TITLE 252. DEPARTMENT OF ENVIRONMENTAL QUALITY CHAPTER 301. LABORATORY ACCREDITATION

SUBCHAPTER 1. GENERAL PROVISIONS

252:301-1-3. 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." For purposes of this Chapter, "analyte" also means one of a set of inorganic or organic chemical, physical, radiochemical or microbiological properties whose value determines the characteristics of a water or wastewater sample.

"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 and includes primary accreditation and reciprocity accreditation.

"Corrective Action Plan" is a written plan of action, including a schedule for implementation, to correct deficiencies 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.

<u>"Critical Finding"</u> 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. For purposes of certifications issued and enforcement matters arising prior to July 1, 1993, "DEQ" also means predecessor agencies of the DEQ which had jurisdiction over environmental water quality laboratories on June 30, 1993.

"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.

"Finding" <u>means a conclusion of noncompliance of the evaluation process supported by</u> 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 in analytes for 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.

"Mobile laboratory" means a mobile facility that performs analyses in a self-contained environment with professional analytical instrumentation, excluding field testing of those analytes that require immediate measurement on site (conductivity, residual chlorine, pH, dissolved oxygen, temperature).

"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.

"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.

252:301-1-4. Terms

Terms used in this Chapter shall have the meanings given to them in OAC 252:301-1-2 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.

252:301-1-7. General water quality laboratory

(a) **Category groups.** A general water quality laboratory may be accredited in the following category groups: metals, nutrients, demands, extractable organics, general chemistry I and/or II, microbiology, pesticides - herbicides - PCBs, purgeable organics, radiological, bioassay, hazardous waste characterization, petroleum hydrocarbons, perchlorate, and/or basic environmental laboratory.

(b) **Basic environmental laboratory analytes.** Basic environmental laboratory analytes include five day biochemical oxygen demand, carbonaceous biochemical oxygen demand, chemical oxygen demand, total organic carbon (TOC), total Kjeldahl nitrogen (TKN), nitrate-nitrite nitrogen, organic nitrogen, ammonia nitrogen, total dissolved solids (filterable residue), total suspended solids (non-filterable residue), volatile residue, total phosphorous, orthophosphate phosphorus (reactive phosphorus), chloride, fluoride, oil and grease, sulfate, pH, specific conductance, dissolved oxygen, turbidity, total residual chlorine, hardness, alkalinity, color, fecal

coliform, <u>Escherichia coli</u>, total coliform, cyanide, phenolics, copper, zinc, iron, sulfide, chromium, and hexavalent chromium.

252:301-1-9. Fees

(a) Applicable fees. The following fees apply:

(1)	Initial accreditation	\$1,140.00
(2)	Interim accreditation	671.00
(3)	Renewal fee	34.00
(4)	Renewal late fee	335.00
(5)	Accreditation amendment	67.00
(6)	Fee for 1 category	470.00
(7)	Fee for 2 categories	940.00
(8)	Fee for 3 categories	1,410.00
(9)	Fee for 4 categories	1,880.00
(10)	Fee for 5 or more categories	2,350.00
(11)	Inspections On-site evaluation	-O- <u>Reimbursable</u> Expense

(b) **Renewal.** Fees to renew accreditation consist of the renewal application fee and the applicable category fee.

(c) **Public water supply system fee exemption.** There is no laboratory accreditation fee for public water supply systems that pay the minimum annual public water supply regulatory service rate fee in accordance with 27A O.S. § 2-6-306.

(d) Annual fee adjustment. To assist in meeting rising costs to the DEQ of the environmental services and regulatory programs associated with the laboratory accreditation 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.

(e) An On-site evaluation fee shall be calculated at actual cost and includes but is not limited to the following: assessor(s) time and labor (preliminary document review, total travel, time-on-site, report preparation, and corrective action review), transportation, per diem (if required), as

SUBCHAPTER 3. LABORATORY ACCREDITATION PROCESS

PART 1. APPLICATION

252:301-3-3. 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, 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 laboratory's two most recent proficiency testing rounds, at least 15 calendar days apart.

(5) A report of a laboratory inspection evaluation conducted by the DEQ or a DEQ approved agent assessor 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 an application, list any deficiencies and be signed by the DEQ or DEQ approved agent.

(6) If deficiencies are listed in an inspection evaluation report, the applicant shall submit a corrective action plan which specifies deadlines for implementation and completion of the plan. The DEQ may establish conditions, including compliance schedules, for the applicant's corrective action plan.

(7) Hours of operation.

PART 5. GROUNDS TO REVOKE

252:301-3-51. 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 plan, 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, or

(8) failure to make payment when due.

SUBCHAPTER 5. GENERAL OPERATIONS

252:301-5-4. On-site inspections evaluation

(a) Inspections On-site evaluations may be unannounced.

(b) **On-site requirements.** During an inspection <u>on-site evaluation</u> the DEQ may require on-site analyses of proficiency test samples by laboratory personnel.

(c) **Corrective action plan.** Following the inspection <u>on-site evaluation</u> the DEQ will provide the laboratory with a copy of the inspection <u>evaluation</u> report. The laboratory will be afforded a designated time period in which to correct any listed deficiencies. The DEQ<u>may</u> will require a laboratory to develop and implement a Corrective Action Plan (CAP).

(d) **Out-of-state laboratories.** Out-of-state laboratories already in the program may be required to have an on-site inspection <u>on-site evaluation</u> performed by a DEQ approved agent <u>assessor</u>. The laboratory shall be solely responsible for costs associated with the inspection <u>on-site evaluation</u>, if any. The inspection <u>evaluation</u> report shall be submitted to the DEQ along with a <u>any Corrective Action Plan (CAP)</u> if needed.

(e) The laboratory shall have an on-site evaluation prior to granting an initial accreditation.

(f) Prior to granting accreditation for an additional field of accreditation to a laboratory, DEQ may perform an on-site evaluation of the laboratory. All laboratories must pay an appropriate on-site evaluation fee for each evaluation requested by the laboratory for the additional fields of accreditation.

(g) DEQ may conduct on-site evaluation of a laboratory to ensure compliance with this Chapter approximately biennially, or upon receipt of complaint.

SUBCHAPTER 7. PROFICIENCY TESTING

252:301-7-2. Participation required

A 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. and shall conform to all applicable National Environmental Laboratory Accreditation Conference (NELAC).

SUBCHAPTER 9. QUALITY ASSURANCE/QUALITY CONTROL

PART 3. STANDARD OPERATING PROCEDURES AND METHODS MANUAL

252:301-9-37. Methodology incorporated by reference

The following EPA methods are hereby incorporated by reference:

(1) "National Primary Drinking Water Regulations", 40 CFR Part 141, published July 1, 2012 July 1, 2018.

(2) 'Test Methods for Evaluating Solid Waste, Laboratory Manual Physical/Chemical Methods," SW-846 Manual, Third Edition as amended by Final Update I, II, IIA, IIB, III, IIIA, IIIB, and IV and VI. See further SW-846-ON-LINE.; and

(3) 'Guidelines Establishing Test Procedures for the Analysis of Pollutants_40 CFR Part 136, published <u>July 1, 2012</u> July 1, 2018.

PART 5. QA/QC PROGRAM REQUIREMENTS

252:301-9-51. QA/QC program required

Each accredited 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 three (3) 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.

252:301-9-54. Inorganic/classic chemistry

If approved methodologies do not specify minimum laboratory QA/QC requirements for inorganic/classic chemistry, the following frequencies shall apply:

(1) A minimum of three concentrations of standards for daily calibration plus one continuing calibration check standard after each ten samples tested. The lab should repeat all samples tested after the last acceptable continuing calibration check if the continuing calibration check standard is outside \pm plus/minus 10%.

(2) One blank per twenty samples tested (or batch).

(3) If applicable, one spike per twenty samples tested or one per batch.(or at least once per month, whichever is the greater frequency).

(4) One duplicate or spiked duplicate per twenty samples tested or one per batch. or at least once per month, whichever is the greater frequency.

252:301-9-57. Support equipment

All support equipment shall be calibrated or verified at least annually, using a recognized Nation Metrology Institute, such as NIST, traceable references when available, bracketing the range of use. The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or the equipment shall be removed from service and tagged as such until repaired.