

# Attachment C - Lab Certification Requirements

RFx No. 3000006035

Drinking Water Analysis, DHH-OPH

Title 48, Part V

E. The parish sanitarian may store relevant sections of the plan. Other sections may be returned to the builder/owner/developer. The parish sanitarian shall, at the end of three years, offer in writing to return the plans to the builder/owner/developer. If the builder/owner/developer does not claim them within 30 calendar days, the plans will be destroyed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4, and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 13:246 (April 1987).

## §7903. Plans Reviewed by the District Engineer

A. There shall be four OPPHS district areas. District 1 consists of State Planning Regions I and III. District 2 consists of State Planning Regions II and IV. District 3 consists of State Planning Regions IV and V, and District 4 consists of State Planning Regions VI and III.

B. The following plans shall be submitted by the builder/owner/developer to the district engineers (or to parish health unit who in turn will forward them to the district engineer) for review.

1. State projects
2. Jails
3. Schools
4. Institutions
5. Hospitals
6. Nursing homes
7. Public swimming pools
8. Public water facilities greater than 3,000 per day
9. Public sewerage facilities greater than 3,000 per day

C. District engineers, after approving the plans, shall notify the builder/owner/developer in writing that the plans are approved and forwarded to the parish health unit for keeping.

D. District engineers, after disapproving the plans, shall notify the builder/owner/developer in writing of failings or defects. The builder/owner/developer may correct the cited deficiencies and resubmit the revised plans for review.

E. A major defect is a defect that is an imminent health hazard. A minor defect is a defect that is a potential health hazard but not an imminent health hazard. A letter explaining the defect will be sent if the defect is minor. If the defect is major, part of the reviewed plans will have to be redrawn.

F. All parties involved—the builder/owner/developer, the regional engineer, and the parish sanitarian—will notify in writing all other parties of suggested plans changes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4, and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 13:246 (April 1987).

## Subpart 28. Drinking Water Laboratories

### Chapter 80. Accreditation of Laboratories Performing Drinking Water Analyses

#### Subchapter A. General Provisions

##### §8001. Scope and Authority

A. This Chapter, adopted pursuant to R.S. 36:254(B)(7), the federal Safe Drinking Water Act (42 USC 300f et seq.) and its implementing regulations (40 CFR Parts 141 and 143), the 2009 The NELAC Institute (TNI) Standard, the National Environmental Laboratory Accreditation Program (NELAP), and the Louisiana State Sanitary Code (LAC 51) constitutes the Department of Health and Hospitals, Office of Public Health (hereinafter referred to as "department") regulations governing the accreditation of laboratories performing drinking water analyses required to be performed by regulations or orders issued pursuant to those acts and regulations. The authority of the department to grant, maintain or revoke a laboratory's TNI NELAP or State Accreditation shall not be delegated to an outside person or body. Portions of the accreditation process may be contracted out by the department but the authority to grant, maintain, suspend or revoke accreditation remains with the department. This Chapter establishes the procedures for obtaining and maintaining accreditation, and the criteria and procedures laboratories shall follow in analyzing drinking water samples.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3215 (December 2012).

##### §8003. Construction

A. These rules shall be liberally construed to permit the department to discharge its statutory functions, and to effectuate the purposes of the laboratory accreditation program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216 (December 2012).

##### §8005. Purpose of the Regulations

A. This Chapter is promulgated for the following purposes:

1. to establish an accreditation program for laboratories performing analyses of drinking water samples;

2. to establish the administrative procedures to be followed by laboratories seeking accreditation and by laboratories maintaining accreditation;

3. to establish the categories and parameters for which laboratories may be accredited;

4. to require that the accreditation status of a laboratory be contingent upon that laboratory's continued compliance with the standards set forth herein and with the standards established by The NELAC Institute National Environmental Laboratory Accreditation Program (TNI NELAP); and

5. to establish the enforcement procedures the department shall follow to ensure that all accredited laboratories or laboratories seeking accreditation are in compliance with this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216 (December 2012).

#### **§8007. Accreditation Program Requirements**

A. The laboratory accreditation program is voluntary and open to any laboratory to apply for accreditation. However any laboratory wishing to analyze drinking water samples for compliance with regulations adopted or orders issued pursuant to the Safe Drinking Water Act, or R.S. 36:254(B)(7), R.S. 36:254(B)(8), R.S.40:4(A)(8), R.S.40:5(6), R.S.40:5.9, or Part XII of the department's Sanitary Code (LAC 51) shall follow the procedures set forth herein in order to obtain and maintain accreditation.

B. Accredited laboratories and laboratories seeking accreditation shall analyze all drinking water samples in accordance with the procedures and methods required by this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216 (December 2012).

#### **§8009. Incorporation by Reference**

A. The department hereby adopts and incorporates into these regulations:

1. the "National Primary Drinking Water Regulations," 40 CFR 141, as amended;

2. the "National Secondary Drinking Water Regulations," 40 CFR 143, as amended;

3. the NELAC Institute 2009 Standard (TNI Standard); and

4. the Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance Fifth Edition (EPA 815-R-05-04) January 2005 including Supplement 1(EPA 815-F-08-006), June 2008, both published by the United States Environmental Protection Agency (USEPA or EPA).

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216 (December 2012).

#### **§8011. Program Information**

A. Unless otherwise specified, any questions concerning the requirements of this program as detailed in this Chapter should be directed to:

Laboratory Accreditation Section  
Louisiana Department of Health and Hospitals  
Office of Public Health  
3101 West Napoleon Avenue – Room 201  
Metairie, Louisiana 70001  
504-219-4662  
www.lab.dhh.louisiana.gov

1. All requests for information, applications for laboratory accreditation, and submittals of fees and performance testing data shall be submitted to the address above.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216 (December 2012).

#### **§8013. Severability**

A. If any Section, Subsection, Paragraph, Clause, Subclause, Division, or other portion of this Chapter is adjudged unconstitutional or invalid by a court of competent jurisdiction, the remainder of this Chapter shall not be affected thereby.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216.

### **Subchapter B. Program Procedures and Requirements**

#### **§8015. Scope**

A. This Subchapter establishes the following:

1. requirements of accreditation;
2. categories for which accreditation is available;
3. procedures for becoming an accredited drinking water laboratory;
4. procedures for an accredited drinking water laboratory to renew or modify its accreditation;
5. procedures for cancellation, suspension, and revocation of accreditation; and,
6. fees for accreditation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3216 (December 2012).

### §8017. Requirements of Accreditation

A. All water sample analyses performed for the purpose of determining compliance with the chemical, physical, or radiological requirements of the State's primary and secondary drinking water regulations, or when required by order issued by the department pursuant to the authority of the federal Safe Drinking Water Act, or any other regulations adopted pursuant to those acts, shall be performed in laboratories accredited for this purpose pursuant to this Chapter. Analyses performed in laboratories not so accredited shall not be accepted by the department as being in compliance with the requirements, regulations or orders of the federal Safe Drinking Water Act. Effective July 1, 2011 or the effective date of this rule, whichever occurs later, any laboratory accredited or seeking accreditation in one or more of the categories specified in §8019 of this Chapter shall comply with the following modules (as appropriate for the category or categories which the laboratory is seeking accreditation) which are contained in Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis of the TNI Standard:

1. Module 1—Proficiency Testing [Environmental Laboratory (EL)-Volume (V) 1 Module (M) 1 - 2009];
2. Module 2—Quality Systems General Requirements [EL-VIM2-International Standards Organization (ISO)-2009];
3. Module 3—Asbestos Testing (EL-VIM3-2009);
4. Module 4—Chemical Testing (EL-VIM4-2009); and,
5. Module 6—Radiochemical Testing (EL-VIM6-2009).

B. To be clear, the requirements of LAC 48:V.8009.A.1 and 8009.A.2 shall apply to all laboratories regardless of the number of categories specified in §8019 for which the laboratory is seeking accreditation. The requirements of Paragraphs 8019.A.1, 8019.A.2 and 8019.A.3 shall apply dependent upon the particular category or categories for which the laboratory is seeking accreditation.

C. The department shall, in accord with the provisions of this Section, grant reciprocity to a laboratory located outside of the State of Louisiana if the laboratory requesting accreditation also meets each of the following requirements:

1. the laboratory is accredited by a TNI NELAP-recognized primary accreditation body;
2. the laboratory submits an acceptable application for accreditation to the State; and
3. the laboratory pays all applicable fees;

D. The department shall consider only the current certification of accreditation issued by the TNI NELAP recognized primary accreditation body and shall grant reciprocal accreditation for the fields of testing, methods and analytes for which the laboratory holds primary TNI NELAP

accreditation. The department will issue a Louisiana accreditation certificate within thirty calendar days of receipt of the laboratory's application if all the above reciprocity requirements are met by the laboratory. The department, as a TNI NELAP-recognized secondary accreditation body, does not require any additional proficiency testing, quality assurance, or on-site assessment requirements for fields of testing for which the laboratory holds primary TNI NELAP accreditation.

E. A laboratory that is TNI NELAP-accredited by the department that has lost recognition may seek renewal of TNI NELAP accreditation through any TNI NELAP-recognized federal or state accreditation body. The laboratory's TNI NELAP accreditation from an accreditation body that has lost TNI NELAP recognition shall remain valid throughout its current certificate of accreditation.

F. TNI NELAP accredited laboratories whose home state becomes a recognized TNI NELAP accreditation body may retain their primary accreditation through the state that holds their current accreditation. The laboratory may retain their existing certificate of accreditation through to the date on the certificate, or until such time that they choose to renew. Depending on the regulations of their home state, the laboratory may still be required to apply for secondary accreditation from their home state until time for renewal for their primary accreditation. At the time of renewal, they must apply for their primary accreditation through their home state accreditation body as applicable based on requested fields of accreditation.

G. Only laboratories accredited pursuant to these regulations may be called a TNI NELAP or State Accredited Drinking Water laboratory and no laboratory may adopt any name or make any oral or written statement intended or likely to mislead the public with the respect to its accreditation status.

H. Once a laboratory is accredited, the period of accreditation shall extend to the end of the calendar year in which accreditation is received. For laboratories seeking to renew accreditation, the period of accreditation shall be one year beginning on January 1 and shall be considered to be ongoing if the appropriate fees are timely received by the department.

I. The TNI Standard is examined periodically and is subject to being amended or changed. If an accredited laboratory seeks to renew its accreditation under TNI NELAP, the laboratory shall be re-evaluated using the current TNI Standard adopted in this Chapter along with any of these TNI-NELAP adopted minor amendments/adjustments to such standard.

J. If there is a difference in the drinking water regulations of the USEPA, the regulations of the department or the requirements of the TNI Standard, a laboratory must follow the more stringent requirement(s).

1. Notwithstanding the general requirements of Subsection J above, a laboratory seeking State of Louisiana drinking water laboratory certification only may be allowed,

at the discretion of the department, to meet less than the more stringent requirement(s) [e.g., see Subsection 8031.A wherein a lesser frequency of proficiency analyses is acceptable as compared to Subsection 8031.C's frequency of proficiency analyses requirements (which is applicable to a laboratory seeking TNI certification)]. The department shall require laboratories seeking or maintaining only a State of Louisiana drinking water laboratory certification to comply with Paragraphs 8009.A.1, 8009.A.2 and 8009.A.4. Paragraph 8009.A.3 is applied only when a laboratory is seeking or maintaining a TNI certification.

K. Applications shall be processed in the chronological order in which they have been received.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3217 (December 2012).

### **§8019. Categories for Accreditation**

A. A laboratory may apply for accreditation in any one or more of the following accreditation categories and shall be accredited in those fields of accreditation within the category for which it demonstrates acceptable performance on proficiency samples and meets all other requirements of this Chapter. The laboratory certificate shall specify the categories and the fields of accreditation within each category for which the laboratory is accredited and shall be conspicuously displayed in the laboratory in a location visible to the public. In addition, the current laboratory certificate specifying the accreditation categories, the fields of accreditation, and the expiration date of the certificate shall be posted on its publicly accessible website. The certificate must be removed and returned to the department if the laboratory's accreditation has been revoked. In addition, the laboratory shall post such revocation or suspension of the laboratory's accreditation on its publicly accessible website. The certificate does not have to be returned if it simply expired (reached the expiration date). The following are the accreditation categories available.

1. **Inorganic Chemistry.** The inorganic chemistry category comprises chemical and/or physical tests or analyses required to determine compliance with the federal Safe Drinking Water Act regulations (40 CFR 141 and 40 CFR 143) and Part XII of the Louisiana Sanitary Code (LAC 51), except those analyses for which gas or liquid chromatography methods are specifically required. Tests or analyses for the inorganic chemistry category shall be conducted in accordance with the methods and procedures specified in 40 CFR 141 and 40 CFR 143 for compliance with the federal Safe Drinking Water Act and Part XII of the Louisiana Sanitary Code (LAC 51).

2. **Organic Chemistry.** The organic chemistry category comprises chemical tests or analyses required to determine compliance with the federal Safe Drinking Water Act regulations (40 CFR 141 and 40 CFR 143) and Part XII of the Louisiana Sanitary Code (LAC 51) for which the gas or liquid chromatography methods are applicable or required. Tests or analyses for the organic chemistry category shall be

conducted in accordance with the methods and procedures specified in 40 CFR 141 and 40 CFR 143 for compliance with the federal Safe Drinking Water Act and Part XII of the Louisiana Sanitary Code (LAC 51).

3. **Radiological Testing.** The radiological testing category comprises those tests or analyses for radioactivity required to determine compliance with the federal Safe Drinking Water Act regulations (40 CFR 141 and 40 CFR 143) and Part XII of the Louisiana Sanitary Code (LAC 51). Tests or analyses for the radiological category shall be conducted in accordance with the methods and procedures specified in 40 CFR 141 and 40 CFR 143 for compliance with the federal Safe Drinking Water Act and Part XII of the Louisiana Sanitary Code (LAC 51).

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3218 (December 2012).

### **§8021. Application Procedures for Laboratories Located in Louisiana**

A. The owner or director of a laboratory who wishes an in-state laboratory to be accredited in any or all of the accreditation categories and fields of accreditation/parameters thereof, described in the federal Safe Drinking Water Act regulations or §8019 of this Chapter, shall apply for accreditation to the department in writing on forms provided by the department. Laboratories applying for accreditation may be fixed-base or mobile. The department shall determine what constitutes an individual fixed-base laboratory when noncontiguous laboratory facilities operate under the same ownership, technical directorship, and quality system as the parent laboratory. A separate accreditation is not required for a mobile laboratory that is owned by an accredited fixed-base laboratory, operates under the same quality system as the fixed-based laboratory, performs a subset of the analyses for which the fixed-base laboratory is accredited, and analyzes samples exclusively from within the state. Separate accreditation is required for a mobile laboratory that is owned by a fixed-base laboratory but operates under a different quality system or performs analyses for which the parent fixed-base laboratory is not accredited.

B. If the applicant fails to submit all the information requested or fails to submit the appropriate fees, the department shall reject the application without prejudice and the applicant notified. The application fee is nonrefundable.

C. If the applicant submits a complete, signed application, the appropriate fee, proficiency data (if required), quality manual (if required), and the information submitted meets the minimum requirements of this Chapter for the category or categories for which accreditation is requested, the application shall be accepted. Acceptance of the application does not authorize the laboratory to perform water analyses regulated by this Chapter. The applicant shall be notified of the acceptance and shall be subject to an evaluation including but not limited to the following:

1. personnel;
2. proficiency testing;
3. on-site assessment; and
4. quality assurance/quality control procedures.

D. Neither accredited nor interim accredited status will be granted to any laboratory which has not met the performance criteria specified in any federal Safe Drinking Water Act regulations or, for those chemicals or other analyses wherein performance criteria may not be specified under the federal Safe Drinking Water regulations, by the performance criteria specified under a written policy of the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3218 (December 2012).

**§8023. Application Procedures for Laboratories Not Located in Louisiana**

A. Laboratories located in a state that does not offer TNI NELAP accreditation and have not obtained TNI NELAP accreditation from another source (i.e., a third state or the federal government) and desiring to perform water analyses in any or all of the categories described in §8019 for public water systems (PWSs) and for other potable water supplies located in Louisiana, or as required by the federal Safe Drinking Water Act regulations or Part XII of the Louisiana Sanitary Code (LAC 51), shall apply for accreditation in accordance with the procedures set forth in §8021 and shall submit the standard fee amount(s) specified under §8027 for the category or categories being applied for. In addition, the laboratory shall submit to the department, as an additional fee, the sum the department determines to be sufficient to cover the transportation costs (including airfare, mileage, tolls, car rental, public transportation and parking) and room and board expenses of the department's accreditation assessors.

B. Laboratories possessing TNI NELAP accreditation from an approved NELAP accreditation body and desiring to perform water analyses in any or all of the categories described in §8019 for PWSs and for other potable water supplies located in Louisiana, or as required by the federal Safe Drinking Water Act regulations or Part XII of the Louisiana Sanitary Code (LAC 51), shall apply for accreditation in accordance with the procedures set forth in §8021. Any out of state laboratory located in a state that has a NELAP recognized accreditation body may not apply for accreditation from the department for any field of accreditation that is offered by the home state accreditation body.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3218 (December 2012).

**§8025. Renewal of Accreditation**

A. Applications for renewals of accreditation will be accepted by the department during November of each year and shall be submitted at least 30 calendar days prior to the expiration date of the current certificate on forms provided by the department. The appropriate application fee must accompany the application in accordance with §8027.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3219 (December 2012).

**§8027. Fees**

A. Owners of laboratories applying for accreditation or renewal of accreditation, for the calendar year commencing January 1, 1990 and for subsequent calendar years shall submit the appropriate fee obtained from the annual fee schedule below along with the required application materials. Fees are nonrefundable.

| Annual Laboratory Accreditation Fee Schedule |        |
|--|--------|
| Chemistry Category/Categories                | Fee    |
| Inorganic                                    | \$750  |
| Organic                                      | \$800  |
| Both Inorganic and Organic                   | \$1000 |
| Radiological Testing                         | \$800  |

B. The annual fees shall not be prorated and shall apply in full to any portion of the calendar year which remains prior to the annual renewal date, November 1.

C. This Section is also applicable to intermily approved laboratories.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7) [the same fee schedule amounts initially adopted in LR 15:968 (November 20, 1989) under this statute's authority].

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3219 (December 2012).

**§8029. Required Laboratory Personnel Policies**

A. Every accredited laboratory and laboratories seeking accreditation shall have sufficient properly qualified personnel commensurate with the workload and types of tests or analyses required to be performed for the parameters for which the laboratory is accredited, or is seeking accreditation, pursuant to the requirements of this Chapter; Volume 1, Module 2, Section 5.2 of the TNI Standard; and Chapters IV and VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

1. General requirements for technical staff. The management of an accredited laboratory or laboratory seeking accreditation shall ensure the competency of all technical staff employed by the laboratory.

a. An environmental laboratory accredited under this Chapter or seeking accreditation under this Chapter shall have sufficient personnel with the necessary education, training, technical knowledge, and experience for their assigned functions.

b. Each technical staff member of the environmental laboratory accredited under this Chapter or seeking accreditation under this Chapter shall be responsible for complying with all quality assurance/quality control requirements that pertain to their organization/technical function.

c. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function, and a general knowledge of laboratory operations, analytical procedures, quality assurance/quality control, and records management.

d. The department will consider that the accountability for negligence, the falsification of data, records or instrument parameters will rest upon the analyst, the laboratory management and parent company.

B. Current employee records shall be maintained, which shall include a résumé documenting each employee's training, experience, duties, and date or dates of relevant employment.

1. Evidence must be on file that demonstrates all employees are aware of and are using the latest edition of the laboratory's in-house quality documentation.

2. Training courses or workshops on specific equipment, analytical techniques or laboratory procedures that relate to employee's job responsibilities shall all be documented.

3. Analyst training shall be considered up-to-date when documentation in the files indicate acceptable performance of a blind sample (singly blind to the analyst) at least once per year and a certification that technical personnel have read, understood, and agreed to perform the most recent version of the method, the approved method (if applicable) or standard operating procedure.

C. Data Integrity Training. Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees. The laboratory shall implement all of the data integrity training requirements in Section 4.3, Volume 1, Module 2 of the TNI Standard.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3219 (December 2012).

**§8031. Proficiency Testing**

A. At the time each laboratory applies for accreditation, it shall notify the department which field(s) of testing it chooses to become accredited for and shall participate in the appropriate proficiency test (PT) studies. Except when determined by the department that an appropriate proficiency test is not readily available, all accredited laboratories or laboratories seeking accreditation shall participate in a TNI Proficiency Testing Provider Accreditor (PTPA) approved proficiency testing program covering all

tests, analytes and analytical methods as made available within the category and categories in which the laboratory is accredited or seeks accreditation. The laboratory shall purchase proficiency test studies from any PTPA accredited Proficiency Testing Provider (PTP) for the parameters for which accreditation is requested. For initial and continued accreditation, the laboratory shall meet the proficiency testing requirements pursuant to Volume 1, Module 1, Proficiency Testing of the TNI Standard. A laboratory seeking State of Louisiana drinking water laboratory certification only shall participate in proficiency studies at the frequency that meet the requirements of federal Safe Drinking Water Act regulations (40 CFR 141 and 40 CFR 143).

B. The laboratory shall meet all of the requirements for PT record retention as defined in Volume 1, Module 1, Section 5.3 of the TNI Standard. All PT records shall be retained for a minimum of five years and available for assessment by the department pursuant to Volume 2, Module 2, Section 6 of the TNI Standard.

C. To be accredited initially and to maintain accreditation the laboratory shall participate in two PT studies, where available, per year for each PT field of testing for which it seeks or wants to maintain accreditation. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date for accreditation with the analysis date of the most recent PT sample having been no more than six months prior to the application date for accreditation. The department will complete the assessment of the final evaluation report for PT studies within 60 days of receipt of each study report pursuant to Volume 2, Module 2, Section 7 of the TNI Standard. The department shall suspend the accreditation of a laboratory for a field of proficiency testing pursuant to the conditions specified in Volume 2, Module 2, Section 10 of the TNI Standard.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3220 (December 2012).

**§8033. On-Site Assessment**

A. The department will perform an initial on-site assessment of an environmental laboratory seeking accreditation, except as provided in §8017, prior to granting accreditation, and reassessments at intervals of two years plus or minus six months and at such other times as the department deems necessary to determine continued compliance to this rule. All assessments performed by the department shall be pursuant to Volume 2, Module 3 of the TNI Standard.

B. The department may conduct announced or unannounced on-site assessments of an environmental laboratory to ensure compliance with this Chapter or orders issued by the department at any time.

C. The laboratory shall ensure that records including its quality manual, analytical methods, standard operating

procedures, quality assurance/quality control data, proficiency testing data, and all records needed to verify compliance to the TNI Standard, the federal Safe Drinking Water Act (42 USC 300f et seq.) and its implementing regulations (40 CFR Parts 141 and 143); the Louisiana State Sanitary Code (LAC 51) and this rule are available for review during the on-site assessment. The laboratory shall allow the department's authorized personnel to examine records, observe laboratory procedures, facilities, equipment and to interview staff during the on-site assessment.

D. The department will provide the laboratory with a written assessment report documenting any findings found by the department, observations documenting competence and conformity, within 30 calendar days of the last day of the assessment.

E. The laboratory shall submit a corrective action plan to the department within 30 calendar days from receipt of the on-site assessment report from the department where the department has found deficiencies. The corrective action plan shall document the corrective action taken by the laboratory to correct each deficiency.

F. In addition to on-site assessments, the department shall perform other surveillance activities to monitor accredited laboratories' continued compliance to the provisions of this Chapter throughout the period of accreditation. Annually, the department shall review among other things, proficiency testing, internal audits, corrective action reports and any other accreditation-related laboratory records the department deems appropriate to establish continued compliance to the provisions of this Chapter.

G. Nothing in this Section shall be construed as requiring the department to reassess a laboratory prior to taking a regulatory or administrative action affecting the status of the laboratory's accreditation. Nothing in this Section shall be construed as limiting in anyway the department's ability to revoke or otherwise limit a laboratory's accreditation upon the identification of such deficiencies as to warrant such action.

H. Copies of all assessment reports, checklists, and laboratory responses shall be retained by the department for a period of at least 10 years, or longer if required by specific State or Federal regulations.

**AUTHORITY NOTE:** Promulgated in accordance with R.S. 36:254(B)(7).

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3220 (December 2012).

### **§8035. Issuance and Display of Certificate and Use of Accreditation**

A. The department will issue a certificate to each laboratory meeting the requirements of this Chapter indicating that the laboratory is accredited by the department. The department will issue the certificate of accreditation following the requirements in Volume 2, Module 1, Section 7.5 of the TNI Standard. The numbered certificate will be signed by a laboratory director of the

department's Laboratory Services Section and the designated laboratory accreditation staff personnel and will be considered an official document. It will be transmitted as a sealed and dated (effective date and expiration date) document and contain the accreditation logo. Addenda or attachments to the certificate shall be considered official documents. Information on the addenda or attachments shall include the matrix, fields of accreditation, methods, analyte/analyte group and technologies.

1. The accredited laboratory shall display their most recent certificate of accreditation in a prominent place in the laboratory, visible to the public. The certificate shall include the accreditation status of the laboratory and a list all fields of testing for which the laboratory is accredited.

B. An accredited laboratory must not use its certificate, accreditation status and/or accreditation logo to imply, either orally or in any literature, endorsement of the laboratory by the State of Louisiana or the department. An accredited laboratory must not make any inaccurate statements concerning their fields of accreditation and accreditation status.

C. An accredited laboratory's accreditation number or other identifier shall be included when the accreditation body's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other material.

D. The laboratory must distinguish between proposed testing for which the laboratory is accredited and the proposed testing for which the laboratory is not accredited.

E. The laboratory must return to the department any revoked accreditation certificate(s) and must discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to their past accreditation status and/or display their past accreditation logo.

F. The department shall take suitable actions including, but not limited to, legal action when incorrect references to the accreditation body's accreditation, misleading use of the laboratory's accreditation status and/or unauthorized use of the accreditation logo is found in catalogs, advertisements, business solicitations, proposals, quotations, laboratory analytical reports or other materials. All reports of questionable laboratory practices must be reported to the department's laboratory director and to the department's laboratory certification program manager. The department's laboratory certification program manager shall investigate the merits of the report and forward the findings to the department's laboratory director. If it is determined that a formal investigation is needed, the department's laboratory director shall contact the Bureau of Legal Services within the Department of Health and Hospitals (DHH) for guidance and assistance in the investigation. If the investigation determines that action is merited, the laboratory shall be issued a revocation order via certified mail revoking the laboratory's accreditation. All legal actions taken by the department shall proceed in accordance with the Louisiana Administrative Procedure Act (R.S. 49:950 et seq.) and

under the direction of DHH's Bureau of Legal Services. No laboratory's accreditation shall be revoked without the right to due process. The laboratory has a right to an administrative hearing thereon, if requested in writing within 20 days of receipt of the revocation order. Said hearing shall be held before an Administrative Law Judge and in accordance with the Louisiana Administrative Procedure Act (R.S. 49:950 et seq.) All documents related to the investigation(s), including the final disposition, shall be retained by the department for 10 years from the date of such final disposition.

G. Accreditation may be transferred when the legal status or ownership of an accredited laboratory changes without affecting its staff, equipment, and organization. The department may conduct an on-site assessment to verify the effects, if any, of such changes on laboratory performance.

H. The following conditions apply to the change in ownership and/or the change in location of a laboratory, as well as to a change in top management, key personnel, resources, or premises that is, or previously was, accredited by the department under a previous owner and/or at a previous location.

1. In the event there are any changes in the name, location, ownership, top management, key personnel, main polices, resources or premises of an accredited laboratory to which the provisions of this Chapter apply, written notice thereof shall be made within 30 days to:

Laboratory Certification Program  
 Laboratory Services  
 LA Department of Health and Hospitals,  
 Office of Public Health  
 3101 West Napoleon Avenue  
 Metairie, LA 70001

2. The department shall evaluate the significance of any change that might alter or impair the laboratory's capability and quality, and indicate to the affected laboratory the results of the evaluation in writing. The department shall retain records to indicate that such an evaluation was conducted.

3. A change in ownership and/or location will not necessarily require reaccreditation or reapplication in any or all of the categories in which the laboratory is currently accredited.

4. A change in ownership and/or location may require an on-site assessment with the elements of the assessment being determined by the assessor.

5. Any change in ownership shall assure historical traceability of the laboratory accreditation number(s).

6. For a change in ownership, the following additional conditions shall be in effect.

a. The previous owner (transferor) shall agree in writing, before the transfer of ownership takes place, to be

accountable and liable for any analyses, data and reports generated up to the time of legal transfer of ownership.

b. The buyer (transferee) must agree in writing to be accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.

c. All records and analyses performed pertaining to accreditation shall be kept for a minimum of 10 years and are subject to review and inspection by the department during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability or liability.

d. If ownership is transferred, the transferee shall not be responsible for payment of fees to the department during the remainder of the calendar year, provided that the previous owner has fully paid the required fees to the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3221 (December 2012).

**§8037. Management System Establishment**

A. The laboratory shall establish and maintain a management system pursuant to and meeting the required elements contained in Volume 1 of the TNI Standard.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3222 (December 2012).

**§8039. Denial, Suspension, Revocation and Voluntary Withdrawal of Accreditation**

A. Denial of Accreditation. Denial means to refuse to accredit in part or in total a laboratory applying for initial accreditation or resubmission of initial application.

1. Reasons to deny an initial application may include:

- a. failure to submit a completed application;
- b. failure of laboratory staff to meet the personnel qualifications as required by the TNI Standard. These qualifications include, but are not limited to, education, training and experience requirements;
- c. failure to successfully analyze and report proficiency testing samples as required in Volume 1, Module 1; Volume 2, Module 2, and Volume 3 of the TNI Standard;
- d. failure to attest that analyses are performed by methodologies as required in Volume 1, Module 2, Section 5.4 of the TNI Standard;
- e. failure to implement a quality system as defined in Volume 1, Module 2 of the TNI Standard;
- f. failure to respond to a deficiency report from the on-site assessment with a corrective action report within 30 calendar days after receipt of the assessment report;

g. failure to implement the corrective actions detailed in the corrective action report within the specified time frame as required by the department;

h. failure to pay required fees;

i. failure to pass required on-site assessment(s) as specified in §8033 of this Chapter;

j. misrepresentation of any material fact pertinent to receiving or maintaining accreditation; or

k. denial of entry during normal business hours for an on-site assessment as required in Volume 2, Module 1, Section 7.5 of the TNI Standard and as mentioned under §8033.B of this Chapter.

2. A laboratory shall have two opportunities to correct the areas of deficiencies which results in a denial of accreditation.

3. If the laboratory is not successful in correcting the deficiencies as required by §8033 of this Chapter and the TNI Standard, the laboratory must wait six months before again reapplying for accreditation.

4. Upon reapplication, the laboratory shall be responsible for all or part of the fees incurred as part of the initial application for accreditation.

5. No laboratory's accreditation will be denied without the right to due process. The laboratory has a right to an administrative hearing thereon, if requested in writing within 20 days of receipt of the denial letter. Said administrative hearing shall be held before an Administrative Law Judge and in accordance with the Louisiana Administrative Procedure Act (R.S. 49:950 et seq.).

B. Suspension of Accreditation. Suspension means the temporary removal of a laboratory's accreditation for a defined period of time which shall not exceed six months. The purpose of suspension is to allow a laboratory time to correct deficiencies or areas of non-compliance with this Chapter and the TNI Standard.

1. A laboratory's accreditation may be suspended in part or in total. The laboratory shall retain those areas of accreditation where it continues to meet the requirements of this Chapter and the TNI Standard.

2. Reasons for suspension may include:

a. the department finds during the on-site assessment that the public interest, safety or welfare requires emergency action;

b. failure to successfully complete PT studies and maintain a history of at least two successful PT studies for each affected accredited field of testing out of the most recent three PT studies;

c. failure to notify the accreditation body of any changes in key accreditation criteria, as set forth in §8029 of this Chapter;

d. failure to maintain a quality system as defined in §8037 of this Chapter; or

e. failure of the laboratory to employ staff who meet the personnel qualifications including, but not limited to, education, training and experience as required by this Chapter and Volume 1, Module 2, Section 5.2 of the TNI Standard.

3. A laboratory under suspension will not have to reapply for accreditation if the cause/causes for suspension are corrected within six months. The laboratory's suspended accreditation status will change to accredited when the laboratory complies with this Chapter and the TNI standard.

4. A suspended laboratory:

a. cannot continue to analyze samples for the affected fields of testing for which it holds accreditation; and

b. shall remain suspended (without appeal rights) due to unacceptable proficiency testing sample results.

5. If the laboratory is unable to correct the reason for the suspension, the laboratory's accreditation shall be revoked in total or in part within six months after the effective date of the suspension.

6. No laboratory's accreditation will be suspended without the right to due process. The laboratory has a right to an administrative hearing thereon, if requested in writing within 20 days of receipt of the suspension order. Said administrative hearing shall be held before an Administrative Law Judge and in accordance with the Louisiana Administrative Procedure Act (R.S.49:950 et seq.)

C. Revocation of Accreditation. Revocation means partial or total withdrawal of a laboratory's accreditation by the department.

1. The accreditation body shall revoke a laboratory's accreditation, in part or in total, for failure to correct the deficiencies after accreditation had been suspended. The laboratory shall retain those areas of accreditation where it continues to meet the requirements of this Chapter and the TNI Standard.

2. Reasons for revocation, in part or in total, include a laboratory's:

a. failure to submit an acceptable corrective action report in response to a deficiency report and failure to implement corrective action(s) related to any deficiencies found during a laboratory assessment(the laboratory may submit two corrective actions plans within the time limits specified by the department); or

b. failure to correctly analyze a parameter(s) in three consecutive PT studies. Should this occur, the laboratory's accreditation shall be revoked for each affected accredited field of testing(s), method(s) and analyte(s).

3. Reasons for total revocation include a laboratory's:

a. failure to respond with a corrective action report within the required 30 calendar days;

b. failure to participate in the proficiency testing program as required by §8031 of this Chapter and the TNI Standard;

c. submittal of proficiency test sample results generated by another laboratory as its own;

d. misrepresentation of any material fact pertinent to receiving or maintaining accreditation;

e. denial of entry during normal business hours for an on-site assessment as required by §8033 of this Chapter and the TNI Standard;

f. conviction of charges for the falsification of any report of or relating to a laboratory analysis; or

g. failure to remit the accreditation fees within the time limit as established by the department may be grounds for immediate revocation.

4. After correcting the reason/cause for revocation, the laboratory may reapply for accreditation sooner than six months from the official date of revocation.

5. No laboratory's accreditation will be revoked without the right to due process. The laboratory has a right to an administrative hearing thereon, if requested in writing within 20 days of receipt of the revocation order. Said administrative hearing shall be held before an Administrative Law Judge and in accordance with the Louisiana Administrative Procedure Act (R.S. 49:950 et seq.).

D. Voluntary Withdrawal of Accreditation. If an environmental laboratory wishes to withdraw from the laboratory accreditation program, it must submit written notification to the department no later than 30calendar days before the end of the accreditation year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3222 (December 2012).

**§8041. Interim Accreditation**

A. If a laboratory completes all of the requirements for accreditation except that of an on-site assessment because the department is unable to schedule the assessment in a timely manner, the department may issue an interim accreditation. Interim accreditation is not available for first time accreditation of a laboratory or after revocation of accreditation. Interim accreditation will allow a laboratory to perform analyses and report results with the same status as a fully accredited laboratory until the on-site assessment requirements have been completed. Interim accreditation status may not exceed 12 months. The interim accreditation status is a matter of public record and will be entered into the national database.

B. Revocation of Interim Accreditation. Revocation of interim accreditation may be initiated for due cause in accord with the requirements of §8039 of this Chapter.

C. The department may approve a laboratory application to add an analyte or method to its scope of accreditation by performing a data review without an on-site assessment. An addition to the scope of accreditation via a data review of PT performance (if available), quality control performance, and

written standard operating procedure is at the discretion of the department. An addition of a new technology or test method requiring specific equipment may require an on-site assessment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3223 (December 2012).

**§8043. Ethics, Standards of Professional Conduct and Conflict of Interest**

A. Professional standards apply to every employee of the department including laboratory assessors, whether a government employee or an employee of a third party organization conducting assessments under an agreement with the department or other accreditation body.

1. Department employees, including assessors that knowingly engage in unprofessional activity, may be liable for punitive actions as initiated by the department. Standards for professional conduct outlined herein are based upon 5 CFR 2635 (Standards of Ethical Conduct for Employees of the Executive Branch) and will be followed in all laboratory accreditation related matters. Additionally, conformance with the Louisiana Code of Governmental Ethics, R.S. 42:1101 et seq., is required.

2. All employees including assessors representing the department or other accreditation body shall:

a. have no interest at play other than that of the department or other accreditation body and NELAP during the entire accreditation process;

b. act impartially and not give preferential treatment to any organization or individual;

c. provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age and/or disability;

d. not use their position for private gain;

e. 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 business with, or affected by, the actions of the assessor's employer or the department;

f. not hold financial interests that conflict with the conscientious performance of their duties;

g. not engage in financial transactions using information gained through their positions as assessors to further any private interest;

h. 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;

i. not knowingly make unauthorized commitments or promises of any kind purporting to bind the department or other affected accreditation body; and

j. 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.

3. It is the individual's responsibility to report to the department any personal issues or activities that constitute a conflict of interest before an assessment occurs. It is up to the department to determine if the reported issues and activities regarding a specific assessor constitute, or may be construed as, a conflict of interest. The department's laboratory director shall contact the Bureau of Legal Services within the Department of Health and Hospitals (DHH) for guidance and assistance in deciding a conflict of interest case and the course of action the department should take.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3223 (December 2012).

### **Subchapter C. Criteria and Procedures for Chemical Testing and Analysis**

#### **§8045. Scope**

A. This Subchapter establishes the department's requirements which an accredited laboratory or laboratory seeking accreditation shall continually meet and follow when performing chemical analyses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3224 (December 2012).

#### **§8047. Laboratory Facilities and Safety**

A. All accredited laboratories or laboratories seeking accreditation pursuant to this Subchapter shall have laboratory facilities and safety procedures that meet the requirements in Volume 1, Module 2, Section 5.3 of the TNI Standard and Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. The analysis of compliance samples shall be conducted in a laboratory where the security and integrity of the samples and the data can be maintained.

C. The laboratory facilities must be clean, have adequate temperature and humidity control, have adequate lighting at the bench top and must meet applicable Occupational Safety and Health Administration (OSHA) standards.

D. The laboratory must have provisions for the proper storage and disposal of chemical wastes. The appropriate type of exhaust hood is required, where applicable.

E. There must be sufficient bench space for processing samples. Workbench space should be convenient to sink, water, gas, vacuum and electrical sources free from surges.

F. Instruments must be properly electrically grounded.

G. For safety reasons, facilities for inorganic and organic analyses shall be in separate rooms. Organic analysis and sample extraction should also be separated to prevent cross contamination.

H. The analytical and sample storage areas must be isolated from all potential sources of contamination.

I. There should be sufficient storage space for chemicals, glassware and portable equipment, sufficient floor and bench space for stationary equipment and areas for cleaning materials.

J. Volatile or corrosive chemicals and flammable solvents shall be stored in accordance with the federal Occupational Safety and Health Act and its attendant regulations.

K. Adequate fire precautions shall be taken including, but not limited to, having readily available a fire extinguisher rated for the types of fires that may reasonably be foreseen given the types of testing and analyses performed by and the types of materials handled by the laboratory.

L. Appropriate occupational safety and health laws and regulations shall be posted and observed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3224 (December 2012).

#### **§8049. Specifications for Laboratory Equipment and Instrumentation**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall have on the premises and under the control of the technical manager, all of the equipment and instruments necessary to analyze each parameter in which the laboratory is accredited, or is seeking accreditation. All instruments shall be properly maintained and calibrated and such equipment and instruments including records shall meet the requirements in Volume 1, Module 2, Section 5.5 of the TNI Standard and Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3224 (December 2012).

#### **§8051. Measurement Traceability**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall meet the measurement traceability requirements specified in Volume 1, Module 2, Section 5.6 of the TNI Standard and Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3224 (December 2012).

#### **§8053. Sample Collection, Handling and Preservation**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall have procedures for sample collection, handling and preservation techniques that meet the requirements in Volume 1, Module 2, Sections 5.7 and 5.8 and Volume 1, Module 4, Section 1.7.5 of the TNI Standard as well as the requirements in Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. Samples requiring preservation shall be preserved at the time of collection. A laboratory that has interim approval or accreditation shall accept only samples which are properly labeled, and for which there is reasonable assurance that they have been collected, preserved, processed, stored and transported in such a manner as to identity and stability of the sample with respect to the requested tests or analyses. If the identity/stability of the sample has not been assured, the laboratory report shall clearly state that the result may be invalid due to an unsatisfactory sample.

C. All samples requiring thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container is either within 2° Celsius (C) of the required temperature or the method's specified range. Additional acceptance criteria are specified in Volume 1, Module 4, Section 1.7.5 of the TNI Standard. The laboratory must measure and record the temperature of the sample when it arrives when temperature preservation is required by the method.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3225 (December 2012).

#### **§8055. Methodology and Method Validation**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall use the test procedures specified in 40 CFR Parts 141 and 143 in the analysis of drinking water parameters. Additionally, the laboratories shall comply with the requirements in Volume 1, Module 2, Section 5.4 and Volume 1, Module 4, Section 1.4 of the TNI Standard as well as the requirements in Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. The laboratory shall list, in its quality manual, and have on-hand the standard operating procedures (SOPs) for each analytical method used. This listing should include the name of the method and a complete reference as to the source.

C. Applicable SOPs shall be available in the laboratory at the analyst's work station. All SOPs shall meet the

requirements in Volume 1, Module 2, Section 4.2.8.5 of the TNI Standard.

D. The laboratory shall validate reference methods via the procedures specified in Volume 1, Module 4, Section 1.5 of the TNI Standard and the requirements in Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

E. Prior to the acceptance and institution of any method, a satisfactory initial Demonstration of Capability (DOC) shall be performed by the laboratory pursuant to the requirements in Volume 1, Module 4, Section 1.6 of the TNI Standard. Documentation shall be maintained by the laboratory for the initial and any ongoing DOC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3225 (December 2012).

#### **§8057. Quality Assurance for Environmental Testing**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall have established quality control procedures pursuant to Volume 1, Module 2, Sections 5.9.1 and 5.9.2 of the TNI Standard as well as the quality control procedures in Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. The laboratory shall implement the essential quality control procedures in Volume 1, Module 2, Section 5.9.3 and in Volume 1, Module 4, Section 1.7 of the TNI Standard, as well as implementing the essential quality control procedures in Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

C. The laboratory shall perform all quality control procedures at the frequency required in the approved reference method(s) specified in 40 CFR Parts 141 and 143 in the analysis of drinking water parameters. In addition, the laboratory shall meet the acceptance criteria specified in the applicable, approved reference method(s) specified in 40 CFR Parts 141 and 143 in the analysis of drinking water parameters.

D. Control charts, generated from the laboratory's control sample (however named), shall be maintained by the laboratory. Until sufficient data are available from the laboratory, usually a minimum of 20 to 30 test results on a specific analysis, the laboratory shall use the control limits (if specified) in the method. When sufficient data becomes available, the laboratory shall develop control charts from the mean percent recovery ( $\bar{X}$ ) and the standard deviation (S) of the percent recovery for the Quality Control (QC) checks specified in the above Subsections of this Section (also, see Chapter VI of the *Handbook for Analytical QC in Water and Wastewater Laboratories*, EPA-600/4-79-019 or *Standard Methods for the Examination of Water and Wastewater*, 20th edition, Part 1020B, or similar laboratory analytical QC reference texts for further information). These

data are used to establish upper and lower control limits as follows:

1. upper control limit =  $\bar{X} + 3S$   
(upper warning limit, use + 2S instead of + 3S);

2. lower control limit =  $\bar{X} - 3S$   
(lower warning limit, use - 2S instead of - 3S).

E. After each five to ten new recovery measurements, new control limits should be calculated using the most recent 20-30 data points. These calculated control limits shall not exceed those established in the method. If any of these calculated control limits are tighter than the control limits specified within the method, the laboratory shall use the tighter criteria.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3225 (December 2012).

### **§8059. Records and Data Reporting**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall meet the requirements for reporting results pursuant to Volume 1, Module 2, Section 5.10 of the TNI Standard and Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. Compliance monitoring data shall be made legally defensible by keeping thorough and accurate records. The quality manual and/or SOPs shall describe the policies and procedures used by the facility for record retention and storage. If samples are expected to become part of a legal action, chain of custody procedures shall be used.

C. Maintenance of Records. Public water systems are required to maintain records of chemical analyses of compliance samples for 10 years (40 CFR 141.33) and lead and copper for 12 years (40 CFR 141.91). The laboratory should maintain easily accessible records for 10 years. The client water system should be notified before disposing of records so they may request copies if needed. This includes all raw data, calculations, and quality control data. These data files may be either hard copy, microfiche or electronic. Electronic data shall always be backed up by protected tape or disk or hard copy. If the laboratory changes its computer hardware or software, it should make provisions for transferring old data to the new system so that it remains retrievable within the time frames specified above.

D. Sampling Records. Data should be recorded in ink with any changes lined through such that the original entry is visible. Changes shall be initialed and dated. The following information should be readily available in a summary or other record(s):

1. date of sampling, location (including name of utility and PWS ID # if the water system is a PWS), sampling site within the water system, time of sampling, name, organization and phone number of the sampler, and analyses required;

2. identification of the sample as to whether it is a routine distribution system sample, check sample, raw or finished water sample, repeat or confirmation sample or other special purpose sample;

3. date of receipt of the sample by the laboratory;

4. sample volume/weight, container type, preservation and holding time and condition on receipt;

5. pH (from plant records) and disinfectant residual at time of sampling (from on-site analysis by sampler at the time of sampling);

6. disinfectant residual by laboratory immediately prior to analysis; and

7. transportation and delivery of the sample (person/carrier, conditions).

E. Analytical Records. Data shall be recorded in ink with any changes lined through such that original entry is visible. Changes shall be initialed and dated. The following information shall be readily available:

1. laboratory and persons responsible for performing the analysis;

2. analytical techniques/methods used;

3. date and time of analysis;

4. results of sample and quality control analyses; and

5. calibration and standards information.

F. Personnel Records. Résumés and training records shall be maintained for all personnel.

Documentation of the initial demonstration of capability for analysts/technicians shall be kept on file as well as the results of proficiency testing.

G. Reconstruction of Data. Adequate information shall be available to allow the assessor to reconstruct the final results for compliance samples and performance evaluation samples.

H. Computer programs. Computer programs shall be verified initially and periodically by manual calculations and the calculations shall be available for inspection. Access to computer programs and electronic data shall be limited to appropriate personnel.

I. The original or true duplicate of the results of the test or analysis shall be sent promptly to the person who requested such tests or analysis. In addition, the results of compliance monitoring samples are to be sent to:

Louisiana Department of Health and Hospitals

Office of Public Health

Engineering Services Section - M/S #3

P O Box 4489

Baton Rouge, Louisiana 70821-4489

1. The results data shall be signed by the technical manager or a designee whose designation is in writing and

whose name has been submitted to the department. Results submitted to the department shall be submitted electronically and in writing in the format specified by the Engineering Services Section of the department. Any sample result that exceeds the maximum contaminant level (MCL) or may cause a treatment technique requirement violation for any regulated contaminant listed in the federal Safe Drinking Water Act (42 USC 300f et seq.) and its implementing regulations (40 CFR Parts 141 and 143); an accredited laboratory shall report the result to the supplier of water and the department as soon as possible but no later than the end of the next business day after the result was determined.

**AUTHORITY NOTE:** Promulgated in accordance with R.S. 36:254(B)(7).

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3226 (December 2012).

### **§8061. General Laboratory Practices**

A. **Chemicals/Reagents.** Chemicals and reagents used must meet the specifications in the referenced method. If not specified therein, then analytical reagent (AR) grade or American Chemical Society (ACS) grade chemicals or better shall be used for analyses in accredited laboratories.

B. **Reagent Water.** The laboratory shall have a source of reagent water having a resistance value of at least 0.5 megohms (conductivity less than 2.0 micromhos/cm) at 25°C. High quality water meeting such specifications may be purchased from commercial suppliers. Quality of reagent water is best maintained by sealing it from the atmosphere. Quality checks to meet specifications above shall be made and documented at planned intervals based on use. This planned interval should not exceed daily. Individual analytical methods may specify additional requirements for the reagent water to be used. Reagent water for organic analysis must be free from interferences for the analytes being measured. It may be necessary to treat water with activated carbon to eliminate all interferences. If individual methods specify additional requirements for the reagent water to be used, these must be followed.

C. **Glassware Preparation.** Specific requirements in the methods for the cleaning of glassware must be followed. If no specifications are listed, then glassware should be washed in a warm detergent solution and thoroughly rinsed first with tap water and then with reagent water. This cleaning procedure is sufficient for general analytical needs. It is advantageous to maintain separate sets of suitably prepared glassware for the nitrate, mercury, and lead analyses due to the potential for contamination from the laboratory environment. For a summary of glassware cleaning procedures, refer to Chapter IV of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

D. **Distilled and deionized water** shall have at a minimum, resistivity values between 0.5 to 2.0 megohms-cm (2.0 to 0.5 micromhos/cm.) at 25° C. Preferably, distilled and deionized water should have resistivity values greater than 1.0 megohms-cm (less than 1.0 micromhos/cm) at 25°C. When purchasing distilled or deionized water, laboratories should request a list of quality specifications for the water

purchased. Containers of distilled or deionized water should be capped when not in use and should be capped immediately after each use.

E. All solutions shall be properly labeled with identification of the compound, concentration, solvent, date, and analyst who prepared the solution.

F. All chemicals, solutions, and standards, shall be dated upon receipt by the laboratory; and the date opened by the laboratory shall also be noted.

G. Compositing of samples for inorganic and organic analyses must be done in the laboratory. Samples shall only be composited if the laboratory detection limit is adequate for the number of samples being composited (up to a maximum of five) and the holding times will not be exceeded.

**AUTHORITY NOTE:** Promulgated in accordance with R.S. 36:254(B)(7).

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3226 (December 2012).

### **§8063. Management Systems General Requirements**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall establish, implement and maintain a management system as outlined in Volume 1, Module 2, Section 4.2 of the TNI Standard. The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The quality manual shall include all the requirements in Volume 1, Module 2, Section 4.2 of the TNI Standard. The quality manual shall be made available to all laboratory personnel.

B. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall establish and maintain a documented data integrity system. There are four elements within a data integrity system. These are:

1. data integrity training;
2. signed data integrity documentation for all laboratory employees;
3. in-depth, periodic monitoring of data integrity; and
4. data integrity procedure documentation.

C. The procedures of the data integrity system required under Subsection B of this Section shall be signed by top management. The requirements for data integrity investigation are listed in Volume 1, Module 2, Section 4.16 of the TNI Standard. The requirements for data integrity training and documentation are listed in Volume 1, Module 2, Section 5.2.7 of the TNI Standard.

D. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses, shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling

customer complaints and all analytical methods. All of the requirements for the laboratory's SOPs are outlined in Section 4.2.8.5 of Volume 1, Module 2 of the TNI Standard. All quality control data and records required by this Section shall be retained by the laboratory for a minimum of 10 years and shall be made available for inspection by the department. Such retained data shall include, but shall not be limited to, the results of and raw data generated by proficiency test analyses.

E. Document Control. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall establish and maintain procedures to control all laboratory documents as specified in Volume 1, Module 2, Section 4.3, of the TNI Standard.

F. Review of Requests, Tenders and Contracts. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for review of requests, tenders and contracts pursuant to Volume 1, Module 2, Section 4.4 of the TNI Standard.

G. Subcontracting of Environmental Testing. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for subcontracting environmental testing pursuant to Volume 1, Module 2, Section 4.5 of the TNI Standard.

H. Purchasing Services and Supplies. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for purchasing services and supplies pursuant to Volume 1, Module 2, Section 4.6 of the TNI Standard.

I. Service to the Client and Complaints. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for service to the clients and complaint policy and processes pursuant to Volume 1, Module 2, Sections 4.7 and 4.8 of the TNI Standard.

J. Control of Nonconforming Environmental Testing Work. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for the control of nonconforming environmental testing pursuant to Volume 1, Module 2, Sections 4.9 of the TNI Standard.

K. Laboratory Improvement, Corrective Action and Preventive Action. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for improving the laboratory, corrective and preventive actions pursuant to Volume 1, Module 2, Sections 4.10, 4.11, and 4.12 of the TNI Standard.

L. Internal Audits and Management Reviews. Laboratories which have received accreditation or are seeking accreditation to perform any of the required chemical analyses shall meet the requirements for establishing and conducting internal audits and management

reviews of laboratory activities pursuant to Volume 1, Module 2, Sections 4.14 and 4.15 of the TNI Standard.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3227 (December 2012).

## **Subchapter D. Criteria and Procedures for Radiological/ Radiochemical Testing and Analysis**

### **§8064. General**

A. This Subchapter, in conjunction with other requirements contained in other portions of this Chapter, establishes the department's requirements to which an accredited laboratory or laboratory seeking accreditation shall continually meet and follow when performing radiological/radiochemical analyses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3228 (December 2012).

### **§8065. Laboratory Facilities and Safety**

A. All accredited laboratories or laboratories seeking accreditation pursuant to this Subchapter shall have laboratory facilities and safety procedures that meet the requirements in Volume 1, Module 2, Section 5.3 of the TNI Standard and Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. The analysis of compliance samples shall be conducted in a laboratory where the security and integrity of the samples and the data can be maintained.

C. The laboratory facilities must be clean, have adequate temperature and humidity control, have adequate lighting at the bench top and must meet applicable OSHA standards.

D. The laboratory must have provisions for the proper storage and disposal of chemical and radiological wastes. The appropriate type of exhaust hood is required where applicable.

E. There must be sufficient bench space for processing samples. Workbench space should be convenient to sink, water, gas, vacuum and electrical sources free from surges.

F. Instruments must be properly electrically grounded.

G. Counting instruments must be located in a room other than one in which samples and standards are being prepared or where other types of chemical analyses are performed.

H. The analytical and sample storage areas must be isolated from all potential sources of contamination.

I. There should be sufficient storage space for chemicals, glassware and portable equipment, sufficient floor and bench space for stationary equipment and areas for cleaning materials.

J. Volatile or corrosive chemicals and flammable solvents shall be stored in accordance with the federal Occupational Safety and Health Act and attendant regulations.

K. Adequate fire precautions shall be taken including, but not limited to, having readily available a fire extinguisher rated for the types of fires that may reasonably be foreseen given the types of testing and analyses performed by and the types of materials handled by the laboratory.

L. Appropriate occupational safety and health laws and regulations shall be posted and observed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3228 (December 2012).

#### **§8067. Specifications for Laboratory Equipment and Instrumentation**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses, shall have on the premises and under the control of the technical manager, all of the equipment and instruments necessary to analyze each parameter in which the laboratory is accredited, or is seeking accreditation. All instruments shall be properly maintained and calibrated and such equipment and instruments including records shall meet the requirements in Volume 1, Module 2, Section 5.5 of the TNI Standard and Volume 1, Module 6, Section 1.7.1 of the TNI Standard as well as the requirements in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3228 (December 2012).

#### **§8069. Measurement Traceability**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the measurement traceability requirements specified in Volume 1, Module 2, Section 5.6 of the TNI Standard and Volume 1, Module 6 of the TNI Standard as well as the requirements in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3228 (December 2012).

#### **§8071. Sample Collection, Handling and Preservation**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall have procedures for sample collection, handling and preservation techniques

that meet the requirements in Volume 1, Module 2, Sections 5.7 and 5.8 and Volume 1, Module 6, Section 1.7.4 of the TNI Standard as well as the requirements in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. Samples requiring preservation shall be preserved at the time of collection. A laboratory that has interim approval or accreditation shall accept only samples which are properly labeled, and for which there is reasonable assurance that they have been collected, preserved, processed, stored and transported in such a manner as to identity and stability of the sample with respect to the requested tests or analyses. If the identity/stability of the sample has not been assured, the laboratory report shall clearly state that the result may be invalid due to an unsatisfactory sample.

C. All samples requiring thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container is either within 2°C of the required temperature or the method's specified range. Additional acceptance criteria are specified in Volume 1, Module 6, Section 1.7.4 of the TNI Standard. The laboratory must measure and record the temperature of the sample when it arrives when temperature preservation is required by the method.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3228 (December 2012).

#### **§8073. Methodology and Method Validation**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall use the test procedures specified in 40 CFR Parts 141 and 143 in the analysis of drinking water parameters. Additionally, the laboratories shall comply with the requirements in Volume 1, Module 2, Section 5.4 and Volume 1, Module 6, Section 1.4 of the TNI Standard as well as the requirements in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. The laboratory shall list, in its quality manual, and have on hand the SOPs for each analytical method used. This listing should include the name of the method and a complete reference as to the source.

C. Applicable SOPs shall be available in the laboratory at the analyst's work station. All SOPs shall meet the requirements in Volume 1, Module 2, Section 4.2.8.5 of the TNI Standard.

D. The laboratory shall validate reference methods via the procedures specified in Volume 1, Module 6, Section 1.5 of the TNI Standard and the requirements in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

E. Prior to the acceptance and institution of any method, a satisfactory initial Demonstration of Capability (DOC) shall be performed by the laboratory pursuant to the

requirements in Volume 1, Module 6, Section 1.6 of the TNI Standard and Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water. Documentation shall be maintained by the laboratory for the initial and any ongoing DOC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3229 (December 2012).

#### §8075. Quality Assurance for Radiochemical Testing

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses, shall have established quality control procedures pursuant to Volume 1, Module 2, Sections 5.9.1 and 5.9.2 of the TNI Standard and Volume 1, Module 6 of the TNI Standard as well as the quality control procedures in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. The laboratory shall implement the essential quality controls procedures in Volume 1, Module 2, Section 5.9.3 and Volume 1, Module 6, Section 1.7.2 of the TNI Standard as well as implementing the essential quality control procedures in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

C. The laboratory shall perform all quality control procedures at the frequency required in the approved reference method(s) specified in 40 CFR Parts 141 and 143 in the analysis of drinking water parameters. In addition, the laboratory shall meet the acceptance criteria specified in the applicable, approved reference method(s) specified in 40 CFR Parts 141 and 143 in the analysis of drinking water parameters.

D. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses, shall maintain control charts for each instrument and method used by the laboratory for compliance monitoring sample measurements. Instrument initial calibrations and all efficiency and instrument background checks shall be maintained in a permanent record. Control charts shall be maintained as specified in Chapter VI of the USEPA *Manual for the Certification of Laboratories Analyzing Drinking Water*. Until sufficient data are available from the laboratory, usually a minimum of 20 to 30 test results on a specific analysis, the laboratory shall use the control limits (if specified) in the method. When sufficient data becomes available, the laboratory shall develop control charts from the mean percent recovery ( $\bar{X}$ ) and the standard deviation (S) of the percent recovery for the Quality Control (QC) checks specified in the above Subsections of this Section (also, see Chapter VI of the *Handbook for Analytical QC in Water and Wastewater Laboratories*, EPA-600/4-79-019 or *Standard Methods for the Examination of Water and Wastewater*, 20th Edition, Part 1020B, or similar laboratory analytical QC reference texts for further information). These data are used to establish upper and lower control limits as follows:

1. upper control limit =  $\bar{X} + 3S$   
(upper warning limit, use + 2S instead of + 3S);
2. lower control limit =  $\bar{X} - 3S$   
(lower warning limit, use - 2S instead of - 3S).

E. After every 20 new recovery measurements, new control limits should be calculated using the most recent 20-30 data points. These calculated control limits shall not exceed those established in the method. If any of these calculated control limits are tighter than the control limits specified within the method, the laboratory shall use the tighter criteria.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3229 (December 2012).

#### §8077. Records and Data Reporting

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses, shall meet the requirements for reporting results pursuant to Volume 1, Module 2, Section 5.10, of the TNI Standard and Volume 1, Module 6, Section 1.7 of the TNI Standard as well as meeting the requirements for reporting results in Chapter VI of the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water.

B. Compliance monitoring data shall be made legally defensible by keeping thorough and accurate records. The quality manual and/or SOPs shall describe the policies and procedures used by the facility for record retention and storage. If samples are expected to become part of a legal action, chain of custody procedures shall be used.

C. Maintenance of Records. Public water systems are required to maintain records of radiological/radiochemical analyses of compliance samples for 10 years (40 CFR 141.33). The laboratory should maintain easily accessible records for 10 years. The client water system should be notified before disposing of records so they may request copies if needed. This includes all raw data, calculations, and quality control data. These data files may be either hard copy, microfiche or electronic. Electronic data shall always be backed up by protected tape or disk or hard copy. If the laboratory changes its computer hardware or software, it should make provisions for transferring old data to the new system so that it remains retrievable within the time frames specified above.

D. Sampling Records. Data should be recorded in ink with any changes lined through such that the original entry is visible. Changes shall be initialed and dated. The following information should be readily available in a summary or other record(s):

1. date of sampling, location (including name of utility and PWS ID #, if the water system is a PWS), sampling site within the water system, time of sampling, name, organization and phone number of the sampler, and analyses required;

PUBLIC HEALTH—GENERAL

2. identification of the sample as to whether it is a routine distribution system sample, check sample, raw or finished water sample, repeat or confirmation sample or other special purpose sample;

3. date of receipt of the sample by the laboratory;

4. sample volume/weight, container type, preservation and holding time and condition on receipt;

5. pH (from plant records) and disinfectant residual at time of sampling (from on-site analysis by sampler at the time of sampling);

6. disinfectant residual by laboratory immediately prior to analysis; and

7. transportation and delivery of the sample (person/carrier, conditions).

E. Analytical Records. Data shall be recorded in ink with any changes lined through such that the original entry is visible. Changes shall be initialed and dated. The following information shall be readily available:

1. laboratory and persons responsible for performing the analysis;

2. analytical techniques/methods used;

3. date and time of analysis;

4. results of sample and quality control analyses; and

5. calibration and standards information.

F. Personnel Records. Résumés and training records shall be maintained for all personnel.

Documentation of the initial demonstration of capability for analysts/technicians shall be kept on file as well as the results of proficiency testing.

G. Reconstruction of Data. Adequate information shall be available to allow the assessor to reconstruct the final results for compliance samples and performance evaluation samples.

H. Computer programs. Computer programs shall be verified initially and periodically by manual calculations and the calculations shall be available for inspection. Access to computer programs and electronic data shall be limited to appropriate personnel.

I. The original or true duplicate of the results of the test or analysis shall be sent promptly to the person who requested such tests or analysis. In addition the results of compliance monitoring samples are to be sent to:

Louisiana Department of Health and Hospitals  
Office of Public Health  
Engineering Services Section – M/S #3  
P O Box 4489  
Baton Rouge, Louisiana 70821-4489

1. The results data shall be signed by the technical manager or a designee whose designation is in writing and whose name has been submitted to the department. Results submitted to the department shall be submitted electronically

and in writing in the format specified by the Engineering Services Section of the department. Any sample result that exceeds the maximum contaminant level (MCL) or may cause a treatment technique requirement violation for any regulated contaminant listed in the federal Safe Drinking Water Act (42 USC 300f et seq.) and its implementing regulations (40 CFR Parts 141 and 143); an accredited laboratory shall report the result to the supplier of water and the department as soon as possible but no later than the end of the next business day after the result was determined.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3229 (December 2012).

**§8079. General Laboratory Practices**

A. Chemicals/Reagents. Chemicals and reagents used must meet the specifications in the referenced method. If not specified therein, then analytical reagent (AR) grade or American Chemical Society (ACS) grade chemicals or better shall be used for analyses in accredited laboratories.

B. Reagent Water. The laboratory shall have a source of reagent water meeting the requirements of being an American Society of Testing Materials (ASTM) Type 1, 2, or 3 reagent water, having a minimum resistivity of 10 megohms/cm (conductivity less than 0.1 microhms/cm) at 25°C. It shall be monitored daily by measuring the reagent water's conductivity or resistivity and documented. Radioactive components have been known to break through reagent water manufacturing units before an increase in resistivity is noted. To monitor the background radioactivity of the reagent water, it is to be screened for radioactivity each time the treatment unit is serviced, and periodically thereafter depending on the volume of reagent water use at the laboratory between servicing units.

C. Glassware Preparation. Specific requirements in the methods for the cleaning of glassware must be followed. The purpose of these requirements are to minimize the possibility that glassware can contaminate samples, and should include acid rinsing. Acid rinsing not only mobilizes any metals remaining adhering to their surfaces, but also hydrates the outer silica layer on the glassware which inhibits contamination with radioactive materials. If there are no specifications for cleaning glassware in the method, then the glassware should first be washed in detergent solution, then thoroughly rinsed in tap water followed by a second rinse in a dilute acid solution, and finally rinsed with reagent water and dried.

D. Distilled and deionized water shall have at a minimum, resistivity values between 0.5 to 2.0 megohms-cm (2.0 to 0.5 micromhos/cm.) at 25° C. Preferably, distilled and deionized water should have resistivity values greater than 1.0 megohms-cm (less than 1.0 micromhos/cm) at 25°C. When purchasing distilled or deionized water, laboratories should request a list of quality specifications for the water purchased. Containers of distilled or deionized water should be capped when not in use and should be capped immediately after each use.

E. All solutions shall be properly labeled with identification of the compound, concentration, solvent, date, and analyst who prepared the solution.

F. All chemicals, solutions, and standards, shall be dated upon receipt by the laboratory; and the date opened by the laboratory shall also be noted.

G. Compositing of Samples. If deemed acceptable by the department, samples may be composited by the utility or the laboratory, provided that all the sample aliquots are properly preserved at the time of collection. Since the required compliance protocol monitoring measurements is "total activity" (i.e., the composited sample is required to represent the maximum potential exposure from drinking water), samples shall not to be filtered before preservation. Samples must be drawn on a quarterly basis and where compositing is not done by the laboratory, there shall be documentation submitted with the composited sample detailing on what particular day(s) each aliquot was obtained, its volume, and when it was preserved. A sample of the preservative itself shall accompany the composited sample to the laboratory to determine the contribution of radioactivity, if any, from the addition of the preservative to the sample. Analysis of the composited sample shall be completed within 1 year after the first sample is collected or within normal holding times if the compositing period is less than 90 days. Wherever possible, the laboratory should be responsible for managing the compositing of samples.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3230 (December 2012).

#### **§8081. Management System General Requirements**

A. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall establish, implement and maintain a management system as outlined in Volume 1, Module 2, Section 4.2 of the TNI Standard. The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The quality manual shall include all the requirements in Volume 1, Module 2, Section 4.2 of the TNI Standard. The quality manual shall be made available to all laboratory personnel.

B. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall establish and maintain a documented data integrity system. There are four elements within a data integrity system. These are:

1. data integrity training;
2. signed data integrity documentation for all laboratory employees;
3. in-depth, periodic monitoring of data integrity; and
4. data integrity procedure documentation.

C. The procedures of the data integrity system required under Subsection B of this Section shall be signed by top management. The requirements for data integrity investigation are listed in Volume 1, Module 2, Section 4.16 of the TNI Standard. The requirements for data integrity training and documentation are listed in Volume 1, Module 2, Section 5.2.7 of the TNI Standard.

D. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints and all analytical methods. All of the requirements for the laboratory's SOPs are outlined in Section 4.2.8.5 of Volume 1, Module 2 of the TNI Standard. All quality control data and records required by this Section shall be retained by the laboratory for a minimum of 10 years and shall be made available for inspection by the department. Such retained data shall include, but shall not be limited to, the results of and raw data generated by proficiency test analyses.

E. Document Control. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall establish and maintain procedures to control all laboratory documents as specified in Volume 1, Module 2, Section 4.3, of the TNI Standard.

F. Review of Requests, Tenders and Contracts. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for review of requests, tenders and contracts pursuant to Volume 1, Module 2, Section 4.4 of the TNI Standard.

G. Subcontracting of Environmental Testing. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for subcontracting environmental testing pursuant to Volume 1, Module 2, Section 4.5 of the TNI Standard.

H. Purchasing Services and Supplies. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for purchasing services and supplies pursuant to Volume 1, Module 2, Section 4.6 of the TNI Standard.

I. Service to the Client and Complaints. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for service to the clients and complaint policy and processes pursuant to Volume 1, Module 2, Sections 4.7 and 4.8 of the TNI Standard.

J. Control of Nonconforming Environmental Testing Work. Laboratories which have received accreditation or are

seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for the control of nonconforming environmental testing pursuant to Volume 1, Module 2, Sections 4.9 of the TNI Standard.

K. Laboratory Improvement, Corrective Action and Preventive Action. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for improving the laboratory, corrective and preventive actions pursuant to Volume 1, Module 2, Sections 4.10, 4.11, and 4.12 of the TNI Standard.

L. Internal Audits and Management Reviews. Laboratories which have received accreditation or are seeking accreditation to perform any of the required radiological/radiochemical analyses shall meet the requirements for establishing and conducting internal audits and management reviews of laboratory activities pursuant to Volume 1, Module 2, Sections 4.14 and 4.15 of the TNI Standard.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254(B)(7).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 38:3231 (December 2012).

## Subpart 29. Immunization Services

### Chapter 81. Vaccine Preventable Disease Program

#### §8101. Purpose

A. The purpose of this program is to prevent the occurrence and transmission of disease through immunization, surveillance, epidemiology, surveys, and mass immunizations in outbreak and low protection locations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 13:246 (April 1987).

#### §8103. Eligibility

A. Immunization delivery services are available to each individual in Louisiana. A \$5 fee will be collected in parish health units for each childhood vaccination visit by a patient whose other pediatric services are provided outside the Department of Health and Hospitals system. No One will be denied services due to inability to pay .All persons in the state may be considered to be at risk of infection although the target population are individuals susceptible to the following vaccine preventable diseases: Diphtheria, Tetanus, Pertussis, Poliomyelitis, Rubeola, Rubella, Mumps, and Haemophilus influenzaeb..

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public

Health Services, LR 13:246 (April 1987), amended LR 15:1084 (December 1989).

#### §8105. Consent Forms

A. When an individual seeks immunization services, an immunization record is completed. The patient, parent or guardian, as appropriate, is required to execute an informed consent form. Each time the patient returns to the health unit for an additional immunization the patient, parent or guardian, as appropriate, is required to execute an informed consent form. The signed portion of the consent form is retained and filed by the health unit; the remainder of the informed consent form is returned to the patient for reference. A public health nurse shall review the consent form with the patient, parent or guardian, as appropriate, to discuss the illness, the risks, contraindications, and side effects of the vaccine and to answer any questions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 13:246 (April 1987).

## Chapter 83. Cancer and Lung Trust Fund Board

#### §8301. Purpose

A. The purpose of the Louisiana Cancer and Lung Trust Fund Board is to annually receive monies appropriated by the legislature and other sources to be used solely for research on cancer and cardio-pulmonary diseases and clinical investigations and training in the fields of cancer and cardio-pulmonary diseases. The board is to direct the disbursement of these monies to those persons/institutions whose proposed grant applications have been reviewed and approved by peer review committees and reaffirmed by a majority vote of the board. The board is also responsible for other activities as provided under R. S. 40:1299.80 through 1299.90 including developing policies for the operation of a Louisiana State Tumor Registry and establishing rules and regulations for accumulation and distribution of data collected.

AUTHORITY NOTE: Promulgated in accordance with R. S. 40:1299.80 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services.

#### §8303. Board Membership

A. Membership of the board is determined by R.S. 40:1299.88(D) and consists of members appointed and reappointed by the governor, to serve at his pleasure, upon recommendation of each institution and organization represented: (1) a representative from Tulane University School of Medicine, (2) a representative from the Louisiana State University School of Medicine, New Orleans, (3) a representative from the Louisiana State University School of Medicine, Shreveport, (4) a representative from the Alton Ochsner Medical Foundation, (5) a representative of the American Cancer Society, Louisiana Division, (6) a