

## NOTICE OF INTENT

Department of Environmental Quality  
Office of Environmental Assessment  
Environmental Planning Division

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Office of the Secretary regulations, LAC 33:I.Subpart 3 (Log #OS035).

The laboratory accreditation rule requires accreditation of commercial environmental laboratories by the department every three years. The accreditation program requires third-party audits, submission of samples for independent analysis, and inspection of regulated laboratories. The rule provides for quality assurance/quality control procedures, laboratory personnel qualifications, and sampling protocol. The proposed rule establishes the requirements to ensure the quality of data generated by commercial environmental laboratories that are accredited by the department, and provides clarification to facilitate a better understanding of the program requirements. The proposed rule also promulgates the changes made in the emergency rule OS035E, which was effective on December 15, 1999. These changes extend the deadline to apply for accreditation to July 1, 2000, and the deadline for accreditation by the department to December 31, 2000. The basis and rationale for the proposed rule are to provide clarification for the laboratory accreditation rule and to promulgate the changes in the emergency rule, OS035E.

This proposed rule meets an exception listed in R.S. 30:2019 (D) (3) and R.S.49:953 (G) (3); therefore, no report regarding environmental/health benefits and social/economic costs is required. This proposed rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

A public hearing will be held on May 25, 2000, at 1:30 p.m. in the Trotter Building, Second Floor, 7290 Bluebonnet Boulevard, Baton Rouge, LA 70810. Interested persons are invited to attend and submit oral comments on the proposed amendments. Should individuals with a disability need an accommodation in order to participate, contact Patsy Deaville at the address given below or at (225) 765-0399.

All interested persons are invited to submit written comments on the proposed regulations. Commentors should reference this proposed regulation by OS035. Such comments must be received no later than June 1, 2000, at 4:30 p.m., and should be sent to Patsy Deaville, Regulation Development Section, Box 82178, Baton Rouge, LA 70884-2178 or to FAX (225) 765-0486. Copies of this proposed regulation can be purchased at the above referenced address. Contact the Regulation Development Section at (225) 765-0399 for pricing information. Check or money order is required in advance for each copy of OS035.

This proposed regulation is available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 7290 Bluebonnet Boulevard, Fourth Floor, Baton Rouge, LA 70810; 804 Thirty-first Street, Monroe, LA 71203; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 3519 Patrick Street, Lake Charles, LA 70605; 3501 Chateau Boulevard, West Wing, Kenner, LA 70065; 100 Asma Boulevard, Suite 151, Lafayette, LA 70508; 104 Lococo Drive, Raceland, LA 70394 or on the Internet at <http://www.deq.state.la.us/planning/regs/index.htm>.

James H. Brent, Ph.D.  
Assistant Secretary

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of the Secretary  
Subpart 3. Laboratory Accreditation**

**Chapter 45. Policy and Intent**

**' 4501. Description and Intent of Program**

A. Description and Intent of Program

1. These regulations provide requirements for an accreditation program specifically applicable to commercial laboratories, ~~wherever located, that provide chemical analyses, analytical results, or other test data to the and federal, state, and local government laboratories performing analyses reportable to the Louisiana Department of Environmental Quality (the department), by contract or by agreement, and the data is:~~

- a. submitted on behalf of any facility, as defined in R.S. 30:2004;
- b. required as a part of any permit application;
- c. required by order of the department;
- d. required to be included on any monitoring reports submitted to the  
department;
- e. required to be submitted by contract; or
- f. otherwise required by department regulations.

2. The department laboratory accreditation program is designed to ensure the accuracy, precision, and reliability of the data generated, as well as the use of department-approved methodologies in the generation of that data. Laboratory data generated by commercial environmental laboratories that are not accredited under these regulations will not be accepted by the department.

\* \* \*

[See Prior Text in B-B.6]

- 7. radiologicals/radioassays; ~~and~~
- 8. bioassays/biomonitoring/toxicological testing; and
- 9. asbestos.

\* \* \*

[See Prior Text in C-E]

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:917 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 4503. Definitions**

A. When used in these rules and regulations, the following words and phrases shall have the meanings ascribed to them below:

\* \* \*

[See Prior Text]

Commercial Laboratory ~~any laboratory that performs analyses or tests for third parties for a fee or other compensation, except those commercial laboratories accredited by the Department of Health and Hospitals in accordance with R.S. 49:1001 et seq.~~ any laboratory, wherever located, that performs analyses or tests for third parties for a fee or other compensation and provides chemical analyses, analytical results, or other test data to the department, by contract or agreement, and the data is: submitted on behalf of any facility, as defined in R.S. 30:2004; or required as a part of any permit application; or required by order of the department; or required to be included on any monitoring reports submitted to the department; or otherwise required by department regulations. The term commercial laboratory does not include laboratories accredited by the Louisiana Department of Health and Hospitals in accordance with R.S. 49:1001 et seq.

Corrective Action Proficiency Test Sample ~~3/4~~ a proficiency test sample of known composition provided by an external source (e.g., EPA) that is used to evaluate lab performance after completion of required corrective action(s) of a failed proficiency evaluation test round.

\* \* \*

[See Prior Text]

Field Test ~~any activity or operation conducted on-site resulting in the measurement of a specific parameter. Field tests are generally conducted at or near the site of sampling and include soil classification, pH, temperature, flow rate, fugitive emissions monitoring of valves, pumps, flanges, etc.~~

\* \* \*

[See Prior Text]

Interim Status ~~Ca~~ status that exists in the accreditation process wherein all application requirements have been met by the laboratory, but formal accreditation status has not been granted by the department. Interim status is granted on a case-by-case basis at the discretion of the department and shall not exceed one year in length.

\* \* \*

[See Prior Text]

*NRCC* Nuclear Regulatory Commission.

~~*Pending Accreditation* *Ca* status that exists in the accreditation process wherein all application requirements have been met by the laboratory, but formal accreditation status has not been granted by the department.~~

*Primary Accrediting Authority*  $\frac{3}{4}$  for the purpose of NELAP Accreditation, the Louisiana Department of Environmental Quality, with the exception of those laboratory analyses accredited under the regulatory and statutory authority of the Louisiana Department of Health and Hospitals.

\* \* \*

[See Prior Text]

*Traceable Material* *C* any material whose true value or true measurement can be related to a standard reference, usually national or international, all having stated uncertainties (e.g., NIST traceable thermometers, standards, reagents, etc.).

\* \* \*

[See Prior Text]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:918 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*\*.

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of the Secretary  
Subpart 3. Laboratory Accreditation**

**Chapter 47. Program Requirements**

**' 4701. Accreditation Process**

A. The department accreditation process comprises four basic steps:

1. the submittal to the department's Office of Management and Finance, Laboratory Services Division ~~department~~ of a written request from the laboratory in the form of an application provided by the department, along with payment of all applicable fees;

\* \* \*

[See Prior Text in A.2-4]

B. When all requirements for accreditation have been successfully fulfilled, the department shall grant the applicant laboratory a formal notice of ~~accreditation and a certificate of accreditation~~ certification that lists those parameters analytes and methods for which the laboratory is ~~accredited~~ certified. The certificate of ~~accreditation~~ must be posted within public view in the laboratory setting.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:919 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 4703. Application for Accreditation**

\* \* \*

[See Prior Text in A]

B. An application for environmental laboratory accreditation shall be made in writing to the ~~department~~ Office of Management and Finance, Laboratory Services Division. This application will provide all requested information and be accompanied by the appropriate application fee. Information will include at least one satisfactory round of the most recent department-specified proficiency evaluation test results or an analytical data package for test categories where no accessible proficiency tests exist. Supplemental information may be required.

\* \* \*

[See Prior Text in C-D]

E. In cases where all application requirements have been met, including review of all methodology and quality assurance program data, a special status of "~~pending accreditation~~ interim status" may be granted at the discretion of the department on a case-by-case basis. Interim status shall not exceed one year in length. Before a laboratory is granted full accreditation, all requirements of these regulations must be met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:919 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 4705. Categories of Accreditation**

A. At the time of application each applicant must clearly identify both the fields of testing and the test categories for which accreditation is sought. A copy of the relevant test method documentation and the requisite equipment for the method must be available at the laboratory. A current list of approved methodologies for each parameter/analyte will be maintained by the department ~~s~~ Louisiana Environmental Laboratory Accreditation Program (LELAP) Unit accreditation office in the Office of Management and Finance, and a copy of the list will become a part of the application package. In cases where the methodology used by the laboratory is not listed, the laboratory shall submit documentation that will verify that the results obtained from the method in use are equal to or better than those results obtained from the approved methodology. The department will review the data submitted by the laboratory and will notify the laboratory in writing within 60 calendar days if the method is acceptable or unacceptable as an alternate method of analysis.

\* \* \*

[See Prior Text in B-B.1]

2. air pollutants (including industrial hygiene and Toxic Organic Compounds (T.O.) methods), stack sampling, and ambient air;

\* \* \*

[See Prior Text in B.3-B.8]

9. asbestos; ~~and~~

10. geo-technical properties of soils including, but not limited to, compaction test, permeability, particle size analysis, soils classification, etc.; and

101. minor conventional parameters - BOD<sub>5</sub>, oil and grease, TSS, pH, fecal and total coliform, and residual chlorine.

\* \* \*

[See Prior Text in C]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:919 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**\* 4707. Fees**

\* \* \*

[See Prior Text in A-E]

F. Travel expenses incurred by representatives of the department, traveling within and outside of the state of Louisiana, conducting an assessment/inspection for the purpose of accreditation shall be reimbursed by the laboratory. These rates shall be in accordance with the Division of Administration state general travel regulations, within the limits established for state employees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:920 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**\* 4711. Proficiency Testing Participation**

\* \* \*

[See Prior Text in A-C]

D. Proficiency testing studies will be available at a minimum of every six months. Laboratories shall participate in two proficiency test studies per year for each field of testing. Failure to meet the minimum semiannual schedule shall be regarded as a failed proficiency test study. Laboratories may set up round robin testing programs under the department's supervision in order to satisfy this requirement, using splits where applicable.

E. Laboratories shall satisfactorily ~~analyze at least one~~ complete of the two proficiency test studies offered ~~per year~~ for each test category accredited within the most recent three proficiency test studies attempted. A year shall be considered as the 12-month period from the first day of July until the last day of June. Results shall be considered satisfactory when they are within the acceptable limits established by the testing agency or the department.

F. Each participating laboratory ~~must supply the department with a copy of the~~ shall authorize the proficiency test provider to release the results of the proficiency evaluation (PE) test results to the Office of Management and Finance, Laboratory Services Division at the same time that they are submitted to the laboratory. ~~within 30 days of receipt by the laboratory.~~ Every laboratory that receives test results that are "unacceptable" for a specific analyte must investigate and identify likely causes for these results, resolve any problems, and report such activity to the ~~department~~ Office of Management and Finance, Laboratory Services Division along with the submittal of corrective action proficiency sample test results. The laboratory shall report only the analytes for which corrective action was required.

\* \* \*

[See Prior Text in G-J]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:922 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 4717. Accreditation for Laboratories Participating in the NELAP Certification Program Repealed.**

~~In state laboratories participating in the National Environmental Laboratory Accreditation Program (NELAP) shall be certified under standards established by these regulations and those of the NELAP program as found at <http://www.epa.gov/ttn/nelac> or by writing NELAP, U.S. Environmental Protection Agency (MD-75A), Research Triangle Park, NC 27711, attention: NELAC Director, telephone (919)541-1120. NELAP-certified laboratories shall be required to meet the requirements for reciprocity as set forth in LAC:33:I.4713.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:922 (May 1998), repealed by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 4719. Implementation**

A. All commercial laboratories analyzing data as of the effective date of these regulations that are directly or indirectly submitting data to the department must submit an application for accreditation as required in LAC 33:I.4701.A.1, including the review fee, ~~within 180 days of the effective date of these regulations~~ by July 1, 2000. The department ~~will~~ shall not accept laboratory data generated by laboratories that do not comply with this deadline until such laboratories receive accreditation and fully comply with the requirements of this Section. The department shall not accept environmental data submitted to the department either directly or indirectly until the laboratory has applied for accreditation under these regulations.

B. All laboratories subject to these regulations must receive accreditation from the department, as provided in these regulations, undergo an on-site inspection as specified in LAC 33:I.4701.A.2, and successfully participate in proficiency evaluations as required in LAC 33:I.4701.A.3 ~~within one year of the effective date of these regulations.~~ by December 31, 2000, or as otherwise agreed to by the department and the applicant, not to exceed one year from December 31, 2000. The department ~~will~~ shall not accept data generated by laboratories that do not comply with ~~this~~ these deadlines until such laboratories receive accreditation and fully comply with the requirements of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:922 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of The Secretary  
Subpart 3. Laboratory Accreditation**

**Chapter 49. Organization and Personnel Requirements**

**' 4901. Laboratory Staff for All Programs Covered by these Regulations**

A. Managerial Staff. The laboratory shall have the managerial staff with the authority and resources needed to discharge their duties. The technical director or his/her designated representative shall be a full-time member of the laboratory staff who has the authority to exercise the day-to-day supervision of the laboratory policies and procedures. The laboratory shall be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times. The laboratory shall specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of calibrations and tests. Such documentation shall include:

\* \* \*

[See Prior Text in A.1-H]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:922 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of the Secretary  
Subpart 3. Laboratory Accreditation**

**Chapter 51. On-site Inspection/Evaluation**

**' 5103. Laboratory Facilities**

A. The laboratory conditions in which the tests are undertaken shall not invalidate the test results or adversely affect the required accuracy of measurement. The laboratory shall have the equipment, adequate storage facilities, procedures to preserve the identity, concentration and stability of samples, and energy sources needed for proper testing. They shall be equipped with devices to monitor essential environmental conditions. Specifically, the testing laboratory shall include the following:

\* \* \*

[See Prior Text in A.1-5]

6. adequate procedures and facilities in place for collection, storage, and disposal of wastes, including expired chemicals, reagents, solutions, standards, and other material with a limited shelf-life;

\* \* \*

[See Prior Text in A.7-C]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:924 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of the Secretary  
Subpart 3. Laboratory Accreditation**

**Chapter 53. Quality System Requirements**

**' 5301. Quality Assurance/Quality Control Requirements**

A. Each laboratory seeking accreditation shall maintain their Quality Assurance/Quality Control (QA/QC) program using appropriate document control practices. The quality assurance manual, analytical methods, and administrative procedures necessary to meet requirements of these regulations shall be reviewed for accuracy and approved for release by the appropriate personnel, distributed, and controlled to ensure the use of the current approved version. Each laboratory seeking accreditation shall:

\* \* \*

[See Prior Text in A.1-C]

1. the structure of the laboratory (organizational charts and generic position descriptions) including relationship between management, technical operations, support services, and quality systems;

\* \* \*

[See Prior Text in C.2-6]

7. references to procedures for the control and maintenance of documentations, including document control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting;

8. the laboratory's procedures for achieving traceability of measurements to NIST reference materials or other traceable commercial vendors;

\* \* \*

[See Prior Text in C.9-14]

15. references to ~~policy and~~ procedures for ~~dealing with complaints~~ the resolution of complaints received from clients or other parties. Records of the complaint and subsequent action shall be maintained;

\* \* \*

[See Prior Text in C.16-17]

18. identification of the laboratory's approved signatories; at a minimum, the title page of the quality assurance manual must have the signed and dated concurrence (with appropriate titles) of all responsible parties, including the quality assurance officer(s), technical director, and the laboratory manager;

19. references to processes/procedures for educating and training personnel in their ethical and legal responsibilities, including potential punishment and penalties for improper, unethical, or illegal actions;

~~1820.~~ references to processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training;

21. references to procedures for reporting analytical results; and

22. a table of contents and applicable lists of references, glossaries, and appendices.

\* \* \*

[See Prior Text in D]

E. The laboratory shall conduct annual internal audits to verify the compliance with the laboratory's quality system. The quality assurance officer shall be responsible for planning and organizing audits. Personnel shall not audit their own activities.

F. Standard operating procedures (SOPs) shall be kept in a manual available to the analyst and the inspector. SOPs may be included as a part or section of the laboratory's quality assurance manual. The laboratory shall have clearly defined, written SOPs or an equivalent, addressing, at a minimum, and as appropriate:

1. methods of analysis;
  - a. identification of the test method;
  - b. applicable matrix or matrices;
  - c. detection limit;
  - d. scope and application, including components to be analyzed;
  - e. summary of test method;
  - f. definitions;
  - g. safety;
  - h. equipment and supplies;
  - i. reagents and standards;
  - j. ~~2.~~ sample collection, preservation, storage, handling, and chain of custody;
  - k. quality control;
  - l. calibration;
  - m. procedure;
  - n. calculations;
  - o. method performance;
  - p. pollution prevention;
  - q. data assessment and acceptance criteria for quality control measures;
  - r. corrective actions for out-of-control or unacceptable data;
  - s. contingencies for handling out-of-control or unacceptable data;
  - t. waste management;
  - u. references; and
  - v. any tables, diagrams, flowcharts, and validation data;
  
- ~~32.~~ procurement and inventory procedures;

- 43. preventive maintenance;
- 54. recordkeeping and record storage (archives);
- 65. data reduction, validation, and reporting;
- 76. correcting erroneous reports;
- 87. management of laboratory wastes and hazardous materials; and
- 98. complaints registered against the laboratory's testing procedures, reporting procedures, and/or other general operating procedures.

FG. Supervisory staff shall be responsible for quality assurance/quality control implementation and compliance.

GH. The following general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (e.g., chemical, microbiological, radiological). The standards for any given test type shall assure that the following applicable principles are addressed:

1. all laboratories shall have protocols in place to monitor the following quality controls:
  - a. adequate controls to monitor tests such as blanks, spikes, or reference toxicants;
  - b. adequate tests to define the variability and/or reproducibility of the laboratory results such as duplicates;
  - c. measures to ensure the accuracy of the test data, including sufficient calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;
  - d. measures to evaluate test performance, such as method detection limits, or range of applicability such as linearity;
  - e. selection of appropriate formulae to reduce raw data to final results such as linear regression, internal standards, or statistical packages;
  - f. selection and use of reagents and standards of appropriate quality; and
  - g. measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method, such as temperature, humidity, light, or specific instrument conditions;

2. all quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance limits shall be used to determine the validity of the data. The acceptance/rejection criteria shall be updated at a frequency established by the method or by the department's standards;

3. the laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists; and

4. the method-specified and/or method-recommended quality control protocols shall be followed. The essential standards shall be used if no protocols are written into the method or if the method protocols are less stringent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:925 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5303. Equipment and Supplies**

\* \* \*

[See Prior Text in A-C]

D. Records shall be maintained for each item of equipment and all reference materials significant to the tests performed. Maintenance log book(s) and/or an electronic maintenance database with scheduled backups shall be maintained for all major equipment. Each log shall include:

\* \* \*

[See Prior Text in D.1-6]

7. the details of maintenance, including history of any damage, malfunction, modification, or repair.

\* \* \*

[See Prior Text in E-H.6.b]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:926 (May 1998), repromulgated LR 24:1093 (June 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5311. Quality Assurance for Biomonitoring Laboratories**

\* \* \*

[See Prior Text in A-M.2]

N. Reference toxicants such as sodium chloride (NaCl), potassium chloride (KCl), cadmium chloride (CdCl<sub>2</sub>), copper sulfate (~~CaSO<sub>4</sub>~~ CuSO<sub>4</sub>), sodium dodecyl sulfate (~~SDS~~ CH<sub>3</sub>(CH<sub>2</sub>)OSO<sub>3</sub>Na), and potassium dichromate (K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>) are suitable for use by the laboratory. Standard reference materials can be obtained from commercial supply houses or can be prepared in-house using reagent grade chemicals.

\* \* \*

[See Prior Text in O-O.7]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:929 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

#### ' 5315. Records

A. The laboratory shall maintain a record system that shall produce accurate, readily available records that document all laboratory activities. The testing laboratory shall retain on record all original raw data and observations, calculations and derived data, calibration records, and the final test report in a manner in which the continuity and integrity of the analytical process is preserved. All records shall be maintained for a minimum of five 10 years or as required by regulatory or legal requirement. Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of test data, the laboratory shall ensure that:

1. computer software is documented and adequate for use;
2. procedures are established and implemented to protect the integrity of data. Such procedures shall include, at a minimum, integrity of data entry or capture, data storage, data transmission, and data processing;
3. computers and automated equipment are maintained to ensure proper functioning and retrieval of data; and
4. procedures are developed and implemented to maintain security of data, including prevention of unauthorized access to, or unauthorized amendment of, computer records.

\* \* \*

[See Prior Text in B-F]

G. The laboratory shall maintain administrative records (e.g., training records) in a manner in which the continuity, integrity, and retrievability processes are preserved.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:931 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of the Secretary  
Subpart 3. Laboratory Accreditation**

**Chapter 57. Maintenance of Accreditation**

**' 5701. Display of Accreditation Certificate**

\* \* \*

[See Prior Text in A-B]

C. The accredited laboratory shall not misrepresent its state or NELAP accreditation documents. This shall include use in laboratory reports, catalogs, advertising, business solicitations, or proposals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24: 932 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5705. Discreditation and Suspension**

\* \* \*

[See Prior Text in A-F.16]

G. If the department discredits/suspends a laboratory, the laboratory shall return the certificate of accreditation to the department within 10 calendar days from receipt of notification of the dicreditation or suspension.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:932 (May 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**Title 33  
ENVIRONMENTAL QUALITY**

**Part I. Office of the Secretary**

### Subpart 3. Laboratory Accreditation

#### Chapter 59. Accreditation for Laboratories Participating in the NELAP Program Certification

##### ' 5901. Accreditation Process

A. In-state laboratories participating in the National Environmental Laboratory Accreditation Program (NELAP) shall be certified under standards established by these regulations and those of the NELAP program, as found at <http://134.67.104.12/html/nelac/standards.htm> or by writing NELAP, U.S. Environmental Protection Agency (MD-75A), Research Triangle Park, NC 27711, Attention: NELAP Director, telephone (919)541-1120. NELAP-certified laboratories shall be required to meet the requirements for reciprocity as set forth in LAC 33:I.4713.

B. The NELAP accreditation process comprises these basic steps:

1. the submittal to the department of a written request from the laboratory in the form of an application provided by the department with the payment of all applicable fees;
2. a review of personnel qualifications;
3. an on-site assessment/evaluation of the laboratory submitting the request/application by authorized representatives of the department with the appropriate laboratory background;
4. the successful participation in the NELAP-approved proficiency evaluations; and
5. a review of the quality assurance/quality control practices, and quality systems in use at the laboratory.

C. When all the requirements for accreditation have been successfully fulfilled, the department shall grant the applicant laboratory a formal notice of accreditation and a certificate of accreditation that lists those fields of testing, methods used by the laboratory, and individual analytes determined by a particular method for which the laboratory is accredited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

##### ' 5903. Categories of Accreditation

A laboratory may apply for accreditation in any one or more of the nine fields of testing and in one or more of the eleven test categories applicable to the field(s) of testing selected. The laboratory shall be accredited in those parameters/analytes within the test category(ies) found in LAC 33:I.4705.B. The laboratory shall be accredited in those parameters/analytes within the test category(ies) for which the

laboratory demonstrates acceptable performance on proficiency samples (when available) and meets all other requirements of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

#### **' 5905. Inspections of a Laboratory**

A. As a condition of obtaining and maintaining NELAP accreditation, the laboratory shall permit and facilitate inspections/assessments by personnel or designated representatives of the department. The specific requirements for an on-site inspection are outlined in LAC 33:I.Chapter 51.

B. Inspectors shall conform to appropriate safety procedures during an on-site inspection. The specific requirements for an inspector are outlined in LAC 33:I.4709.B.

C. A comprehensive on-site inspection/assessment of each accredited laboratory shall be conducted at intervals of not more than two years. The department may make an announced or unannounced inspection or assessment of an accredited laboratory whenever the department, in its discretion, considers such an inspection or assessment necessary to determine the extent of the laboratory's compliance with the conditions of its accreditation and these regulations.

D. The primary accrediting authority shall forward a written report of findings to the laboratory within 30 calendar days from the date of the on-site inspection/assessment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

#### **' 5907. Corrective Action Reports in Response to On-Site Inspections**

A. The laboratory shall submit to the department a corrective action plan/report. The plan/report shall include, at a minimum, the action(s) that the laboratory shall implement to correct each deficiency noted in the on-site inspection/assessment report and the time period required to accomplish each corrective action.

1. If the corrective action plan/report is deemed unacceptable, the laboratory shall have an additional 30 days to submit a revised corrective action plan/report.

2. If the corrective action plan/report is deemed unacceptable after the second submittal, the laboratory shall have its accreditation revoked in accordance with section 4.4.3 of the NELAP Standards for all or any portion of its scope of accreditation for any or all fields of testing.

3. If the laboratory fails to implement the corrective actions as stated in their corrective action plan/report, its accreditation shall be revoked.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5909. Proficiency Testing Participation**

All laboratories seeking accreditation under NELAP shall participate in the department-approved proficiency testing program as required in LAC 33:I.4711.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5911. Accreditation for Out-of-State Laboratories Seeking NELAP Accreditation**

Acceptance of accreditation from another NELAP accrediting authority in that field of testing shall be determined by the department. The laboratory must comply with these regulations and the standards established by NELAP. NELAP certified laboratories shall be required to meet the requirements for reciprocity as set forth in LAC 33:I.4713.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5913. Certification of Compliance Statement**

The Certification of Compliance statement as required in section 4.1.9 of the NELAP standards shall be required. This statement shall be signed by the laboratory manager and the quality assurance officer or other designated person.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**' 5915. Accreditation**

A. The period of accreditation shall be one year. To maintain accreditation the laboratory shall meet all requirements of these regulations and the NELAP standards.

B. The department may suspend or discredit a laboratory in any or all of the test categories within the fields of testing for failure to meet the requirements of these regulations and the NELAP standards.

C. The department shall notify the laboratory by registered letter of the suspension or discreditation and the reason for the action.

D. Accreditation shall remain in effect until revoked by the accrediting authority, withdrawn at the written request of the accredited laboratory, or the expiration of the accreditation period.

E. The laboratory may renew accreditation by meeting the requirements outlined in LAC 33:I.5703.

F. Appeals for laboratories that have received discreditation or revocation notices are governed by applicable statutes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:\*\*.

**FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES** LOG #: OSO35

Person Preparing Statement: Louis R. C. Johnson Dept.: Department of Environmental Quality  
 Phone: (225) 765-2405 Office: Environmental Assessment  
 Return Address: P.O. Box 82231 Rule Title: Laboratory Accreditation Amendments (LAC 33: I, Chapters 45, 47, 49, 51, 53, 55, 57 & 59)  
Baton Rouge, LA 70884  
 Date Rule Takes Effect: Upon Promulgation

**SUMMARY**  
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)**

The proposed rule changes should have no fiscal or economic impact. The proposed changes are for clarification of existing requirements established under the regulations.

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)**

The proposed rule changes should not affect the revenue collections of state or local government.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)**

The proposed rule changes should not affect any person or non-governmental groups. The proposed rule changes are for clarification of existing regulations.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)**

The proposed rule changes should not affect employment or competition. The proposed rule changes are for clarification of existing regulations.

\_\_\_\_\_  
Signature of Agency Head or Designee

LEGISLATIVE FISCAL OFFICER OR DESIGNEE

James H. Brent Ph.D. Asst. Secretary  
Typed Name and Title of Agency Head or Designee

\_\_\_\_\_  
Date of Signature

\_\_\_\_\_  
Date of Signature

LFO 7/1/94

**FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES**

The following information is requested in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The laboratory accreditation rule requires accreditation of commercial environmental laboratories by DEQ every three years. The accreditation program requires third-party audits, submission of samples for independent analysis, and inspection of regulated labs. The rule provides for quality assurance/quality control procedures, lab personnel qualifications, and sampling protocol. This rule and program enhances the accuracy, reliability, and veracity of environmental lab data in the state

- B. Summarize the circumstances which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

These proposed rule changes clarify the existing rule and finalize emergency rule Log # OSO35E, LAC 33: 1.4719. The clarification of the existing rule is necessary to facilitate a better understanding of the program requirements.

- C. Compliance with Act II of the 1986 First Extraordinary Session
  - (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The proposed rule changes does not result in an increase in the expenditure of funds

- 2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase? N.A.
  - (a) \_\_\_\_ Yes. If yes, attach documentation.
  - (b) \_\_\_\_ No. If no, provide justification as to why this rule change should be published at this time.

**FISCAL AND ECONOMIC IMPACT STATEMENT**

**WORKSHEET**

**I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED**

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

There should be no increase or decrease in cost

COSTS	FY 00-01	FY 01-02	FY 02-03
PERSONAL SERVICES			
OPERATING EXPENSES			
PROFESSIONAL SERVICES			
OTHER CHARGES			
<u>EQUIPMENT</u>			
<u>TOTAL</u>	0	0	0

**MAJOR REPAIR & CONSTR.**

**POSITIONS(#)**

2. Provide a narrative explanation of the costs or savings shown in "A.1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

There should be no increase or decrease in costs to implement this proposed rule change. The rule change is for clarification and to finalize emergency rule Log # OSO35E, LAC 33:1.4719.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 00-01	FY 01-02	FY 02-03
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
DEDICATED			
FEDERAL FUNDS			
<u>OTHER (Specify)</u>			
<u>TOTAL</u>	0	0	0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

This proposed rule change will not require the agency to expend any additional funding for the implementation of these changes. The rule changes are for clarification and to finalize emergency rule Log # OSO35E.

**B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.**

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

Not applicable, since the proposed rule changes are for clarification of an existing rule and to finalize emergency rule Log # OSO35E.

2. Indicate the sources of funding of the local governmental unit which will be affected by these costs or savings.

Not applicable, since the proposed rule changes are for clarification of an existing rule and to finalize emergency rule Log # OSO35E, LAC 33:1.4719.

**FISCAL AND ECONOMIC IMPACT STATEMENT**

**WORKSHEET**

**II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS**

A. What increase (decrease) in revenues can be anticipated from the proposed action?  
There should be no increase or decreases in revenues.

REVENUE INCREASE/DECREASE	FY 00-01	FY 01-02	FY 02-03
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS			
<u>LOCAL FUNDS</u>			
<u>TOTAL</u>	<u>0</u>	<u>0</u>	<u>0</u>

\*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

Not Applicable

**III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS**

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

There should be no effect on costs, workload adjustments or paper work. The proposed rule changes are for clarification of an existing rule and to finalize emergency rule Log # OSO35E, LAC 33: I.4719.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

Not Applicable

**IV. EFFECTS ON COMPETITION AND EMPLOYMENT**

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

Competition and employment should not be impacted since the proposed rule changes are to clarify an existing rule and to finalize emergency rule Log #OSO35E, LAC 33: I.4719.