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 temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment which has been delayed for reasons beyond the control of the laboratory. It 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

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 director supervisor, which gives the academic training, experience and analytical and supervisory responsibilities of each; 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 inspection evaluation conducted by the DEQ or a DEQ approved agent within the twelve (12) months prior to the date of filing or, for in-state laboratories only, a letter requesting the DEQ to conduct an on-site inspection evaluation. The inspection evaluation report shall verify data submitted in the application, list any deficiencies and be signed by the DEQ or DEQ approved agent.

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

(7) Hours of operation.

PART 5. GROUNDS TO SUSPEND OR REVOKE
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, inspections, 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.

SUBCHAPTER 5. GENERAL OPERATIONS

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, subsection (b) of this section unless un-supervised, in which case the technician must have an additional six (6) months experience performing environmental testing and must have demonstrated satisfactory participation on PT samples. Laboratory technicians under the supervision of a supervisor/consultant must only meet the minimum requirements of subsection (b) of this section.

(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 shall 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 any 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.
252:302-5-6. On-site inspections evaluations
   (a) Inspections. An on-site evaluation may be unannounced.
   (b) On-site requirements. During an inspection evaluation the DEQ may require on-site analyses of proficiency test samples by laboratory personnel.
   (c) Corrective Action Report. Following the inspection evaluation the DEQ will provide the laboratory with a copy of the inspection evaluation report within 45 days of inspection 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.

SUBCHAPTER 7. PROFICIENCY TESTING

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.

SUBCHAPTER 9. QUALITY ASSURANCE/QUALITY CONTROL

PART 3. STANDARD OPERATING PROCEDURES AND METHODS MANUAL


PART 5. QA/QC PROGRAM REQUIREMENTS

252:302-9-32. QA/QC documentation
   (a) Documentation shall be kept to ensure that 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 data 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.