 2017 through December 31, 2019.

3. SCOPE OF SERVICES

The Contractor shall provide the necessary personnel, materials, services and facilities to perform the work as set forth in Attachment 4, Contractor’s Proposal and Attachment 1, Statement of Work attached hereto and made a part hereof.

4. NOTICE TO PROCEED

The Contractor shall proceed with the work only after receipt of an executed contract which has been approved by the Department and participation in a Commencement Conference to be scheduled by the Department at its offices.

5. PAYMENT TERMS

Payment to the Contractor shall be the responsibility of the audited Laboratory. Work performed by the Contract during the term of the contract shall be paid at the rates listed in Attachment 2, Schedule of Prices.

The Contractor shall not perform out-of-scope work not authorized by written amendment prior to the expiration date of the contract. Any out-of-scope work performed by the Contractor without written authorization from the Department in the form of an approved contract amendment shall not entitle the contractor to any

compensation for any corresponding effort. Verbal directives from any employee of the Department that would result in the performance of out-of-scope work shall carry no authority.

a. Payment:

Payment to the Contractor for services rendered shall be made according to the rates in Attachment 2, Schedule of Prices. Payment shall be made by audited laboratories upon completion of each audit. A partial payment by audited laboratories may be pursued as described in Attachment 1, Statement of Work.

The unit rates for lines 1-3 in Attachment 2, Schedule of Prices shall include all associated direct costs (labor, supplies, equipment, incidentals and expendables, duplication/copying, communications, postage, shipping and handling, transportation, taxes, etc.), all indirect costs (fringe, overhead, general and administrative costs) and profit.

Travel and other allowable expenses shall be reimbursed in accordance with the Division of Administration State General Travel Regulations, within the limits established for State Employees, as defined in Division of Administration Policy and Procedure Memorandum No. 49.
<http://www.doa.la.gov/Pages/osp/Travel/travelPolicy.aspx>

b. Payment Procedure:

The procedure for payment shall follow the procedures described in Attachment 1, Statement of Work, 3.0 Contractor's Tasks and 9.0 Measurement and Payment.

The Contractor shall mail, fax or email to the Department a copy of Attachment 3, Form A LaVet/SE-HI Report at each time requests for payments are submitted to audited Laboratories.

6. FISCAL FUNDING

The continuation of this contract is contingent upon the appropriation of funds to fulfill the requirements of the contract by the legislature. If the legislature fails to appropriate sufficient monies to provide for the continuation of the contract, or if such appropriation is reduced by the veto of the Governor or by any means provided in the appropriations act to prevent the total appropriation for the year from exceeding revenues for that year, or for any other lawful purpose, and the effect of such reduction is to provide insufficient monies for the continuation of the contract, the contract shall terminate on the date of the beginning of the first fiscal year for which funds are not appropriated.

7. DELIVERABLES

The Contractor shall provide to the Department the deliverables specified in Attachment

1, Statement of Work as products of the services rendered under this contract. The Department reserves the right to reject any deliverable that is unsatisfactory. The Contractor shall correct any omissions or errors and resubmit the deliverable.

8. OWNERSHIP OF DOCUMENTS

Upon completion or termination of this contract, all data collected by the Contractor and all documents, notes, and files collected or prepared specifically in connection with this work, except the Contractor's personnel and administrative files, shall become and be the property of the Department and the Department shall not be restricted in any way whatsoever in its use of such material. In addition, at any time during the contract period, the Department shall have the right to require the Contractor to furnish copies of any or all data and all documents, notes and files collected or prepared by the Contractor specifically in connection with this contract within five (5) days of receipt of written notice issued by the Department.

9. CORRECTION OF DEFICIENT WORK

If required by the Department, prior to payment, the Contractor shall promptly, without cost to the Department, correct any deficient work performed by him or his subcontractors. Deficient work is defined as work that is (a) unsatisfactory, faulty, or defective, or (b) does not conform to the requirements of the contract documents. If the Contractor does not correct such deficient work within the time specified by the Department, the Department may have the deficiency corrected by a separate party. All direct and indirect costs for such correction shall be paid by the Contractor. If corrections made to deficient work interfere with any other Department work by other parties, the Contractor shall also bear the expenses caused by that interference.

10. INDEMNIFICATION

The Contractor shall indemnify and save harmless the Department against any and all claims, demands, suits and judgments of sums of money to any party for loss of life or injury or damage to person or property growing out of, resulting from, or by reason of, any negligent act or omission, operation or work of the Contractor, its agents, servants, or employees while engaged upon or in connection with the services required or performed by the Contractor hereunder.

11. NONASSIGNABILITY

The Contractor shall not assign any interest in this contract by assignment, transfer, or novation, without the prior written consent of the Department. This provision shall not be construed to prohibit the Contractor from assigning his bank, trust company or other financial institution any money due or to become due from approved contracts without such prior written consent. Notice of any such assignment or transfer shall be furnished promptly to the Department.

12. AUDIT OF RECORDS

The State, through the Legislative Auditor, and/or the Office of the Governor, Division of Administration, the Department's Audit Services, or any of their duly authorized representatives, shall be entitled to audit the books, documents, papers, and records of the Contractor and any subcontractors which are reasonably related to this contract.

13. RECORDS RETENTION

The Contractor and its subcontractors shall maintain all books, documents, papers, accounting records and other evidence pertaining to costs incurred and shall make such materials available at their respective offices at all reasonable times during the contract period and for three (3) years from date of final payment under this contract, for inspection or audit, and copies thereof shall be furnished if requested.

14. TERMINATION FOR CAUSE

The Department may terminate this contract for cause based upon the failure of the Contractor to comply with the terms and/or conditions of the contract; provided that the Department shall give the Contractor written notice specifying the Contractor's failure. If within thirty (30) days after receipt of such notice, the Contractor shall not have either corrected such failure or, in the case of failure which cannot be corrected in thirty (30) days, begun in good faith to correct said failure and thereafter proceeded diligently to complete such correction, then the Department may, at its option, place the Contractor in default and the contract shall terminate on the date specified in such notice.

15. TERMINATION FOR CONVENIENCE

The Department may terminate the contract at any time by giving thirty (30) days written notice to the Contractor. If the contract is terminated by the Department, as provided herein, the Contractor shall promptly submit a statement showing in detail the actual services performed to date of termination. The Contractor shall then be paid the proportion of the total contract amount which bears the same ratio as the services completed bears to the total scope of services called for in this contract, less payments of compensation previously made for allowable costs, including non-cancelable commitments.

16. REMEDIES FOR DEFAULT

Any claim or controversy arising out of this contract shall be resolved by the provisions of LSA-R.S. 39:1672.2 through 1672.4.

17. ANTIDISCRIMINATION

The Contractor agrees to abide by the requirements of the following as applicable: Title VI of the Civil Rights Act of 1964 and Title VII of the Civil Rights Act of 1964, as

amended by the Equal Employment Opportunity Act of 1972, Federal Executive Order 11246 as amended, the Rehabilitation Act of 1973, as amended, the Vietnam Era Veteran's Readjustment Assistance Act of 1974, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, the Fair Housing Act of 1968 as amended, and contractor agrees to abide by the requirements of the Americans with Disabilities Act of 1990.

Contractor agrees not to discriminate in its employment practices, and will render services under this contract without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, veteran status, political affiliation, disability or age in any matter relating to employment. Any act of discrimination committed by Contractor, or failure to comply with these statutory obligations when applicable shall be grounds for termination of this contract.

18. COMPLIANCE WITH LAWS

The Contractor and its employees, subcontractors and agents shall comply with all applicable Federal, State and Local laws and ordinances, in carrying out the provisions of this contract.

19. FORCE MAJEURE

The Contractor or the Department shall be exempt from performance under the contract for any period that the Contractor or the Department is prevented from performing any services in whole or in part as a result of an act of God, strike, war, civil disturbance, epidemic, or court order, provided the Contractor or the Department has prudently and promptly acted to make any and all corrective steps that the Contractor or the Department can promptly perform. Subject to this provision, such non-performance shall not be considered cause or grounds for termination of the contract.

20. TAX RESPONSIBILITY

The Contractor hereby agrees that the responsibility for payment of taxes from the funds received under this contract shall be the Contractor's obligation and shall be identified under the federal tax identification number as noted above.

21. SUCCESSORS AND ASSIGNS

This contract shall be binding upon the successors and assigns of the respective parties hereto.

22. CLAIMS FOR LIENS

The Contractor shall be solely liable for and shall hold the Department harmless from any and all claims or liens for labor, services or material furnished to the Contractor in connection with the performance of its obligations under this contract.

23. EMPLOYMENT OF STATE PERSONNEL

In accordance with LSA-R.S. 39:1624(A)4, the Contractor certifies that it has not employed and will not employ any person to engage in the performance of this contract who is currently an employee of the State of Louisiana except provided for in R.S. 39:1626.

24. COVENANT AGAINST CONTINGENT FEES

The Contractor warrants that it has not employed or retained any company or person, other than a bona fide employee working solely for the Contractor, to solicit or secure this contract, and that it has not paid or agreed to pay any company or person, other than a bona fide employee working solely for the Contractor, any fee, commission, percentage, brokerage fee, gifts, or any other consideration, contingent upon or resulting from the award or making of this contract. For breach or violation of this warranty, the Department shall have the right to annul this contract without liability, or in its discretion to deduct from the contract price or consideration, or otherwise recover, the full amount of such fee, commission, percentage, brokerage fee, gift or contingent fee.

25. CODE OF ETHICS FOR STATE EMPLOYEES

The Contractor is hereby advised that contractors may, in certain circumstances, be deemed "public employees" as interpreted by the Louisiana Board of Ethics. The Contractor shall be responsible for determining that there will be no conflict or violation of the Ethics Code. By signing this contract the company officially certifies that there is no conflict or violation of the Louisiana Code of Ethics.

26. RELEASE OF INFORMATION

The Contractor shall not provide information generated or otherwise obtained in the performance of the Contractor's responsibilities under this contract to any party other than the Department or their authorized agents for the life of the contract and for a period of three (3) years after completion of this contract. The Contractor shall not publish, permit to be published, or distribute, use, or disclose to anyone for public consumption, any information, oral or written, concerning the results or conclusions made pursuant to the performance of this contract, without the prior written consent of the Department.

27. CONTRACTOR'S INSURANCE

The Contractor shall purchase and maintain for the duration of the contract insurance against claims for injuries to persons or damages to property which may arise from or in connection with the performance of the work hereunder by the Contractor, its agents, representatives, employees or subcontractors.

a. **Minimum Scope and Limits of Insurance**

(1) **Workers Compensation**

Workers Compensation insurance shall be in compliance with the Workers Compensation law of the State of the Contractor's headquarters. Employers Liability is included with a minimum limit of \$1,000,000 per accident/per disease/per employee. If work is to be performed over water and involves maritime exposure, applicable LHWCA, Jones Act, or other maritime law coverage shall be included. A.M. Best's insurance company rating requirement may be waived for workers compensation coverage only.

(2) **Commercial General Liability**

Commercial General Liability insurance, including Personal and Advertising Injury Liability, and Products and Completed Operations, shall have a minimum limit per occurrence of \$1,000,000 and a minimum general annual aggregate of \$2,000,000. The Insurance Services Office (ISO) Commercial General Liability occurrence coverage form CG 00 01 (current form approved for use in Louisiana), or equivalent, is to be used in the policy. Claims-made form is unacceptable.

(3) **Automobile Liability**

Automobile Liability Insurance shall have a minimum combined single limit per accident of \$1,000,000. ISO form number CA 00 01 (current form approved for use in Louisiana), or equivalent, is to be used in the policy. This insurance shall include third-party bodily injury and property damage liability for owned, hired and non-owned automobiles.

b. **Deductibles and Self-Insured Retentions**

Any deductibles or self-insured retentions must be declared to and accepted by the Department. The Contractor shall be responsible for all deductibles and self-insured retentions.

c. **Other Insurance Provisions**

The policies are to contain, or be endorsed to contain, the following provisions:

(1) Commercial General Liability and Automobile Liability Coverages

(a) The Department, its officers, agents, employees and volunteers shall be named as an additional insured as regards negligence by the contractor. ISO Forms CG 20 10 (for ongoing work) AND CG 20 37 (for completed work) (current forms approved for use in Louisiana), or equivalents, are to be used when applicable. The

coverage shall contain no special limitations on the scope of protection afforded to the Department.

- (b) The Contractor's insurance shall be primary as respects the Department, its officers, agents, employees and volunteers for any and all losses that occur under the contract. Any insurance or self-insurance maintained by the Department shall be excess and non-contributory of the Contractor's insurance.

(2) Workers Compensation and Employers Liability Coverage

To the fullest extent allowed by law, the insurer shall agree to waive all rights of subrogation against the Department, its officers, agents, employees and volunteers for losses arising from work performed by the Contractor for the Department.

(3) All Coverages

- (b) All policies must be endorsed to require 30 days written notice of cancellation to the Department. Ten-day written notice of cancellation is acceptable for non-payment of premium. Notifications shall comply with the standard cancellation provisions in the Contractor's policy. In addition, Contractor is required to notify Department of policy cancellations or reductions in limits.
- (c) The acceptance of the completed work, payment, failure of the Agency to require proof of compliance, or Agency's acceptance of a non-compliant certificate of insurance shall not release the Contractor from the obligations of the insurance requirements or indemnification agreement.
- (c) The insurance companies issuing the policies shall have no recourse against the Department for payment of premiums or for assessments under any form of the policies.
- (d) Any failure of the Contractor to comply with reporting provisions of the policy shall not affect coverage provided to the Department, its officers, agents, employees and volunteers.

d. **Acceptability of Insurers**

- (1) All required insurance shall be provided by a company or companies lawfully authorized to do business in the jurisdiction in which the Project is located. Insurance shall be placed with insurers with an A.M. Best's

rating of **A-:VI or higher**. This rating requirement may be waived for workers compensation coverage only.

- (2) If at any time an insurer issuing any such policy does not meet the minimum A.M. Best rating, the Contractor shall obtain a policy with an insurer that meets the A.M. Best rating and shall submit another Certificate of Insurance within 30 days.

e. **Verification of Coverage**

- (1) Contractor shall furnish the Department with Certificates of Insurance reflecting proof of required coverage. The Certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf. The Certificates are to be received and approved by the Department before work commences and upon any contract renewal or insurance policy renewal thereafter.

- (2) The Certificate Holder shall be listed as follows:

State of Louisiana
Department of Environmental Quality
Financial Services Division
P.O. Box 4303
Baton Rouge, LA 70821-4303
Attn: LaGov No.

- (3) In addition to the Certificates, Contractor should submit the declarations page and the cancellation provision for each insurance policy. The Department reserves the right to request complete certified copies of all required insurance policies at any time.
- (4) Upon failure of the Contractor to furnish, deliver and maintain required insurance, this contract, at the election of the Department, may be suspended, discontinued or terminated. Failure of the Contractor to purchase and/or maintain any required insurance shall not relieve the Contractor from any liability or indemnification under the contract.

f. **Subcontractors**

Contractor shall include all subcontractors as insureds under its policies OR shall be responsible for verifying and maintaining the Certificates provided by each subcontractor. Subcontractors shall be subject to all of the requirements stated herein. The Department reserves the right to request copies of subcontractor's Certificates at any time.

g. **Workers Compensation Indemnity**

In the event Contractor is not required to provide or elects not to provide workers compensation coverage, the parties hereby agree that Contractor, its owners, agents and employees will have no cause of action against, and will not assert a claim against, the State of Louisiana, its departments, agencies, agents and employees as an employer, whether pursuant to the Louisiana Workers Compensation Act or otherwise, under any circumstance. The parties also hereby agree that the State of Louisiana, its departments, agencies, agents and employees shall in no circumstance be, or considered as, the employer or statutory employer of Contractor, its owners, agents and employees. The parties further agree that Contractor is a wholly independent contractor and is exclusively responsible for its employees, owners, and agents. Contractor hereby agrees to protect, defend, indemnify and hold the State of Louisiana, its departments, agencies, agents and employees harmless from any such assertion or claim that may arise from the performance of this contract.

h. **Indemnification/Hold Harmless Agreement**

1. Contractor agrees to protect, defend, indemnify, save, and hold harmless, the State of Louisiana, all State Departments, Agencies, Boards and Commissions, its officers, agents, servants, employees, and volunteers, from and against any and all claims, damages, expenses, and liability arising out of injury or death to any person or the damage, loss or destruction of any property which may occur, or in any way grow out of, any act or omission of Contractor, its agents, servants, and employees, or any and all costs, expenses and/or attorney fees incurred by Contractor as a result of any claims, demands, suits or causes of action, except those claims, demands, suits, or causes of action arising out of the negligence of the State of Louisiana, all State Departments, Agencies, Boards, Commissions, its officers, agents, servants, employees and volunteers.
2. Contractor agrees to investigate, handle, respond to, provide defense for and defend any such claims, demands, suits, or causes of action at its sole expense and agrees to bear all other costs and expenses related thereto, even if the claims, demands, suits, or causes of action are groundless, false or fraudulent. The State of Louisiana may, but is not required to, consult with the Contractor in the defense of claims, but this shall not affect the Contractor's responsibility for the handling of and expenses for all claims.

28. **SUBCONTRACTORS**

If it becomes necessary for the Contractor to use subcontractors, the Department urges the contractor to use Louisiana vendors, including small and emerging businesses, a small entrepreneurship or a veteran or service-connected disabled veteran-owned small entrepreneurship, if practical. For a list of these businesses go to

<http://smallbiz.louisianaeconomicdevelopment.com> and select the appropriate program.

The Contractor agrees to obtain written Department approval prior to subcontracting any part of the services specified in Attachment 1, Statement of Work. The Contractor shall include, in any subcontract, the provisions contained in this contract. The Contractor shall submit requests for approval, accompanied by copies of proposed subcontractors, to the Department Project Manager. The Contractor further agrees to guarantee and be liable to the Department for all services performed under any such subcontract.

29. SUBSTITUTION OF PERSONNEL

If, during the term of the contract, the Contractor or subcontractor cannot provide the personnel as proposed and requests a substitution, that substitute must be at least equal in education, qualifications, and experience to the person being replaced. A detailed résumé of the individual's qualifications and a written justification for the change must be submitted to the Department for approval prior to any personnel substitution. It shall be acknowledged by the Contractor that every reasonable attempt shall be made to assign the personnel listed in the Contractor's proposal.

30. VETERAN-OWNED AND SERVICE-CONNECTED SMALL-ENTREPRENEURSHIPS (VETERAN INITIATIVE) AND LOUISIANA INITIATIVE FOR SMALL ENTREPRENEURSHIPS (HUDSON INITIATIVE) PROGRAMS REPORTING REQUIREMENTS

During the term of the contract and at expiration, the Contractor will be required to report Veteran-Owned and Service-Connected Disabled Veteran-Owned and Hudson Initiative small entrepreneurship subcontractor or distributor participation and the dollar amount of each. See Attachment 3, Form A. This form shall be submitted with each invoice. Failure to submit this form will result in payment being withheld.

In accordance with LAC 19:VIII.Chapters 11 and 13 and LAC 19:IX.Chapter 11 and 13, this contract may be terminated if the Department becomes aware that the Contractor has failed to use good-faith efforts to obtain certified LaVet and/or SE-HI participation. The state may impose sanctions on a contractor who fails to make good-faith efforts or on a LaVet and/or SE-HI that was found to be guilty of deception relating to certification. Sanctions may include a suspension from doing business with the state for up to 3 years.

31. ENTIRE AGREEMENT AND ORDER OF PRECEDENCE

This contract, together with the Request for Proposals (the RFP) and addenda issued thereto by the Department, the proposal submitted by the Contractor in response to the Department's RFP (the Proposal), and any exhibits specifically incorporated therein by reference constitutes the entire agreement between the parties with respect to subject matter.

This contract shall, to the extent possible, be construed to give effect to all provisions contained therein. However, where provisions are in conflict, first priority shall be given to the provisions of the contract excluding the RFP and the Contractor’s Proposal; second priority shall be given to the provisions of the RFP and amendments thereto; and third priority shall be given to the provisions of the Proposal.

32. AMENDMENTS

All changes to the contract price or term shall require an amendment to the contract. No amendment shall be effective unless it is in writing, signed by duly authorized representatives of both parties, and approved by the Department. Verbal directives from any employee of the Department shall carry no authority, and shall not entitle the Contractor to any compensation for any corresponding effort.

THE DEPARTMENT AND THE CONTRACTOR REPRESENT THAT THIS CONTRACT SUPERSEDES ALL PROPOSALS, ORAL AND WRITTEN, ALL PREVIOUS CONTRACTS, AGREEMENTS, NEGOTIATIONS AND ALL OTHER COMMUNICATIONS BETWEEN THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF.

IN WITNESS WHEREOF, the parties hereto have caused these presents to be executed by their respective officers thereunto duly authorized as of the day and year first above written.

WITNESSES:

DEPARTMENT OF ENVIRONMENTAL QUALITY:

Karyn Andrews
Undersecretary
Office of Management and Finance

WITNESS:

CONTRACTOR:

Company Name

APPENDIX D

Veteran-Owned and Service-Connected Small Entrepreneurships (Veteran Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) Programs Table

(see Sections 2.5 and 4.4 of the RFP)

"Laboratory Auditing" RFP

(Enlarge or duplicate table as necessary)

Name of Certified Veteran Initiative or Hudson Initiative Small Entrepreneurship Subcontractor	Dollar Value of Subcontract (specific to this project) or Anticipated Earnings to Accrue to the Subcontractor (conveyed as percentage of total project/award)	Years of Experience and Qualifications of Subcontractor (conveyed as number of years of relevant experience)	Description of Work Subcontractor will Perform

ATTACHMENT 1
STATEMENT OF WORK
“Laboratory Auditing”
Louisiana Department of Environmental Quality

1.0 INTRODUCTION

The Louisiana Department of Environmental Quality, hereinafter referred to as “the Department” is responsible for implementing the Louisiana Environmental Laboratory Accreditation Program (LELAP). The laboratory accreditation program is designed to ensure that accredited methods are used in the generation of environmental data and that quality (accurate, precise, and reliable) data is provided by commercial laboratories to their clients when said data (chemical analyses, analytical results, or other test data) is required to be submitted to or maintained by the Department. The Department typically assigns approximately 60 annual audits per year. The number of audits will be divided between the number of firms awarded the contract. The assignment of work to the Contractor is at the discretion of the Department, with no minimum amount of work guaranteed.

1.1 Goals and Objectives

The Department is seeking the services of audit firms or companies that have qualified staff that can fulfill the deliverable requirements described in this document in the timeline specified. The objective of this contract is to obtain the services of professional auditors to conduct laboratory audits. The goal is to ensure the accuracy, precision, and reliability of laboratory data generated, as well as the use of Department-approved methods in the generation of that data.

2.0 BACKGROUND INFORMATION

The program has three major components: accreditation, auditing, and proficiency testing.

The number of laboratories seeking or maintaining accreditation from Louisiana, particularly those operating outside of the state, exceeds the agency’s capacity to conduct timely and cost effective audits. The Department needs the support of professional auditing services to conduct laboratory audits. The contracted firm(s) will perform laboratory audits and other tasks described in this Statement of Work. The report will include findings of deficiencies with regulations as found in Title 33, Part I, Subpart 3, Chapter 45-59, and the 2009 TNI standard as applicable. These regulations can be viewed at the following web address:

<http://www.deq.louisiana.gov/portal/DIVISIONS/PublicParticipationandPermitSupport/LouisianaLaboratoryAccreditationProgram.aspx>

3.0 CONTRACTOR TASKS

Services provided by the Contractor shall include the following tasks.

The Contractor will be required to perform audits and audit-related tasks associated with commercial, federal, state, local government or any other laboratories requiring accreditation by the Department.

A list of current LELAP-accredited laboratories may be found at <http://www.deq.louisiana.gov/portal/DIVISIONS/PublicParticipationandPermitSupport/LouisianaLaboratoryAccreditationProgram/AccreditedLaboratories.aspx>

The Contractor shall meet submittal and deliverable requirements according to this section and Section 6.1, Deliverables.

The following deliverables and schedule shall be required of the Contractor when the Department requests an initial accreditation or routine compliance audit to the National Environmental Laboratory Accreditation Program NELAP standards (2009 TNI):

- A. Within 15 calendar days of a Department request to conduct an audit of a specific laboratory, the Contractor will prepare and submit directly to the Department's Project Manager (PM) an estimated cost of services, to include the number of auditors and auditor hours, and estimated travel expenses. At any time during the audit, if the estimated number of hours and travel expenses increase, the Contractor must submit a revised estimate for Department approval. Failure to do so will constitute grounds for non-payment for additional expenses or assignment reduction.
- B. The Department's PM will respond to the Contractor by email with either:
 - i. approval of the estimate, or
 - ii. concerns to be addressed via submittal of a revised estimate.
- C. The Contractor shall seek written approval to proceed from the laboratory to be audited, schedule the audit, and notify the Department's PM of the agreement within 15 calendar days of receipt of notification. The Contractor must copy the Department's PM on any correspondence it sends or receives regarding this approval.
- D. The Contractor may conduct no more than twenty-four (24) hours of pre-audit preparation. Preparation should consist of primarily reviewing the agency's public records for the laboratory available through the Department's Electronic Document Management System (EDMS).
- E. The audit shall be conducted no later than 60 calendar days following the initial request. The audit must be conducted in accordance with the appropriate Standard Operating Procedures, as indicated in Section 3.2 below and in accordance with LAC 33:I.5101.C through E using the Department's checklists.
- F. To reduce audit times, the Contractor shall submit a copy of the audit checklist to the laboratory after receiving approval to proceed from the laboratory.
- G. The Contractor will prepare and submit an Assessment Report draft to the Department's PM within 15 calendar days of completion of the audit. Failure to do so will constitute grounds for assignment reduction.
- H. The Department's LELAP staff will review and issue the report to the laboratory. The laboratory will be required to submit within 30 days a Corrective Action Plan (CAP) to the Contractor if non-compliance was determined.

- I. For CAP-related work by the Contractor, an estimate of hours for CAP evaluation and response will be submitted to the Department's PM for approval. The estimate may be submitted with the estimate for the audit. Failure to do so will constitute grounds for assignment reduction.
- J. The Department's PM will respond to the Contractor by email with either:
 - i. approval of the CAP evaluation and response estimate, or
 - ii. concerns to be addressed via submittal of a revised estimate (every reasonable attempt will be made by the Department to expedite the CAP-evaluation and response cost estimate approval process).
- K. The Contractor will evaluate and submit a response draft to the Department's PM within 15 calendar days of receipt of the CAP. Failure to do so will constitute grounds for assignment reduction.
- L. The Department's PM will notify the laboratory of its accreditation status. If deficiencies persist, the laboratory will be allowed an opportunity to submit a revised CAP to the Contractor for review (see J and K for revised CAP evaluation and response). The Contractor will evaluate the laboratory's revised CAP for acceptability and report the status to the Department's PM within 15 calendar days. Failure to do so will constitute grounds for assignment reduction.
- M. The Department's LELAP Program Supervisor will notify the laboratory of its accreditation status. LELAP will issue either the appropriate certificates of accreditation or a letter of denial.
- N. After the Contractor submits a final assessment report or response to a CAP which is accepted by the Department, the Contractor shall provide the final invoice billed to the laboratory with a copy to the Department's PM.
- O. The Contractor shall provide a copy of the check or payment documentation to the Department's PM within 15 calendar days of receipt.

The Department reserves the right to modify this schedule and deliverables as needed.

3.1 Resources

The Contractor shall provide all personnel, equipment, and materials necessary to conduct the required assignments.

3.2 Compliance with Standard Operating Procedures and Quality Assurance Project Plan

The Contractor shall comply with LDEQ's Standard Operating Procedures (SOPs) and Quality Assurance Project Plan.

Enclosure A - SOP No. 1787—Laboratory Assessment and Assessment Reporting;

Enclosure B - SOP No. 1786—LELAP Proficiency Testing Evaluation;

Enclosure C - QAPP No. 3021—LELAP Quality Assurance Plan which references the Department's Quality Management Plan, See Exhibit 1; and

Enclosure D - SOP No. 1788—Review and Response to Laboratory Corrective Action Plans

4.0 PROJECT SCHEDULE

The Contractor shall comply with the timeline described in Section 3.0 above. Other assignment schedule requirements shall be determined by the Department and the Contractor. Extensions may be granted at the discretion of the Department. Requests for extensions must be submitted in writing prior to due dates.

5.0 MINIMUM QUALIFICATIONS OF THE CONTRACTOR'S PERSONNEL

The Contractor shall provide qualified personnel to accomplish the required tasks. Personnel shall have relevant experience in laboratory auditing and at least one individual should qualify as a stack tester auditor. Education and experience requirements should include, but are not limited to the requirements listed below:

- (1) The Project Manager should:
 - a. hold a bachelor's degree in a science-related or management-related field;
 - b. three (3) year's experience in a project management capacity in the analytical laboratory field;
 - c. possess working knowledge, as demonstrated in resumes, of basic laboratory testing operations.
- (2) The Auditor(s) should:
 - a. hold a bachelor's degree in a science-related field;
 - b. possess the basic and technical audit training certificate, and proof of any required refresher courses required by "The National Environmental Laboratory Accreditation Conference (NELAC) Institute" (TNI); and
 - c. have a minimum of 5 years performing laboratory audits (2 of which must be NELAP-style audits, according to the 2009 TNI standard.
- (3) The Stack Test Auditor(s) should:
 - a. provide proof of training (i.e. certificate of completion with mention of TNI or other regulatory agency, and stack/engine referenced as the focus of the training, along with course agenda);
 - b. have 2 years' experience conducting stack test evaluations by providing a client list.

6.0 PROJECT MANAGEMENT

The Contractor shall provide efficient management throughout the term of the contract to ensure the successful completion of assigned projects. The duties and responsibilities for project management shall continue throughout the term of the contract. The resources and methods for project management activities shall be the responsibility of the Contractor.

Project management shall include, but not be limited to, the following activities:

- (1) supervision of the Contractor's personnel;
- (2) ensuring that all audits are performed by approved auditors;
- (3) contract administration:

- (a) invoicing;
 - (b) changes to the contract;
 - (c) resolving disputes between the Contractor and the Department; and
 - (d) compliance by the Contractor with all contract clauses and conditions;
- (4) scheduling meetings and training sessions;
 - (5) record-keeping;
 - (6) providing all personnel, equipment, and materials necessary to conduct the required audits;
 - (7) securing all necessary permits, licenses, and certificates that may be required in the performance of this contract;
 - (8) being responsible for safety and safety training of all contractor personnel;
 - (9) ensure compliance with all federal, state, and local laws, ordinances, rules, and regulations related to the performance of this work;
 - (10) ensuring the quality and timeliness of any subcontracted auditor approved by the Department for performance of work under this contract, and correcting any mistakes, errors, or omissions in the subcontractors' work;
 - (11) ensuring that any Department-approved subcontractor(s) possess the required licenses, permits, safety training, and insurance coverage to conduct work under this contract; and
 - (12) preparation and timely submission of submittals and deliverables.

The Contractor shall assign a Project Manager, as listed in the Contractor's proposal to represent the Contractor's organization and to manage the project. The Department reserves the right to approve the person assigned as Project Manager.

The Contractor's Project Manager shall be responsible for project monitoring and compliance. The Contractor's Project Manager must keep the Department Project Manager informed of the project status through written monthly progress reports and informal communication, i.e., email and phone contact.

The Contractor shall be responsible for the security of all audit findings and documentation. The Contractor audit reports and CAPs shall be released only to the Department.

6.1 Deliverables

The Contractor shall prepare and submit the written deliverables described below and in Section 3.0 to the Department within the time specified.

All deliverables, which include the quotes, audit reports and attachments (checklist and Assessor Compliance Commitment Certifications), responses to corrective action plans, and itemized invoices (which were billed to the laboratories), shall be presented to the Department in both one hard copy and an electronic version. The electronic version of deliverables may be submitted by email or other agreed upon device in Microsoft Word or RTF format.

The Department checklist shall be completed for each audited laboratory and signed by the auditor.

The Department will review the report and response, provide comments as necessary, and forward any comments to the Contractor. The Contractor shall address all comments and submit a final document for acceptance. Upon completion of the contract, the Contractor shall return all materials provided by the Department for use during the contract.

7.0 DEPARTMENT RESPONSIBILITIES

As part of its responsibilities under the contract, the Department shall:

- (1) provide points of contact (liaisons) for technical and contract activities (Project Manager and Contract Manager);
- (2) provide the Department materials (documents, reports, photographs, etc.) for the Contractor's work as necessary; and
- (3) review, require revision as necessary, and accept deliverables.

The Department will be available for assistance to the Contractor in solving problems or answering questions that may arise and will meet with the Contractor as necessary. However, the Department shall not be responsible for the Contractor's performance of the work and reserves the right to reject deficient work.

The Department's LELAP staff will be responsible for providing the Contractor with a list of laboratories to be audited, a projected audit timeline (including deliverables and task to be conducted) and appropriate documents and forms to be used during the audit.

The Department's LELAP staff will provide oversight of all contracted activities and deliverables.

The Department's LELAP staff will be available for assistance to the Contractor in solving problems or answering questions that may arise.

8.0 MONITORING AND METHODS TO MEASURE PERFORMANCE

The Department's Project Manager will monitor the progress of the Contractor during the contract by:

- (1) providing Department materials (documents, reports, photographs, etc.) for the Contractor's work as necessary;
- (2) monitoring the Contractor's work through telephone communication, meetings and review of Monthly Progress Reports;
- (3) ensuring that deliverables are submitted within the timeframe of the contract;
- (4) reviewing, requiring correction as necessary, and approving all deliverables and submittals;

The Department's Project Manager will measure the successful performance of the Contractor by reviewing and evaluating the acceptability and timeliness of all deliverables and submittals.

9.0 MEASUREMENT AND PAYMENT

The Contractor shall be compensated for the tasks required in this Statement of Work according to the rates specified in Attachment 2, Schedule of Prices by the audited laboratories. See Section 3.0 above for invoicing procedures, and how they fit within the steps of the audit process.

A partial payment by audited laboratories may be requested to cover the pre-audit and pre-travel expenses due to the possibility of last-minute cancellation by the laboratory to be audited, airfare costs by the auditor, etc. Payment for all other tasks may be requested by the Contractor upon successful completion of each task and issuance of the audit report and/or responses to Corrective Action Plan(s) to the Department. The amount invoiced to the audited lab shall not exceed estimates submitted to and approved by the Department.

All costs accrued by the contractor for activities performed under this contract are to be billed directly to the laboratory being audited. At no time shall the Department be billed for any activities associated with the contract.

9.1 Laboratory Auditing—Physical Audit and Corrective Action Plan (CAP) Related Work

This rate is to be used to compensate the Contractor for physically auditing laboratories and for Corrective Action Plan (CAP) related work. Payment shall not exceed the number of hours approved by the Department in writing (via email) during the cost estimate process. The rate shall be all-inclusive regardless of parameters involved, excluding only travel time, travel expenses, audit preparations, and report writing.

9.2 Travel Time Rate Related to Audits

The Contractor shall be compensated by audited laboratories for no more than 16 hours of travel time per audit.

9.3 Audit Preparation and Report Writing

The Contractor shall be compensated by audited laboratories for audit preparation for no more than 24 total hours and 8 hours for report writing. Although the Department will consider reallocation of the 32 total hours (24+8) on a case-by-case basis, approval of reallocation is not guaranteed. Consideration for additional hours will be handled on a case-by-case basis by the Department and will not be guaranteed to either party.

9.4 Travel Expenses Related to Audits

The Contractor shall be reimbursed by the audited laboratories for travel expenses related to audits according to the Louisiana State Travel Regulations, which can be found at the following web address: <http://www.doa.la.gov/Pages/osp/Travel/travelPolicy.aspx>.

Enclosure A

Lab Assessment and Assessment Reporting
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Document Prepared 05/21/2014
Page 1 of 25

Standard Operating Procedure
for
Laboratory Assessment and Assessment Reporting

Revision 14

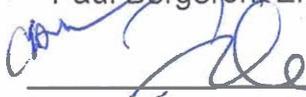
Public Participation and Permit Support Division

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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
04/13/06	5	Changed to new format
05/11/2007	6	Name change for LELAP Supervisor and technical changes related to NELAC and TNI
11/14/2007	7	General Revision
03/03/2008	8	Name change for one development team member and minor changes related to document format
10/31/2008	9	General Revision
03/23/2009	10	General Revision
10/06/2009	11	Name change of SOP, minor revisions, use of agency SOP format, and relocation of duties to the Permit Support Services Division.
10/06/2011	12	Restoration of provisions for third party assessors and minor revisions
12/20/2012	12	Reviewed with no revisions.
06/10/2013	13	Inclusion of the requirements of the 2009 TNI Standard
06/02/2014	14	Minor revisions and shared folder location updated

Table of Contents

1.0	Purpose / Applicability	4
2.0	Definitions / Acronyms / Abbreviations	4
3.0	Personnel Qualifications	4
4.0	Procedure	5
4.1	Frequency of Assessment	5
4.2	Announced and Unannounced Assessments	5
4.3	Follow-up Assessments	6
4.4	Changes in the Laboratory	7
4.5	On-Site Assessment Schedule and Format	7
4.6	Off-Site Review of Laboratory Documentation	13
4.7	Assessor Documentation of On-Site Assessments	14
4.8	Length of Assessment	15
4.9	Opening Conference	16
4.10	Laboratory Staff Interviews	17
4.11	Records Review	17
4.12	Closing Conference	18
4.13	Assessment Reporting Procedures	20
4.14	Report Distribution	23
4.15	Release of Report	23
5.0	Records Management	23
6.0	Quality Control / Quality Assurance	24
7.0	SOP Review / Revision / Approval	24
8.0	References	24
9.0	Attachments	25

1.0 Purpose / Applicability

The purpose of this SOP is to provide instructions for staff and establish requirements used by the Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) to conduct an on-site assessment (assessment). This activity is performed in accordance with LAC 33:I.5101. LELAP is recognized by the NELAP Board to accredit laboratories to the national standard it has adopted. The on-site assessment is used to determine initial and continuing compliance with the Louisiana Administrative Code, Part I, Subpart 3, Laboratory Accreditation regulations (see 8.0 References), and when appropriate, the TNI standards (see 8.0 References). This SOP also applies to mobile laboratories as defined by TNI.

This SOP applies to staff members in the Louisiana Environmental Laboratory Accreditation Program, Notifications and Accreditations Section, Permit Support Services Division, their supervisor, their Manager, and Administrator.

2.0 Definitions / Acronyms / Abbreviations

AAMS:	Accrediting Authority Management System
CBI:	Confidential Business Information
CTM:	Conditional Test Method
EDMS:	Electronic Document Management System
ES:	Environmental Scientist
LELAP:	Louisiana Environmental Laboratory Accreditation Program
NELAC:	National Environmental Laboratory Accreditation Conference
NELAP:	National Environmental Laboratory Accreditation Program
OES:	Office of Environmental Services
NAS:	Notifications and Accreditations Section
PPPSD:	Public Participation and Permit Support Division
PT:	Proficiency Test
SOP:	Standard Operating Procedure
TEMPO:	Tools for Environmental Management and Protection Organizations. It is the central data management system to track facilities, people, and organizations that are of interest to LDEQ and to track the activities of the Department, such as Permitting, Surveillance, and Enforcement. This system is the central piece of the new <u>Integrated Data Management System (IDMS)</u>
TNI:	The NELAC Institute

3.0 Personnel Qualifications

The SOP identifies job titles of staff members who perform certain activities. These staff members are qualified to perform these activities based on the qualifications in their job descriptions.

Staff members receive training from supervisory staff or designee in the section and outside trainers. Once the supervisory staff or designee determines that the ES is sufficiently trained, staff members will assume all the duties related to them. The supervisory staff or designee will provide guidance and backup.

4.0 Procedure

Note: Unless otherwise indicated, the assigned assessor or staff member will submit any official record associated with his/her participation in this activity to EDMS for scanning.

4.1 Frequency of Assessment

4.1.1 The Louisiana Department of Environmental Quality (LDEQ), LELAP regulations, and TNI Standard require a comprehensive on-site assessment of each accredited facility every two years. It shall be the responsibility of the LELAP Assessor (Assessor) to conduct an assessment at a minimum of once every two years. Assessments conducted by the Assessors may be conducted more frequently at the discretion of the LELAP Supervisor.

4.1.2 Emission testing facilities shall receive a home-base assessment and field assessment every two years. Whenever feasible, the home-base assessment and field assessment shall be scheduled at the same time and where practical shall coincide within the same week. Assessments conducted by the Assessors may be conducted more frequently at the discretion of the LELAP Supervisor, and/ or NAS Manager.

4.1.3 Biennial assessment deadlines will be tracked by the assigned assessor using the Microsoft Outlook Calendar, and the program supervisor will monitor these deadlines by using an excel spreadsheet.

4.2 Announced and Unannounced Assessments

4.2.1 The Assessor shall schedule the initial on-site assessment with the applicant laboratory (includes stack testers). Initially, the Assessor shall contact the laboratory representative via the telephone. The date of the assessment shall be scheduled at that time. The Assessor will submit a letter confirming the date and time of the assessment. Written notification will include at a minimum, the most current Assessment Checklist for NELAP-Accredited Facilities and Assessment Checklist for State-Accredited Facilities found in the LELAP shared folder (See 8.0 References); technology or method checklists; a copy of the Louisiana Administrative Code Laboratory Accreditation Regulations; Volume 1 Module 2 of the 2009 TNI Standard; and Confidential Business Information (CBI) regulations.

4.2.2 Assessors have the authority to conduct either announced or unannounced on-site assessments whenever necessary to determine the extent of the laboratory's

compliance with the LELAP regulations or TNI Standards. The ES Manager must approve any unannounced on-site assessment.

4.2.3 Assessors will work with federal departments/agencies/contractors to expedite the attainment of all necessary clearances, and such clearances shall be obtained as far in advance as possible.

4.3 Follow-up Assessments

4.3.1 LELAP Assessors may conduct follow-up (extra-ordinary) assessments at laboratories where findings have been identified by previous assessments or in response to complaints.

4.3.2 Assessors may use follow-up assessments to determine if the laboratory has corrected findings, or at the request of the laboratory to determine compliance with regulations and standards.

4.3.3 When, in the judgment of LELAP, findings are of such severity as to possibly warrant the downgrading of a laboratory's accreditation status, the assigned Assessor shall conduct a follow-up assessment within thirty (30) calendar days after the approved corrective action plan has been implemented. The Assessor shall have thirty (30) calendar days to complete the assessment report. At that time any findings left uncorrected from the previous assessment shall be viewed as grounds for discreditation or suspension. The process for discreditation or suspension shall begin immediately.

4.3.4 Reassessment and Surveillance

4.3.4.1 Reassessments shall be performed following an initial assessment according to the frequency described in Section 4.1.1 above. Reassessments shall take into account experience gained from the previous assessment. LELAP shall use a re-scheduling window of plus or minus six months. Reassessment intervals shall not exceed two years if the laboratory is not assigned surveillance assessments.

4.3.4.2 Surveillance assessments shall be conducted for laboratories which demonstrate a high level of compliance, i.e., no repeat findings identified in reassessments, no findings based on a lack of required submissions to the department, and greater than 90% acceptable results rate in proficiency tests. A surveillance assessment shall be less comprehensive than an initial assessment or a reassessment, but shall have a scope representative of the quality system of the laboratory. The planning for the surveillance assessment shall take into account other surveillance activities. Surveillance assessment intervals shall not exceed two years.

4.3.4.3 For surveillance and reassessment of laboratories with multiple premises, a sufficient number of premises shall be reviewed to cover a representative example of

the analytical work covered by the Scope of Accreditation. Each Assessor shall establish and document the location of premises for review after consultation with the laboratory's designated representative. The assessment team shall complete the surveillance or reassessment within a reasonable period of time. A reasonable period of time shall be considered 1-2 days for small laboratories and 2-4 days for large laboratories. The actual length of the assessment will be determined by the amount of time spent at the designated location of the assessment and any time spent away from the location on tasks directly related to the assessment.

4.3.4.4 Corrective action for non-conformities identified during reassessments or surveillance assessments shall be implemented six months from the date of receipt of the assessment report or sooner based on the severity of the non-conformity..

4.4 Changes in the Laboratory

When a change occurs in a laboratory's ownership, location, key personnel, or major instrumentation, notification to LELAP is required within 30 calendar days. LELAP shall evaluate the significance of a change that might alter or impair the laboratory's capability and quality, and indicate to the laboratory the results of their evaluation in writing. LELAP shall retain records to indicate that such an evaluation was conducted. An assessment of any laboratory that changes locations within thirty (30) calendar days of completion of the laboratory's move will be conducted. Assessments will be performed to determine the competency of the laboratory to perform methods which involve a new technology, as well as to verify that the laboratory has implemented new requirements established by LELAP.

4.5 On-Site Assessment Schedule and Format

4.5.1 An on-site assessment will be conducted by LELAP Assessors, in accordance with standards recognized by NELAP and as required by state regulation. The on-site assessment is an integral requirement of the laboratory accreditation program and one of the primary means by which a laboratory's capabilities and qualifications are evaluated. Before the on-site assessment is scheduled, the LELAP Supervisor shall conduct a resource review, taking into consideration LELAP policy, the competence and availability of suitable assessors and experts, and the ability of the program to carry out the initial assessment in a timely fashion.

4.5.2 The assigned Assessor will schedule the initial on-site assessment with the applicant laboratory. LELAP shall be responsible for pursuing the date that is in accordance with the surveillance and reassessment plan. The Assessor shall not schedule the assessment with the laboratory until it has been determined that the laboratory has submitted a complete application. *LELAP shall not proceed with any assessment until all applicable fees have been paid to the State.* Subsequent on-site assessments do not have to be scheduled in advance by Assessors.

4.5.3 The Department reserves the right to conduct scheduled and unscheduled on-site assessments to determine compliance with these regulations. In the event of scheduled assessments, the laboratory will be notified in advance for assessments related to the biennial on-site review requirement of the Louisiana Administrative Code, Part I, Subpart 3, §4709.C. The written notification will establish the intent of LELAP to conduct the required on-site assessment that supports the laboratory application for initial or continuing accreditation. The letter will provide the following:

- proposed schedule;
- notification that all information must be updated as required by the Louisiana Administrative Code, Part I, Subpart 3, §5707;
- identification of assessors, including any third party assessors under contract to LELAP and notification of expenses related to third party assessment;
- electronic copy of current applicable regulations;
- electronic copy of all checklists to be completed by the laboratory prior to the on-site assessment along with detailed instructions on how to complete the checklists;
- notification that all submissions must be received as electronic copies or hard copies by LELAP no later than two weeks prior to the on-site assessment; and
- notification that any claim of CBI must be made within thirty days of the confirmed date of receipt of the letter.

4.5.4 The written notification will include a list of documents that may be requested by the assessors prior to the on-site assessment. Assessors may emphasize that the submission of the documents prior to the assessment will contribute to a more efficient use of time for the assessor and the laboratory. The documents include but are not limited to:

4.5.4.1 A complete list of all quality system documents including the Quality Assurance Manual (QAM) and all SOPs currently in force at the laboratory. The list must include the title, unique identification number, date of issue, date of last revision, and date of last review;

4.5.4.2 Copies of all test method SOPs for which accreditation is being sought including any related SOPs such as sample receipt and log in, sample preparation, calibration, quality assurance/quality control (QA/QC), and data review and reporting. Documents may be provided in both hard copy and electronic copy (compact disk);

4.5.4.3 An up-to-date organizational chart and employee roster including job assignment(s);

4.5.4.4 An up-to-date spreadsheet of all staff training related to the performance of analyses, e.g. initial demonstration of capability by method, vendor training courses, or any other relevant training; and

4.5.4.5 Data packages from recent (within the past year) PT samples for each field of testing included on the list described in 4.5.4.1 above for which results have been received. Only if PT data is not performed for a particular test, then the Assessor should obtain completed sets within the last six months along with calibration data and batch QC. All records must be clearly labeled.

Data Package Content (as applicable to the analytical technique/method), includes:

- Correspondence between the client and laboratory regarding sample collection and sample containers. If laboratory personnel did not collect the sample, a copy of the laboratory's sample acceptance policy that was sent to the client;
- Example(s) of Sample Labeling (Field and Laboratory Labels);
- Analytical final report issued to the client including any re-issuance of the report;
- Case narrative with an explanation of qualified data, as applicable;
- Completed Chain-of-Custody (CofC) form(s) (include all types of CofC forms, internal tracking forms, and evidentiary CofC forms, if applicable);
- Daily instrument run log;
- Associated instrument performance check(s) performance summary with record determining acceptance, for example:
 - a) Gas Chromatograph/Mass Spectrometer (GC/MS) tune;
 - b) Inductively Coupled Plasma (ICP) spectral interference check; and
 - c) Graphite Furnace Atomic Absorption (GFAA) stability check;
- Method Blank(s) (instrument printout(s) including instrument response and concentration with record determining acceptance);
- Associated Initial Calibration including:
 - a) instrument printout(s) with instrument response and concentration with record determining linearity acceptance, include equation for the curve as applicable; and
 - b) copy of applicable page(s) of standard receipt/preparation log(s);
- Associated Initial Calibration Verification Check including:
 - a) instrument printout(s) with instrument response and concentration with record determining acceptance; and
 - b) copy of applicable page(s) of standard preparation log(s);
- All Continuing Calibration Checks including:
 - a) instrument printout(s) with instrument response and concentration with record determining acceptance; and
 - b) copy of applicable page(s) of standard preparation log(s);

- All Continuing Calibration Blanks including instrument printout(s) with instrument response and concentration with record determining acceptance;
- Surrogate Performance Summary with record determining acceptance, as applicable, and quality control charts, as applicable;
- Internal Standard Performance Summary with record determining acceptance, as applicable;
- Matrix Spike with:
 - a) instrument printout(s) including instrument response and concentration with record determining acceptance;
 - b) copy of applicable page(s) of standard preparation log(s); and
 - c) quality control charts, as applicable;
- Matrix Spike Duplicate or Sample Duplicate with:
 - a) instrument printout(s) including instrument response and concentration with record determining acceptance; and
 - b) quality control charts, as applicable;
- Laboratory Control Sample with:
 - a) instrument printout(s) including instrument response and concentration with record determining acceptance;
 - b) copy of applicable page(s) of standard preparation log(s); and
 - c) quality control charts, as applicable;
- Analytical Sample Results (including any confirmatory and/or re-analyses) with instrument printout(s) including instrument response and concentration with qualifiers, as applicable;
- Copy of applicable page(s) of Preparation/Extraction Log(s);
- Copy of applicable page(s) documenting chemical preservation, turbidity checks, percent solids determination, weights, etc. This documented information may have been provided in one of the previous documents;
- Copy of documentation verifying the completion of data review/cross checks;
- Record of Sample Disposal;
- Copies of any corrective action reports issued during the associated analyses with investigation and corrective action;
- Associated worksheets or other documents where manual calculations have been performed on the data; and
- Information on reporting limits and the laboratory's reasoning for setting limits or reference to where this is documented.

4.5.4.6 Those documents that provide insight into the level of independence and impartiality of the laboratory from its related bodies, where applicable

4.5.5 During the on-site assessment, the Assessor or Assessment Team will collect and evaluate information and make observations to determine if the laboratory is in conformance with regulations and applicable standards. LELAP shall formally appoint an assessment team and shall ensure that the expertise brought to each assignment is appropriate, that is:

- The team shall have appropriate knowledge of the specific scope for which accreditation is sought and
- The team shall have understanding sufficient to make a reliable assessment of the competence of the laboratory to operate within its scope of accreditation.

An assessment team may include technical support personnel approved by LELAP. These individuals need not be formally qualified by LELAP as assessors, but these individuals still must meet the requirements of the standards concerning conflicts of interest and professional conduct. Members of the assessment team who provide technical assistance but are not qualified as assessors are not eligible to conduct interviews in the absence of the assessor or to cite any findings.

4.5.6 The LELAP Supervisor shall ensure through training and seminars that all Assessors conduct uniform and consistent assessments, in order to:

- allow confidence in comparison of results generated by different laboratories;
- facilitate recognition by other accrediting agencies; and
- promote acceptance of the accreditation standards by the regulated community.

4.5.7 If a third party assessor is used, LELAP shall provide the third party assessor copies of all essential correspondence related to the scheduled laboratory assessment. Third party assessors shall be notified by the LELAP Supervisor or his designee of their laboratory assessment assignments. It is the responsibility of the third party assessor to schedule, perform and draft assessment reports within the contract time frames.

4.5.8 Combined Home Base and Field Assessments

4.5.8.1 Per LAC 33:I.4709.E, stack testers and facilities with mobile laboratories are required to have two assessments: one of the home base and one of the mobile or field units in the field. To facilitate timely scheduling of required assessments per LAC 33:I.4709.C and LAC 33:I.4709.F, and to reduce the potential for confusion of findings determined during the two assessments and corrective action taken for said findings, assessors shall proceed as described below.

4.5.8.2 The home base assessment and the field assessment shall be scheduled within five weeks of each other. The assessment findings shall be combined into one report.

4.5.8.3 The preference is that the field assessment shall be conducted at an active site, in coordination with the site owner or management.

4.5.8.4 If an active site is not available within five weeks of the home base assessment, the assessor shall schedule the stack tester or mobile laboratory for a static assessment, to be conducted at the home base as follows:

4.5.8.5 Static field assessments at the stack tester home base

4.5.8.5.1 Logistics

4.5.8.5.1 .1 This assessment should take place at the home base location at the same time as the biennial home base assessment. The following outline provides a stepwise approach to the assessment.

4.5.8.5.1 .2 The Assessor shall select the methods listed in the stack tester scope that are based on the use of in-line monitors or continuous emission monitors during the pre-assessment phase.

4.5.8.5.1 .3 The Assessor shall establish an acceptable schedule with the stack tester such that a field trailer that is actually used at client locations is available at the home base along with the test equipment modules related to the tests being assessed.

4.5.8.5.1 .4 After the field procedure assessment, the home base assessment will occur as currently performed.

4.5.8.5.2 Technical

4.5.8.5.2.1 Upon arrival at the assessment location, the Assessor shall notify the stack tester which tests will be assessed. In most cases this can include all the fixed gases, oxides of carbon, nitrogen and sulfur, sulfur-containing gases, low molecular weight hydrocarbons, etc. The stack tester staff will then set up the monitoring equipment under the observation of the Assessor and conduct initial calibrations as required by the method using calibrants from the stack tester stocks.

4.5.8.5.2.2 The analysis of target analytes will be from cylinders of Environmental Protection Agency (EPA) protocol gases or equivalents purchased and arranged for by the stack tester for the scheduled assessment. This will help address the issue of failure to run the required PTs which is frequently found in stack tester operations.

4.5.8.5.2.3 The off-line analysis of parameters such as ammonia from entrapment trains (CTM-027) can occur on-site or be shipped to an off-site laboratory based on the stack tester normal manner of operation. The Assessor is responsible only for verifying that the sample was submitted to a laboratory listed on the tester's register which satisfies LELAP accreditation requirements.

4.5.8.6 The assessment report will be prepared and submitted to the stack tester in the normal time frame. The stack tester corrective action plan submitted in response to the assessment report will report the EPA protocol gas test results associated with the LELAP-observed test procedures.

4.5.8.7 LELAP will establish acceptable levels of performance for stack tester accreditation based on the completed corrective actions.

4.5.8.8 The static field assessment approach will not assess the field implementation of tests which monitor physical properties such as velocity, opacity, moisture content, and particulate load/characteristics. These assessments will rely upon review of data packages.

4.5.9 The Lead Assessor shall have the following roles and responsibilities:

- plan the assessment,
- direct the assessment team,
- obtain copies of all forms required for the assessment,
- provide information to the laboratory on how to obtain information from LELAP,
- notify LELAP if the assessment team is denied entry to the laboratory,
- handle all business information marked "confidential",
- document in the assessment report the laboratory's exceptions to any findings,
- assure that the results within the assessment report conform to established standards for the evaluated parameters, and
- compile, edit and submit the assessment report to LELAP.

4.5.10 The laboratory shall receive the advanced notice letter in a time frame that will allow it to object to the appointment of any particular assessor or expert to a team conducting a routine assessment. LELAP will replace the assessor or expert if the laboratory's objection is based on demonstrable non-compliance with the TNI Standard. Both the objection and the subsequent action will be documented.

4.6 Off-Site Review of Laboratory Documentation

4.6.1 Assessors shall review the laboratory's records from the Electronic Data Management System (EDMS) prior to the assessment to ensure that the records are complete, and that it contains all of the original documents. In addition, the Assessor shall review any documents submitted by the laboratory in preparation of the on-site assessment. Documents reviewed may include but are not limited to:

- Copies of previous assessment reports and proficiency test results obtained since the previous assessment;
- General laboratory information such as laboratory submitted self assessment forms, e.g. checklists, SOPs and Quality Assurance Plan(s);

- Official laboratory communications with and associated records from LELAP staff (i.e., suspension or discreditation of methods or analytes);
- Available documents from recipients of reports from the laboratory;
- The laboratory's application for accreditation;
- Copies of current approved analytical test methods for which the laboratory has requested accreditation;
- The approved corrective action plan for the findings identified in the previous assessment; and
- LELAP and/or State records pertaining to the applicant laboratory.

4.6.2 At a minimum, sufficient test method SOPs shall be reviewed to cover a representative example of the analytical work covered by the Scope of Accreditation. Each Assessor shall establish and document the exact list of SOPs for review after consultation with the laboratory's designated representative.

4.6.3 The assigned Assessor shall review the QAM, test method SOPs, completed checklists and other documents as necessary and note any items that should require clarification during the on-site assessment. These notes will be written in the form of a preliminary list of findings for the assessment. Assessors shall assess standard operating procedures against the latest version of the reference method if the version is not identified on the original application or request submitted by the laboratory, on the current scope of accreditation issued by LELAP, or in the text of the standard operating procedure document itself.

4.6.4 For non-routine assessments and surveillance assessments, Assessors shall obtain copies of the quality system checklist completed since the previous routine assessment.

4.6.5 The Assessor shall determine the details of the assessment. The application will always determine the scope of the initial assessment. The scope of subsequent assessments will be determined by LELAP staff and the LELAP Supervisor.

4.7 Assessor Documentation of On-Site Assessments

4.7.1 During the on-site assessment, Assessors will collect information and make observations to be used to evaluate the laboratory's compliance with established state accreditation regulations or TNI standards. Any area of non-compliance shall be written as a finding and noted on the quality system checklist.

4.7.2 The Assessor shall review laboratory records to determine whether the testing laboratory has maintained the necessary documentation to technically substantiate previously issued reports.

4.7.3 Assessors shall document all observations to be included in the exit report and the final formal assessment report in an objective manner. Any observations that may

result in a finding shall be added to the preliminary list of issues identified during the off-site assessment (see Section 4.6.4).

4.7.4 During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information must be carefully documented since further action may be necessary. Assessors who encounter questionable laboratory practices shall call the Supervisor. The Supervisor shall assess the information. The Supervisor will direct the Assessor on the correct procedure to follow (close assessment and leave laboratory, or continue the assessment with additional directions).

4.7.5 If the situation is warranted, and subsequent to the audit, the Supervisor shall notify the Criminal Investigation Division (CID) of the Department. These issues, at the discretion of LELAP, may or may not be subjects or issues of the closing conference. However, the Assessor must continue to gather the information necessary to complete the accreditation assessment.

4.7.6 The Assessor's formal assessment report must include the date of the assessment, all personnel present during the opening and closing briefing/debriefing, staff interviewed and date and time of the closing briefing. The Assessor is required to sign and obtain the signature(s) of the laboratory representative(s) on the official copy of the exit debriefing attendance sheet.

4.8 Length of Assessment

4.8.1 Assessors shall consider the following factors when conducting an assessment: the number of tests for which a laboratory desires accreditation; the number of Assessors available; the size of the laboratory (size factors include the amount of work performed by the laboratory, the number of technologies used by the laboratory and the number of staff and management employed by the laboratory); the number of possible findings encountered during the assessment; and the degree of laboratory staff cooperation.

4.8.2 The Assessor shall notify the LELAP Supervisor if the laboratory staff is not fully supportive, and the Supervisor will in turn notify the Manager. The Assessor shall notify the LELAP Supervisor as soon as the assessment is discontinued, with the ES Manager's approval. The Assessor shall act in the manner described to him/her by the ES Manager of the Program at this time.

4.8.3 The LELAP Supervisor shall insure that an adequate number of Assessors are assigned to complete an assessment within a reasonable period of time. A reasonable period of time shall be considered 1-2 days for small laboratories and 2-4 days for large laboratories. The actual length of the assessment will be determined by the on-site assessment. If an assessment must be lengthened due to any circumstances, the

LELAP Supervisor must be notified by telephone as soon as the Assessor is aware of the need to extend the assessment. The LELAP Supervisor will obtain verification from the laboratory representative that the Assessor has requested an extension of the assessment and the laboratory representative is aware that additional costs may be added to the assessment invoice.

4.8.4 LELAP shall report non-conformities found during document and record review in writing to the laboratory should it elect not to proceed with the onsite assessment.

4.9 Opening Conference

4.9.1 Assessors shall arrive at the laboratory during the laboratory's established working hours.

4.9.2 The responsible laboratory official(s) will be contacted as soon as the Assessor or Assessment Team arrives on the premises of the laboratory.

4.9.3 The assigned Assessor shall conduct an opening conference that will address the following topics:

- identification of the assessment team and discussion of the agenda;
- the purpose of the assessment;
- the standards and/or regulations that will be used by the Assessor in judging the adequacy of the laboratory operation;
- discussion of any questions the laboratory may have about the assessment process;
- the procedures related to CBI;
- analyses that will be examined;
- records and operating procedures to be reviewed during the assessment and the names of the individuals in the laboratory responsible for providing the Assessor with the necessary records;
- roles and responsibilities of key managers and staff in the laboratory;
- safety procedures that the laboratory may require for the protection of the Assessor while in certain parts of the facility. Under no circumstance shall an Assessor be required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by the Assessor during an inspection to gain access to the facility;
- presentation of the assessment appraisal form ([see 8.0 References](#)) to the responsible laboratory official, for submission to LELAP; and
- the tentative time and date of the exit conference.

4.9.4 The Assessor may provide a copy of the preliminary findings from the off-site assessment of laboratory documents (see Section 4.6.4) to the laboratory representative(s) during the initial briefing unless it is mutually agreed upon those findings will be presented during the closing conference. The Assessor shall provide

Compliance Commitment Certification for the assessor and any team members upon request by the laboratory.

4.10 Laboratory Staff Interviews

4.10.1 The Assessor shall have the authority to conduct interviews with any and all of the laboratory staff. Interviews with regard to analyses must be conducted with the laboratory personnel responsible for the analytical procedure. If the QA officer or any member of the Laboratory's administrative staff tries to answer for an analyst, the Assessor shall ask that person to give the analyst a chance to answer the question. Then if the analyst cannot answer the question, the Assessor must rephrase the question and ask the analyst again. If the analyst still cannot answer the question, then the Assessor shall direct the question to the QA officer or Laboratory Supervisor that is present.

4.10.2 The Assessor shall assess calculations, data transfers, calibration procedures, quality control/assurance practices, adherence to SOPs and report preparation for each *selected* test with the appropriate analysts.

4.10.3 Assessors are not required to discuss any potential findings during the interview process. Assessor shall discuss potential findings during the closing conference. Potential findings identified during the off-site review, staff interviews, and on-site observations that are not satisfactorily addressed prior to the end of the closing conference shall be included in the exit debriefing.

4.11 Records Review

4.11.1 Assessors shall review records for accuracy, completeness and the use of proper methodology for each test and analyte to be evaluated. The review shall be documented on the appropriate state or NELAP assessment checklists.

4.11.2 The following minimum record set shall be reviewed by the Assessor(s):

- application for accreditation;
- previous assessment results and reports including proficiency testing results obtained since the previous assessment;
- laboratory management structure and chains of responsibility (e.g. organizational charts);
- qualifications of all key staff involved in the analysis or reporting of results for which accreditation has been requested;
- quality assurance plan(s) for the laboratory;
- sample receipt, handling, storage practices, and documentation
- SOPs and/or methods for selected parameters, including any associated sample preparation procedures and analytical reagent stoichiometry (ratio of sample, solvents, reagents);

- maintenance and calibration records of laboratory equipment and instrumentation;
- preparation and standardization of stock solutions and standard reagents;
- origins, purities, assays and expiration dates of primary standards, analytical reagents and standard reference materials;
- records associated with method-specific QA/QC requirements;
- specific records associated with the initial method validation study in the laboratory, including the historical calibration data;
- report formats including the case narratives;
- receipt and handling procedures for proficiency test (PT) samples;
- internal audit reports and corrective action taken by the laboratory; and
- documentation of the annual and/or ongoing management review of the laboratory.

4.11.3 If the laboratory requests that information obtained during the assessment be confidential, then the Assessor shall treat the information as confidential until such a ruling can be made by the Department Secretary. The Assessor shall notify the laboratory that a request for confidentiality can only be granted by the Department Secretary and that the request must be made in writing.

4.12 Closing Conference

4.12.1 The LELAP Assessment Team will confer prior to the exit briefing to discuss and consolidate their findings.

4.12.2 The LELAP Assessment Team will schedule a time for the exit briefing. It will indicate to the laboratory representative that sufficient time will be allotted to answer any questions the laboratory may have, within limitations imposed by travel arrangements or normal laboratory hours.

4.12.3 The exit briefing shall include an oral presentation of specific findings identified during the course of the assessment. The LDEQ LELAP Assessment team shall present an exit debriefing report in electronic form to the laboratory representative from which hard copies may be printed. The report shall be formatted as illustrated in the Exit Debriefing Form (see 8.0 References). This should be provided with sufficient time allotted for the appropriate personnel to read the report and formulate questions.

4.12.3.1 Initial discussion shall include the following:

- Thanks to the laboratory personnel for their hospitality and assistance in the audit.
- A summary of the positive attributes of the organization.
- An explanation that these are preliminary findings and observations and that additional findings may be identified or some findings may be deleted as the reporting process is finalized. Note that LDEQ is the final decision maker with

regard to whether a specific condition represents a finding, and that if the laboratory disagrees with a finding, they are free to explain why they disagree in their corrective action response. While not required, ask if the laboratory disagrees with any findings. Indicate that if they disagree, the laboratory may explain their viewpoint to LDEQ in the corrective action response. Also emphasize that the exit report is not the same as the final assessment report.

4.12.3.2 The discussion shall include the following:

- The Assessor(s) shall ask if the laboratory personnel have any questions regarding the findings.
- The Assessor(s) shall respond as necessary, answer any questions and clarify the findings and observations.
- The Assessor(s) shall determine that if there are no further questions, or if there are no aspects of the findings that, in the judgment of the lead assessor, require further clarification, the onsite portion of the assessment is concluded.

4.12.3.3 The Assessor(s) shall explain the corrective action process:

- The laboratory must submit a corrective action plan (CAP) that addresses each of the cited findings, using the electronic copy of the Finding Report included with the Assessment Report. These are separate files. The laboratory must not submit an unsigned copy of the Assessment Report with the CAP.
- The laboratory response must be concrete, detailed, and specific, and must describe how the corrective action will be implemented and incorporated into the laboratory's quality system documentation.
- The laboratory must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action. Enter the laboratory corrective action response to each finding in the appropriate spaces provided on the attachment. An example is provided in the findings section of the report, in which the sections to be completed by the laboratory are indicated by italics.
- A paper copy and an electronic copy of the completed CAP must be submitted to LELAP within 30 days of the date of receipt of this report. All corrective actions must be completed satisfactorily within six months of the date of receipt. Note that LDEQ will verify that corrective actions are implemented in subsequent audits.

4.12.4 When the LELAP Assessors submit a written exit report, all present should sign and date the assessor's copy of the exit report. A separate form may be used if the number of signatures is too large to fit on the exit report. The report must contain the following statement: "Note: Signature does not necessarily indicate agreement with assessor's stated/written observations/findings)." Note that signing the report does not imply that the laboratory personnel agree with the findings, but only that it was reviewed and understood in the exit briefing.

4.12.5 The Assessor(s) must verify that the scope (with any edits) is signed by the laboratory. The Assessor(s) must also verify that if available, electronic copies of the laboratory's procedures are provided.

4.12.6 At the close of the on-site assessment, the laboratory representatives must sign-off on the debriefing attendance sheet; any of the laboratory staff and management present at the time of de-briefing must sign-off as well.

4.12.7 If CBI was declared, the Assessor(s) must verify that all information is so marked and that CBI forms are signed by the laboratory.

4.12.8 The Assessor(s) shall provide the laboratory representative(s) with assessor evaluation forms for each inspector ([see 8.0](#) References).

4.12.9 The exit debriefing is not required following a field assessment if the field assessment is combined with the home base assessment; in all other cases, the policy shall be followed for field assessments. All field assessments shall be documented with a signed attendance sheet and initialed scope following the completion of the assessment. Assessors conducting home base assessments shall follow this policy.

4.13 Assessment Reporting Procedures

4.13.1 The assigned LELAP Assessor shall submit a formal assessment report within thirty (30) calendar days of the assessment to the facility. If the laboratory is accredited by the state of Louisiana only, the assigned Assessor shall have 60 working days from the last day of the assessment to complete a formal assessment report. The report shall be signed and dated by the Assessment team and LELAP Supervisor and made available to the laboratory by electronic mail (e-mail) or regular mail. Assessment report deadlines will be tracked by the assigned assessor using the Microsoft Outlook Calendar, and the program supervisor will monitor these deadlines by using an excel spreadsheet.

4.13.2 The laboratory must submit a corrective action plan to LELAP within thirty (30) calendar days from the date of receipt of the report. Once the plan has been received by LELAP the date of receipt will be entered into the Database; a route slip shall be attached identifying the document prior to be sent to the appropriate LELAP Assessor. Corrective action plan submission deadlines will be tracked by the assigned assessor using the Microsoft Outlook Calendar, and the program supervisor will monitor these deadlines by using an excel spreadsheet.

4.13.3 Exceptions to adherence to these deadlines may be allowed at the discretion of the LELAP Supervisor. The laboratory must submit an extension request which explains the necessity for the extension. The extension shall not be automatically granted. The assigned LELAP Assessor must respond to the request within 10 working days of receiving the request for an extension.

4.13.4 Assessment reports will be generated in a narrative format. Documentation of existing conditions at the laboratory shall be included in each report. Only portions of quality systems documents which support the identification of areas of non-conformance to requirements shall be included. All assessment reports will include a "List of Findings" for findings identified during the assessment. The "List of Findings" shall be in conventional outline format and numbering.

Assessor reports shall contain the following:

4.13.4.1 Identification of the laboratory (name and address) in a formal transmittal letter and unique identification of all premises assessed;

4.13.4.2 Date (or dates) of the assessment;

4.13.4.3 Identification, status (if trainee), and affiliation of each assessment team member;

4.13.4.4 Identification of participants in the assessment process;

4.13.4.5 A statement of the objectives of the assessment [assessment scope], including determination of correction of prior findings, if applicable;

4.13.4.6 Assessment findings (compliance and deficiencies), requirements that includes

- A statement on the adequacy of the internal organization and procedures adopted by the laboratory to give confidence in its competence, as determined through its fulfillment of the requirements for accreditation and
- a summary of the objective evidence supporting the findings and the citation to the requirement that is not met;
- any further information that may assist in determining fulfillment of requirements and the competence of the laboratory; and
- a summary of the results of proficiency testing or other comparisons conducted by the laboratory and any actions taken as a consequence of the results.

4.13.4.7 A list of attachments which shall include but is not limited to:

- Laboratory organizational chart;
- Attendance sheet (with initials of interviewees);
- List of laboratory SOPs;
- List of data packages reviewed on-site or off-site (by unique laboratory number);
- List of PT studies reviewed;
- All checklists (including quality system checklists) completed by the laboratory; and
- Assessor's compliance commitment certification.

4.13.4.8 A signed copy of the exit report, a copy of the pre-assessment checklist (see 8.0 References), and a copy of the application for accreditation may be included as attachments.

4.13.4.9 The report shall be formatted as illustrated in the current assessment report format (see 8.0 References).

4.13.5 The assigned Assessor shall ensure that the findings within the final report are consistent with established regulations and standards.

4.13.6 Assessment reports generated by LELAP Assessors in regional offices and LELAP third party assessors shall follow the same protocol as for LELAP Assessors based at Headquarters, except as noted in this Section and Sections 4.13.8 through Section 4.15.5. Once the Assessor has drafted the assessment report and placed a "Draft" watermark on the report and the date of the draft, it will be submitted via e-mail to the LELAP Supervisor.

4.13.7 The LELAP Supervisor shall review the report drafted by the LELAP assessor and shall forward the report drafted by the LELAP third party assessor to the LELAP assessor assigned to the facility. The LELAP assessor assigned to the facility shall review the report from the LELAP third party assessor, then meet with the LELAP Supervisor to consolidate comments for the LELAP third party assessor.

4.13.7.1 If the LELAP Supervisor concurs with the draft written by the LELAP assessor, he/she shall forward the information on to the Assessor. If the Supervisor does not agree then the "Draft" report shall be sent back to the LELAP Assessor to make additional changes. The LELAP Assessor will complete the requested changes and return the draft to the LELAP Supervisor for further review and approval.

4.13.7.2 If the LELAP Supervisor concurs with the draft written by the third party assessor, he/she will instruct the assigned LELAP assessor to notify the third party assessor to issue a signed final draft. If the Supervisor does not agree then the "Draft" report shall be sent back to the third party assessor to make additional changes. The third party assessor will complete the requested changes and return the draft to the LELAP Supervisor for further review and approval.

4.13.8 The LELAP Supervisor shall ensure that all requested changes have been made and then forward to the designated LDEQ staff. If the Assessor is required to make changes to the document he/she shall make the changes and resubmit to the LELAP Supervisor via e-mail. The revised draft shall be watermarked "Draft" and the new revision date added.

4.13.9 Once LELAP has approved all requested changes in the "Draft" assessment report, the designated LDEQ staff or third party contractor will email the complete

assessment report package or an electronic copy on a re-writeable compact disk (CD-RW) to LELAP. The LELAP Supervisor will review the completed report and sign a printed cover page. The PPPSD Administrator will review the completed report and sign a printed cover letter. The signed report will be made available to the Laboratory via EDMS after the corrective action plan (if necessary) is approved.

4.13.10 During this last review of the Assessment report if there are any minor editorial changes such as a period in the wrong place or misspelled word, it will be corrected with a single line drawn through it, initialed and dated.

4.14 Report Distribution

The laboratory shall receive a copy of the signed assessment report from LELAP.

4.15 Release of Report

4.15.1 On-site assessment reports will be released by LELAP only.

4.15.2 The reports shall be released to the responsible laboratory official(s) within thirty (30) calendar days after the last day of the on-site visit.

4.15.3 The assessment report shall NOT be released to the National Accreditation Database or the public until findings of the assessment and corrective actions have been finalized. In addition, all CBI and information related to national security shall be stricken from the report in accordance with prescribed procedures, and the report must have been provided to the laboratory prior to release to the public.

4.15.4 The assessment report shall become public record once the report has been provided to the laboratory as required by the Louisiana Revised Statute 44:31([see 8.0 References](#)).

4.15.5 In accordance with the state public records policy and confirmed by LDEQ Legal Division staff, if a request for a public record is made prior to a completed report, the request shall be fulfilled.

5.0 Records Management

Official records are described in *Managing Records* (see 8.0 References).

Official records associated with this activity and maintained in EDMS according to the LDEQ Records Management Policy are:

- Assessment Reports (See step 4.13)
- Checklists (see 8.0 References)
- Other supporting documentation

LELAP shall retain copies of all assessment reports, and checklists for a period of at least ten years or longer if required by specific state or federal regulations.

Third parties involved in the assessment shall retain all records for the period of time stipulated in the contract with LDEQ. No records shall be disposed of by the third party contractor without the written permission of the LDEQ contract official.

TEMPO and AAMS databases are also maintained as repositories of official information records.

6.0 Quality Control / Quality Assurance

This process includes the following quality control measures:

- The primary quality assurance for the documentation is the review of the record by the LELAP Supervisor or his/her designee.
- Prior to the assessment, the Supervisor or his/her designee reviews the pre-assessment checklist and the assessment agenda. (see 8.0 References and step 4.6.4)
- At the opening of the assessment the assessors present the assessor evaluation form to the attending laboratory staff. (see 8.0 References and step 4.9.3)
- At the close of the assessment, the assessors and the attending laboratory staff sign the debriefing attendance sheet. (see step 4.12.6)
- Within thirty (30) days for assessments by the NELAP recognized standard and sixty (60) days for assessments by the LAC, the assessment report is reviewed by the Supervisor or his/her designee. (see step 4.13)
- Deadlines are tracked with Outlook Express and an excel spreadsheet. (see steps 4.1.3, 4.13.1, and 4.13.2)

7.0 SOP Review / Revision / Approval

Designated reviewers for this SOP are:

- Permits Support Services Division's, Notifications and Accreditations Section
Environmental Scientist Manager
- Permits Support Services Division's, Notifications and Accreditations Section,
LELAP Supervisor

The Laboratory Services Division Administrator approved the original SOP, and the Permits Support Services Division Administrator has final approval authority for any revisions to this SOP.

8.0 References

- Managing Records located on LDEQ's intranet at: <http://intranet/records/>
- LAC 33.I Chapters 45-59 located on LDEQ's intranet at: <http://www.deq.louisiana.gov/portal/LinkClick.aspx?fileticket=0h79jV%2fkc00%3d&tabid=1674> or at: <http://www.deq.louisiana.gov/portal/DIVISIONS/LegalAffairs/RulesandRegulations/Title33.aspx>
- The 2009 TNI Standard is located in the TNI website at: http://www.nelac-institute.org/standards.php?pab=1_1#pab1_3
- The most current Assessment Checklist for NELAP-Accredited Facilities and Assessment Checklist for State-Accredited Facilities is found at: \\deqshares\lelap\NELAP Checklist
- The assessor evaluation form is found in the LELAP shared folder \\deqshares\lelap\SOP Attachments\Assessment and Assessment Reports\Evaluation of Assessors Form
- The exit debriefing form is found in \\deqshares\lelap\SOP Attachments\Assessment and Assessment Reports\Exit Debriefing Form
- The pre-assessment checklist is found in \\deqshares\lelap\SOP Attachments\Assessment and Assessment Reports\Pre-Assessment Checklist
- The current assessment report is found in \\deqshares\lelap\SOP Attachments\Assessment and Assessment Reports\Assessment Report Format
- Confidential Business Information regulations may be found at: <http://www.deq.louisiana.gov/portal/DIVISIONS/LegalAffairs/RulesandRegulations/Title33.aspx>
- Louisiana Revised Statute 44:31 is found in <http://www.legis.state.la.us/lss/lss.asp?doc=99688>

9.0 Attachments

Not applicable

Enclosure B

LELAP Proficiency Test Evaluation
sop_1786_r12
Document Prepared 5/21/2014
Page 1 of 12

Standard Operating Procedure

for

LELAP Proficiency Test Evaluation

Revision 12

Public Participation and Permit Support Division

Office of Environmental Services

Louisiana Department of Environmental Quality

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Document Review and Revision Record

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Table of Contents

1.0	Purpose / Applicability	4
2.0	Definitions / Acronyms / Abbreviations	4
3.0	Personnel Qualifications	4
4.0	Procedure	5
5.0	Records Management	11
6.0	Quality Control / Quality Assurance	11
7.0	SOP Review / Revision / Approval	12
8.0	References	12
9.0	Attachments.....	12

1.0 Purpose / Applicability

The purpose of this SOP is to provide instructions for staff to follow when the Louisiana Environmental Laboratory Accreditation Program (LELAP) evaluates proficiency test (PT) results. PT results are essential to demonstrate the laboratory's competency to perform analyses. This activity is performed by LELAP staff to ensure that laboratories (includes stack testers) are meeting the required proficiency tests are described in LAC 33:1.4711.

This SOP applies to staff members in the LELAP group, Notifications and Accreditations Section, Public Participation and Permit Support Division, and their supervisor.

2.0 Definitions / Acronyms / Abbreviations

ACCLASS:	Assured Calibration and Laboratory Accreditation Select Services
A2LA:	American Association for Laboratory Accreditation
AAMS:	Accrediting Authority Management System
AASHTO	American Association of State Highway and Transportation Officials
ADP	Analytical Data Package
AMRL	The AASHTO Materials Reference Laboratory
EDMS:	Electronic Document Management System
ES:	Environmental Scientist
Test category:	matrix type, technology/method, and analyte/analyte group
LELAP:	Louisiana Environmental Laboratory Accreditation Program
NAS:	Notifications and Accreditations Section
NELAC:	National Environmental Laboratory Accreditation Conference
NELAP:	National Environmental Laboratory Accreditation Program
OES:	Office of Environmental Services
PPPSD:	Public Participation and Permit Support Division
PT:	Proficiency Test
SOP:	Standard Operating Procedure
TEMPO:	Tools for Environmental Management and Protection Organizations. It is the central data management system to track facilities, people, and organizations that are of interest to LDEQ and to track the activities of the Department, such as Permitting, Surveillance, and Enforcement. This system is the central piece of the new <u>Integrated Data Management System (IDMS)</u>
TNI:	The NELAC Institute

3.0 Personnel Qualifications

The SOP identifies job titles of staff members who perform certain activities. These staff members are qualified to perform these activities based on the qualifications in their job descriptions. Staff members receive training from supervisory staff or designee in the section and outside trainers. Once the supervisory staff or designee determines that

the ES is sufficiently trained, staff members will assume all the duties related to them. The supervisory staff or designee will provide guidance and backup.

4.0 Procedure

Note: Staff member will send any official record associated with his/her participation in this activity to EDMS for scanning.

4.1 Applicant Laboratories PT Participation

4.1.1 LELAP regulations require all laboratories accredited or seeking accreditation to participate in a Louisiana Department of Environmental Quality (LDEQ, Department) approved proficiency-testing program. The laboratory must perform PT analyses for each test category for which the lab seeks to receive accreditation.

4.1.2 Applicant laboratory PT results must be from a Department approved PT vendor. The list of approved PT providers shall be made available to the applicant laboratories by the LELAP Assessor (Assessor) or may be acquired from LELAP's website ([see 8.0 References](#)). LELAP shall accept results from non-proficiency test provider accreditor-accredited proficiency test providers selected by the laboratory when the matrix-method-analyte is not available from any accredited proficiency test provider

4.1.3 Assessors shall verify with TNI, A2LA, or ACLASS the approved and/or certified PT providers. Each Assessor shall check the TNI web site ([see 8.0 References](#)), A2LA web site ([see 8.0 References](#)), and the ACLASS website ([see 8.0 References](#)) to obtain the list of PT vendors and the scope of the PT vendors' accreditation or approval.

4.1.4 In the event that PT tests are not available for a particular test category, the laboratory must submit an "analytical data package (ADP)" as defined by LAC 33:I.4711.B.

4.1.5 Proficiency test studies shall be conducted at a minimum of once every six months. Laboratories set their own semi-annual schedule. Quality assurance test results will not be accepted as PT results.

4.1.6 The laboratory must perform satisfactorily in at least two proficiency test studies within the most recent three proficiency test studies attempted in order to be accredited or to maintain accreditation.

4.1.7 Laboratories must return results to the PT provider no later than 45 calendar days from the opening of the PT study.

4.1.8 The analysis date of the PT samples for a test category shall be no more that 18 months prior to the application date for accreditation, with the analysis date of the most recent PT sample for a test category having been no more than 6 months prior to the

application date for accreditation. The applicant's PT evaluation results must be submitted to LELAP within 30 days of the laboratory having received their results. Laboratories must also authorize the PT provider to have a copy of the PT evaluation results sent directly to LELAP at the same time as the results are sent to the laboratory.

4.1.9 Laboratories receiving evaluation results that are "unacceptable" for a specific analyte must investigate and identify likely cause for "unacceptable" results, resolve the problem and report the activities to LELAP within 30 calendar days upon receipt of the evaluation from the PT provider. This is called the corrective action report for failed PTs.

4.1.10 Laboratories receiving unacceptable evaluation results must participate in a PT study for "only" the failed analytes/methods. This is called a corrective action or remedial PT. A corrective action or remedial PT evaluation result for analytes for which corrective action was required must be reported to LELAP. Laboratories must authorize PT providers to submit copies of the corrective action PT evaluation results to LELAP.

4.1.11 When PT samples are not available for the test category from any accredited PT provider at least twice per year, LELAP shall require the laboratory to analyze the PT samples in the minimum time frame in which the PT samples are available from any accredited PT provider.

4.1.12 LELAP shall accept the assessment decisions made by the primary accreditation body regarding a laboratory's performance and compliance with the proficiency testing requirements set forth in the TNI standard.

4.2 Receiving and Uploading of PT Results in the LELAP Database

4.2.1 All PT providers shall submit to LELAP PT data electronically in the format necessary to import the information into the LELAP's database. The format and fields required for the database import are shown in the LELAP shared folder (See 8.0 References).

4.2.2 To be able to upload all PT data into the database, every laboratory must have an Environmental Protection Agency laboratory code. However, not all laboratories can acquire an EPA lab code. Hence, LELAP generates laboratory codes that are unique for each laboratory. The codes start with the abbreviation of the state where the laboratory is located, followed by the assigned LELAP Lab ID. The unique ID will be called the LELAP laboratory code. Currently, LELAP is using EPA lab codes as the unique identifier of the laboratory with respect to PT data import.

4.2.3 LELAP receives electronic copies (and occasionally, paper copies) of evaluation results from PT providers. Other PT providers send email notification to the LELAP supervisor and a designated assessor when new PT data are available for download off

the provider's webpage. The supervisor then forwards the electronic copies and/or instructions to the designated shared folders (see 8.0 References). The files are saved in the shared folder and in EDMS. PT providers submit one PT data file for the entire laboratories that participated in the study. Each PT provider has its own folder PT data which are separated by laboratory and saved in each of the facility's folder. Instructions for downloading PT data from the PT Providers are located in the shared folders (see 8.0 References).

4.2.4 PT data are imported into the database following the procedure for uploading data. In the event that an error occurs while uploading the data, the error summary report can be printed. The report shows where and why the error occurred, and the number of rows or lines rejected. The assigned Assessor verifies the problem by calling the PT provider or sending a copy of the error summary report. One type of an error is a typographical error. For example the laboratory's code in the database is LA00432 and the code in the electronic file submitted is LA00342. The PT provider notifies the assigned Assessor of the correct lab code and the name of the laboratory or organization. The problem is resolved via two mechanisms: a) the PT provider corrects the error and electronic copy is sent back to the assigned Assessor, or b) the assigned Assessor corrects the error and saves the file with a different file name. The revised PT data file is then uploaded into the database.

4.3 Assessors Evaluation of PT Results for Accredited Laboratories

4.3.1 Assessors shall evaluate laboratories having completed two rounds of proficiency testing on the PT results submitted to LELAP. Laboratories must employ the same procedures (including tracking, preparation, and analysis) used for sample analysis in the analysis of PT samples. Compliance with this requirement is assessed during the on-site assessment described in the standard operating procedure for Laboratory Assessment and Assessment Reporting according to SOP # 1787(see 8.0 References). Accredited laboratories must document the following:

- PT samples are prepared according to the PT provider's instructions and subsequently handled as routine samples
- The type, composition, concentration, and frequency of quality control samples analyzed with the PT samples are the same as with routine samples
- Procedures for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement

4.3.2 PT evaluation results shall be submitted to LELAP by the Department approved PT provider or the laboratory-selected provider if there are no accredited providers. PT evaluation results submitted by the laboratory must be copies of the original PT reports on the PT provider's stationary in order to be accepted. The LELAP staff shall handle the PT results as described in the LELAP procedures for records management according to SOP # 1789 (see 8.0 References). The assigned assessor shall ensure that the analysis dates of successive PT samples for the same test category are at least

5 months apart and no longer than 7 months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same test category shall be at least 15 days apart. LELAP shall consider the result for a test category acceptable when the result reported by the laboratory for a test category is evaluated acceptable by the PT provider.

4.3.3 The assigned Assessor shall review PT results to identify all “unacceptable” or “unsatisfactory” scores and to ensure that the laboratory has performed proficiency tests for all test categories for which they have applied for accreditation. This review shall be documented as a pdf using the most current PT Pivot Table report (see 8.0 References). If the laboratory has not participated in proficiency tests for all test categories, then the assigned Assessor shall notify the laboratory in writing of this finding as soon as it is discovered. The Assessor shall not recommend an applicant laboratory for accreditation for test categories for which the laboratory has not completed proficiency testing. The Assessor shall complete the review of the scores within 60 days of receipt of each study report.

4.3.4 The assigned Assessor shall compare the current set of PT results against the application or Scope of Accreditation and the last set of PT results submitted by the applicant laboratory. The assigned Assessor shall notify the laboratory of any discrepancies between the application or Scope of Accreditation and the PT results.

4.3.5 Laboratories receiving initial accreditation shall not be accredited for those analytes for which the PT results were “unacceptable” or “unsatisfactory” in two of the last three consecutive rounds of PT studies.

4.3.6 Accredited laboratories having received scores of “unacceptable” or “unsatisfactory” for any specific test category in two of the last three consecutive rounds shall be suspended for accreditation of that analyte until such time as the laboratory has successfully performed two of three PT rounds for that test category.

4.3.7 The assigned Assessor shall notify the laboratory of the suspension or discreditation of accreditation for any specific analyte meeting the criteria established in Section 4.3.6 of this SOP in writing within 60 calendar days.

4.3.8 The assessor will also determine if the laboratory has received an acceptable score for at least 80% of analytes for analyte group PT samples. If the laboratory has failed more than 20% of analytes in an analyte group, the laboratory will receive a score of “Not Acceptable” for all analytes in that group. The laboratory must be informed in writing within 60 calendar days.

4.3.9 If at any time the assessor becomes aware that a laboratory has sent any portion of a PT sample to another laboratory for analysis, analyzed a PT sample for another

laboratory, communicated with another laboratory concerning a PT sample, or attempted to obtain the value of a PT, the assessor will notify the LELAP Supervisor immediately. Any of the above actions are cause for suspension or discreditation per LAC 33:I.5705.A.

4.3.10 If the suspended laboratory is successful in correcting the cause(s) for suspension within six (6) months, it will not have to reapply for accreditation. If the suspended laboratory is not successful in correcting the cause(s) for suspension within six (6) months of the effective date of the suspension, the laboratory shall be discredited in part or in total.

4.3.11 If the discredited laboratory is not successful in correcting the deficiencies as required by the TNI standards, the laboratory must wait six (6) months before reapplying for accreditation.

4.4 Corrective Action Proficiency Tests

4.4.1 The assigned Assessor shall review all PT results and when necessary ensure that the laboratory has submitted any necessary corrective action findings and the corrective action PT results. The laboratory is required to submit a corrective action report and a corrective action PT for any failed PT study. Quick or supplemental studies provided by an approved PT provider are acceptable. Corrective action PTs must be completed within 60 days of a failed PT test.

4.4.2 If a laboratory fails a corrective action PT, the laboratory has failed two consecutive studies and is treated as in Section 4.3.6 and 4.3.7 of this SOP.

4.4.3 Corrective Action Proficiency test results will be considered when establishing the requirement that a laboratory pass two of three PT studies to maintain accreditation.

4.5 Supplemental Proficiency Tests

4.5.1 A supplemental proficiency test is a proficiency test which is elective on the part of the participating laboratory.

4.5.2 If a laboratory participates in a supplemental proficiency test, the analysis data must be at least fifteen (15) calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing.

4.6 TNI Requirements

4.6.1 If LELAP discovers that a PT provider has suggested or directed a laboratory to purchase QC standards that are specifically designed for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in the

TNI standard, LELAP shall report the results of its findings to the PT provider's accreditor.

4.6.2 LELAP shall consider the analytical result for a test category not acceptable when:

- The result reported by the laboratory does not meet the criteria for "acceptable" as specified in the standards for accreditation bodies and proficiency test providers. If the criteria in the standard for proficiency test providers are met and the result for the test category was scored "not acceptable", LELAP shall overturn the performance evaluation and score the analytical result "acceptable;"
- The laboratory does not report results for an accredited test category within the timeframes specified by the standard;
- The laboratory makes any reporting error or omission that results in a non-specific match between the analytical result for the test category and any criterion that identifies the laboratory or the test category for which the PT sample was analyzed for the purpose of initial or continued accreditation; or
- The laboratory submits analytical results for a test category from a PT provider that is not accredited by the PT provider accreditor(s) unless there are not any PT provider-accredited PT providers for the test category in which case the PT sample may be purchased from any PT provider and LELAP shall accept the results from the PT provider selected by the laboratory.

4.6.3 LELAP shall accept the results of a PT sample used for corrective action when the laboratory follows these requirements:

- The PT sample used for corrective action shall be obtained from any PT provider accredited by a PT provider accreditor listed on the TNI webpage. A scheduled or a supplemental PT sample may be used for the corrective action.
- The laboratory shall notify the PT provider that the PT sample is for corrective action to ensure that the PT provider provides a PT sample that meets the requirements for supplemental PT samples as specified in the standard.
- There shall be at least fifteen (15) calendar days between the closing date of a previous study and the analysis date of any subsequent study for the same test category
- The subsequent PT sample shall be analyzed and reported in accordance with the requirements described in the standard.

4.7 LELAP shall submit questions about PT samples or performance evaluations made by the PT provider to the PT provider. If the PT provider is unable or unwilling to resolve the questions, LELAP shall refer the questions to the PT provider's accreditation body.

4.8 Suspension and Revocation

4.8.1 LELAP shall suspend the accreditation of a laboratory for a test category if the laboratory does not provide a corrective action report within thirty (30) calendar days of request for the report.

4.8.2 To reinstate accreditation of a test category after suspension, LELAP shall ensure that the laboratory meets the requirements for continued accreditation as described in the standard.

4.8.3 LELAP shall revoke the accreditation of a laboratory for a test category when the laboratory does not participate in the PT program as required by the standard (see also LAC 33:I.5705.F.16)

4.8.4 To reinstate accreditation of a test category after revocation, LELAP shall require the laboratory to meet the requirements for initial accreditation as described in the standard.

5.0 Records Management

Official records are described in *Managing Records* (see 8.0 References).

Official records associated with this activity and maintained in EDMS according to the LDEQ Records Management Policy are:

- Proficiency Test Results (see step 4.3.2)
- The pdf generated by the most current PT Pivot Table report (see step 4.3.3 and 8.0 References).
- Any correspondence to the facility regarding proficiency tests and/or results.

TEMPO and AAMS databases are also maintained as repositories of information records.

6.0 Quality Control / Quality Assurance

This process includes the following quality control measures:

- The primary quality assurance for the documentation is the review of the record by the LELAP Supervisor or his/her designee.
- The PT Pivot Table (see 8.0 References) is being developed for assessors to be able to create a summary of all PT evaluation results by laboratory. The summary will include accredited analyte/ method, study number, study date, and evaluation result (Acceptable or Unacceptable).
- The summary is documented as a pdf generated by the PT Pivot Table report (see step 4.3.3 and 8.0 References).
- Status of approved PT providers will be verified (see step 4.1.3)
- Required PT's will be performed for the methods listed on the initial application or the Scope of Accreditation (see step 4.3.4)
- Sources of errors discovered during attempt uploading of PT data will be verified with PT providers and documented in an error summary report (see step 4.2.4)

- Handling of proficiency test samples will be verified during onsite assessments (see step 4.3.1)

7.0 SOP Review / Revision / Approval

Designated reviewers for this SOP are:

- Public Participation and Permit Support Division's, Notifications and Accreditation Section's Environmental Scientist Manager
- PPPSD's, NAS's, LELAP Supervisor
- PPPSD's QA Reviewer (for review of QA elements only)

The Laboratory Services Division Administrator approved the original SOP, and the Public Participation and Permit Support Permits Division Administrator has final approval authority for any revisions to this SOP.

8.0 References

Managing Records located at: <http://intranet/records/user/editinfo/files/official-pubrecords-nonrecords.pdf>.

The database import requirements are located at \\deqshares\lelap\SOP Attachments\LELAP Proficiency Test Evaluation\Format and Fields Required for Database Import of PT Data

Electronic copies of PT data and/or instructions are located at \\deqshares\lelap\PT Data

The PT Data Pivot Table is located at S:\PT Project

The LELAP list of approved proficiency test providers is found at: <http://www.deq.louisiana.gov/portal/tabid/2925/Default.aspx>

The TNI list of approved proficiency test providers is found at: <http://www.nelac-institute.org/ptproviders-accreditors.php>

The A2LA list of approved proficiency test providers is found at: <http://www.a2la.org/dirsearchnew/nelacptproviders.cfm>

The ACLASS list of approved proficiency test providers is found at <http://www.aiclasscorp.com/search-accredited-companies.aspx>

LELAP SOPs can be found at <http://intranet/sop/soplist.asp>

9.0 Attachments

Not applicable

Louisiana Environmental Laboratory Accreditation Program

Quality Assurance Project Plan

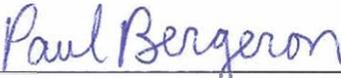
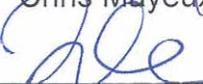
Revision 13

Notifications and Accreditations Section (NAS)
Public Participation and Permit Support Division (PPPSD)
Office of Environmental Services (OES)
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4/13/06	5	Changed to new format
05/11/2007	6	Name change for LELAP Supervisor and technical changes related to NELAC and TNI
03/07/2008	7	General Revision
11/03/2008	8	General Revision
03/23/2009	9	General Revision
10/6/09	10	Minor revisions, use of agency approved format, and relocation of duties to the Permit Support Services Division.
10/06/2011	11	Inclusion of provisions for contractors, revisions including division name change to Public Participation and Permit Support Division (PPPSD) and Permits Support Division. Supersedes document #QAP_1784_r10.
06/10/2013	12	Inclusion of requirements of the 2009 TNI Standard
06/02/2014	13	Definition of "practicable" added to Section 5.5 and shared folder location updated

Table of Contents

1.0	SCOPE.....	5
2.0	POLICY	5
3.0	ORGANIZATION.....	5
4.0	RESPONSIBILITIES AND AUTHORITIES	6
5.0	CONFLICT OF INTEREST CERTIFICATION	10
6.0	PERSONNEL QUALIFICATIONS.....	10
7.0	GENERAL PERSONNEL QUALIFICATIONS	11
8.0	TRAINING	14
9.0	CONSULTATION	15
10.0	QUALITY ASSURANCE ORGANIZATION.....	15
11.0	DOCUMENTS AND RECORDS.....	17
12.0	QUALITY ASSURANCE PLAN	18
13.0	TNI STANDARDS	19
14.0	APPLICANT LABORATORY DOCUMENTS AND RECORDS	20
15.0	STANDARD OPERATING PROCEDURES	20
16.0	IMPLEMENTATION SCHEDULE.....	21
17.0	COMPUTER HARDWARE AND SOFTWARE.....	21
18.0	DATA AND INFORMATION.....	21
19.0	IMPLEMENTATION OF WORK	21
20.0	PURCHASING	21
21.0	CONTRACT SERVICES	21
22.0	COMPLAINTS/ RESOLUTIONS	23
23.0	APPEALS.....	24
24.0	NOTIFICATION OF CHANGES TO THE LELAP PROGRAM.....	24
25.0	USE OF ACCREDITATION BY LELAP AND NELAP ACCREDITED LABORATORIES.....	25
26.0	RERERENCES.....	22

1.0 SCOPE

The Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) Quality Assurance Plan (QAP) is intended to meet all applicable requirements concerning quality assurance/quality control (QA/QC), as well as to describe the activities of the Program. The Department Quality Management Plan (QMP) and LELAP QAP govern activities required to ensure that LELAP properly administers the Louisiana Administrative Code (LAC), Title 33, Part I, Subpart 3, Laboratory Accreditation regulations ([See Section 26.0](#)). The LELAP staff and LELAP contractors are bound by the requirements delineated in this QAP and the Department's QMP. Wherever applicable, The National Environmental Laboratory Accreditation Conference Institute (TNI) criteria are used to ensure that these regulations are fulfilled, and this document is written to fulfill TNI requirements. The Program is responsible for providing the public with current and timely information on the accreditation status of laboratories and the regulatory requirements of the State of Louisiana. Quality in LELAP contributes to the technical credibility of the Louisiana Department of Environmental Quality (LDEQ, the Department).

2.0 POLICY

LELAP is committed to carrying out the assigned responsibilities within the quality requirements of its quality system documents, TNI standard, and state regulations. All employees have access to this manual and are responsible for being familiar with and adhering to its contents. Department management, staff and contractors functioning as LELAP assessors and technical experts assisting with an assessment shall be required to sign a Compliance Commitment Statement ([See Section 26.0](#)); signed copies are to be maintained in the staff's individual training file, and printed on letterhead prior to assessing or auditing any laboratory applying for accreditation. Compliance Commitment Statements shall be signed by all LELAP personnel involved in the on-site assessment of any laboratory.

3.0 ORGANIZATION

3.1 LELAP is a unit within the Notifications and Accreditations Section of the Public Participation and Permit Support Division (PPPSD) within the Office of Environmental Services (OES), LDEQ. LELAP is an accrediting agency within the Department as found in the Louisiana Department of Environmental Quality's Quality Management Plan, located on LDEQ's Intranet ([see Section 26.0](#)).

3.2 The Department's organizational charts are found in the LELAP shared folder ([see Section 26.0](#)).

4.0 RESPONSIBILITIES AND AUTHORITIES

4.1 Assistant Secretary

4.1.1 The OES, Assistant Secretary reports to the Secretary of the Department of Environmental Quality.

4.1.2 The Assistant Secretary approves denial of applications for accreditation and suspension and discreditation of facilities which are determined to be non-compliant with the program requirements.

4.2 Environmental Scientist Administrator (Administrator)

4.2.1 The Administrator reports to the Assistant Secretary.

4.2.2 The Administrator is the approved LELAP signatory for certificates and amended Scopes of Accreditation. The Administrator also approves assessment reports submitted by the Supervisor. The Administrator does not perform assessments.

4.3 Environmental Scientist Supervisor (Supervisor)

4.3.1 The Supervisor is responsible for planning, monitoring, evaluating, and improving the program's operations. The supervisor is responsible for ensuring that the staff functions in accordance with the regulations. The Supervisor reports to the Manager of the Notifications and Accreditations Section within the PPPSD.

The Supervisor performs the following additional tasks:

4.3.1.1 Reviews all correspondence before signing or prior to being sent to the Manager, Administrator, or the Assistant Secretary for review and approval.

4.3.1.2 Performs all the duties of an Assessor, particularly conducting on-site assessments as required by regulation.

4.3.1.3 Attends conferences and training sessions as necessary.

4.3.1.4 Serves as liaison between LELAP and the regulated industry.

4.3.1.5 Maintains an active role in work groups and committees of TNI and other various governmental and industrial organizations.

4.3.1.6 Maintains a list of the qualified assessors and technical support personnel with areas of responsibility, education, and experience.

4.3.1.7 Prepares the quality assurance plan.

4.3.1.8 Ensures conformance with the LELAP Quality Assurance Plan and the Department's Quality Management Plan.

4.3.1.9 Plans and schedules internal audits according to SOP # 1785 (see Section 26.0). Internal audits may be conducted by other designated LDEQ staff.

4.3.1.10 Approves responses to corrective action plans submitted by the assessors.

4.3.1.11 Serves as point of contact between LELAP and its external contractor(s) to ensure a clear understanding of the factors associated with the scope of the contract.

4.3.1.12 Works with the contractor(s) if assigned for onsite assessments and any requested additional tasks.

4.3.1.13 Supervises the finances of the program.

4.3.2 The Supervisor formally approves assessment team leaders in collaboration with the assessors and shall ensure that 1) the expertise brought to each assignment is appropriate, that is:

- The team shall have appropriate knowledge of the specific scope for which accreditation is sought, and
- The team shall have understanding sufficient to make a reliable assessment of the competence of the laboratory to operate within its scope of accreditation.

The supervisor shall also ensure that an adequate number of Assessors are assigned to complete an assessment within a reasonable period of time. A reasonable period of time shall be considered 1-2 days for small laboratories and 2-4 days for large laboratories. The actual length of the assessment will be determined by the on-site assessment. If an assessment must be lengthened due to any circumstances the Supervisor and/or his designee must be notified by telephone as soon as the Assessor is aware of the need to extend the assessment. The Supervisor will obtain verification from the laboratory representative that the Assessor has requested an extension of the assessment and the laboratory representative is aware that additional costs may be added to the assessment invoice.

4.4 Assessor

4.4.1 LELAP is responsible for the accreditation of laboratories per LAC, Title 33, Part I, Subpart 3. Personnel are responsible for discharging their duties in accordance with the Department's QMP, the QAP, applicable Standard Operating Procedures (SOPs), and the Department's policies and procedures. All regulations must follow promulgation procedures outlined by the Administrative Procedures Act (APA).

4.4.2 The Assessor is responsible for implementing the accreditation process of the individual laboratories assigned. The Assessor reports to the Supervisor. The Assessor performs the following tasks:

4.4.2.1 Reviews assigned laboratories applications in accordance with SOP # 1792; corrective action documents in accordance with SOP # 1788; proficiency test results in accordance with SOP #1786; accreditation programs of other states and recognition accreditation packages in accordance with SOP # 1790 (see Section 26.0).

4.4.2.2 Conducts the on-site assessments notifying the laboratory of deficiencies as required by regulation and drafts assessment reports in accordance with SOP # 1787 ([see Section 26.0](#)).

4.4.2.3 Monitors the assigned laboratory's compliance with regulations.

4.4.2.4 Recommends assigned laboratories for accreditation based on compliance with all regulations in accordance with SOP # 1790.

4.4.2.5 Develops and maintains lines of communication and a working relationship between LELAP and assigned laboratories in the program.

4.4.2.6 Maintains the database current for assigned laboratories.

4.4.2.7 Ensures that the Supervisor is aware of his/her day-to-day activities.

4.4.2.8 Attends conferences and training sessions as necessary.

4.4.2.9 Provides information on accredited laboratories, proficiency test requirements, Department approved methods, and any other information in response to public inquiries consistent with the Department's policies and procedure governing the release of information.

4.4.2.10 Ensures that the LELAP website is maintained with current information and that the status of laboratories having applied for accreditation is correct and current.

4.4.2.11 Notifies the Financial Services Division (FSD) on all invoices required for LELAP. Reviews fee payment status of assigned laboratories.

4.4.2.12 Works with the contractor(s) if assigned for onsite assessments and any requested additional tasks.

4.4.3 Assessors assigned as Lead Assessor shall have the following additional responsibilities:

4.4.3.1 Issues the notification letter to the laboratory;

- 4.4.3.2 Plans the assessment;
- 4.4.3.3 Directs the assessment team;
- 4.4.3.4 Obtains copies of all forms required for the assessment;
- 4.4.3.5 Provides information to the laboratory on how to obtain information;
- 4.4.3.6 Notifies the Supervisor if the assessment team is denied entry;
- 4.4.3.7 Handles all business information marked "confidential" as described in LAC 33:1.503 and LAC 33:1.505;
- 4.4.3.8 Documents the laboratory's exceptions to any findings in the assessment report;
- 4.4.3.9 Assures that the results within the assessment report conform to the established standards for the evaluated parameters; and
- 4.4.3.10 Compiles, edits, and submits the assessment report.

4.4.4 Assessors who encounter questionable laboratory practices shall call the Supervisor and/or his/her designee. The Supervisor shall assess the information. The Supervisor and/or his/her designee will direct the assessor on the procedure to follow (close assessment and leave laboratory, or continue the assessment with additional directions). If the supervisor feels that it is appropriate to end the assessment prior to completion, approval must be authorized by the ES Manager and/or the Administrator.

4.4.5 The Assessor is responsible for the following administrative tasks:

- Assist in data entry for the LELAP database.
- Creates and maintains the LELAP files.
- Logs the receipt of all records and documents from applicants into the database.
- Tracks all assessment reports, corrective actions, and other official documents required by regulations.
- Assists with mail and phone duties, as necessary.
- If a new facility is accredited subsequent to annual invoicing, a separate request will be made to FSD for invoicing.

4.4.6 The clerical staff will provide the following activities:

- Date stamps and directs incoming mail as necessary.
- Assists with copying, mail, submitting documents to Electronic Document Management System (EDMS), and receipt, verification and documentation of fee payments.

5.0 CONFLICT OF INTEREST CERTIFICATION

5.1 Department management, staff and contractors functioning as LELAP assessors and technical experts assisting with an assessment shall be required to sign a Compliance Commitment Certification with a provision for Conflict of Interest (See Section 26.0), or the staff's individual training file, and printed prior to assessing or auditing any laboratory applying for accreditation. Any assessor unable to sign a Compliance Commitment Certification with regard to a particular applicant laboratory shall be ineligible to conduct an assessment at that laboratory, review documents submitted by the applicant laboratory, etc.

5.2 In the event an Assessor is unable to sign the Compliance Commitment Certification, the Supervisor shall re-assign the applicant laboratory to another Assessor.

5.3 Additionally, LELAP personnel are governed by the State of Louisiana's Code of Ethics (see Section 26.0). Violations of this Code of Ethics may lead to termination, fines and/or imprisonment. Department or contract personnel who offer consultation or perform testing are allowed to perform services for LELAP only if they operate under separate management, do not participate in accreditation decisions, cannot influence the outcome of an assessment for accreditation, and use a distinctly different name, logo, and/or symbols. The Supervisor of the program, with the participation of interested parties, shall be responsible for identifying, analyzing, and documenting the relationships with all Department or contract personnel.

5.4 Conflict of Interest issues that arise shall be handled by the Supervisor of the program and shall follow the requirements of the Louisiana Code of Ethics.

5.5 If the assessors or laboratory personnel become aware of previously unforeseen conflicts of interest, the lead assessor shall consult with the Supervisor, as soon as practicable, i.e., able to put into effect, to determine how to proceed. The Supervisor shall take action to ensure that the assessment can proceed without compromising its integrity and impartiality or shall request that the assessment team terminate the assessment. If it is necessary to appoint a new assessment team, the Supervisor shall appoint it as soon as practicable without jeopardizing the laboratory's request for accreditation.

6.0 PERSONNEL QUALIFICATIONS

LELAP personnel shall be qualified to perform assigned tasks. Initial and ongoing personnel qualifications shall be determined, training needs shall be identified, access to appropriate training opportunities shall be provided, and the acquisition of needed knowledge and skill shall be verified by the Supervisor.

7.0 GENERAL PERSONNEL QUALIFICATIONS

7.1 Requirements are determined on job class and position specific bases. Personnel qualifications for job classes are determined by the Human Resources Division and must be approved by the Louisiana Department of State Civil Service. The Human Resources Division shall maintain documentation concerning individual employee qualifications. LDEQ's personnel procedures are located in LDEQ's Policy and Procedures Manual.

7.1.1 Qualifications for Assessors

Qualifications for the LELAP employees and contractors shall meet the requirements of the LAC 33:I.4709.B and the standards most recently adopted by TNI. These qualifications include, but are not limited to:

- Assessors must be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;
- Assessors must have a thorough knowledge of the relevant assessment methods and assessment documents;
- Assessors must be thoroughly familiar with the various forms of records described in TNI V1M2 4.13—Control of Records and TNI V2M3 6.4 – Document and Records Review, which may be found in the LELAP shared folder ([See Section 26.0](#)).
- Assessors must be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;
- Assessors must have a working knowledge and be conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures; and
- Assessors must be able to communicate effectively, both orally and in writing.
- Assessors must have appropriate personal attributes.

7.1.2 Documentation of Qualifications for Assessors

7.1.2.1 The LDEQ Student Center maintains records on all training conducted through the LDEQ and State training office ([See Section 26.0](#)).

7.1.2.2 The Supervisor shall be responsible for documenting and maintaining training records for all LELAP personnel and contract personnel. A file containing copies of training certificates, LELAP training log, and signed Compliance Commitment Certifications will be maintained for each LELAP staff member along with the following information:

- Name and Address
- Position held
- Educational qualifications and professional status
- Work experience
- Training in management systems, assessment, and conformity assessment activities
- Competence for specific assessment tasks
- Experience in assessment and results of their regular monitoring

Training records of Assessors will be located in the office of the Supervisor. The Manager maintains a copy of training files for the Supervisor. The Supervisor will update training records as soon as training has been completed by each of the staff. The Compliance Commitment Certifications shall be provided to the laboratories upon request.

7.1.2.3 Documentation of qualification of LELAP contractors shall be part of the signed contract. A copy of the original Request for Proposals and the signed contract shall be maintained by the Office of Management and Finance, Contracts and Grants. Additionally, a copy of the signed contract shall be maintained by the Supervisor of the program.

7.1.2.4 The LELAP Supervisor shall maintain a record of the position held by contractor assessors and experts in their own organization.

7.1.3 Position/ Job Descriptions

Job descriptions must be prepared for each LDEQ position. The job descriptions shall specify essential job functions, the level of effort devoted to the job functions, physical and environmental demands and hazards, and job-related knowledge and skills. Personnel evaluations and Performance Planning and Reviews (PPRs) shall be conducted annually by immediate supervisors following the procedures established for PPRs in Chapter 10 of the Louisiana Civil Service Rules located at: <http://www.civilservice.louisiana.gov/CSRules/Chapter10.aspx>. Human Resources shall maintain job descriptions and official personnel ratings. The Notifications and Accreditations Section, Permit Support Services Division shall maintain performance-planning documents. The Supervisor shall also maintain records of the staff job descriptions.

7.1.4 Performance Planning and Review (PPR)

7.1.4.1 The Supervisor and/or his designee shall be responsible for completing the State required PPR for each LELAP employee. The Louisiana State Employees Performance Planning and Review (PPR) form, is located at: <http://www.civilservice.louisiana.gov/Divisions/EmployeeRelations/pes.aspx>, and is used by the Supervisor or his designee to establish performance expectations or criteria for each employee specific to the type of work or tasks performed by the Assessor and support personnel. The Supervisor and/or his designee documents the performance requirements for LELAP personnel on the PPR form.

7.1.4.2 The planning session of the PPR is conducted with the LELAP employee annually. This ensures that all parties are knowledgeable of their areas of responsibility for the coming rating period. The employee is given a copy of the planning document to review and sign. The Supervisor rates the employee's performance using the PPR. The Supervisor shall conduct monitoring to evaluate an assessor's performance and to recommend appropriate follow up actions to improve performance. Each assessor shall be observed on-site regularly, normally every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently.

7.1.4.3 The Human Resources Division maintains official copies of employee evaluations, and the Supervisor maintains a copy in each staff members' personnel file.

7.1.5 Standards of Professional Conduct

Assessors performing NELAP assessments shall:

- have no interest at play other than that of LELAP and NELAP during the entire accreditation process;
- act impartially and not give preferential treatment to any organization or individual;
- provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, or disability;
- not use their position for private gain;
- not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative, or any other affected individual or organization doing with business with, or affected by, the actions of the assessor's employer or LELAP;
- not hold financial interests that conflict with the conscientious performance of their duties;

- not engage in financial transactions using information gained through their positions as assessors to further any private interest;
- not engage in employment activities (seeking or negotiating for employment) or attempt to arrange contractual agreements with a laboratory that would conflict with their duties and responsibilities as an assessor;
- not knowingly make unauthorized commitments or promises of any kind purporting to bind LELAP; and
- attempt to avoid any actions that could create even the appearance that they are violating any of the standards of professional conduct outlined in this section.

8.0 TRAINING

8.1 To be formally approved, Assessors shall be experienced professionals with at least a Bachelor's degree in a basic science and have experience in laboratory assessment or related fields as required in LAC 33:1.4709.B. New candidate Assessors must obtain passing scores for the NELAP basic training course and technical training course(s) written examination and undergo training with a qualified Assessor during two actual assessments if there is no previous documented assessment experience, or one actual assessment if there is previous documented assessment experience. The qualified assessor shall document his/her conclusions for the Supervisor. Additional shadow assessments may be required of the new candidate assessor until he/she is judged proficient by the Supervisor. All Assessor-training programs must meet TNI standards and the Assessors will participate in at a minimum, a basic and technical training course deemed acceptable by TNI or the LELAP.

8.2 The assessor training program must include completion of the applicable technical training requirements for each field of accreditation. The LELAP Supervisor shall identify the specific fields of accreditation for which each assessor and expert has demonstrated competence to assess. Assessors must take annual refresher/update training as defined in the TNI standards.

8.3 Training needs shall be determined annually on an individual basis by supervisors in consultation with employees. Training determinations shall be based on statutory requirements, management directives, career ladder requirements, SOPs, QAPs and annual employee performance evaluations. Training needs should be documented in the PPRs.

8.4 The LDEQ Student Center maintains employee-training records for all state-required training conducted through the LDEQ. The Supervisor maintains training records for Assessors. The Manager maintains training records for the Supervisor. LELAP-required technical training is maintained in an excel database (See Section 26.0).

9.0 CONSULTATION

LELAP personnel or its contractors shall not offer consultancy or any other services that would compromise the objectivity or impartiality of the accreditation process and decisions.

10.0 QUALITY ASSURANCE ORGANIZATION

10.1 LDEQ utilizes an agency-wide QMP and relies on the individual offices, divisions and programs to implement their respective quality assurance program plans. Each person in LELAP is responsible for conducting his/her functions in accordance with the Department's QMP and program's QAP.

10.2 The quality assurance staff shall have access to all work areas and sufficient authority to identify, initiate, recommend and provide solutions to quality issues and to verify the implementation of solutions to these issues through corrective action. All LELAP personnel, contractors and interested parties shall report opportunities to eliminate the causes of potential non-conformities during management reviews, internal audits or meetings with the Supervisor. The report shall identify the potential non-conformities and their causes. The Supervisor shall determine and implement preventative action(s) needed and record the results of the action(s) taken. A review of the effectiveness of the preventative action(s) taken shall be included in the internal audit report.

10.3 Quality assurance activities are typically some form of audit or review by designated LDEQ staff other than those who perform the activity to be audited or reviewed. If the audit or review reveals deficiencies in the process, a timeline must be established for corrective actions to be completed and the process to be back within the parameters established by the SOPs.

10.4 COMMUNICATION

Management is responsible for the LELAP quality system being understood and effectively implemented through planning activities, employee training, ongoing assessments, and quality improvement activities to interested parties. These activities, programs, and controls are described in either the Department QMP or this QAP.

10.5 CORRECTIVE ACTION

10.5.1 LELAP staff shall report any non-compliance issues by initiating a corrective action form. In the event of nonconformance with the QAP or QMP, the LELAP staff will notify the Supervisor of the nonconformance to safeguard the program's objectives.

10.5.2 The Supervisor shall approve proposed corrective actions, verify that the corrective actions have been completed, and document that the program is in compliance with the QAP or QMP.

10.6 MANAGEMENT REVIEW AND INTERNAL AUDIT REPORT

10.6.1 The designated LDEQ staff provides management with reports concerning the effectiveness of the quality system, existing non-conformities, and the adequacy of resources. Internal audits shall take into consideration the importance of processes and areas to be audited, as well as the results of previous audits.

10.6.2 The designated LDEQ staff shall follow the requirements established in SOP #1785_r04 to conduct internal audits. Reviews of the quality system shall be conducted annually using the most current TNI technical review checklist found in [The NELAC Institute \(TNI\)](#) webpage. Reports will be generated by the designated LDEQ staff and submitted to the Supervisor. The Supervisor shall evaluate the need for actions to ensure that the non-conformities do not recur. Responses to the reports shall identify the cause of non-conformances and shall include corrective actions within a certain time frame. The corrective actions shall be designed with the purpose of preventing recurrence of non-conformity to requirements. A follow-up quality systems internal audit shall be conducted 6 months after completion of all corrective actions. The Supervisor shall inform personnel who are responsible for the area audited of the outcome of the audit.

10.7 RESOURCES

Management must ensure that resources are adequate to achieve and maintain quality in the program. Resource allocations for quality assurance and quality control activities and personnel shall be determined on an annual basis and adjustments made as necessary to achieve program objectives.

10.8 IMPLEMENTATION

Implementation shall be conducted as noted in Section 4.4.1 of this QAP. SOPs shall be developed, reviewed annually and revised as needed under the supervision of the Supervisor.

10.9 CONTRACTORS

10.9.1 LELAP shall monitor its contractor's performance as described in Section 7.1.4.2. The contractor's performance will be monitored in accordance with the requirements of the Louisiana Division of Administration. The LELAP Supervisor shall be responsible for ensuring that the contractor meets the requirements as set forth in the regulations, the Department QMP, and the LELAP QAP and SOPs. In addition the Contractor shall meet the requirements set forth in the most recently adopted TNI Standards.

10.9.2 Contractors shall be governed by the same ethical requirements as the LELAP employees and shall not provide contractual services to applicant laboratories.

10.9.3 Contractors shall submit a signed Compliance Commitment Certification. A copy of this document shall be maintained in the Contractor's file maintained by the LELAP Supervisor. The certification shall be provided to the laboratory upon request.

10.9.4 Reserved.

11.0 DOCUMENTS AND RECORDS

11.1 A document is any volume that contains information that describes, defines, specifies reports, certifies, requires, or provides data, results or information pertaining to the program. All records and documents are considered public record and as such shall be available to the public during working hours. Documents that specify requirements and instructions affecting the quality of the program shall be formulated by committees or persons possessing the necessary competence, and where appropriate, with participation by interested parties; the documents shall be adequate for the intended purpose and shall be controlled. Quality assurance records shall be produced, controlled and maintained to reflect the achievement of the required quality and to fulfill statutory, regulatory, and contractual requirements.

11.2 Document control procedures are specified in the QMP, Section 5 and referenced therein. Relevant versions of applicable documents shall be made available by the Supervisor to personnel, contractors, and interested parties at points of use. The Supervisor is responsible for ensuring that the documents are and remain legible and readily identifiable.

11.3 Record Retention and Location

Records and documents will be maintained based on the following:

11.3.1 All current records are submitted to EDMS except assessment reports, corrective action plans, and responses to corrective action plans (CAPs) where the CAP is not approved, in accordance with TNI standards.

11.3.2 If a request is made for the above noted documents as part of a public records request, the request shall be fulfilled, in accordance with LDEQ staff attorneys review of such requests.

11.3.3 All original documents will be maintained a minimum of 10 years before destruction or disposal.

11.3.4 Electronic files may be included as records and documents.

11.3.5 Other records such as checks or other original fee documents are submitted to the FSD.

11.4 Records/ Files

11.4.1 A record is any document related to a specific laboratory or facility however named.

11.4.2 All records shall be identified with the appropriate laboratory name and identification numbers. There are two identification numbers, the agency interest number and the internal LELAP number. The agency interest number is assigned using the Tools for Environmental Management and Protection Organizations (TEMPO) database by the TEMPO Master File group. TEMPO is the Department's centralized database. The Supervisor assigns the internal LELAP numbers in ascending order when needed. Newly accredited facilities will receive a new internal LELAP number. Re-accredited facilities will receive the previously assigned LELAP number to ensure historical continuity of the record.

11.4.3 Documents not pertaining to a specific laboratory having applied for accreditation shall be maintained in a general document file in EDMS or the LELAP group's cubicle area.

11.4.4 All contracts and records pertaining to contracts shall be maintained in the centralized file area within the LELAP section of the Public Participation and Permit Support Division.

11.5 Records Review

LELAP personnel shall be responsible for reviewing the accreditation process and the documents submitted by the applicant laboratories.

11.6 Receipt of Electronic Documents

LELAP will accept and respond to electronic transmissions and hard copy of documents submitted by facilities. Electronic transmission of documents will be received for the purpose of deadline compliance. All unsigned electronic copies must be followed by hard copies.

12.0 QUALITY ASSURANCE PLAN

The Supervisor shall be responsible to ensure that QAP is reviewed annually to ensure that this document remains accurate and current.

13.0 TNI STANDARDS

13.1 LELAP personnel shall meet regularly and at a minimum of twice a year to discuss the accreditation process. Sign-In sheets will be provided at all LELAP meetings and must be signed by all attendees. This may include staff from within the Department as well as contractors, members of TNI, representatives of other accreditation bodies and government agencies and anyone else who is capable of providing expert advice on matters of accreditation. The Supervisor shall keep records of all meetings. These meetings will be conducted after the LELAP representatives return from the TNI annual and interim meetings.

13.2 Assessors shall be responsible for reviewing proposed and finalized updates to the TNI Standards as they become available. LELAP will amend its regulations or adopt new regulations as necessary when TNI publishes revised Standards, when the Program must extend its activities or when the program responds to the needs of interested parties. All applicable requirements of the standard shall be addressed in the QAP or in associated documents.

13.2.1 Regulatory changes will follow the Louisiana Department of Environmental Quality's procedures for adopting or amending regulations, LDEQ PPM 0003-88, revised May 20, 2005, Rule Development Procedures. The process for adopting revised Standards shall begin within six (6) months of the revisions becoming final.

13.2.2 The procedure for expanding the accreditation offerings of LELAP includes the following:

13.2.2.1 The Supervisor will analyze the present competence of the program, the suitability of the expansion, and the resources available to commit to the expansion.

13.2.2.2 The Supervisor will determine the timing of the request for the expansion of the accreditation offerings, including the submission of an application for recognition by the NELAP Accreditation Council.

13.2.2.3. The Supervisor will recommend the selection of assessors and ensure that the assessors are trained for the assessment of the new technologies, methods, or analytes.

13.3 Accreditation Process Committees

13.3.1 The appointment, terms of reference, and operation of committees that are involved in the accreditation process shall be governed by the following rules:

13.3.1.1 Committee membership shall be recommended by the Supervisor and approved by the Manager

13.3.1.2 The committee shall have the following terms of reference (charter)

13.3.1.2.1 identification of what has to be achieved

13.3.1.2.2 identification of who will be involved

13.3.1.2.3 description of how it will be achieved

13.3.1.2.4 statement of when it will be achieved.

13.3.1.3 The identification of committee members shall be documented in meeting minutes which will be maintained by the Supervisor

14.0 APPLICANT LABORATORY DOCUMENTS AND RECORDS

The Supervisor shall assign an Assessor to each applicant laboratory. The Assessor shall be responsible for reviewing all documents and records for the applicant laboratories in accordance with the most recent revision of SOP #1790, SOP #1791, and SOP # 1792. Review of records shall be documented through the use of the Application Review Checklist, Application Evaluation form and correspondence generated between the applicant laboratories and LELAP.

15.0 STANDARD OPERATING PROCEDURES

15.1 Standard operating procedures are developed reviewed, and revised by LELAP personnel. SOPs are reviewed by the Notifications and Accreditations Manager and approved by the PSSD Administrator. All SOPs shall be reviewed every two years and revised as necessary under the supervision of the Supervisor. The SOP review must be documented. New SOPs and revisions to existing SOPs will be uniquely identified in the document control format.

15.2 All SOPs must be clearly worded. Procedures must be written in a step-by-step format that clearly describes the steps in chronological order. SOPs will be written using EPA QA/G-6 "Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents" ([See Section 26.0](#)) and the Department's "LDEQ SOP template and the standard operating procedure for the Development and Control of LDEQ Standard Operating Procedures (SOPs)" (See Section 26.0).

15.3 The PPPSD has an official site for SOPs ([See Section 26.0](#)).

15.4 SOPs for the program shall be drafted in accordance with the Department's requirements found in "Development and Control of LDEQ Standard Operating Procedures (SOPs)". Each SOP shall remain intact and will not lose its identity concerning SOP owner, purpose, approval, revision number, etc.

15.5 All SOPs written, revised and approved for the use of LELAP must contain the following disclaimer on the title page as required by the Department's "LDEQ SOP template":

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.

16.0 IMPLEMENTATION SCHEDULE

16.1 SOPs must be reviewed and revised biennially, or as necessary to document significant changes.

16.2 SOPs must be implemented as soon as approval has been given by the Administrator. All required signatures must be present on the approval page and posted on the LDEQ intranet site before a new or revised SOP will be put into use by LELAP.

17.0 COMPUTER HARDWARE AND SOFTWARE

The acquisition and installation of computer hardware and software shall be controlled to ensure conformance with standards and compatibility with existing and planned network, hardware, and software. The Office of Management and Finance sets standards and the Information Services Division approves acquisitions and performs installations. Purchase of hardware and software is described in detail in Section 6 of the Department's QMP.

18.0 DATA AND INFORMATION

LDEQ backs up all data per the requirements established in the Department's QMP. LELAP shall also make the following information available on its webpage:

- Suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided
- International arrangements in which LELAP is involved
- Notice of the possibility of assessments performed in response to complaints and changes reported by the accredited facility.

19.0 IMPLEMENTATION OF WORK

LELAP shall perform so as to ensure the needs and requirements of the program are met. All work products will be produced in a timely manner. Contract work performed on behalf of LELAP shall be implemented in accordance with the approved contract or plan. Exceptions, deviations, and changes to these documents shall be approved and documented prior to implementation.

20.0 PURCHASING

Purchasing for LELAP shall follow the Department's Purchasing Policy and Procedure (PPM 2003-88, see Section 26.0).

21.0 CONTRACT SERVICES

21.1 In support of the laboratory accreditation program, LELAP may use the professional services of private-sector laboratory assessors. Independent contractors shall be bound to the requirements specified in their contract; the Department's QMP, Section 4; the LELAP QAP; and the LAC, Title 33, Part I, Subpart 3. LELAP contractors shall be considered employees of the State of Louisiana and as such governed by state regulations.

21.2 The contract shall specify the tasks and products, technical requirements, quality requirements, administrative requirements, deliverables, methods used to measure and monitor the contract performance and any other requirements as specified in the contract.

21.3 LELAP Contractors shall be required to meet all requirements of TNI for On-Site Assessment Human Resources as found in the 2009 TNI Standards ([See Section 26.0](#)). LELAP contractors shall be experienced personnel with at least a bachelor's degree in a scientific discipline or have equivalent experience in environmental laboratory assessment. LELAP contractors shall complete the training for assessing quality systems, and when available they will complete the TNI specified technical training. New LELAP contractors with no documented assessment experience shall participate in two assessments under the direction of a lead assessor prior to performing assessments unassisted or as lead assessors. New LELAP contractors with previous documented assessment experience shall participate in one assessment under the direction of a lead assessor prior to performing assessments unassisted as lead assessors. The lead assessor shall document his/her conclusions for the LELAP contractor. The LELAP contractor shall use the lead assessor's conclusion to determine if an assessor candidate may perform unsupervised assessments or if additional unsupervised assessments beyond the minimum specified in the TNI standard are required to qualify the candidate assessor. All contractor training must be documented; the LELAP Supervisor shall maintain a copy of all contractor training. In addition LELAP contractors must:

21.3.1 be familiar with the relevant legal regulations, accreditation procedures, accreditation requirements and appropriate TNI Standards;

21.3.2 have a thorough knowledge of the relevant assessment methods and assessment documents;

21.3.3 be thoroughly familiar with the forms of records;

21.3.4 be thoroughly cognizant of data reporting, data analysis, and reduction techniques and procedures;

21.3.5 have a working knowledge and be conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures; and,

21.3.6 be able to communicate effectively, both orally and in writing.

21.4 LELAP contractors shall use the department-approved checklists and report format for all on-site assessments conducted on behalf of the Department. The report format shall meet the requirements of LELAP SOP # 1787.

21.5 LELAP shall take full responsibility for contracted work. The Program will ensure that its contractor(s) are competent and comply with the requirements of the Louisiana Laboratory Accreditation regulations and TNI Standards. The LELAP contractor shall comply with the Department's requirements for confidentiality and shall not act or be directly involved with any laboratory seeking accreditation. LELAP must approve the use of subcontractors by the contractor.

21.6 LELAP contractors shall be governed by the State of Louisiana's Code of Ethics. Violations of this code of Ethics may lead to termination of the contract, fines and/or imprisonment. Signed Compliance Commitment Certifications shall be required of LELAP contractors and their staff. These signed statements shall be filed in the Contractor's file maintained by the Supervisor of the program. Laboratories seeking initial or maintenance of accreditation shall have the right to exclude a LELAP contractor from the assessment team if the LELAP contractor has a conflict of interest.

21.7 LELAP contractors shall submit a Confidential Business Information Policy. A copy of this policy shall be maintained in the Contractor's file maintained by the Supervisor of the program.

22.0 COMPLAINTS/ RESOLUTIONS

22.1 LELAP shall decide on the validity of all complaints. LELAP shall document all complaints and respond in writing to the complainant within 20 working days, in accordance with the TNI standards. All complaints will be documented and investigated by the LELAP designee for the program. The LELAP designee shall ensure that complaints concerning an accredited laboratory are first addressed by the laboratory, as appropriate. A copy of any report derived from said complaints will be forwarded to the Supervisor. Actions taken by the laboratory or the program to address the complaint(s) shall be assessed by the LELAP designee and the Supervisor, respectively, for their effectiveness.

22.2 Documented complaints and resolutions to said complaints shall be filed in the appropriate file or a general complaint file. The LELAP designee shall maintain a record of all complaints and resolutions.

22.3 Laboratories shall be advised of the possibility of extra-ordinary assessments performed in response to complaints.

22.4 The laboratory shall be allowed to object to the appointment of any particular assessor or expert to a team conducting a routine assessment. LELAP will replace the assessor or expert if the laboratory's objection is based on demonstrable non-compliance with the TNI Standard. Both the objection and the subsequent action will be documented.

23.0 APPEALS

23.1 Notices of suspensions, discreditation or revocation of accreditation, or denial of an application will be effective upon approval and signature of the Assistant Secretary for the Office of Environmental Services.

23.2 Any laboratory that receives a notice of suspension or discreditation will have the right to an appeal in accordance with the Administrative Procedures Act. The laboratory must file a written request with the Secretary no later than thirty working days after receipt of the notice.

23.3 The request for appeal must specify the provisions of the notice on which the hearing is requested and briefly describe the basis for the request. Failure to timely request an appeal constitutes a waiver of the laboratory's right to an appeal on a disputed issue of material fact, and the notice of suspension or discreditation shall become final.

23.4 If the suspended laboratory is successful in correcting the cause(s) for suspension within six (6) months, it will not have to reapply for accreditation. If the suspended laboratory is not successful in correcting the cause(s) for suspension within six (6) months of the effective date of the suspension, the laboratory shall be discredited in part or in total.

23.5 If the discredited laboratory is not successful in correcting the deficiencies as required by the TNI standards, the laboratory must wait six (6) months before reapplying for accreditation.

24.0 NOTIFICATION OF CHANGES TO THE LELAP PROGRAM

24.1 LELAP shall notify the National Environmental Laboratory Accreditation Program (NELAP) Board of Directors and TNI Executive Director of any changes to the Program within thirty (30) calendar days of implementation.

24.2 The notification shall cover a change in organizational structure, rules, regulations, standard operating procedures, physical address, mailing address, telephone numbers, electronic mailing addresses, and contractual agreements.

25.0 USE OF ACCREDITATION BY LELAP AND NELAP ACCREDITED LABORATORIES

25.1 LAC 33:1.5313.A requires that work carried out by a laboratory must be covered by a report that accurately, clearly, and unambiguously presents the test results and all other relevant information. LELAP will require all accredited laboratories to include the LELAP certificate number on all laboratory reports and the agency interest number on all correspondence. The LELAP certificate number shall be placed in the upper right corner of all laboratory correspondence and results. Analytical results that are not certified by LELAP must be so indicated. LELAP will require the NELAP accredited laboratories to use the NELAP logo in conjunction with the LELAP certificate number.

25.2 LAC 33:1.5701 requires the laboratory to display the current certificate in a location visible to the public. In the case of suspension or discreditation, the laboratory shall remove the certificate and discontinue the use of all advertizing matter that contains any reference to an accredited status. Should a change in accreditation status occur, the Department will submit documentation to the certificate holder describing the change in status and also submit the documentation to EDMS.

25.3 LELAP shall initiate the process for discreditation or suspension of the accreditation status should a laboratory be identified as misrepresenting its accreditation certificate or making statements regarding its accreditation that LELAP may consider misleading or unauthorized. Assessors shall review client reports to ensure that the laboratory's accreditation status is accurately represented on the documents. Assessors shall verify that accreditation symbols are only used for premises of the laboratory that are specifically included on the accreditation documents. The Assessor shall document findings of misuse of accreditation. LELAP will proceed with discreditation or suspension if it is found that accreditation status has been misrepresented with incorrect references or that accreditation symbols have been misused in advertisements, catalogues and other literature.

26.0 REFERENCES

The Compliance Commitment Certificate may be found in the LELAP shared folder at: \\deqshares\lelap\QAPP and Attachments\Compliance Commitment Certification

The Department's organizational charts are located at: <\\deqshares\lelap\QAPP and Attachments\Organization charts>

The 2009 TNI standard is located at <\\deqshares\lelap\TNI\TNI standards>

Training records are located in the LELAP shared folder at: \\deqshares\LELAP\LELAP Technical Training File

The accreditation regulations are located at:

<http://www.deq.louisiana.gov/portal/DIVISIONS/LegalAffairs/RulesandRegulations/Title33.aspx>

The Department's Quality Management Plan is found at:

<http://intranet/sop/index/index.htm>

The LELAP standard operating procedures can be found at:

<http://intranet/sop/soplist.asp?showlist=True&qr1=3&OfficeType=OES&qr2=1&DivisionType=PSSD&UnitType=LELAP>

The Code of Ethics can be found at: <http://www.ethics.state.la.us/>

The Department's Policy and Procedure Manual is found at:

<http://intranet/ppms/ppmsnew.htm>

LDEQ Student Center Records can be found at: <http://intranet/human/training.htm>

The Department's PPM 0003-88 revised May 20, 2005 is located at:

<http://intranet/ppms/0003-88.pdf>

The EPA QA/G-6 "Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents is located at:

http://intranet/sop/index/EPAdocs/EPA_QA_G6.pdf

The Department's "LDEQ SOP template and standard operating procedure for the development and control of LDEQ Standard Operating Procedures (SOPs) is located at:

<http://intranet/sop/index/index.htm> and http://intranet/sop/shared/sop_1263_r03.pdf

The PPPSD official site for SOPs is located at

<http://intranet/sop/soplist.asp?showlist=True&qr1=3&OfficeType=OES&qr2=1&DivisionType=PSSD&qr3=2>

The Department's PPM 2003-88 is located at: <http://intranet/ppms/2003-88.pdf>, and the Department's QMP

Louisiana Department of Environmental Quality
Quality Management Plan

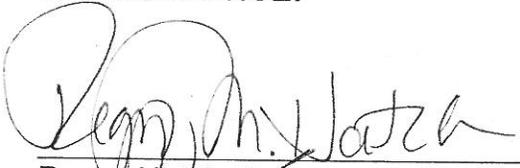
REVISION 9.0

July 9, 2014

APPROVAL PAGE

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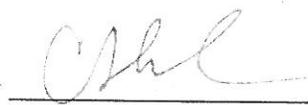
CONCURRENCE:


Peggy Hatch, Secretary, LDEQ

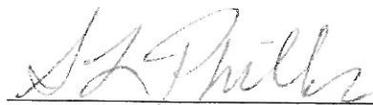
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Date


Vince Sagnibene, Undersecretary
Office of Management and Finance, LDEQ

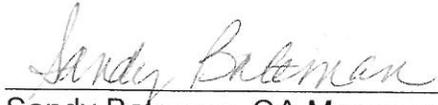
7-24-14
Date


Cheryl Nolan, Assistant Secretary
Office of Environmental Compliance, LDEQ

24 July 2014
Date


Sanford Phillips, Assistant Secretary
Office of Environmental Services, LDEQ

7/15/14
Date


Sandy Bateman, QA Manager, LDEQ

7/15/14
Date


Donald Johnson, QA Manager, USEPA Region 6

August 4, 2014
Date

EPA Q-TRAK No. 14-409

DOCUMENT REVIEW AND REVISION RECORD
 Note: Actions older than 5 years may be removed from this record

Date	Revision No.	Record of Activity
8/06/1998	0	Initial document approved.
1/25/2005	5	Address EPA comments by changes to Section 7.4, 8.0, 9.0 and Appendix A. Project planning checklists were added to Appendix E. Also, the approval page and Appendix B were updated for the organizational changes.
11/28/2007	6	Update and revision to address elimination of QA Officer positions and distributing their functions into all agency positions. Revised document outlines how all staffs are involved in the quality management system and how it will be implemented. Revised SOP review from 1 yr to 2 yrs. Updated signature page.
3/17/2011	7	Minor organizational changes to eliminate Office of Env. Assessment; updated signature page.
12/20/2011	8	Revised sections 1.3.10, 3.2.3, 8.2 and 8.3, updated org chart to reflect QA structure, updated signature page.
9/25/2012	8	Negative declaration
8/26/2013	8	QA Manager change; otherwise negative declaration
07/09/2014	9	Update and revision throughout to address organization changes; competency policy.

TABLE OF CONTENTS

CONCURRENCE: 2

INTRODUCTION..... 6

STATEMENT OF POLICY 6

QUALITY MANAGEMENT PLAN STRUCTURE 6

1.0 MANAGEMENT AND ORGANIZATION 7

 1.1 Applicability 7

 1.2 LDEQ Organization 7

 1.3 LDEQ Quality Responsibilities and Authorities 7

 1.3.1 LDEQ Secretary 8

 1.3.2 Executive Staff 8

 1.3.3 Quality Assurance (QA) Manager 8

 1.3.4 Administrators 8

 1.3.5 Managers and Supervisors 9

 1.3.6 Environmental Scientists Staff (DCL A) and Senior (DCL B) (“DCLs”) 9

 1.3.7 Project Managers 10

 1.3.8 Contract Managers 10

 1.3.9 All Employees 11

 1.3.10 Quality Assurance Team 11

2.0 QUALITY SYSTEM COMPONENTS 11

 2.1 Planning 12

 2.1.1 Quality Management Plan (QMP) 12

 2.1.2 Quality Assurance Project Plans (QAPPs) 12

 2.1.3 Sampling and Analysis Plans (SAPs) 12

 2.2 Implementation Tools and Practices 12

 2.3 Evaluation and Assessment Tools 13

3.0 PERSONNEL QUALIFICATIONS AND TRAINING 13

 3.1 Personnel Qualifications 13

 3.2 Training Program 13

 3.2.1 Agency Level Training 13

 3.2.2 Environmental Program Training 14

 3.2.3 Quality System Training 14

 3.3 Training Records 14

4.1 Authority and Procedures 15

4.2 Procurement and Contract Documents 16

4.3 Technical Requirements for Procurement and Contracts 16

4.4 Quality Requirements for Procurement and Contracts 16

4.5 Changes to Procurement and Contract Documents 17

4.6 Solicitation Responses and Supplier Selections 17

4.7 Acceptance of Items and Services 18

5.0 DOCUMENTS AND RECORDS 19

- 6.0 COMPUTER HARDWARE AND SOFTWARE 21
 - 6.1 Hardware 21
 - 6.2 Software 22
 - 6.3 Geographic Information System 22
 - 6.4 Data and Information 22
- 7.0 PLANNING 23
 - 7.1 Requirements 23
 - 7.2 Specifications 23
 - 7.3 Quality System Planning 23
 - 7.4 Project Planning 24
 - 7.4.1 Systematic Planning Process 24
 - 7.4.2 Preparation, Review, Approval, and Distribution of QAPPs 25
 - 7.5 Sampling and Analysis Plans (SAPs) 27
- 8.0 IMPLEMENTATION OF WORK PROCESSES 29
 - 8.1 Work Process Implementation Policy 29
 - 8.2 SOP Policy 30
 - 8.3 Preparation, Review, Approval, and Distribution of SOPs 31
- 9.0 ASSESSMENT AND RESPONSE 32
 - 9.1 Assessment Types 32
 - 9.1.1 Quality Systems Assessments (QSA) 33
 - 9.1.2 Technical Systems Audits (TSA) 33
 - 9.1.3 Data Quality Assessments (DQA) 33
 - 9.1.4 Performance Evaluation System (PES) 34
 - 9.2 Assessment Planning 34
 - 9.3 Assessment Implementation 35
 - 9.4 Suspension of Assessments 35
- 10.0 QUALITY IMPROVEMENT 35
 - 10.2 Quality System Improvement Process 36
 - 10.3 Quality System Communication 36
 - 10.4 Dispute Resolution Process 37

INTRODUCTION

This Quality Management Plan (QMP) describes a management system established by the department to ensure that the collection, analysis and quality of its environmental data is sufficient for its intended uses. The plan outlines the procedures to be used to generate quality data, the means to verify accuracy and completeness, and corrective action procedures to promote continual improvement. The plan conforms to EPA QA/R-2 – *EPA Requirements for Quality Management Plans* and is in support of the Quality Management Statement of Policy. The quality system is implemented in accordance with applicable federal and state laws and rules, standards, requirements documents, guidance documents, contractual requirements, and sound management practices.

STATEMENT OF POLICY

It is LDEQ's policy that data of the appropriate type and quality be used by the department in all of its environmental programs and decision making processes. All employees are responsible for adhering to this statement of policy and other policies and procedures stated in this document.

QUALITY MANAGEMENT PLAN STRUCTURE

The QMP contains 10 main sections organized to meet the provisions of the EPA QA/R-2 requirements document:

1. Management and Organization
2. Quality System Components
3. Personnel Qualifications and Training
4. Procurement of Items and Services
5. Documents and Records
6. Computer Hardware and Software
7. Planning
8. Implementation of Work Processes
9. Assessment and Response
10. Quality Improvement

1.0 MANAGEMENT AND ORGANIZATION

Quality in environmental programs contributes to protection, preservation and enhancement of the environment, public health and safety, economic development, efficient use of public funds and resources, technical credibility, and recognition of excellence. The QMP outlines the structure which employees will use to produce quality work products and services.

1.1 Applicability

Activities governed by this QMP include permits and enforcement, remediation, geology, engineering, environmental monitoring, technical and analytical support, inspections, and environmental assessments. Agency staff and external contractors are bound by the requirements in this QMP.

1.2 LDEQ Organization

The LDEQ is the primary state environmental regulatory agency. LDEQ operations are under the management of the Secretary, who is appointed by the Governor. The LDEQ consists of four offices: Office of the Secretary (OSEC) headed by the Secretary; Office of Management and Finance (OMF) headed by the Undersecretary; the Office of Environmental Compliance (OEC) and Office of Environmental Services (OES), each headed by an Assistant Secretary. These positions comprise the executive staff who ensure that the activities governed by this plan are carried out.

The executive staff assigns responsibility for environmental programs, projects and grants to the administrators who oversee agency operations within each office at the division level. Administrators ensure that the managers, supervisors, project managers, staff scientists and senior scientists (technical personnel known as DCLs) are aware of and perform their roles outlined in the quality system. A complete description of roles and responsibilities is found in Section 1.3.

The LDEQ quality system organization chart is presented on page 38.

1.3 LDEQ Quality Responsibilities and Authorities

All agency personnel are responsible for ensuring that work products and services within their areas of responsibility meet the needs and expectations of the customer by performing their duties in accordance with applicable plans and procedures and by implementing applicable elements of the quality system described in this plan.

Administrators, managers, supervisors, and other personnel review and respond to deficiencies, findings, or significant conditions related to their areas of responsibility. Individuals responsible for establishing or executing elements of the quality system may

delegate portions of the work but will retain responsibility for the accomplishment of such work.

The following positions have been assigned specific quality-related roles and responsibilities:

1.3.1 LDEQ Secretary

The Secretary is responsible for directing LDEQ programs and operations, including the quality system. The Secretary directs executive staff and reports to the Governor.

1.3.2 Executive Staff

Executive staff, consisting of the Deputy Secretary, Undersecretary, the Assistant Secretary for Environmental Compliance and the Assistant Secretary for Environmental Services, is responsible for ensuring that environmental programs produce the type and quality of results expected. Their role is to:

- Set goals for data quality in environmental programs
- Define authorities and responsibilities of Administrators and Managers
- Communicate to the organization the importance of meeting customer (internal and external), statutory, and regulatory requirements
- Ensure adequate resources (staff, equipment, and facilities) are available to accomplish quality goals and objectives
- Review and approve the quality improvement process

1.3.3 Quality Assurance (QA) Manager

The QA Manager, an Environmental Scientist Senior in the Office of Environmental Compliance, reports to the Secretary. The QA Manager oversees the planning, development and implementation of the quality system by:

- Coordinating with executive staff and administrators to set program quality goals and strategies
- Leading and providing guidance to quality representatives operating in each division
- Assuring the maintenance of quality plans and procedures
- Coordinating and overseeing independent internal and external assessments

1.3.4 Administrators

Administrators report to assistant secretaries, the deputy secretary or undersecretary and are responsible for:

- Oversight of planning, implementation, assessment, and improvement of

environmental programs in their respective divisions

- Ensuring that environmental programs and associated work activities performed within their divisions produce the type and quality of results expected
- Ensuring that quality policies and procedures are maintained
- Oversight of the development and/or implementation of training and certification programs within their divisions
- Assigning sufficient authority and independence to staff to allow them to plan, implement, assess and improve the environmental programs
- Notifying the QA Manager if requirements are developed for a program that are different than stated in the QMP

1.3.5 Managers and Supervisors

Managers report to administrators and supervisors report to managers; they are responsible for:

- Planning, implementation, assessment, and improvement of environmental programs in their respective sections/units
- Ensuring that permits and enforcement actions are produced and remediation activities, geological activities, engineering activities, technical and analytical support activities, inspections, and environmental assessments are conducted in accordance with applicable plans, procedures, and with state and federal requirements
- Ensuring that employee performance is measured against specifications and documented in employee performance evaluation system (PES) documents
- Maintaining a thorough knowledge of work activities, commitments, deliverables, and time lines in their sections/units
- Reviewing and approving or concurring with Standard Operating Procedures (SOPs) and work processes within the section/unit
- Assisting with environmental program assessment activities
- In the event deficiencies are found during assessments, recommending to their Administrator that work be stopped or redirected in order to safeguard program objectives, worker safety, public health, or environmental protection
- Developing and approving proposed corrective actions
- Monitoring the implementation of corrective actions
- Reporting on the status of corrective actions to Administrators and Environmental Scientist Seniors
- Ensuring corrective actions are carried out in a timely manner
- Ensuring staff is properly trained

1.3.6 Environmental Scientists Staff (DCL A) and Senior (DCL B) (“DCLs”)

The DCLs are the experts in their fields and report to supervisors, managers or administrators. They serve as the QA representatives/team leaders for a division and are responsible for:

- Assisting the administrators, managers and supervisors in the planning, development and implementation of procedures to ensure quality in environmental programs
- Assisting with and coordinating the development and documentation of SOPs and work instructions
- Performing routine independent reviews of data, documents and processes
- Participating in assessments and/or overseeing corrective action activities
- Serving as a divisional liaison for quality system activities, reporting quarterly to the QA Manager

1.3.7 Project Managers

Project managers (may also be known as Team Leaders) are assigned to this functional role by administrators and managers to manage environmental projects, including work performed by contractors, and are accountable for the successful completion of project-related tasks and objectives. Project managers could be any technical employee in the Civil Service professional series. Project managers are responsible for:

- Maintaining a thorough knowledge of work activities, commitments, deliverables, and time lines associated with projects
- Developing necessary lines of communication and good working relationships between division staff and personnel of other divisions and organizations participating in a project
- Ensuring that management and the LDEQ/OMF contract managers are informed of changes, revisions, or additions to the project
- Monitoring the effectiveness of the project
- Elevating quality issues requiring resolution to the manager or supervisor
- Assisting in preparing contracts and intergovernmental agreements
- Ensuring contractors understand their commitment to meet deadlines and scheduled commitments
- Enforcing corrective action measures when contractors do not meet deadlines and scheduled commitments

1.3.8 Contract Managers

Contract Managers in OMF provide fiscal and administrative oversight for all agency-generated contracts. Contract managers are responsible for:

- Assisting in preparing contracts and intergovernmental agreements
- Maintaining a thorough knowledge of commitments, deliverables, regulations, policies and time frames associated with contracts
- Developing necessary lines of communication and good working relationships between the agency staff and outside entities participating in a contract
- Reviewing and requiring revisions, as necessary, to administrative submittals

- Responding to contractor non-technical administrative needs and concerns on a timely basis
- Processing all invoices for review by the assigned Project Manager
- Ensuring Financial Services Division is informed of changes, revisions or additions to the contract
- Advising supervisory personnel when contract timetables, tasks and coordination procedures are not being met, as communicated by EPA or LDEQ contact persons

1.3.9 All Employees

Employees who generate permits and enforcement actions and/or participate/conduct remediation activities, geological activities, engineering activities, technical and analytical support, inspections, environmental monitoring, and environmental assessments are responsible for following applicable policies, plans and procedures, producing quality information and products, and recommending improvements to processes.

1.3.10 Quality Assurance Team

The QA Team is comprised of the QA Manager (QAM) and QA representatives from the divisions in the environmental offices, OEC and OES, appointed by managers and administrators. The QA Team is be available to answer questions and provide guidance concerning staff responsibilities, reports, and SOPs. Team members will assist the QA manager with the following tasks:

- Outline an annual QA plan at start of the grant year and produce a report at the end of the grant year that will be submitted to executive staff and EPA QA manager
- Coordinate a review of the quality system and QMP to ensure adequacy
- Assist with training and guidance to implement quality assurance and quality improvement in environmental work processes

The team will meet periodically to review progress of annual goals and consider improvements and strategies to accomplish them. Members will serve for a period of one or two years with staff rotations among the divisions staggered to assure continuity.

2.0 QUALITY SYSTEM COMPONENTS

LDEQ generates environmental data from compliance monitoring, ambient monitoring and assessment programs every year that is used to make decisions that affect human health and the environment. LDEQ receives information from regulated facilities that is also used in business processes (for example, permitting) and decision making.

Successful implementation of the quality system requires a consistent and graded approach to QA practices. The QA approach will be commensurate with the intended uses of the data and degree of confidence needed in the results. A variety of tools and practices and procedures are employed for planning, implementing, and evaluating the quality system.

2.1 Planning

This section describes the plans required to ensure environmental programs produce and use quality data.

2.1.1 Quality Management Plan (QMP)

This document describes the system, organization, policies, processes, documentation, communication and tools used to ensure that the quality of data created or received by LDEQ complies with its data policy. The QMP describes a dynamic system of processes that will be continuously improved and updated as programmatic practices and procedures change and evolve. It serves as the “umbrella” document for all QA operations, as well as a demonstration of competency for LDEQ as an agency. Revisions and updates to the QMP will be facilitated by the QA Manager working with management and technical staff for submission to EPA by August of each year.

2.1.2 Quality Assurance Project Plans (QAPPs)

QAPPs integrate all technical and quality aspects of a project, including planning, implementation, and assessment. The purpose of the QAPP is to document planning results for environmental data operations and to provide a project-specific “blueprint” for obtaining the type and quality of environmental data needed for a specific decision or use.

2.1.3 Sampling and Analysis Plans (SAPs)

SAPs document sampling and analytical procedures to be performed. SAPs are not necessary if these details are included in a QAPP. SAPs will describe all sampling activities by media and include information on number of samples, type of samples (environmental, duplicate, etc.), sampling locations, methodologies, and equipment, and sample preservation techniques, if applicable. They will describe what analyses are to be performed on each sample, including information such as EPA or other method reference number, detection limits, sample holding times, and any special analytical considerations.

2.2 Implementation Tools and Practices

The use of SOPs serves as the primary implementation tool to ensure comparability across programs and within individual environmental data collection projects. SOPs detail the work processes that are conducted or followed within the agency. SOPs also

provide objective tools to evaluate the process and an individual's performance.

2.3 Evaluation and Assessment Tools

Primary evaluation and assessment tools include: Technical Systems Audits (TSAs), Quality System Assessments (QSAs), Data Quality Assessments (DQAs), Internal Assessments (QC checks), and Performance Evaluation System (PES) reviews (See Section 9). TSAs and QSAs are coordinated by the QA Manager and QA representatives from the environmental offices. The QA Manager will also facilitate review processes as needed.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

LDEQ personnel performing work in environmental programs must be qualified to perform assigned work.

3.1 Personnel Qualifications

Qualifications are described in Civil Service job specifications that include specific education and experience requirements for each position title, for example, Environmental Scientist. The Human Resources Section evaluates existing individual employee education and experience and notifies the division when the employee meets the qualifying requirements to advance to the next level in the career ladder.

Management prepares job descriptions for each LDEQ position. LDEQ position descriptions specify technical expertise requirements. The job descriptions specify essential job functions, physical and environmental demands and hazards, and job-related knowledge, skills and experience.

3.2 Training Program

3.2.1 Agency Level Training

The OMF designs training programs based on formal assessments of agency, office, division, program, and job requirements (*Policy 4008-01 Training and Policy 4010-02 LDEQ Leadership Development Program*). Qualified instructors are identified on a course-by-course basis through resumes, interviews, proposals, and demonstrated competence.

Training needs are determined annually on an individual basis by supervisors in consultation with employees. Supervisors develop training plans that outline training requirements for employees. These are used in the annual Performance Evaluation System (PES) process to assess training status. Training needs are based on statutory requirements, management directives, policies and procedures and outlined in the employee's annual PES plan.

PES plans may address remedial training needed to correct deficiencies in performance, educational preparation, or professional experience and to address prerequisites for advancement and new or unique job requirements. Training topics may include technical, operational, non-technical, and managerial topics. Additional training needs may be specified in QAPPs.

3.2.2 Environmental Program Training

Managers and Supervisors train new employees regarding each employee's role related to the agency's environmental data projects. The Supervisors also review relevant policies and SOPs with employees. This ensures that all employees are aware of the relevance and importance of their activities and how they contribute to the data quality goals and objectives.

Management determines whether training programs and courses offered outside of LDEQ by educational institutions, professional associations, and other providers are available and useful. These programs and courses may include such activities as instructional courses, seminars, professional meetings, and workshops or on-site training by external organizations approved by management.

Mentors are experienced employees who are assigned to staff members to assist in their training. Mentors provide input to the Supervisor or Manager as to the competency level of the employee as the training progresses. Supervisors and Managers ensure appropriate training is received.

3.2.3 Quality System Training

Quality system training requirements for LDEQ personnel are as follows:

- All DEQ technical and managerial staff in the environmental programs will complete "An Overview of the LDEQ Quality System".
- DEQ technical staff in the environmental programs, specifically the DCLs and the supervisors who develop, implement and oversee quality project plans, will complete "An Overview of Quality Assurance Project Plans". The course is optional for other technical environmental staff (ES 2,3).
- Environmental staff (ES2 and above) assigned to serve as auditors of the QA system processes will also complete "Conducting Quality System Internal Audits".

The QA Manager will coordinate with the divisions to establish course schedules. Personnel will take either the DEQ quality courses or the EPA led training for the required courses. QA Manager will determine suitable equivalent training courses.

3.3 Training Records

The agency maintains employee training records for all training in LEO. Supervisors maintain training records of the staff they supervise.

4.0 PROCUREMENT OF ITEMS AND SERVICES

Two groups manage the procurement of items and services. The Procurement Section resides within another state agency - the Louisiana Department of Natural Resources (LDNR) - and handles purchase of items and facility-related support services, high-end technology and complex services. Professional, personal and consulting services are documented and managed through the Contracts and Grants Section of LDEQ to ensure compliance with requirements, i.e., that contracted activities produce results of acceptable quality (quality planning which includes contractor requirements described in Section 7.0). Requirements and specifications will be included or referenced in procurement and contract documents. The acceptability of purchased items and services will be verified with technical staff and documented. Analytical services may be handled by either section depending on whether the contract also involves professional services.

4.1 Authority and Procedures

Statutory requirements concerning procurement are managed by the Louisiana Office of State Purchasing and posted on their web site at <http://www.doa.louisiana.gov/osp/osp.htm>. It contains or provides links to current versions of the following:

- Louisiana Revised Statutes Titles 38, 39, and 43
- Purchasing Rules and Regulations and the LA Procurement Code
- Louisiana Revised Statutes Title 39:1593 C: Methods of Procurement
- Louisiana Revised Statutes Title 39:1481-1526 and Chapter 34 Part V: Procurement of Professional, Personal, Consulting and Social Services (Division of Administration Rules and Regulations)
- Procurement Handbook

Procurement procedures are in the *LDEQ Policy & Procedures Manual 2003-88 Purchasing*. These documents describe assignments of authority and procedures for planning and approving procurements, determining specifications and requirements to be included in procurement documents, selecting vendors, awarding procurements, and accepting purchased goods and services.

Statutory requirements concerning contracts are managed by the Louisiana Office of Contractual Review and posted on their web site at <http://www.doa.louisiana.gov/ocr/>. It contains or provides links to current versions of the following, as well as, Executive Orders and other pertinent contract information.

- LSA-R.S. 39:1481-1526 [Chapter 16. Professional, Personal, Consulting and Social Services Procurement, Part 1. General Provisions]
- Title 34, Part V, Louisiana Administrative Code [Government Contracts, Procurement, and Property Control, Part V., Procurement of Professional, Personal, Consulting and Social Services]

Other statutory requirements regarding contract procedures are provided in the *LDEQ Policy & Procedures Manual 5001-89, Contracts*, and are listed below. PPM 5001-89 describes assignments of authority, types of contract agreements, methods of source selection, and minimum statutory requirements for contract content and procedures for administration of contracts.

- LSA-R.S. 30:2206 [Contracting for Hazardous Waste Cleanup]
- LSA-R.S. 36:236 [Undersecretary: Functions: Office of Management and Finance]
- 40 CFR, Part 35, Subpart O [Cooperative Agreements and Superfund State Contracts for Superfund Response Actions]: §35:655- - §35:6610 [Procurement Requirements Under a Cooperative Agreement]
- 40 CFR, Part 31 (§31:36) [Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, Procurement]

4.2 Procurement and Contract Documents

Procurement documents include purchase orders, internal requisitions, invitations to bid, procurement contracts, justification for sole source or proprietary purchase forms, and scopes of service. These documents specify tasks and products, goals and objectives, technical requirements, quality requirements, administrative requirements, deliverables, methods used to measure and determine contract performance, a monitoring plan and other requirements. All procurements are approved prior to issuance. Approval requirements vary depending on the nature and cost of the goods or services being procured. As a matter of policy, maximum competition among potential bidders and contractors is encouraged.

Contract documents include request for proposals, request for emergency contracts, request for bids, contract request forms, non-competitive selection forms, contract certification forms, contract request for proposed contract and expenditures forms, and scopes of services/statements of work. These documents specify tasks, goals and objectives, technical requirements, quality requirements, administrative requirements, deliverables, methods used to measure and determine contract performance, monitoring plans and other requirements.

4.3 Technical Requirements for Procurement and Contracts

Technical requirements are determined by the program technical staff and incorporated into procurement documents. For contracts, technical requirements are incorporated in the Statement of Work or Scope of Services. Information Technology products and services are also reviewed and approved by the ES senior in OMF with technical expertise.

4.4 Quality Requirements for Procurement and Contracts

Quality requirements are determined by the program technical staff with assistance of Purchasing or Contracts staff, and documented in procurement and contract documents. These documents include or reference appropriate design bases, certifications, and other requirements necessary to assure adequate quality, and to the extent necessary, require suppliers and subcontractors to have quality programs consistent with the LDEQ program. Any certifications and or license required by statute, state law, or LDEQ regulations will be a requirement set forth in contract documents, the bid or negotiation process, i.e. Request For Proposals (RFP), Invitation to Bid (ITB), Solicitations. Evidence of such requirements must be provided prior to award. In competitive bid documents (RFP, ITB, Solicitations) requirements for sub-contractors (certifications, licenses, accreditations, etc.) will be identified and verification of such made prior to award.

For non-competitive negotiations, it shall be the responsibility of the negotiating unit within LDEQ to determine and verify the requirements for contractors and sub-contractors prior to issuance of the contract. In any event, state and federal laws, statutes and regulations with stated requirements will be adhered to.

Procurement documents may include pre- and post- award source inspections, supplier audits, evaluations of objective evidence of quality furnished by the supplier, acceptance testing, and other requirements determined to be appropriate.

For Personal, Professional, and Consulting contracts and contracts for high-end technology or complex services the monitoring plan in the contract ensures that the services and deliverables of the contract are fulfilled and that acceptable levels of service are provided. It is the Project Manager's responsibility to monitor the contractor's performance, including on-site visits, to assure compliance with the technical requirements of the contract.

4.5 Changes to Procurement and Contract Documents

Changes to procurement documents generally receive the same reviews and approvals as original procurement documents. Changes may be authorized only through written amendment or change order. Also, approval requirements for changes are determined on the basis of allowable cost changes within the realm of state statutes.

During the term of a contracting project, LDEQ may identify a need to change the contract term, price or Scope of Services. These changes may be effected only through a written amendment to the contract authorized by the Contractor and LDEQ, and approved by the Office of Contractual Review.

4.6 Solicitation Responses and Supplier Selections

Responses to solicitations are reviewed by Procurement and Contract personnel and personnel from the requesting unit who have technical expertise. Review ensures that the item or service being procured meets required specifications.

For all contracts resulting from a request for proposal process, a selection committee performs the technical review. The selection committee is composed of LDEQ technical personnel from the office/division requesting the solicitation and a member of the Contracts or Procurement staff. The selection committee will evaluate and rank all proposals according to the criteria listed in the solicitation. At a minimum, criteria will include technical approach, relevant experience of the company, qualifications of key personnel assigned to the project and the price.

The Financial Services Division within LDEQ performs the cost reviews for these proposals (*LDEQ Policy Manual 5001-89 Contracts*).

4.7 Acceptance of Items and Services

Items are received by receiving personnel in accordance with written LDEQ procedures (*Policy 2011-93 Central Receiving*) and in line with acceptable receiving practices as defined by state law. Items are inspected upon receipt for noticeable damages/defects and are evaluated against criteria contained in purchasing documents. Items not meeting written criteria or which show a noticeable defect are rejected for delivery and vendor/supplier immediately contacted. End users determine whether acceptance criteria have been met and whether items or services are adequate or appropriate for use.

Items and services which contain latent defects are also not accepted for use. Corrective actions are initiated in accordance with state statutes, contract provisions and LDEQ procurement procedures. Corrective actions may range from replacement of defective deliverables to re-award of purchases.

For contracts, LDEQ will monitor the contractor's work through telephone communications, meetings and review of Progress Reports. The Progress Report shall include a description of the progress made during the previous month for each activity, including problems experienced, requests of approved changes in personnel, and the effect of the problems/ changes on the due date of deliverables. For laboratory contracts, data deliverables may be used as evidence of contractor's tasks in lieu of Progress Reports. LDEQ will also review, require revision as necessary, and accept deliverables and submittals.

For contracts, if required by LDEQ, prior to payment, the contractor shall promptly, without additional cost to LDEQ, correct any deficient work performed by him. Deficient work is defined as work that is (a) unsatisfactory, faulty, or defective, or (b) does not conform to the requirements of the contract documents. If the contractor does not correct such deficient work within the time specified by LDEQ, LDEQ may have the deficiency corrected by a separate party. All costs to LDEQ for such correction shall be paid by the contractor. If corrections made to deficient work interfere with any other LDEQ work by other parties, the contractor shall also bear the expenses caused by that interference. Invoices are reviewed by the Contract Manager, approved by the Project

Manager and submitted to Fiscal Services for payment. The Performance Evaluation form is used to submit quality related information on contractors.

Vendors are on a list of registered suppliers. There is a state procedure to debar vendors for poor quality service or supplies. The Contractor Performance Evaluation form is used to submit quality related information on contractors.

5.0 DOCUMENTS AND RECORDS

Control of documents and records is necessary to ensure consistent implementation of processes thereby producing quality decisions, items, and services. This includes electronic as well as printed versions of documents and records.

Documents requiring control include anything pertaining to LDEQ environmental data processes and any associated requirements documents. Examples of documents requiring control may include, but are not limited to:

- State and federal laws
- State and federal regulations
- QA Documents
 - Planning documents such as
 - LDEQ Quality Management Plan (QMP)
 - Quality Assurance Project Plans (QAPPs)
 - Sampling and Analysis Plans (SAPs)
 - Process documents such as
 - Standard Operating Procedures (SOPs)
 - Policy and Procedure Manuals (PPMs)
- Work instructions
- Equipment Operations manuals
- Environmental data collection and generation forms

Records requiring control include items that may provide objective evidence of how processes were implemented and the quality of any resulting data and decisions. Examples of records requiring control may include, but are not limited to:

- Reports
- Completed forms
- Equipment calibration records
- Logbooks (instrument, field, etc.)
- Drawings
- Photographs
- Data
- Calculations
- Assessment results

Managers and Supervisors are responsible for ensuring documents and records

requiring control are identified, produced, revised as needed and maintained in accordance with state, agency or program-specific requirements, whichever is more stringent. LDEQ has agency-wide procedures in place for preparing, reviewing, approving and distributing the QMP, QAPPs and SOPs (see below). Additionally, the Permitting, Compliance and Enforcement programs use an Electronic Document Management System (EDMS) to control documents and records.

Control of QA documents is provided through use of a control header and Document Review and Revision Record page. Document control information appears in the header on the upper right corner or at the bottom of each page, including the title page.

EXAMPLE:

Short Title
File Name
Document Review or Revision Date (Month, Day and Year)
Page X of Y

The file name is used for posting QA documents to the LDEQ intranet. The file name must be in the following format of **qmp_xxxx_rxx**, **qapp_xxxx_rxx** or **sop_xxxx_rxx**, where "**qmp**" identifies the QMP, "**qapp**" identifies a quality assurance project plan and "**sop**" identifies a standard operating procedure; "**xxxx**" is the unique 4-digit file number that is assigned by designated staff (identified on the intranet SOP page) to each QAPP or SOP; and "**rxx**" is the revision number for the QAPP or SOP with "**r**" standing for revision and "**xx**" the 2-digit revision number. The original issue of a document is r00.

The Document Review and Revision Record is maintained within the document. This record provides historical information on the review with or without revision of the document. During the revision process, changes may be recorded and tracked. For minor revisions, the document owner briefly describes the change(s) and may reference the affected section(s). For major revisions, the document owner may state, "broad revisions throughout document".

The QA Manager and designated staff maintain the QMP, QAPPs and SOPs on the intranet with approval dates noted. These documents must be submitted by email to designated staff (see SOP Intranet Page for names) and include electronic versions of both the Word document and Adobe PDF (with scanned signature page). The submitter must identify in the email the applicable office(s), division(s) and section(s), or if it is agency-wide (those who must use the plan or SOP).

Obsolete versions of these documents will be retained on the intranet server for three years by the QA Manager (and those designees who assist with SOP posting) from the end of the project period, unless a longer retention period is required. The employee submitting the document for posting will notify the QA Manager if a longer retention schedule applies.

Any other documents requiring control, such as SAPs, forms, and work instructions are the responsibility of Managers and Supervisors who will ensure that the documents are

kept current and controlled. If it is determined that these documents need to be developed or revised, all affected parties must be involved in the process. Levels of review and approval are the same as for SOPs.

Records are items that furnish objective evidence of the quality of items or activities that have been produced or implemented. QA records may include chain-of-custody, photographs, drawings, forms, reports, and recorded data either paper, electronically, or other media. These records are identified in QAPPs and SOPs and handling procedures are specified.

Assignments of authority and procedures concerning the identification, verification, authentication, handling, retention, and disposition of documents and records needed to safeguard the legal and financial rights of the State of Louisiana and any person directly affected by activities of the LDEQ are contained in Title 44 of the Louisiana Statutes and identified in each of LDEQ's SOPs. Records produced by LDEQ and maintained as official records of the State of Louisiana are documented in the agency Records Retention Schedule.

6.0 COMPUTER HARDWARE AND SOFTWARE

The acquisition and installation of computer hardware and software will be controlled to ensure conformance with standards and compatibility with existing and planned network, hardware, and software. The Louisiana Division of Administration (DOA) sets standards, LDEQ approves acquisitions, and DOA's Office of Technical Support (OTS) performs installations. The Office of the Governor's Procurement Support Team, as authorized by RS 39:196-200, must approve all requisitions of \$50,000 or greater for computer hardware and all requisitions of \$100,000 or greater for computer software.

6.1 Hardware

Servers and Network components are purchased, installed, and maintained by the Technical Support Section of OTS. This equipment is routinely upgraded as cost efficient alternatives become available to meet the existing and projected infrastructure needs of the agency. Uninterrupted power supplies (UPS) are utilized on all servers, network hubs, routers, and switches. Annual maintenance contracts with manufacturer approved service centers are utilized where appropriate.

Client workstations are installed and maintained by the Technical Support Section of OTS. The DOA establishes minimum configurations for CPU, memory, and disk storage. All client workstations are routinely upgraded or replaced to conform to this standard.

High speed networked printers are made available to every workgroup, with limited use of desktop printers for special circumstances such as confidentiality.

6.2 Software

Standards are set by DOA for system software and tools on client workstations. The Undersecretary, on an individual basis, approves exceptions to these standards. The Technical Support Section of OTS installs and maintains all client workstation software.

Quality assurance begins with the involvement of the end users prior to, and during development. The first step is the building of a requirements document that is a joint effort between users and OTS staff and signed off by all. The actual development of the code is the responsibility of the programmers, both in-house and consultants. Preliminary testing is done by the programmers then the software is installed on a 'test server'. A subset of the end users is then given access to the test server to thoroughly test the application before it is placed into production. After users execute their test scenario plan, they sign the original work request indicating their acceptance of the software product.

6.3 Geographic Information System

The GIS Section of OTS has developed quality standards for positional data. All positional data, whether obtained from external sources or agency personnel using global positioning systems, is accompanied by codes giving the method by which it was gathered and from which its accuracy may be inferred. It is the responsibility of the program organizations to insure that the data meets the standard.

6.4 Data and Information

The responsibility for data quality lies with the program organization, regardless of whether the information is produced from or collected by computers. During software development, the requirements for data quality are captured by the requirements-gathering process like any other requirements, and the inspection and testing procedures insure that the software delivered meets those requirements.

LDEQ backs up all critical data following a regular protocol:

Weekly

Monday - Thursday
Friday
Monday

Backup

Incremental backups daily
Full systems backup
All data tapes from the previous week are shipped to an offsite, environmentally controlled storage facility

All weekly data tapes are retained in storage for 6 weeks and then recycled. Monthly data tapes (backups at first of the month) are kept in storage for 2 years and then recycled. Two complete systems backups are made once at the first of the calendar year and again at the first of the fiscal year (July 1). These two full backups are kept in storage. When backups will be rendered obsolete by new equipment, plans will be developed to migrate important data to the new platform.

The migration of the backup data is performed by DOA employees in the Technical Support Section of OTS. This is the same staff that maintains the hardware and performs the daily backups.

7.0 PLANNING

Environmental programs shall be planned in accordance with state and federal laws and rules, agency policies and procedures, and contractual requirements.

7.1 Requirements

Organizational and programmatic requirements concerning environmental programs are defined in statutes enacted by the Louisiana Legislature and United States Congress, strategic plans developed by LDEQ, rules promulgated by LDEQ and federal agencies, and requirements documents adopted by LDEQ and federal agencies. These documents determine goals, establish stakeholder and customer relationships, and define needs and expectations for environmental programs implemented by LDEQ. Each grant program must also include a statement of competency as required by EPA directive FEM 2012-02 Rev. 1 in its grant work plan and/or in program QA documents. All grant programs may be combined into one agency-wide grant work plan. LDEQ may demonstrate competency for all of its grant programs through references of past grant performance and/or maintenance of any of the following documents, but not limited to: the QMP, current organizational charts and position descriptions, or audit and assessment results.

7.2 Specifications

Environmental programs and projects are planned through the development of organizational business plans and budgets, Performance Partnership Agreements, grant work plans, the QMP, QAPPs, SAPs, policies, SOPs, PES reviews, and contracts executed by LDEQ and external organizations. These documents translate requirements and expectations into measurable specifications, commitments, and performance criteria.

7.3 Quality System Planning

The QMP documents the results of the quality system planning process performed by LDEQ management following the process below.

1. LDEQ will maintain a QMP utilizing the outline found in *EPA Requirements for Quality Management Plans, EPA QA/R-2*, (latest version). The QMP will clearly state any interpretations, limitations, or exceptions to those requirements. The QA Manager oversees the agency QMP review and revision process.
2. The QMP will be reviewed and revised with the involvement and assistance of

the Executive Staff, Administrators, Managers, Supervisors, DCLs and other key personnel.

3. The QMP shall be approved prior to implementation. The signatures of the Secretary, the environmental offices' executive management, and the QA Manager as well as the EPA Region 6 QA Manager shall document approval of the agency QMP. The QA Manager will ensure that the QMP review and approvals are achieved within the stated timelines.
4. The QA Manager will ensure that the approved QMP is available electronically to all LDEQ personnel and the public. Managers and Project Managers will distribute copies of the LDEQ QMP to contractors whose work requires knowledge of and adherence to requirements and specifications contained in the document.
5. The QA Manager or designee shall maintain an approved copy of the current QMP on the LDEQ intranet. The QMP shall be reviewed and approved annually or revised and approved within 120 days of significant changes or reorganizations, whichever occurs first.
6. If the QMP accurately reflects current agency policies and procedures, the annual approval may be done by a certification to EPA that the plan is current, to include a copy of new, signed approval pages for the QMP.
7. Changes, if needed, will be incorporated into the QMP during the annual review process or within 120 days in cases of significant changes.

7.4 Project Planning

Each environmental data collection project conducted by or for the LDEQ shall follow the systematic planning process outlined below. Project Managers, with assistance from DCLs, as needed, are responsible for project planning and QAPP preparation, review, approval, and distribution.

7.4.1 Systematic Planning Process

All project stakeholders, including contractors, will be represented during the planning of environmental data projects. For example, representatives from field operations, the laboratory, and the data managers and users must be involved in planning.

- a. QAPPs will be developed (see Section 7.4.2) and revised by individuals that have expertise in the subject of the QAPP.
- b. All personnel conducting reviews must have a working knowledge of the project objectives and training in QAPP review.
- c. QAPPs involving contractors shall, at a minimum, also be approved in writing

by the contractor's Project Manager. Analytical services provided by a contractor are an exception. In these cases, specific language is included in all contracts for agreement to comply with all Louisiana Environmental Laboratory Accreditation (LELAP) standards and all applicable LDEQ QAPPs for which services shall be provided by the contractor. Signature of an official laboratory representative on an approved analytical services contract serves as contractor approval and compliance with all applicable LDEQ QAPPs.

The planning group will address each of the following and document in the resulting QAPP:

- a. Determine the project goal(s) and objectives based on the questions to be answered and issues to be addressed.
- b. Determine resources available to implement the project.
- c. Determine responsibilities for each activity.
- d. Determine project schedules and milestones.
- e. Outline specific requirements that will determine quality and quantity of data needed for the project. For example, are there action levels that will require very low analytical sensitivity levels or other quality requirements?
- f. Outline any other performance requirements for measuring quality of the data (precision, bias, etc.).
- g. Determine and document assessment methods that will be used to determine if project is being implemented according to plan and pertinent SOPs and if data are meeting quality criteria. See Section 9 for assessment methods.
- h. Describe sample collection and analysis methods, frequency of sample collections and the monitoring design (where samples will be collected and number of samples). If a generic QAPP is developed and does not cover these details, these details will be incorporated into a SAP (see below).
- i. Specify constraints on data collection, for example, critical seasons.
- j. Describe data management process.
- k. Describe how data will be reviewed, and who will do the review, to determine its quality and usefulness for the project.
- l. If data are not directly collected for the project, for example, if data are used from existing literature sources, the quality requirements and review for these indirect data must be documented in the QAPP.

7.4.2 Preparation, Review, Approval, and Distribution of QAPPs

QAPPs will be written for all environmental data projects. The format for QAPPs will follow that outlined in EPA's QA/R-5 guidance document "EPA Requirements for Quality Assurance Project Plans."

- a. In addition to project specific QAPPs, generic QAPPs for programs may be developed. Generic QAPPs will be developed for programs routinely implementing the same types of projects (e.g. watershed intensive dissolved oxygen surveys and RCRA activities). When generic QAPPs are developed

- for a program area, the project or site-specific details will be planned through development of SAPs.
- b. No environmental data collection or analysis work addressed in the QAPP shall be started until the QAPP has been appropriately reviewed, approved, and distributed to project personnel (except in situations requiring immediate action to protect human health and the environment, for example, response to catastrophic events). Should such an event occur, LDEQ will notify EPA and seek concurrence. Projects involving federal funds must be approved by EPA prior to implementation; projects not involving federal funds do not require EPA approval.
 - c. Review and approvals will be performed by staff selected by Administrators to oversee the project.
 - d. Each QAPP must use a document control format that provides its version number and effective date (see Section 5).
 - e. The level of detail in each QAPP will vary according to the nature of the work being performed and the intended use of the data.
 - f. Staff chosen to implement the QAPP will receive an approved copy from the Project Manager, including external parties when appropriate.
 - g. Managers, Supervisors and Project Managers are responsible for ensuring QAPPs are updated and submitted to the QA Manager to be maintained on the department intranet. Note: SAPs are not currently posted on the intranet.
 - h. The Project Manager is responsible for ensuring that all QAPPs receive an annual quality assurance review and approval, including EPA when federal funds are used.
 - i. If the QAPP accurately reflects the current project goals and the organization's policy, the annual approval may be done by a certification letter that the plan is current, to include a copy of new, signed approval pages for the QAPP. The revision level and preparation date remains the same with only a change in the approval date noted on the Document Review and Revision Record page.
 - ii. If revisions are required, update the document, obtain approvals, update the Document Review and Revision Record page, and update the control header with the new revision number and date.
 - iii. If QAPP updates are needed prior to the annual review, then the revisions must be made within 120 days of the process change, if significant.
 - iv. Expedited changes to QAPPs may be approved to reflect changes in project organization, tasks, schedules, objectives, and methods, address deficiencies, improve operational efficiency, and accommodate unique or unanticipated circumstances. Expedited changes are effective immediately upon approval. Expedited changes to QAPPs and the reasons for the changes shall be documented. Changes to QAPPs shall be distributed to all individuals and organizations contained in the QAPP distribution list.

7.5 Sampling and Analysis Plans (SAPs)

These plans provide specific details for environmental monitoring events including, but not limited to, site location, sampling protocol, equipment, personnel, resources and schedules. SAPs outline project or site-specific processes that are not covered in higher level QAPPs; however, if these details are included in a QAPP, an SAP is not required.

The SAP includes:

- QC performed in the field and at the laboratory
- One or more maps of the facility or area that clearly indicate:
 - The location of all existing and proposed soil borings, surface samples, groundwater monitoring wells, surface drainage sampling points, and air sample points;
 - Important on-site structures, including tanks, sumps, catch basins, and pipelines;
 - The location of past spills, disposal areas, and other waste and product management areas; and
 - All pertinent structures adjacent to or near the sampling site, such as drainage ditches, pipelines, roads, wells, and utility corridors.

The following details examples of information that should be included in the SAP for all samples collected (by pathway):

Soil

a. Sampling

- number and locations of surface and subsurface samples
- depth of any subsurface samples
- type and category of samples (grab or composite; environmental, duplicate, or background)
- if composite, method of compositing samples
- sample collection methods and tools
- equipment decontamination procedures
- sample preservation techniques
- types of sample containers to be used
- collection/disposal of excavated soil, if necessary

b. Analyses

- analyses to be performed on each sample
- EPA or other method reference number
- detection limits
- special analytical considerations

Groundwater

a. Sampling Existing Wells

- number of samples
- location of each sample, such as well number or location of well
- type of samples (i.e., environmental, duplicate, trip blank)
- screened interval of well being sampled
- type of well being sampled (domestic, municipal, etc.)
- well construction details, if known
- purge methods and tools
- sample collection methods and tools
- sample filtration methods, if any
- equipment decontamination procedures
- sample preservation techniques
- types of sample containers used
- collection/disposal of purge water, if necessary

b. Installing and Sampling New Wells

In addition to the items listed above for sampling existing wells, include the following information in the SAP when the sampling plan calls for the installation of new wells:

- proposed well locations
- well construction details
- well drilling and installation methods
- well development and completion methods
- decontamination of drilling equipment, casing, etc.
- collection/disposal of drill cuttings and fluids, if necessary

c. Analyses

- analyses to be performed on each sample
- EPA or other method reference number
- detection limits
- special analytical considerations

Surface Water/Sediment

a. Sampling

- number and locations of samples
- media sampled (water, sediment, or both)
- depth of any sediment samples
- field measurements
- types of samples (environmental, duplicate, etc.)

- sample collection methods and tools
- equipment decontamination procedures
- sample preservation techniques
- types of sample containers

b. Analyses

- analyses to be performed on each sample
- EPA or other method reference number
- detection or quantification limits
- special analytical considerations

Air

a. Sampling

- number and locations of samples
- type of samples (i.e., environmental, collocated, filter blanks)
- sample collection methods and tools
- equipment decontamination procedures
- special sampling handling procedures
- predominant wind direction, diurnal wind shift
- period of time to be sampled, volume of air to be sampled
- filter type (PUF, cellulose fiber filter, etc.)
- sample container
- sample preservation techniques

b. Analyses

- analyses to be performed on each sample
- EPA or other method reference number
- detection limits
- special analytical considerations

8.0 IMPLEMENTATION OF WORK PROCESSES

Environmental programs shall be performed to ensure that customer needs and requirements are met in a timely manner. The Administrators, Managers and Supervisors ensure environmental work is implemented according to plans (QMP, QAPPs, SAPs, etc. – See Section 7) and SOPs. The primary tool for implementation of work processes is the use of SOPs. SOPs are needed when consistency in implementation of processes is necessary to ensure uniformity in data, products and/or services and will be used during training of new employees.

8.1 Work Process Implementation Policy

All LDEQ personnel are required to adhere to the following implementation and practice policies:

- All sampling, analysis, and assessment activities that generate environmental data will be performed according to approved plans and SOPs.
- These activities will have managerial oversight and inspection.
- SOPs will be developed, documented, and implemented for appropriate routine, standardized, distinctive or critical operations.

8.2 SOP Policy

- SOPs will be developed using the EPA SOP Guidance Document (*EPA Guidance for Preparing Standard Operating Procedures (SOPs)*, EPA QA/G-6).
- SOPs will be written in a format that can be readily comprehended by the user and will contain sufficient detail and clarity to ensure that results are achieved effectively.
- SOPs will be reviewed for adequacy and approved by qualified personnel prior to use.
- SOPs must be followed by all employees involved in the described process. The best written SOPs will fail if not followed. The use of SOPs will be reviewed and maintained by management. Direct Supervisors are responsible for ensuring that SOPs are followed.
- SOPs need to remain current, therefore, whenever procedures are changed (e.g., changes in technology methodology or process, changes in compounds being monitored or regulated, or in the allowable concentration levels, etc.), SOPs must be updated, reviewed, and approved. Changes or modifications may be made to only the pertinent section of an SOP, but the process must indicate the changed date and/or revision number in the document control header, a brief description of the changes/review performed in the Document Review and Revision Record Table, as well as within the text of the document. New revision numbers are not required if the body of the SOP remains unchanged.
- Current SOPs are maintained on the intranet using document control numbering systems by selected staff in each office. Managers are responsible to ensure this takes place in their respective sections.
- Employees are encouraged to suggest improvements to processes to the document owners and management.
- To ensure SOPs remain current and appropriate, they will be reviewed annually unless process improvements are determined necessary to ensure best practices prior to that time. The QA Manager may allow an extension of 3 to 6 months for an SOP that requires revisions, in particular those that may impact several sections or divisions. Management will provide a justification request for the extension based on priority and need.
- If an SOP describes a process that is no longer used, the QA representative will notify the QA Manager (or SOP designee) to remove it from the intranet and archive it.
- SOPs must be incorporated either in full or by reference into the pertinent QAPP.

- Any SOPs referenced in a QAPP sent to EPA may be sent electronically in PDF format.

8.3 Preparation, Review, Approval, and Distribution of SOPs

When it has been determined that an SOP is needed for an activity, management initiates the development. The following process is used to develop a new SOP.

- Management selects document owner(s) to develop an SOP. If several staff are involved, one person will be designated as the document team leader and will coordinate the document development.
- Document owner obtains a filename for the SOP from the designated staff (listed on the intranet).
- Document owner(s) draft the SOP.
- Document is forwarded to reviewers selected by management for comments. Comments are considered in the preparation of the final draft. Once the draft is finalized it is forwarded to the final approval authority. SOPs are internal documents approved by LDEQ and do not require approval by EPA.
- If activities within a section or group will have an impact on other sections or groups within the agency, the SOP must be reviewed by a representative of those sections/groups and may become a division-level or office-level SOP.
- Document owner updates the Review and Revision Record to indicate approval date.
- Document owner scans approval page and emails Word document with scanned approval page to designated staff.
- Designated staff in each office receives signed approval page and electronic version (in Word) to post on intranet as an Adobe PDF file.
- Designated staff (listed on intranet) posts the SOP on the intranet and notifies document owner that it is available for use. Document owners will immediately notify users that the document is available for use. For agency-wide SOPs, the QA Manager will email notification to all employees.
- The SOPs on the intranet are grouped by area (Department-wide, Office/Division/Section or Unit) to help staff identify applicable documents.
- Managers and Supervisors are responsible for ensuring SOPs are reviewed and revised, as needed, and maintained on the department intranet. The QA representatives will assist by tracking SOP timelines to ensure they are current.
- If there are revisions, managers and supervisors will work with the document owner to update the SOP within the prescribed timelines. Revisions will be detailed in the Document Review and Revision Record section of the SOP.
- A review date will be in the Document Review Record that it has been reviewed, whether or not it has been revised. The date in the document header will reflect a review or revision date to show that it is "current".

It may be necessary to change processes prior to completion of the SOP revision process. Sending the proposed change by email to the affected staff will indicate approval of the changed process. If the SOP change has the potential to affect other

areas, the email notice of the change will be sent to all affected staff. Managers, Supervisors and/or Project Managers will assure notification of groups, including contractors, affected by a new or revised SOP by email after it is posted on the Intranet.

9.0 ASSESSMENT AND RESPONSE

LDEQ will evaluate the performance of its environmental projects and the effectiveness of the LDEQ Quality System by planning, implementing, and documenting its assessment effort. Assessments are planned, scheduled and carried out and audit results are reviewed and corrective actions enacted to ensure that the environmental programs meet LDEQ's quality system criteria.

It is LDEQ's policy that all assessment teams shall have access to all work areas, documents, records, personnel, and Supervisors that are necessary to:

- conduct an assessment to verify that plans, policies and procedures are being followed
- identify and document quality problems and noteworthy practices
- communicate deficiencies to management
- determine if corrective actions have been implemented and are effective

LDEQ evaluates the adequacy of its quality system in relation to its environmental projects at least annually, which includes a review of the QMP and the effectiveness of its assessment/response processes. The QMP is then revised as needed consistent with the *EPA Requirements for Quality Management Plans (EPA QA/R-2)*.

Assessment and monitoring routinely occurs to ensure quality products and services at LDEQ by Administrators, Managers and Supervisors performing periodic checks to assure processes are being followed. QSAs and TSAs are planned and coordinated by the QA Manager and Administrators and conducted by audit teams led by DCLs within and outside of their divisions. Intra-office assessments will be conducted by DCLs within their respective offices to ensure that procedures are being followed, as outlined in SOPs and policies established by division administrators. Inter-office audits will be conducted by audit teams from outside the office to be audited to ensure independence in the audit process. Assessments conducted within offices will be documented in writing and audit records maintained at the division or office level; inter-office audits will be documented in writing and audit records maintained at the office level. A summary of assessments and audits will be included in the end of year report that is generated by the QA manager and QA team.

9.1 Assessment Types

LDEQ uses four types of assessments including:

- Quality System Assessments
- Technical Systems Audits

- Data Quality Assessments
- Performance Evaluation System

9.1.1 Quality Systems Assessments (QSA)

QSAs will be performed in all offices involved in data collection, generation, management, and use; the goal is to perform a QSA in at least one program (for example, water permits, air quality assessments) every 3 years. The QSA will qualitatively assess a program's organization and data collection procedures to determine if the management procedures are in place and are adequate to ensure the quality of the program data. The QA Manager will work with the administrators to assemble audit teams and coordinate audit activities. The QA Manager will mentor audit teams from outside the evaluated program to conduct audits using EPA QA/G-3 *Guidance on Assessing Quality Systems*. Results of QSAs will be forwarded to the administrators upon completion of the review (but prior to a final written report). The administrator of the program reviewed is responsible for taking any necessary corrective actions and determining whether additional audit activities are required.

9.1.2 Technical Systems Audits (TSA)

All programs that employ environmental sample collection and analyses are subject to a TSA. The TSA involves a thorough review of the facilities, equipment, sampling, analysis and documentation procedures, data validation, management processes, training procedures, and the reporting aspects of the technical system for collecting or processing environmental data. TSAs will either be routinely planned by the administrators, or can be specifically requested by a division, section, the QA Manager or may result from audit or review findings. The audit team leader, assigned by an administrator, is responsible for scheduling the TSA, assembling the audit team, and coordinating the TSA. TSA results will be reported to the audited organization in the form of a written report. EPA guidance is available on how to conduct TSAs (EPA QA/G-7 *Guidance on Technical Audits and Related Assessments for Environmental Data Operations*).

9.1.3 Data Quality Assessments (DQA)

Data will be evaluated for quality and integrity. Data review, data verification, and data validation procedures are documented in the appropriate QAPP and typically performed within the program area. The procedures will document the decision process and factors used in arriving at the choice of the particular qualification method. Limitations on data use will be identified quantitatively to the extent practicable and fully documented. Data that was not collected under, or did not fully comply with, a QAPP or equivalent planning document for data collection and analysis must be qualified (for example, validated for use).

Data validation is used to determine if the verified data met the acceptable level of certainty required for a decision. Confidence levels may be stated in the QAPP as

performance measures for the project. This process may include application of statistical methods during the data quality assessment process.

Environmental data generated outside of a quality assurance program or an approved QAPP and used in an environmental program will be qualified according to its intended use. The data and the methods used to qualify such data will be identified in the any reports produced with the data. The suitability of the monitoring and measuring devices will also be identified and may include the accuracy and precision of the device.

Guidance documents are available to assist in determining appropriate data assessments and determining the usability of data including EPA quality system documents QA/G-3, QA/G-7, QA/G-8, QA/G-9 (http://www.epa.gov/quality/qa_docs.html), EPA Contract Laboratory Program (CLP) guidelines and EPA Risk Assessment Guidelines.

9.1.4 Performance Evaluation System (PES)

It is the responsibility of executive staff, administrators, managers and supervisors to ensure that PES reviews have the appropriate level of quality work product expectations planned and reviewed. This should be commensurate with their level of quality system responsibilities. Supervisors and managers shall ensure that their staff is properly trained in sampling locations, sampling and calibration techniques, and equipment usage. Any employee deficiencies shall be identified during the planning process and addressed prior to any sampling or analytical events.

9.2 Assessment Planning

Assessment plans and schedules will take into account such factors as public health and safety, budgets, results of prior assessments, grant/program coverage and continuity, complexity of work activities, management criteria, and existing commitments (for example, QAPPs). Scheduled assessments may be supplemented by unscheduled or unannounced assessments requested by managers or a division administrator. EPA-sponsored programs are subject to review at any time. Formal assessment of performance under EPA assistance agreements occurs as part of a comprehensive review and evaluation of LDEQ programs.

The Quality Assurance Team will meet at the end of a grant year, to document the status of the quality system implementation efforts. The Team will meet at the start of a grant year to propose assessments for the current grant year. The plan will list QA activities planned for the grant year, including audits, assessments and training. An assessment schedule, which outlines scope and audit dates, will be approved by the appropriate division administrators. The approval will be done prior to implementation and distribution to managers and supervisors.

Based on the type of audit and the program to be audited, auditors will have appropriate training. The LDEQ auditor training and EPA online courses are available to those

performing audits and assessments (<http://www.epa.gov/quality/trcourse.html>). The QA Manager will coordinate assessment and audit training with managers and QA reps.

9.3 Assessment Implementation

Implementation of work processes should include the routine measurement of performance against established technical and quality specifications. The work process shall be monitored to ensure continued satisfactory performance. The independence of personnel monitoring the work performance shall be commensurate with the nature and importance of the activity as determined by management.

The assessments will be planned and coordinated by the QA Manager and approved by administrators and executive staff. Assessments will be led by an assessment team leader and conducted by teams consisting of one or more individuals. The Division Administrators, with assistance from the QA Manager and the assessment team leader, will ensure that personnel conducting assessments are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed. The role of each team member shall be specified.

An assessment team leader shall forward a written assessment report to management and the QA Manager within 30 calendar days of completing the on-site phase of an assessment. If an assessment report contains adverse findings, managers and supervisors of the affected projects shall forward written responses that describe appropriate corrective actions to the assessment team leader, appropriate DCLs, administrator(s), and the QA Manager within 30 calendar days of receiving the assessment report.

9.4 Suspension of Assessments

An assessment may be suspended if, in the judgment of the assessment team leader, the objectives of an assessment cannot be achieved or a continuation of an assessment could jeopardize the health or safety of any member of the assessment team. The assessment team leader shall notify the QA Manager and administrator(s) as soon as practicable after suspending an assessment and shall describe the reasons for the suspension. The assessment will be rescheduled when the reasons for suspension have been addressed.

10.0 QUALITY IMPROVEMENT

1.0 Quality System Plan

Management will strive to maintain and continually improve the overall quality system established for its environmental programs. To ensure that there is continual improvement in the quality system, an annual review will be conducted.

The QA Manager and the Quality Assurance Team will meet regularly to discuss the

status of QA efforts and provide updates to executive staff and administrators. The quality system report will contain the following information, at a minimum:

- Status of the quality system, including:
 - program and data quality objectives
 - corrective actions
 - resource adequacy
- Significant QA changes (i.e. changes to policies, guidance documents, audit protocols, etc.)
- Status of QAPPs and SOPs
- Resource changes
- Audits conducted and planned
- Training courses conducted and planned
- Revisions to the QMP

The Quality System plan and quarterly reports will be reviewed and approved by the executive staff during the annual QMP review and revision process.

10.2 Quality System Improvement Process

Assessments and audits (Section 9) identify deficiencies. The corrective action process determines the cause of the deficiency, evaluates the need for action to prevent occurrence/reoccurrence, implements the action and records the results of the action taken.

Managers and supervisors will oversee the implementation of corrective action plans. If corrective action plans are not completed in a timely manner, the QA Rep who tracks corrective actions will notify the QA Manager and administrator(s) to ensure the corrective actions are addressed.

The following activities could initiate corrective actions:

- Data quality audits
- Failure of a QAPP, SOP, or SAP to provide the appropriate outcomes and results
- Failure to adhere to the approved QMP, QAPP or SOP
- Technical system audits
- Performance audits

The Secretary and executive staff are authorized to stop work as necessary to safeguard programmatic objectives, worker safety, public health, and environmental protection.

10.3 Quality System Communication

The QA Manager will maintain a close liaison with management staff and QA Reps in each Office to maintain and review quality system implementation efforts.

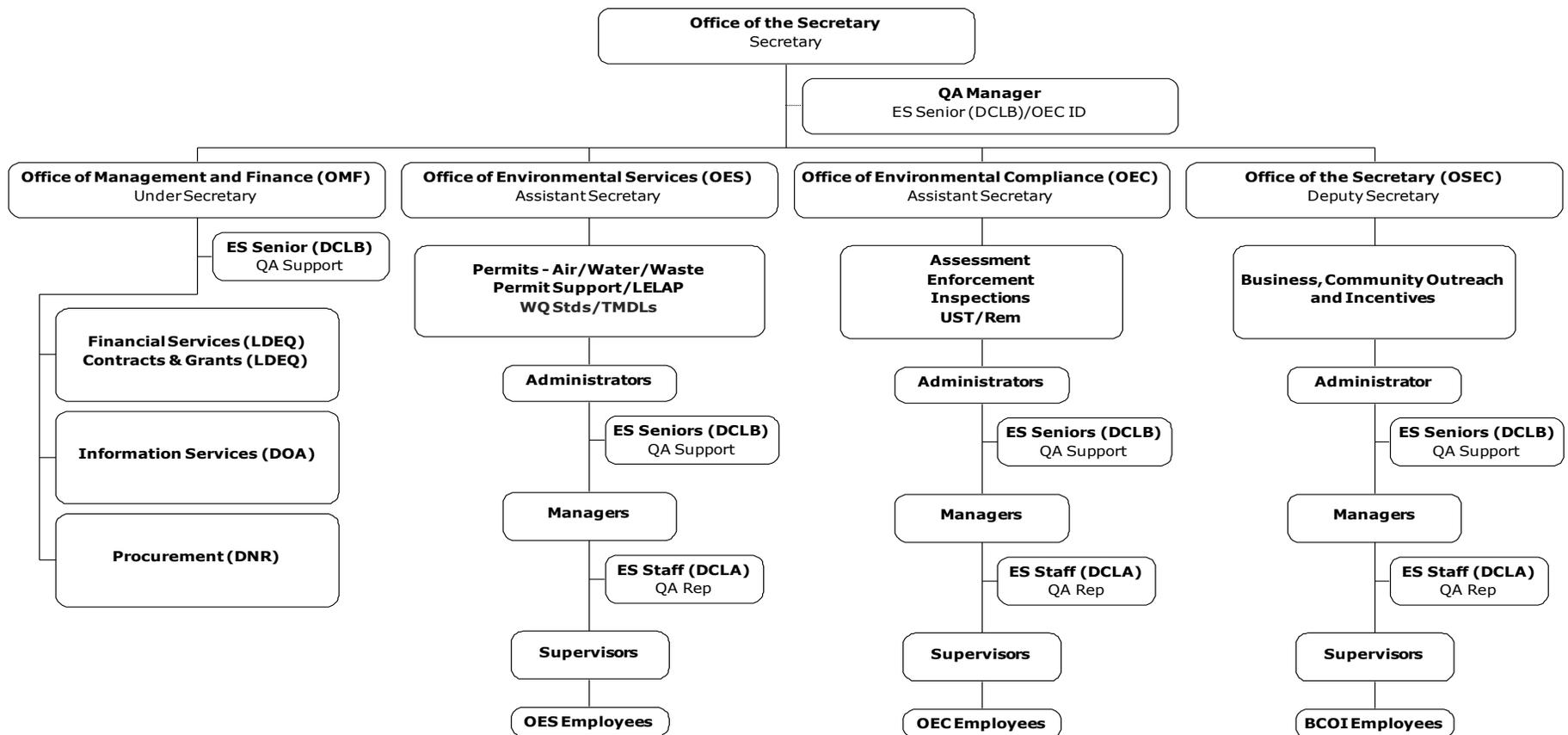
Observations and/or findings in one area can be sources of preventive actions that are taken to prevent the occurrence of deficiencies. Management reviews are other sources of preventive actions.

10.4 Dispute Resolution Process

The QA Representatives work with supervisors and managers as needed to resolve disputes. If they are unable to resolve the dispute, the matter is submitted to the administrators and/or executive staff. Some QA issues may include projects involving managers or technical staff from EPA and LDEQ. In such a dispute, the LDEQ QA Manager and/or executive staff will coordinate discussion with EPA and LDEQ staff to resolve the dispute. If the group is unable to resolve the dispute, the LDEQ QA Manager and the EPA QA Manager will be asked to resolve the matter.

The Quality System organization follows.

LDEQ Quality System Structure



Standard Operating Procedure
for
Review and Response to Laboratory Corrective Action Plans

Revision 11

Public Participation and Permit Support Division

Office of Environmental Services

Louisiana Department of Environmental Quality

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Approved by:

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Date:

6-2-14

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
2/12/01	0	Initial document approved.
Unknown	1	Approval date is not available.
10/29/04	2	General revisions
2/23/05	3	New Administrator
04/13/06	4	Changed to new format
05/11/2007	5	Name change for LELAP Supervisor and technical changes related to NELAC and TNI
03/29/2008	6	General Revision
03/23/2009	7	General Revision
10/08/2009	8	Name change of SOP, minor revisions, use of agency SOP format, and relocation of duties to the Permit Support Services Division
10/06/2011	9	Minor Revisions, and new administrator
12/20/2012	9	Reviewed with no revisions.
06/10/2013	10	Inclusion of requirements of the 2009 TNI standard
06/02/2014	11	Shared folder location update

Table of Contents

1.0 Purpose / Applicability 4
2.0 Definitions / Acronyms / Abbreviations 4
3.0 Personnel Qualifications 4
4.0 Procedure 5
5.0 Records Management 7
6.0 Quality Control / Quality Assurance 7
7.0 SOP Review / Revision / Approval 7
8.0 References 8
9.0 Attachments..... 9

1.0 Purpose / Applicability

The purpose of this SOP is to provide instructions for staff to follow when reviewing and responding to corrective action plans submitted by laboratories (includes stack testers) in response to findings identified during the assessment process. This procedure prescribes the use of a formatted document which shall be used by LELAP Assessors and LELAP contractors to document deficiencies and also for laboratories to respond to deficiencies found during the assessment process, as described in LAC 33:I.5107.A. In addition, the LELAP assessors will use this document to review Corrective Action Plans (CAPs) submitted by facilities in response to findings identified during the assessment process. This activity is performed in accordance with LAC 33: 5107.A.

This SOP applies to staff members in the LELAP group, Notifications and Accreditations section, Public Participation and Permit Support Division (PPPSD) and their supervisor.

2.0 Definitions / Acronyms / Abbreviations

EDMS:	Electronic Document Management System
ES:	Environmental Scientist
LELAP:	Louisiana Environmental Laboratory Accreditation Program
NAS:	Notifications and Accreditations Section
NELAC:	National Environmental Laboratory Accreditation Conference
NELAP:	National Environmental Laboratory Accreditation Program
OES:	Office of Environmental Services
PPPSD:	Public Participation and Permit Support Division
PT:	Proficiency Test
SOP:	Standard Operating Procedure
TEMPO:	Tools for Environmental Management and Protection Organizations. It is the central data management system to track facilities, people, and organizations that are of interest to LDEQ and to track the activities of the Department, such as Permitting, Surveillance, and Enforcement. This system is the central piece of the new <u>Integrated Data Management System (IDMS)</u>
TNI:	The NELAC Institute

3.0 Personnel Qualifications

The SOP identifies job titles of staff members who perform certain activities. These staff members are qualified to perform these activities based on the qualifications in their job descriptions. Staff members receive training from supervisory staff or designee in the section and outside trainers. Once the supervisory staff or designee determines that the ES is sufficiently trained, staff members will assume all the duties related to them. The supervisory staff or designee will provide guidance and backup.

4.0 Procedure

Note: Staff member will send any official record associated with his/her participation in this activity to EDMS for scanning.

4.1 Evaluation of Corrective Action Plans (CAPs)

The assigned LELAP Assessor or LELAP contractor shall review and evaluate all corrective action plans submitted by the laboratory (includes stack testers) within 30 working days of receipt of the documents. CAP response deadlines will be tracked by the assigned LELAP assessor using the Microsoft Outlook Calendar, and the Supervisor will monitor these deadlines by using an excel spreadsheet. The assigned LELAP Assessor shall determine if the proposed CAP has adequately addressed each individual finding subject to final approval by the Program Supervisor. The laboratory corrective action with respect to each finding shall be assigned to one of three categories by the Assessor:

4.1.1 Approved – Corrective actions in this category must address the specific finding and must be sufficient to meet all existing requirements of the Louisiana Administrative Code (LAC) or 2009 TNI Standard when successfully implemented and documented.

4.1.2 Incomplete – Corrective actions in this category are incomplete and shall require the laboratory to submit more information before a determination can be made as to whether the corrective action is satisfactory. The assigned Assessor shall identify the information that must be submitted to allow a final determination to be made.

4.1.3 Not Approved – Corrective actions in this category fail to adequately address the specific finding, or are insufficient to meet existing LAC requirements or the 2009 TNI Standard. This category shall include but not be limited to those instances where no corrective action has been submitted for a specific finding.

4.2 LELAP Response to Corrective Action Plans

The assigned LELAP Assessor shall submit a response to the laboratory's designated representative. The Assessor's response must include the evaluation of corrective actions specific to each finding listed in the Assessment Report. The response shall indicate where the laboratory is required to submit additional information, documentation, or corrective action for any finding. The following templates, which are found in the LELAP shared folder, shall be used by the Assessor to respond to corrective actions submitted by the laboratory:

4.2.1 Template for LELAP Response to Corrective Action Plans that are All Approved, found in the LELAP shared folder ([see 8.0 References](#));

4.2.2 Template for LELAP Response to Initial Corrective Action Plans that are Incomplete or Not Approved, found in the LELAP shared folder (see 8.0 References); and

4.2.3 Template for LELAP Response to Revised Corrective Action Plans that are Incomplete or Not Approved, found in the LELAP shared folder ([see 8.0 References](#)).

4.3 Revised Corrective Action Plans

The laboratory must submit a revised corrective action plan for any finding for which the previous corrective action has been found to be Incomplete or Not Approved. The laboratory must submit the revised corrective action plan no later than thirty (30) calendar days from date of receipt of the finding notice. The Assessor shall review and respond to these submissions by the same procedure as described in Sections 4.1-4.5 of this SOP.

4.4 LELAP Response to Continuing Findings in Corrective Actions

The accreditation process shall be subject to termination if the laboratory fails to submit proposed or completed corrective actions (CAP) within the time limits established by LAC 33:I.5107. If it is determined by LELAP that the laboratory has failed to correct known findings within the statutory timeframe, the laboratory's designated representative shall be notified by certified mail that its accreditation is suspended or revoked under LAC 33:I.5705.F.4.

4.5 Completion of Corrective Action

4.5.1 If the laboratory has failed to meet the statutory requirements of LAC, the Assessor shall draft a letter for management's review notifying the designated laboratory representative. The assigned Assessor shall initiate suspension or discreditation of the laboratory as established by LAC 33:I.5705 with the approval of the Supervisor, Manager, Administrator, and OES Assistant Secretary, who is the signatory for the letter.

4.5.2 If it has been determined by the Assessor that the laboratory has provided an acceptable corrective action plan or corrected all outstanding findings and provided satisfactory documentation of said correction, the Assessor shall draft a letter of notification to the laboratory indicating that no further corrective action shall be required at this time, and request that the laboratory sign the Attestation of Compliance for Corrective Action ([see 8.0 References](#)).

4.5.3 If the suspended laboratory is successful in correcting the cause(s) for suspension within six (6) months, it will not have to reapply for accreditation. If the suspended laboratory is not successful in correcting the cause(s) for suspension within six (6)

months of the effective date of the suspension, the laboratory shall be discredited in part or in total.

4.5.4 If the discredited laboratory is not successful in correcting the deficiencies as required by the TNI standards, the laboratory must wait six (6) months before reapplying for accreditation.

5.0 Records Management

Official records are described in *Managing Records* (see 8.0 References).

Official records associated with this activity and maintained in EDMS according to the LDEQ Records Management Policy are:

- Cover letter and response to corrective action plan (see step 4.2 and 8.0 References); and
- Attestation of Compliance for Corrective Action (see step 4.5.2 and 8.0 References).
- Any other documentation in regard to this activity.

TEMPO and the LELAP databases are also maintained as repositories of information records.

6.0 Quality Control / Quality Assurance

This process includes the following quality control measures:

- The primary quality assurance for the documentation is the review of the record by the LELAP Supervisor or his/her designee.
- The review is documented in the cover letter and response (see step 4.2 and 8.0 References).
- Within 30 working days of receipt of the corrective action plan or revised corrective action plan, the response is reviewed by the LELAP Supervisor or his/her designee (see steps 4.1, 4.3, and 4.5.1)
- Deadlines are tracked with Outlook Express and an excel spreadsheet (see step 4.1)

7.0 SOP Review / Revision / Approval

Designated reviewers for this SOP are:

- Permit Support Services Division's, Notifications and Accreditation Section's Environmental Scientist Manager;
- PSSD's, NAS's LELAP Supervisor; and
- PSSD's QA Reviewer (for review of QA elements, only).

The Laboratory Services Division Administrator approved the original SOP, and the Public Participation and Permit Support Division Administrator has final approval authority for any revisions to this SOP.

8.0 References

Managing Records located at: <http://intranet/records/user/editinfo/files/official-pubrecords-nonrecords.pdf>.

LAC 33:I Chapters 45-59 located on LDEQ's Intranet at: <http://www.deq.louisiana.gov/portal/LinkClick.aspx?fileticket=0h79jV%2fkc00%3d&tabid=1674>.

2009 TNI Standard located in the TNI website at: http://www.nelac-institute.org/standards.php?pab=1_1#pab1_3.

The cover letter template for "all approved" responses is found in \\Alpha_nt\lelap\SOPs and Attachments\LELAP CAP Response\Template for CAP--All Approved

The cover letter template for "incomplete" or "not approved" responses is found in <\\deqshares\lelap\SOPs and Attachments\LELAP CAP Response\Template for Initial CAP--Incomplete or Not Approved\Template for LELAP Response to Initial Corrective Action Plans Incomplete or Not Approved 10-6-11.docx>

The cover letter template for "incomplete" or "not approved" responses to corrective action plans for findings identified during assessments performed by contractors is found in <\\deqshares\lelap\SOPs and Attachments\LELAP CAP Response\Template Initial CAP Contractor - Incomplete or Not Approved>

The cover letter template for "incomplete" or "not approved" responses to revised corrective action plans is found in <\\deqshares\lelap\SOPs and Attachments\LELAP CAP Response\Template for Revised CAP--Incomplete or Not Approved\Template for LELAP Response to Revised Corrective Action Plans Incomplete or Not Approved 10-6-11.docx>

The Attestation of Compliance for Corrective Action is found in LELAP shared folder at: <\\deqshares\lelap\SOPs and Attachments\LELAP CAP Response\Attestation of Compliance for Corrective Actions\ATTESTATION OF COMPLIANCE FOR CORRECTIVE ACTIONS.docx>

9.0 Attachments

Not applicable

ATTACHMENT 2
SCHEDULE OF PRICES
“Laboratory Auditing”
Louisiana Department of Environmental Quality

Line Item No.	Pay Item Description	Payment Unit	Unit Rate
1	Laboratory Auditing: Physical Audit and Corrective Action Plan (CAP) Related Work	Hour	\$
2	Travel Time	Hour	\$
3	Audit Preparation and Report Writing	Hour	\$
4	Travel Expenses ¹	In Accordance with PPM49	

• Unit rates for lines 1-3 shall include all associated direct costs (labor, supplies, equipment, incidentals and expendables, duplication/copying, communications, postage, shipping and handling, transportation, taxes, etc.), all indirect costs (fringe, overhead, general and administrative costs) and profit.

•¹ Travel and other allowable expenses shall be reimbursed in accordance with the Division of Administration State General Travel Regulations, within the limits established for State Employees, as defined in Division of Administration Policy and Procedure Memorandum No. 49.

<http://www.doa.la.gov/Pages/osp/Travel/travelPolicy.aspx>

***ALL BLANKS MUST BE COMPLETED**

**ATTACHMENT 3
Form A**

**Veteran-Owned and Service-Connected Disabled Veteran-Owned Small Entrepreneurship (LaVet) and
Hudson Initiative small entrepreneurship (SE-HI) Procurement Invoice Reporting**

Contractor: _____

Project Title: “ _____ ”

Reporting Period: _____

Procurement Made By: (check appropriate box)		Name (If Subcontractor)	Business Enterprise: (check appropriate box)		Dollar Value of Procurement	LED Certification Number of Contractor or Subcontractor
Contractor	Subcontractor		LaVet	SE		

A good faith effort has been made to obtain LaVet and/or SE-HI vendor participation:

Signature

Date