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TITLE 252. DEPARTMENT OF ENVIRONMENTAL QUALITY
CHAPTER 302. FIELD LABORATORY ACCREDITATION

Subchapter:

SUBCHAPTER 1. GENERAL PROVISIONS

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252:302-1-1. Purpose, basis, authority, applicability

(a) The rules in this Chapter provide standards for accreditation of privately and publicly owned laboratories for performance of analyses of wastewater. This Chapter was promulgated and adopted pursuant to the Oklahoma Environmental Quality Code (Code), 27A O.S. § 2-4-101 *et seq.*, and shall apply to laboratories accredited or applying to be accredited by the Department of Environmental Quality as a field laboratory.
(b) As the Board promulgates new rules, accredited laboratories shall incorporate those procedures for all accredited analytes upon the effective date of the rule, July 1 of each year.
(c) The implementation date of this Chapter is January 1, 2013.

252:302-1-2. Field laboratory category

A laboratory may be accredited in the category of field laboratory. A field laboratory is a small laboratory which does not want to participate in The NELAC Institute accreditation standards and is limited to analysis for pH, residual chlorine (total residual chlorine, free chlorine, total oxidants or free oxidants), turbidity, conductivity, temperature and dissolved oxygen.

252:302-1-3. Terms

Terms used in this Chapter shall have the meanings given to them in this Subchapter or the Oklahoma Environmental Quality Code. Any technical term not defined thereby shall be defined by its generally accepted scientific meaning or its standard dictionary meaning.

252:302-1-4. Definitions

In addition to the definitions contained in the Environmental Quality Code (27A O.S. § 2-1-101 *et seq.*) and OAC 252:4 (Department of Environmental Quality Rules of Practice and Procedure), the following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise.

"Acceptable results", as defined in 27A O.S. § 2-4-101, *means a result within limits determined on the basis of statistical procedures as prescribed by the Department.*

"Accreditation" means the process by which the DEQ recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

"Analyte" means the characteristics of a laboratory sample determined by an analytical laboratory testing procedure and is synonymous with "parameter".

"Applicant" means the owner of a laboratory, or a representative authorized by the owner to act on the owner's behalf, seeking accreditation from the DEQ.

"Applicant laboratory" means the laboratory and its owner or authorized representative for

which an application for accreditation has been filed with the DEQ.

"Approved method" means an analytical test method which has been required by law or is recognized by the DEQ as acceptable for a specific usage.

"Blind audit" means a process whereby the DEQ or any other designated agent submits proficiency testing samples to an accredited laboratory in a manner such that the laboratory is not aware of the process.

"Certificate" is defined in 27A O.S. § 2-4-101 and means the same as laboratory accreditation.

"Corrective Action Plan" or **"Corrective Action Report"** is a written plan of action, including a schedule for implementation, to correct deficiencies or findings identified in the DEQ or DEQ-approved agent's inspection report, including a timeline for implementation; or to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent its recurrence.

"Critical Finding" means a conclusion of noncompliance that would require an immediate corrective action or an immediate stop to testing.

"DEQ" means the Oklahoma Department of Environmental Quality.

"Evaluation", as defined in 27A O.S. § 2-4-101, *means a review of the quality control and quality assurance procedures, recordkeeping, reporting procedures, methodology, personal qualifications, equipment, facilities and analytical technique of a laboratory for measuring or establishing specific parameters.*

"Field laboratory" is a small laboratory which does not want to participate in The NELAC Institute accreditation standards and is limited to analysis for pH, residual chlorine (total residual chlorine, free chlorine, total oxidants or free oxidants), turbidity, conductivity, temperature and dissolved oxygen.

"Finding" means a conclusion of noncompliance of the evaluation process supported by objective evidence.

"Initial accreditation" means a first-time accreditation granted to a laboratory not previously accredited by the DEQ.

"Interim accreditation" means an out-of-time accreditation issued to a DEQ accredited laboratory for analytes in which the laboratory is not currently accredited by the DEQ.

"Laboratory" as defined in 27A O.S. § 2-4-101, means *a facility that performs analyses to determine the chemical, physical or biological properties of air, water, solid waste, hazardous waste, wastewater or soil or subsoil materials or performs any other analyses related to environmental quality evaluations.* "Laboratory" includes mobile laboratories.

"Laboratory waste" means by-products of the analytical process, residues of samples analyzed, discarded reagents or standards and any materials contaminated by any of these.

"Owner" means the sole proprietor of an individually owned laboratory, the controlling or managing partner of a laboratory held by a partnership, the major stockholders of a corporate owned laboratory, or a municipality or other local government entity which owns or operates a laboratory.

"Parameter" is defined in 27A O.S. § 2-4-101 and is synonymous with "analyte".

"Proficiency testing (PT) sample" means a sample submitted to a laboratory by the DEQ or other designated agent for the purpose of assessing the ability of the laboratory to correctly analyze samples using an approved method.

"Program" means the DEQ laboratory accreditation program.

"Residual chlorine" means total residual chlorine, free chlorine, total oxidants or free oxidants.

"QA Plan" or **"Quality Assurance Plan"** means a written description of quality assurance activities (quality control) that will ensure the generation of data that are scientifically valid, defensible and of known and acceptable limits of precision and accuracy.

"SOP manual" or **"Standard Operating Procedure manual"** means a document approved by a laboratory director that includes approved methods, equipment and instruments used by the laboratory for analyses.

252:302-1-5. Fees

(a) **Applicable fees**. The following fees apply:

(1) Initial accreditation - $350.00
(2) Renewal accreditation - $350.00
(3) Interim accreditation - $200.00
(4) Renewal late fee - $100.00
(5) Accreditation amendment - $ 70.00
(6) On-site evaluation (initial) - $1,000.00
(7) On-site evaluation (renewal) - $500.00 annually
(8) On-site evaluation (interim) - $1,000.00

(b) **Annual fee adjustment**. To assist in meeting rising costs to the DEQ of the environmental services and regulatory programs associated with the laboratory services program, the fees set out in this Section shall be automatically adjusted on July 1st every year to correspond to the percentage, if any, by which the Consumer Price Index (CPI) for the most recent calendar year exceeds the CPI for the previous calendar year. The DEQ may round the adjusted fees up to the nearest dollar. The DEQ may waive collection of an automatic increase in a given year if it determines other revenues, including appropriated state general revenue funds, have increased sufficiently to make the funds generated by the automatic adjustment unnecessary in that year. A waiver does not affect future automatic adjustments.

(1) Any automatic fee adjustment under this subsection may be averted or eliminated, or the adjustment percentage may be modified, by rule promulgated pursuant to the Oklahoma Administrative Procedures Act. The rulemaking process may be initiated in any manner provided by law, including a petition for rulemaking pursuant to 75 O.S. § 305 and OAC 252:4-5-3 by any person affected by the automatic fee adjustment.

(2) If the United States Department of Labor ceases to publish the CPI or revises the methodology or base years, no further automatic fee adjustments shall occur until a new automatic fee adjustment rule is promulgated pursuant to the Oklahoma Administrative Procedures Act.

(3) For purposes of this subsection, "Consumer Price Index" or "CPI" means the Consumer Price Index - All Urban Consumers (U.S. All Items, Current Series, 1982-1984=100, CUUR0000SA0) published by the United States Department of Labor. The CPI for a calendar year is the figure denoted by the Department of Labor as the "Annual" index figure for that calendar year.

(c) **On-site evaluation fee.** The evaluation fee is $1000 for initial or interim applications. The on-site evaluation fee will be invoiced with initial or renewal application fees.

SUBCHAPTER 3. FIELD LABORATORY ACCREDITATION PROCESS

PART 1. APPLICATION

Section

252:302-3-1. **Accreditation**

A laboratory may apply at any time for initial, interim or renewal accreditation. A laboratory applying for interim accreditation shall meet the same requirements as a laboratory applying for initial accreditation.

252:302-3-2. Application required

(a) **General.** A laboratory shall submit one copy of an application for accreditation to the DEQ. Application forms are available on the DEQ's website. Applications shall be accurately completed, signed and submitted to the DEQ electronically or by mail, with all required attachments.

(b) **Application fees.** Fees shall be submitted to the DEQ at the same time that applications are submitted. Applications shall not be considered until fees are received.

(c) **Signature and verification.** An application shall be signed by the sole proprietor of an individually owned laboratory, the controlling or managing partner or partners of a laboratory held by a partnership, the authorized agent of a corporate owned laboratory, or the principal executive officer or ranking elected official of a municipality or other local government entity which owns or operates the applicant laboratory. The signer shall verify in the application that it was prepared under his direction or supervision and that the information it contains is, to the best of his knowledge, true, accurate and complete.

252:302-3-3. Contact information

In addition to other information required by this Chapter, an application shall contain the following information:

(1) The name, mailing address, street address, telephone numbers, e-mail address and telefax number (if any) of the applicant.

(2) The signature, typewritten name, mailing address, telephone numbers, e-mail address and telefax number (if any) of the authorized representative of the owner.

(3) The name, mailing address, street address, telephones, e-mail address and telefax number (if any) of the applicant laboratory's authorized technical representative.

(4) The location(s) (address or legal description) of the laboratory, including county and driving directions and latitude/longitude.

(5) Identification as a field laboratory.

(6) The name and address of any owner, stockholder, or officer of the applicant laboratory or

any person who receives compensation from the applicant laboratory, who has been or currently is an owner, stockholder, or officer of, or who has received compensation from, any laboratory whose accreditation application has been previously denied or whose accreditation has been previously suspended or revoked in part or in whole by the DEQ.

252:302-3-4. Operational information

The application shall address the following operational issues:

(1) A listing of equipment to be used for sample analysis, storage and reporting.

(2) A description of the methods, equipment and instruments used by the applicant laboratory for specific analytes which may be in the form of an SOP manual when required.

(3) A written laboratory QA plan which includes but is not limited to:

(A) A listing of laboratory personnel, including the laboratory supervisor, which gives the academic training, experience and analytical and supervisory responsibilities; and

(B) A narrative description of the methods used for sample receipt, storage and disposal.

(4) Results of the laboratory's two most recent proficiency testing rounds, at least 15 calendar days apart from the date of analysis.

(5) A report of a laboratory evaluation conducted by the DEQ shall verify data submitted in the application, list any deficiencies and be signed by the DEQ.

(6) If findings are listed in an evaluation report, the applicant shall submit a Corrective Action Report which specifies deadlines for correction and correction of the finding. The DEQ may establish conditions, including compliance schedules, for the applicant's Corrective Action Report.

(7) Hours of operation.

252:302-3-5. Reasons to deny an initial application

(a) An intial application for accreditation shall be denied in the following circumstances:

(1) Failure to submit a completed application;

(2) Failure to pay required fees;

(3) Failure of laboratory staff to meet the personnel qualifications of education, training and experience;

(4) Failure to successfully analyze and report proficiency testing samples;

(5) Failure to respond to an assessment report from the on-site assessment with a corrective action report within the 30 calendar days after receipt of the assessment report;

(6) Failure to implement the corrective actions detailed in the corrective action report within the specified time frame as approved by the primary accreditation body;

(7) Failure to implement a quality assurance plan;

(8) Failure to pass required on-site assessment(s);

(9) Misrepresentation of any fact pertinent to receiving or maintaining accreditation; or

(10) Denial of entry during normal business hours for an on-site assessment.

(b) If the laboratory is not successful in correcting the deficiencies, the laboratory must wait six months before again reapplying for accreditation.

(c) Laboratory accreditation will not be denied without the right to due process as addressed in OAC 252: 4, Rules of Practice and Procedure.

252:302-3-6. Renewals

(a) **Annual renewal required.** A laboratory must apply to renew accreditation annually. Renewal applications are available on the DEQ's website. Renewal applications shall be accurately completed, signed and submitted to the DEQ electronically on or before June 15 of each year.
(b) **Laboratory responsibility.** Each laboratory is responsible for renewing its accreditation by the annual renewal date. Failure to receive a renewal notification and invoice does not exempt laboratories from meeting the renewal deadline.
(c) **DEQ invoice date.** By April 15 of each year, the DEQ shall mail invoices to each accredited laboratory.
(d) **Deadline.** All applicable fees shall be submitted to the DEQ by 4:30 p.m. on or before June 15 or postmarked on or before that date. Any renewal application which is not received electronically by the DEQ on or before June 15 shall be considered only if the electronic application form, renewal fee and a late fee are submitted on or before July 15 . Applications and fees received or postmarked after July 15 will be returned and accreditation shall not be renewed. PTs received later than 4:30 p.m. on July 15 of each year will not be considered for accreditation renewal.
(e) **Specified dates.** If any date specified in this section falls on a weekend or holiday, the date of the following working day shall be the effective date.
(f) **Failure to renew.** To become accredited again, a laboratory that failed to renew its accreditation in a timely manner must apply for initial accreditation as a new laboratory.

PART 3. CONDITIONS OF ACCREDITATION

Section

252:302-3-21. Conditions applicable to all accreditations

The following conditions shall apply to all existing accreditations and shall be incorporated expressly or by reference into all accreditations issued or renewed after the effective date of this Chapter.

(1) **Proper operation and maintenance.** The Laboratory shall at all times properly operate and maintain all facilities and equipment installed or used by the Laboratory to achieve compliance with the laboratory accreditation requirements of the Code, rules of the Board as they relate to laboratory accreditation, and the provisions and conditions of this Accreditation. Proper operation and maintenance includes effective performance of operations and adequate funding, operator staffing and training, and the provision of appropriate sample-handling equipment. All operational practices and procedures used at this site shall conform to the best possible public health and safety practices.

(2) **Duty to mitigate.** The Laboratory shall take all reasonable steps to minimize or correct any adverse impact on the environment and the public health resulting from noncompliance with this Accreditation and to minimize or correct any adverse impact on the environment arising from its analytical activities.

(3) **Duty to provide information.** The Laboratory shall furnish to the DEQ, within a time

specified, any information which the DEQ may request to determine:

(A) whether cause exists for amending, suspending, or revoking this Accreditation;

(B) compliance with this Accreditation; or

(C) whether an accreditation should be issued or renewed.

(4) **Records.** The Laboratory shall keep its Accreditation, the application on which it is based, copies of all records required to be kept by this Chapter and the provisions of its Accreditation on file at the accredited facility.

(5) **Reporting requirements.** The Laboratory shall give advance notice to the DEQ as soon as possible of any planned physical alterations, additions to the accredited facility or planned changes in the accredited facility which may result in noncompliance with accreditation requirements.

(6) **Signatory requirement.** All applications, reports, or information submitted to the DEQ shall be signed by the applicant.

(7) **Consent to conditions.** Commencing analytical activities as an accredited laboratory under DEQ accreditation shall constitute consent to all conditions of accreditation.

(8) **Transfer of accreditation.** Accreditation is not transferable. An accredited laboratory may apply to amend ownership or change names, provided that facilities, equipment, personnel and all other conditions of accreditation remain unchanged.

(9) **Duty to apply.** To maintain its accredited status, the Laboratory shall make timely application for annual renewal of accreditation.

(10) **Severability.** The provisions of accreditation are severable, and if any of its provisions or the application of its provisions are held invalid, the application of such provisions to other circumstances and the remaining provisions of the accreditation shall not be affected thereby.

252:302-3-22. Amendments to accreditations

(a) **Changes to be reported.** Changes in laboratory name, ownership, form of ownership, location, and other changes, including personnel and/or equipment, which may significantly affect the performance of analyses for which the laboratory was originally accredited shall be reported in writing to the DEQ within 30 days of occurrence. If requested by owner, the DEQ may amend the accreditation to reflect reported changes.

(b) **Amendment fee.** An amendment fee shall be assessed in accordance with this Chapter.

(c) **Cause.** The DEQ may amend an accreditation for cause, with notice to the affected accredited laboratory and opportunity for hearing.

252:302-3-23. Self-reporting

(a) An accredited laboratory shall promptly submit correct facts or information to the DEQ and/or to the client when:

(1) it becomes aware that it failed to submit a material fact or submitted incorrect information in an application or a report to the DEQ or to a client for submission to the DEQ; or

(2) the DEQ becomes aware of same and notifies the laboratory.

(b) Failure to make a prompt submission may result in an enforcement action.

PART 5. GROUNDS TO SUSPEND OR REVOKE

Section
252:302-3-31. Grounds to take enforcement action
252:302-3-32. Notice
252:302-3-33. Individual proceedings

252:302-3-31. Grounds to take enforcement action

In addition to the grounds listed in 27A O.S. §2-3-501 *et seq*., § 2-4-305(A) and OAC 252:4-7-15, the DEQ may suspend, revoke or refuse to renew in part or in whole the accreditation of any laboratory for the following grounds:

(1) consistent and significant errors in analyses, erroneous reporting or evidence of professional or technical incompetence;

(2) misrepresentation to others regarding the type and conditions of DEQ accreditation and the reliance of others on such misrepresentation;

(3) failure to perform any of the following:

(A) to correct deficiencies, comply with a Corrective Action Report, or take other action required by the DEQ pursuant to these rules;

(B) to participate or produce acceptable results in required proficiency testing;

(C) to cooperate with or allow on-site laboratory evaluations, or access to records; or

(D) failure to notify or submit reports to the DEQ as required by this Chapter

(4) submission of a proficiency testing sample to another laboratory for analysis, and reporting data received as its own;

(5) collaboration with other laboratories on results before proficiency testing sample results are submitted to the required agency;

(6) allowing persons other than qualified laboratory employees to perform and report results of accredited analytes; or

(7) any other violation, action or inaction presenting good cause for such action.

252:302-3-32. Notice

The DEQ may require an accredited field laboratory to give written notice to its clients of the suspension or revocation of any part of its accreditation.

252:302-3-33. Individual proceedings

Proceedings for accreditation revocation, suspension or reinstatement shall be conducted in accordance with 27A O.S. § 2-3-501 *et seq.,* and OAC 252:4, DEQ Rules of Practice and Procedure.

SUBCHAPTER 5. GENERAL OPERATIONS

Section
252:302-5-1. Posting of accreditation
252:302-5-2. Laboratory technician
252:302-5-3. Data produced whiel in training
252:302-5-4. Laboratory supervisor/consultant

252:302-5-1. Posting of accreditation

A field laboratory shall maintain on file the list of analytes for which it is accredited and shall provide a copy of the list upon request.

252:302-5-2. Laboratory technician

(a) All field laboratories shall have at least one on-site employee meeting the minimum requirements of this chapter.
(b) The laboratory technician shall have at least a high school diploma or equivalent, complete a method training program under an experienced analyst and have six months bench experience in the analysis of process samples.
(c) The laboratory technician shall have knowledge of the use of analytical equipment and support equipment used for the analysis of pH, chlorine residual, turbidity, conductivity, temperature and dissolved oxygen.
(d) Before analyzing compliance samples, the laboratory technician must demonstrate acceptable results on at least four (4) replicates of a known standard. These are analyzed as unknown samples over a period of 3 to 5 days by the technician; or demonstrate satisfactory participation on PT samples and adhere to required QC procedures specified in the methods for blanks, precision, accuracy, sensitivity, and specificity. The demonstration must be documented according to the laboratory's QA plan.
(e) Laboratory technicians must be under the supervision of a supervisor/consultant until the minimum requirements of this subsection are met.

252:302-5-3. Data produced while in training

Data produced by laboratory technicians while in the process of obtaining the required training or experience are acceptable only when documented, reviewed and validated by a fully qualified laboratory supervisor/consultant.

252:302-5-4. Laboratory supervisor/consultant

The laboratory supervisor/consultant shall have earned at least a bachelor’s degree in chemistry or equivalent and two years experience with environmental analyses using approved methodologies. The supervisor/consultant shall have a working knowledge of QA principles and shall be responsible to ensure that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meets the required QA and regulatory criteria.

252:302-5-5. Facilities, equipment and supplies

(a) All equipment, reagents, glassware and supplies necessary for the proper performance of laboratory analyses shall be on hand or readily available on the premises for analytes certified or analytes listed in an application for accreditation.
(b) Reagents and standards shall not exceed their expiration dates.
(c) Equipment shall be in good working order and properly maintained and shall consist of, at a

minimum, the apparatus and supplies for which the laboratory is accredited.
(d) Facilities shall have a sink with hot and cold running water, electricity, a source of distilled and/or deionized water, and other features/equipment necessary to properly perform approved EPA analytical methodologies.
(e) Facilities may be physically located apart in separate buildings if the sites are within one (1) mile of each other and under the same direct management.

252:302-5-6. On-site evaluations
(a) An on-site evaluation may be unannounced.
(b) During an evaluation the DEQ may require on-site analyses of proficiency test samples by laboratory personnel.
(c) Following the evaluation the DEQ will provide the laboratory with a copy of the evaluation report within 45 days of the on-site evaluation. The laboratory will be afforded 30 days from receipt of report in which to correct any listed deficiencies. The DEQ may require a laboratory to develop and implement a Corrective Action Report (CAR). The DEQ will provide an evaluation of the CAR within 45 days of receipt of same.
(d) Prior to granting initial accreditation to a laboratory, DEQ will perform an on-site evaluation of the laboratory.
(e) Prior to granting a laboratory an accreditation for an additional analyte, DEQ may perform an on-site evaluation of the laboratory.
(f) DEQ may conduct routine on-site evaluation of a laboratory every other year to ensure compliance with the conditions of this Chapter, or upon receipt of complaint.

252:302-5-7. Recordkeeping and reporting
(a) The laboratory shall keep the following records on file in its accredited facility for at least five (5) years:
(1) accreditation and the application on which it is based;
(2) copies of all records and documentation required to be kept by this Chapter;
(3) repair and maintenance records;
(4) reports filed with the DEQ or submitted to clients for filing with the DEQ;
(5) equipment changes, additions or malfunctions; and
(6) QA/QC plans and reports.
(7) data reported for regulatory compliance purposes, including:
(A) calibration or standardization information, or both;
(B) quality controls, including standards and duplicates;
(C) calculations;
(D) sampling and analytical data; and
(E) reports.
(8) sampling and analytical data to be retained shall include the following:
(A) date, time and location of sampling and analysis;
(B) name of the person collecting the sample;
(C) name of the analyst; and
(D type of analysis, method utilized, and results.
(b) Any data report by an accredited laboratory shall identify that the laboratory is a field laboratory.

SUBCHAPTER 7. PROFICIENCY TESTING

Section

252:302-7-1. Participation required

A field laboratory must participate in two single-blind, single-concentration, regularly scheduled Proficiency Testing (PT) studies per calendar year for each analyte in each class of accreditation for which it seeks accreditation or renewal of accreditation. PT samples must be provided by a National Environmental Laboratory Accreditation Program (NELAP) approved PT provider.

252:302-7-2. PT sample treatment

(a) Samples shall be analyzed and the results returned to the PT study provider no later than the provider's closing date. The laboratory shall ensure that all PT samples are handled, *i.e.*, managed, analyzed and reported, in the same manner as actual environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

(b) When analyzing a PT sample, a laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

252:302-7-3. Initial accreditation

To gain initial or interim accreditation, a laboratory shall have obtained acceptable results for two consecutive proficiency testing (PT) rounds. Proficiency testing (PT) rounds must have been performed within the last twelve (12) months and at least fifteen (15) calendar days apart from the date of analysis.

252:302-7-4. PT Requirements

(a) **General requirements.** Field laboratory proficiency testing samples must be Water Pollution (WP) type testing samples

(1) Laboratories seeking to renew accreditation must obtain acceptable results for vendor supplied, regularly scheduled proficiency testing samples approximately six (6) months apart in each calendar year. Failure to meet the semiannual schedule shall be regarded as a failed

study on the last day of the seventh (7th) month.

(2) Laboratories shall successfully analyze at least two (2) PT studies within the most recent three rounds attempted (2 of 3) prior to renewal. Laboratories may analyze additional or supplemental studies; however, such studies must be reported to the DEQ.

(b) **Cost responsibility**. Laboratories shall bear the cost of any subscription to a proficiency testing program required by the DEQ. The DEQ shall not be charged a fee for the analysis of any proficiency testing samples.

(c) **Alternate program.** The DEQ may designate an alternate proficiency testing program if it determines such designation is appropriate.

(d) **DEQ PT samples.** As part of a laboratory's proficiency testing, the DEQ may also submit blind audit samples to an accredited laboratory.

(e) **Restrictions on exchanging information.** A laboratory shall not attempt to obtain the prepared value of any PT sample from its PT Provider prior to the conclusion of the PT study.

252:302-7-5. Maintenance of PT records

(a) **Required records**. The laboratory shall maintain copies of all written, printed and electronic records, including but not limited to bench sheets, raw data, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for a minimum of five (5) years. The records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made readily available during on-site inspections of the laboratory.

(b) **PT report.** The PT study provider shall provide the participant laboratories and the DEQ a report showing the laboratory's DEQ identification number and EPA identification number, prepared value, the acceptance range, and the acceptable/not acceptable status for each analyte reported by the laboratory and any other information the DEQ deems necessary for accreditation purposes. The report and all associated data shall also be made available in electronic format as specified by the DEQ. The report shall be submitted electronically as specified by the DEQ.

252:302-7-6. Evaluation of PT results

PT study providers shall evaluate results from all PT studies using mandated acceptance criteria.Each result shall be scored on an acceptable/not acceptable basis

252:302-7-7. PT criteria for laboratory accreditation

The following criteria apply individually to each analyte as defined by the laboratory seeking accreditation in its application:

(1) Results of the PT study shall be considered successful when the results are "acceptable" and are within the acceptable limits established and published by the PT Provider.

(2) The DEQ shall consider PT results along with the other elements of these rules when determining a laboratory's accreditation status;

(3) For initial accreditation or supplemental testing, the studies must be at least fifteen (15) calendar days apart from the date of analysis.

252:302-7-8. Failure to perform

The DEQ shall not renew accreditation for a failed or omitted analyte for a laboratory which does not meet the requirements of this subchapter. Once accreditation for an analyte has been

lost, the procedures for initial or interim accreditation shall apply.

252:302-7-9. Supplemental studies

A laboratory may elect to participate in PT studies more frequently than required by the semiannual schedule. Additional studies are not distinguished from the routinely scheduled studies. They are counted and scored the same way and must be at least fifteen (15) calendar days apart from the date of analysis.

252:302-7-10. Corrective action

When a laboratory fails a study, in part or in whole, it shall determine the cause for the failure and take any necessary corrective action. The laboratory shall then document both the investigation and the action(s) in a corrective action report (CAR). The CAR shall be submitted to the DEQ within forty-five (45) days of PT study report issuance.

SUBCHAPTER 9. QUALITY ASSURANCE/QUALITY CONTROL

PART 1. QUALITY ASSURANCE/QUALITY CONTROL GENERAL CRITERIA

Section

252:302-9-1. Quality Assurance/Quality Control (QA/QC) Plan Required

Every accredited laboratory shall maintain a written QA plan and implement it into a QA/QC program to ensure that all routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy.

252:302-9-2. Format

(a) The QA plan shall list the following on the title page:
   (1) a document title;
   (2) the laboratory's full name and address;
   (3) the names, addresses and telephone numbers of all individuals responsible for the laboratory;
   (4) the name of the quality manager (however titled);
   (5) the identification of all major organizational units which are to be covered by this QA plan; and
   (6) the effective date of the version.

(b) The QA plan shall also contain a Table of Contents, applicable lists of references and glossaries, and appendices.

252:302-9-3. Management information required in QA plan

The QA plan and related quality documentation shall state the laboratory's policies established in order to meet the requirements of this rule. The QA plan and related quality documentation shall also contain:

(1) a quality policy statement, including objectives and commitments, by top management;

(2) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(3) the relationship between management, technical operations, support services and the quality assurance plan;

(4) job descriptions of key staff and reference to the job descriptions of other staff;

(5) identification of the laboratory's approved signatories; at a minimum, the title page of the QA plan must have the signed and dated concurrence, (with appropriate titles) of all responsible parties including the quality manager(s), technical director(s), and the agent who is in charge of all laboratory activities such as the supervisor/consultant; and

(6) the laboratory management arrangements for exceptional departures from documented policies and procedures or from standard specifications.

252:302-9-4. Procedures required for QA Plan

The QA plan shall address supporting procedures including technical procedures and shall outline the structure of the documentation used in the quality assurance plans, including but not limited to the following:

(1) ensuring that all records required are retained

(2) control and maintenance of documentation through a document control system which ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force;

(3) achieving traceability of measurements;

(4) handling submitted samples;

(5) feedback and corrective action whenever testing discrepancies are detected or departures from documented policies and procedures occur;

(6) dealing with complaints;

(7) protecting confidentiality (including national security concerns) and proprietary rights;

(8) audits and data review; and

(9) establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training.

252:302-9-5. References included in QA Plan

The QA plan shall make reference to the following:

(1) the calibration and/or verification test procedures used;

(2) the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;

(3) procedures for calibration, verification and maintenance of equipment;

(4) verification practices which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes; and

(5) procedures for reporting analytical results.

252:302-9-6. Additional items included in QA Plan

The QA plan shall also include the following:
(1) a list of all test methods under which the laboratory performs its accredited testing; and
(2) mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work.

PART 3. STANDARD OPERATING PROCEDURES AND METHODS MANUAL

Section

252:302-9-21. General

(a) The laboratory shall use appropriate methods and procedures for all environmental tests within its scope. These include sampling, handling, transport, storage and preparation of samples.
(b) The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples where the absence of such instructions could jeopardize the results of environmental tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel. Deviation from environmental test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

252:302-9-22. Standard Operating Procedures (SOPs)

(a) Laboratories shall maintain Standard Operating Procedures (SOPs) that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.
(b) SOPs may be equipment manuals provided by the manufacturer or internally written documents. Test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the methods manual.
(c) Copies of all SOPs shall be accessible to all personnel.
(d) SOPs shall be well organized and shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.

252:302-9-23. Test method(s)

Each test method shall include or reference the following, where applicable:
(1) Identification of the test method;
(2) Applicable matrix or matrices;
(3) Detection limit;
(4) Scope and application, including components to be analyzed;
(5) Summary of the test method;
(6) Definitions;

(7) Interferences;
(8) Safety;
(9) Equipment and supplies;
(10) Reagents and standards;
(11) Sample collection, preservation, shipment and storage;
(12) Quality control;
(13) Calibration and standardization;
(14) Procedure;
(15) Calculations;
(16) Method performance;
(17) Data assessment and acceptance criteria for quality control measures;
(18) Corrective actions for out-of-control data;
(19) Contingencies for handling out-of-control or unacceptable data;
(20) References; and
(21) Any tables, diagrams, flowcharts and validation data.

252:302-9-24. Selection of methods

(a) The laboratory shall analyze water samples in accordance with methods approved by the laboratory accreditation officer as required by the Clean Water Act.
(b) The laboratory shall use methods for environmental testing, including methods for sampling, which meet the needs of the client and which are appropriate for the environmental tests it undertakes.

252:302-9-25. Methodology incorporated by reference

"Guidelines Establishing Test Procedures for the Analysis of Pollutants" 40 CFR Part 136, as published on July 1, 2018, is hereby incorporated by reference.

PART 5. QA/QC PROGRAM REQUIREMENTS

Section

252:302-9-31. QA/QC program required

Each accredited field laboratory shall maintain a QA/QC program to demonstrate the precision and accuracy of analyses. The program shall be in place before accreditation is granted. For a minimum of five (5) years, each laboratory shall maintain records of all analyte accredited analyses, including but not limited to those necessary for a QA/QC program. Laboratories shall perform individual quality control for every analyte for which the laboratory is accredited or is applying for accreditation.

252:302-9-32. QA/QC documentation

(a) Documentation shall be kept to ensure quality control has been maintained and that proper

methodologies have been used for the preparation and analysis of samples. All documentation shall be maintained and be readily available for reference or inspection.

(b) The following QC documentation shall be maintained in each laboratory.

(1) **Bench records.** Data associated with analysis, date, time, analyst, method, amounts, calculations, sample matrix, sample identification.

(2) **Calibration data.**

(A) Each instrument shall have documented calibration on each day of use.

(B) Each calibration shall be verified with a quality control standard that is of a source separate from the calibration source.

(C) Each aliquot of a solution used for calibration and quality control shall be used only once.

(D) Calibration shall be documented either by the instrument printout or by calculations which show the curve or coefficient of the linear equation or slope.

(E) Automated on-line equipment shall be calibrated according to manufacturer's instructions.

(3) **Maintenance logs.** By instrument, dates and description of repairs, preventive maintenance, malfunctions, and other actions or events affecting instrument performance

(4) **QC charts.** Quality control procedures for monitoring the validity of each environmental test must be in place. The resulting data shall be recorded in such a way that trends are detectable. Data recorded shall consist of blanks, quality control standards and duplicates

(5) **Sample login.** Sample login, including unique sample identification, date, time, source of sample (including name, location and sample matrix), preservative used, analysis required, name of collector and any pertinent field.

252:302-9-33. Sample storage for pickup

Each day of use, laboratories shall record refrigerator temperature readings and any temperature excursions with corrective action in a logbook. Any thermometer used shall be calibrated or verified at least annually, using a recognized National Metrology Institute such as NIST, traceable references when available, bracketing the range of use.

252:302-9-34. Reagents and standards

(a) Laboratories shall use calibration standards established through the use of reference materials that are either:

(1) purchased by the laboratory with a certificate of analysis or purity,

(2) prepared by the laboratory using support equipment that has been calibrated,or

(3) verified to meet specifications.

(b) Laboratories shall record the lot number and expiration date of reagents and standards that do not have certificates of analysis.