# CHAPTER 307. NATIONAL TNI LABORATORY ACCREDITATION

## SUBCHAPTER 1. INTRODUCTION

**252:307-1-3. Definitions**

In addition to the definitions contained in Title 27A of the Oklahoma Statutes, OAC 252:004 (Department of Environmental Quality Rules of Practice and Procedure), and the TNI Standard, the following words or terms, when used in this Chapter, shall have the following meaning unless the context clearly indicates otherwise. Any technical term not defined shall be defined by its generally accepted scientific meaning or its standard dictionary meaning.

**"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 DEQ.

**"Accreditation"** or **"accredited"** means the process by which ~~the~~ DEQ evaluates an environmental laboratory's quality systems, staff, facilities, equipment, test methods, records, and reports against the requirements of this Chapter. Laboratories determined to meet the qualifications and standards of this Chapter are thereby accredited. The term "certification", as used in 27A O.S. §2-4-101, is synonymous with the term accreditation.

**"Accreditation Body"** means a governmental agency that holds a current Certificate of Recognition from TNI to administer a laboratory accreditation program.

**"Analyte"** means the ~~component, compound, element or isotope to be identified or quantified using a test or analysis~~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 given 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~~that has been required by law or is recognized by ~~the~~ DEQ as acceptable for a specific usage.

**"Assessment"** means the evaluation process used to measure or establish the performance, effectiveness, and conformance of a laboratory to the standards and requirements of this Chapter. The term "Evaluation" as used in 27A O.S. § 2-4-101, is synonymous with the term "Assessment".

**"Basic environmental laboratory"** means a laboratory that is limited to the following analytes: ~~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, Escherichia coli, total coliform, cyanide, phenolics, copper, zinc, iron, sulfide, chromium, and hexavalent chromium~~alkalinity, ammonia nitrogen, carbonaceous biochemical oxygen demand, chemical oxygen demand, chloride, chromium, color, copper, cyanide, dissolved oxygen, Escherichia coli, fecal coliform, five-day biochemical oxygen demand, fluoride, free residual chlorine, hardness, hexavalent chromium, iron, nitrate-nitrite nitrogen, oil and grease (n-hexane extractable material), organic nitrogen, orthophosphate phosphorus (reactive phosphorus), pH, phenolics, specific conductance, sulfate, sulfide, temperature, total coliform, total dissolved solids (filterable residue), total Kjeldahl nitrogen, total organic carbon, total phosphorus, total residual chlorine, total suspended solids (non-filterable residue), turbidity, volatile residue, and zinc.

**"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.

**"Category"** means a set of Fields of Accreditation subject to a single fee.

**"Certificate"** or **"Certificate of Accreditation"** is a document issued by DEQ acknowledging that an environmental laboratory has met standards for accreditation~~,~~ and identifying those Fields of Accreditation for which the laboratory is accredited.

~~**"Critical nonconformity"** or **"critical finding"** means a conclusion of noncompliance that would require an immediate corrective action or an immediate stop to testing.~~

**"Corrective Action Plan (CAP)"** or **"Corrective Action Report"** 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~~It includes a schedule for implementation and actions to eliminate or reduce the cause(s) of a~~n existing~~ nonconformity, defect, or other undesirable situation ~~in order~~ to prevent its recurrence. A CAP may be required in response to identified deficiencies in a DEQ or DEQ-approved agent's assessment report.

**"Critical nonconformity"** or **"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. For purposes of certifications issued and enforcement matters arising prior to July 1, 1993, "DEQ" also means predecessor agencies of ~~the~~ DEQ ~~which~~that had jurisdiction over environmental water quality laboratories on June 30, 1993.

**"Field of Accreditation (FoA)"** means those category, matrix, technology/method, and analyte combinations for which DEQ offers accreditation.

~~**"Finding"** means a conclusion of noncompliance or nonconformity of the evaluation process, referenced to the TNI Standard and supported by objective evidence.~~

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

**"Interim accreditation"** means an ~~out-of-time filing for an~~ accreditation ~~status~~ issued to a DEQ~~-~~-accredited laboratory outside of the renewal accreditation process for a Field of Accreditation or a category not currently accredited by ~~the~~ DEQ, or where appropriate, temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment ~~which~~that has been delayed for reasons beyond the control of the laboratory.

**"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~~*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.

**"Matrix"** means the substrate of a test sample, e.g., drinking water, wastewater, other aqueous, or solid.

**"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 (such as, conductivity, residual chlorine, pH, dissolved oxygen, temperature).

**"Nonconformity"** means a conclusion of noncompliance of the evaluation process, referenced to the TNI Standard, and supported by objective evidence. ~~Also may be considered a Finding~~This term is synonymous with both "deficiency" and "finding".

**"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~~that owns or operates a laboratory.

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

**"Primary accreditation"** is authorization issued to an Oklahoma laboratory following an assessment of the laboratory's total quality system, on-site assessment, and proficiency testing for fields of accreditation.

**"Primary accreditation body" (Primary AB)** means the accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and proficiency testing (PT) performance tracking for fields of accreditation.

**"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's laboratory accreditation program described in this Chapter.

**"Quality manual"** means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of the laboratory to ensure the quality of its product and the utility of its product to its users. The Quality Manual will ensure the generation of data that are scientifically valid, defensible and of known and acceptable limits of precision and accuracy.

**"Quality system"** means a structured and documented management system describing the policies, objective, principles, organizational authority, responsibilities, accountability, and implementation plan of a laboratory for ensuring quality in its work processes, products and services. The quality system provides the framework for planning, implementing, and assessing work performed by the laboratory and for carrying out required quality assurance and quality control activities.

**"Secondary accreditation"** is authorization issued to a laboratory based on recognition and review of an existing primary accreditation for the same fields of accreditation.

**"Secondary accreditation body" (Secondary AB)** means an accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a Primary Accreditation Body for the same fields of accreditation.

**"Standard operating procedures" (SOPs)** means a written document approved by ~~a~~ laboratory ~~director~~management that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs include the methods for performing certain routine or repetitive tasks.

**"Synthetic organic chemicals" (SOCs)** are man-made organic chemicals that are less volatile than volatile organic compounds. SOCs are used as pesticides, defoliants, fuel additives and as ingredients for other organic compounds.

**"The NELAC Institute" (TNI)** means an organization of federal and state agencies whose purpose is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the environmental laboratory community. The TNI Consensus Standards Development Program (CSDP) establishes compliance standards that reflect the best professional practices in the environmental laboratory industry. The TNI National Environmental Laboratories Accreditation Program (NELAP) implements TNI's consensus standards through state agencies recognized by TNI as Accreditation Bodies. DEQ is the TNI Accreditation Body in the State of Oklahoma.

**"TNI Standard"** means the performance standard for analytical testing of environmental samples and the laboratory accreditation process adopted by TNI, current to the date incorporated by reference in this Chapter.

**252:307-1-4. Incorporation by reference**

(a) **TNI Standard.** Laboratories accredited under this Chapter shall meet the requirements of the TNI Standard for the Environmental Laboratory Sector, Volume 1, "Management and Technical Requirements for Laboratories Performing Environmental Analysis." Modules 1, 2, 3, 4, 5, 6 and 7 as adopted January 31, 2020, which are hereby incorporated by reference.

(b) **EPA methodology.** Environmental analysis for compliance with the Federal Safe Drinking Water Act, Federal Clean Water Act and Federal Resource Conservation and Recovery Act require conformance with applicable EPA approved methodology. If EPA has approved a test procedure for analysis of a specific analyte, the laboratory must use an approved test procedure. The following EPA-approved methods are hereby incorporated by reference:

(1) "Guidelines Establishing Test Procedures for the Analysis of Pollutants," 40 CFR Part 136, effective July 19, 2021;

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

(3) "Methodologies set forth in the National Primary Drinking Water Regulations," 40 CFR Part 141 as published July 1, 2021; ~~and~~

(4) "Manual for the Certification of Laboratories Analyzing Drinking Water," Fifth Edition and Supplement 1 (EPA 815-5-05-004, January 2005 and EPA 815-F-08-006, June 2008)~~.~~; and

(5) Any other approved method incorporated by DEQ Laboratory Accreditation Program in writing.

~~(d)~~(c) **DEQ approved methodologies.** The following methods are specifically approved by ~~the~~ DEQ:

(1) TNRCC Method 1005 Total Petroleum Hydrocarbons (>nC6 to nC35) of June 1, 2001;

(2) Oklahoma GRO 8020/8015(Modified) of February 24, 1996;
(3) Oklahoma DRO 8000/8100(Modified) of October 22, 1997;
(4) ASTM mussels of 2006;
(5) ASTM E 1193-97 for whole effluent toxicity tests; and
(6) On a case-by-case basis as approved by DEQ.

~~(c)~~(d) **Inconsistencies between test methods and rules.** In the event there are inconsistencies between the requirements of this Chapter and requirements of those provisions incorporated by reference, the laboratory must meet all applicable requirements. Laboratories are encouraged to consult with DEQ when in doubt about the proper or applicable test method.

**252:307-1-6. Annual accreditation**

The ~~term~~period of accreditation is annual, running from ~~September~~January 1 to ~~August~~December 31~~ the following year~~. Notwithstanding, an applicant laboratory may apply at any time for initial~~,~~ or interim ~~or renewal~~accreditation. A laboratory applying for interim accreditation shall meet the same requirements as a laboratory applying for initial accreditation. Regardless of when a certificate goes into effect, it shall expire on December 31 of the same year, unless provided specific written exception by DEQ.

**252:307-1-7. Annual fees**

(a) **Applicable fees.** The following fees apply:
(1) Initial accreditation: $1,183.00
(2) Interim accreditation: $696.00
(3) Renewal fee: ~~35.31~~$35.00
~~(4) Renewal late fee 347.86~~
~~(5)~~(4) Accreditation amendment: ~~69.57~~$69.00
~~(6) Fee for 1 category 488.05~~
~~(7) Fee for 2 categories 976.09~~
~~(8) Fee for 3 categories 1,464.14~~
~~(9) Fee for 4 categories 1,952.18~~
~~(10) Fee for 5 or more categories 2,440.23~~
(5) Fee per category: $488.00 (5 category fees maximum)
~~(11)~~(6) Onsite Assessment: Fee Reimbursable Expenses

(b) **Calculation of fees.** In addition to the application fee required for initial, renewal, and interim accreditation, a laboratory must submit the applicable category fee(s) to a maximum of 5 category fees even if a laboratory requests more than 5 categories. Fees for accreditation amendment, as described in OAC 252:307-5-2, consist of the accreditation amendment fee. The ~~onsite assessment fee~~fees associated with a laboratory assessment shall be calculated at actual cost, not to exceed $10,000 per individual laboratory, and includes, but is not limited to, the following as applicable: assessor(s) time, ~~and~~labor ~~(preliminary document review, total travel, time-on-site, report preparation, and corrective action review)~~, transportation, and per diem ~~(if required),~~ as described in 252:307-7-1. The onsite assessment will be invoiced at the closing of the assessment.

(c) **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 1 every year after 2008 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. Current laboratory accreditation fees are available on ~~the~~ DEQ website.

(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.

(d) **Onsite assessment fee.** All laboratories must pay an onsite assessment fee for each assessment to continue accreditation or as a result of just cause according to this chapter.

## SUBCHAPTER 3. LABORATORY ACCREDITATION PROCESS

**252:307-3-1. Application requirements**

(a) **General.** A laboratory shall submit one copy of the application, whether for primary accreditation or secondary accreditation. Application forms are available on ~~the~~ DEQ's website. Applications shall be accurate and complete, signed, and submitted to ~~the~~ DEQ electronically or by ~~regular~~ mail, with all required attachments. Application requirements are applicable to initial, interim, and renewal applications unless specifically stated otherwise.

(b) **TNI Standard.** Laboratories shall obtain a copy of the TNI Standard for use in their accredited laboratory programs. Standards may be obtained from The NELAC Institute, ordered on-line at http://www.nelac-institute.org/standards.php.

(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~~that 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.

(d) **Certification of compliance.** A "Certification of Compliance" statement must accompany the application for laboratory accreditation in accordance with the 2009 TNI Standard. The statement must be signed and dated by both the laboratory management and the quality assurance officer, or other designated person, for that laboratory. The certification statement must contain at least the following statements: "The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the Oklahoma Department of Environmental Quality standards and is subject to the enforcement and penalty provisions of that accreditation body. I hereby certify that I am authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answer to the questions on this application."

(e) **Application fees.** ~~Fees shall be submitted to the DEQ at the same time that applications are submitted. Applications will not be reviewed until fees are received.~~Following application processing and approval, DEQ will invoice the laboratory. Accreditation certificates will not be issued until fees are paid in full.

(f) **Environmental permit.**

(1) All laboratory accreditation applicants are subject to the tiered application procedural requirements of the Oklahoma Uniform Environmental Permitting Act, 27A O.S. § 2-14-101 *et seq.*, and Subchapter 7 of OAC 252:4 Rules of Practice and Procedure. Laboratory Accreditation is a Tier 1 action.

(2) Applicant laboratories must certify by affidavit that they own the real property where the laboratory is located, have a current lease or easement for the purpose, or have provided legal notice to the landowner. The landowner affidavits must be filed with the initial application, and thereafter any time there is a change in location or ownership. Landowner affidavit forms are available on ~~the~~ DEQ's website.

(g) **Primary accreditation.** Applicants for primary accreditation shall submit the application and required attachments ~~which~~that shall address all information requirements in 252:307-3-2 and 307-3-3.

(h) **Secondary accreditation**. Applicants for secondary accreditation shall submit the application plus the Primary AB's general scope of accreditation in a format required by DEQ. Applicants for secondary accreditation need not submit information required in 252:307-3-3.

(i) **Processing.** Applications for primary and secondary accreditation shall be processed in the chronological order in which they are received.

**252:307-3-3. Operational information**

The application for primary accreditation shall include the following:

(1) A report of an onsite assessment conducted by ~~the~~ DEQ or a DEQ-approved assessor within the eighteen (18) months prior to the date of filing or, for in-state laboratories only, a letter requesting ~~the~~ DEQ to conduct an on-site assessment. The assessment report shall verify data submitted in an application, list any deficiencies and be signed by ~~the~~ DEQ or DEQ-approved assessor.

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

(3) Standard Operating Procedures (SOPs) for every analyte or method performed by the laboratory. An SOP may be a copy of a published or referenced method or may be written by the laboratory. Each SOP shall include or reference the following topics, as applicable:

(A) Identification of the method;
(B) Applicable matrix or matrices;
(C) Limits of detection and quantitation;
(D) Scope and application, including parameters to be analyzed;
(E) Summary of the method;
(F) Definitions;
(G) Interferences;
(H) Safety;
(I) Equipment and supplies;
(J) Reagents and standards;
(K) Sample collection, preservation, shipment and storage;
(L) Quality control;
(M) Calibration and standardization;
(N) Procedure;
(O) Data analysis and calculations;
(P) Method performance;
(Q) Pollution prevention;
(R) Data assessment and acceptance criteria for quality control measures;
(S) Corrective actions for out-of-control data;
(T) Contingencies for handling out-of-control or unacceptable data;
(U) Waste management;
(V) References; and
(W) Any tables, diagrams, flowcharts and validation data.

(4) A written quality manual ~~which~~that shall meet all requirements, for inclusion or reference, of the TNI Standard.

(5) A statement of personnel qualifications showing that laboratory employees meet the applicable personnel requirements of the TNI Standard. Educational requirements will be considered only if awarded by an accredited institution of higher education.

(6) Results of laboratory's two most recent proficiency testing rounds, at least 15 calendar days apart. All PT laboratory records shall be made readily available prior to and during on-site assessments of the laboratory.

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

**252:307-3-6. Renewal and expiration**

(a) **Annual renewal required.** A laboratory that wishes to remain accredited must ~~timely submit an application for renewal each year, or its accreditation will expire on August 31~~apply to renew accreditation annually. Application forms are available on DEQ's website. Applications shall be accurate and complete, signed, and submitted to DEQ electronically or by regular mail, with all required attachments.
(b) **Laboratory responsibility.** Each laboratory is responsible for ~~renewing~~submitting its ~~accreditation~~renewal application materials by the annual renewal ~~date~~deadline. Failure to receive a renewal ~~notification and invoice~~notice does not exempt laboratories from meeting the renewal deadline.
~~(c) **DEQ invoice date.** By April 15 of each year, the DEQ mails invoices to each accredited laboratory.~~
~~(d)~~(c) **~~Deadline~~Renewal 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.~~ The renewal application shall be accurately completed, signed and received by DEQ along with all applicable materials on or before 4:30 p.m. CST September 15.~~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.~~
(d) **Payment deadline.** DEQ will invoice the accredited laboratory following application processing. Full payment of fees must be received on or before December 15.
(e) **PT ~~provider~~data deadline.** Laboratories shall ensure that the PT provider has submitted all pertinent PT reports to ~~the~~ DEQ electronically ~~or postmarked~~ on or before ~~July~~September 15 of each year. PTs received later than ~~July~~September 15 ~~will~~ may not be considered for accreditation renewal.
(f) **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.
(g) **Failure to renew.** ~~To become accredited again, a laboraotory that failed to renew its accreditation in a timely manner must apply for initial accreditation as a new laboratory.~~A laboratory that fails to submit renewal application materials or payment by the specified deadlines will not be eligible for renewal of their accreditation. They may reapply through the initial application process.

## SUBCHAPTER 5. CONDITIONS OF ACCREDITATION

**252:307-5-1. 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 27A O.S. § 2-4-101 *et seq.*, rules for laboratory accreditation at OAC 252:307, and the provisions and conditions of its 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 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 endangerment of human 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~~that ~~the~~ DEQ may request to determine:
(A) whether cause exists for amending, suspending, or revoking Accreditation;
(B) compliance with Accreditation; or
(C) whether an accreditation should be issued or renewed.
(4) **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~~that may result in noncompliance with accreditation requirements.
(5) **Signatory requirement.** All applications, reports, or information submitted to ~~the~~ DEQ shall be signed by the applicant.
(6) **Consent to conditions.** Commencing analytical activities as an accredited laboratory under DEQ accreditation shall constitute consent to all conditions of accreditation.
(7) **Transfer of accreditation.** Accreditation is not transferable. An accredited laboratory may apply to amend its accreditation to reflect a change of ownership or name change, provided that facilities, equipment, personnel and all other conditions of accreditation remain unchanged.
(8) **Duty to apply.** To maintain its accredited status, the laboratory shall make timely application for annual renewal of accreditation.
(9) **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.
(10) **Use of TNI logo.** The laboratory is allowed to use the TNI symbol on its reports or certificates issued within the scope of its accreditation. Misuse of the logo constitutes a failure to comply with accreditation requirements.
(11) **Withdrawal from TNI.** If a laboratory wishes to withdraw from this program, in total or in part, it must notify DEQ in writing.
(12) **Standard of Conduct.** The laboratory shall not use its accreditation in such a manner as to bring ~~the~~ DEQ's Laboratory Accreditation Program (LAP) into disrepute.

**252:307-5-2. Amendments to accreditations**

(a) **Changes to be reported.** Changes in laboratory name, ownership, form of ownership, location, and other changes, including personnel, main policies, 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 OAC 252:307-1-7.
(c) **Cause.** ~~The~~ DEQ may amend an accreditation for cause, with notice to the affected accredited laboratory and opportunity for hearing.

**252:307-5-3. 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.

**252:307-5-4. Failure to comply**

(a) Any person or laboratory to whom this Chapter applies must comply with the requirements of this Chapter and the statutory requirements of 27A O.S. §2-3-501 *et seq*., §2-4-305(A) and OAC 252:4-7-15. Failure to apply for or receive any part of an accreditation does not negate the requirement to meet any applicable requirement. Failure to comply may result in denial of applications, administrative and monetary penalties, suspension, reduction in scope, revocation or denial of renewal in part or in whole of the accreditation of any laboratory, and civil and/or criminal prosecution. Failure to comply includes:

(1) repeat or 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 potential or actual 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 in or produce acceptable results in required proficiency testing;

(C) to cooperate with or allow on-site laboratory evaluations, assessments, or access to record

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

(E) to maintain required records on file.

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

(5) collaboration with another laboratory or any other individual on PT sample results prior to submittal to DEQ or prior to the closing date of the study;

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

(7) making any false statement or representation in or omitting material information from any required application, analysis, or report;

(8) when the primary accreditation body (Primary AB) suspends a laboratory; or

(9) failure to pay fees when due.

(b) ~~The~~ DEQ reserves the right to enforce against a secondary accredited laboratory if the Primary AB does not take action or during the Primary AB's enforcement action.

(c) As a part of any administrative order issued to a laboratory found to have unacceptable practices, the laboratory may be required, at its own cost, to hire a third party NELAP assessor to conduct an extraordinary assessment. The third party assessor must send the report to DEQ, and results or recommendations from the assessment may be incorporated as requirements of the administrative order.

(d) All information included and documented in an extraordinary assessment report is public information and is subject to the Oklahoma Open Records Act, 51 Oklahoma Statutes, Section 24A *et seq*.

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

**252:307-5-5. Notice**

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

**252:307-5-6. 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, Rules of Practice and Procedure.

## SUBCHAPTER 7. ONSITE ASSESSMENT REQUIREMENTS

**252:307-7-2. Conduct of onsite assessments**

(a) Onsite assessments may be unannounced.

(b) During an onsite assessment ~~the~~ DEQ, or DEQ's subcontractor, may require analyses of proficiency test samples by laboratory personnel. Laboratories shall make all employees available for interviews during onsite assessments.

(c) Following the onsite assessment, ~~the~~ DEQ will provide the laboratory with a written assessment report. The laboratory will be afforded 30 days from the date of receipt in which to develop a corrective action plan, and 90 days in which to correct any listed deficiencies unless extended by written agreement of the parties or unless the laboratory is under an administrative order.

(d) All information included and documented in an assessment report is public information and is subject to the Oklahoma Open Records Act.

## SUBCHAPTER 9. MANAGEMENT AND TECHNICAL REQUIREMENTS

## PART 1. PROFICIENCY TESTING

**252:307-9-2. Participation required**

The laboratory must meet the PT requirements for initial and continued accreditation as specified in the TNI Standard for each field of ~~proficiency testing~~accreditation for which it seeks accreditation or maintenance of accreditation. PT samples must be obtained from a TNI accredited PT provider.

**252:307-9-3. Initial and continuing PT studies evaluation**

A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of ~~proficiency testing~~accreditation within the most recent three (3) rounds attempted. For a laboratory seeking to obtain accreditation, the most recent three (3) rounds attempted shall have occurred within 18 months of the laboratory's application date. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of ~~proficiency testing~~accreditation and maintain a history of at least two (2) acceptable PT studies for each field of ~~proficiency testing~~accreditation out of the most recent three (3). For initial accreditation, the laboratory must successfully analyze two (2) sets of PT studies, the analyses to be performed at least seven (7) calendar days apart from the closing date of one (1) study to the ~~shipment~~opening date of another study for the same field of ~~proficiency testing~~accreditation. For continuing accreditation, completion dates of successive proficiency rounds for a given field of ~~proficiency testing~~accreditation shall be approximately six (6) months apart. Failure to meet the semiannual schedule shall be regarded as a failed study on the last day of the seventh (7th) month. Initial or continuing PT studies must meet all applicable criteria described in this Chapter and the TNI Standard.

**252:307-9-4. Cost responsibility**

Laboratories shall bear the cost of any proficiency testing required by ~~the~~ DEQ.

**252:307-9-5. DEQ PT samples**

As part of a laboratory's proficiency testing, ~~the~~ DEQ may also submit blind audit samples to an accredited laboratory.

**252:307-9-8. Failure to perform PT**

A laboratory's accreditation for a field of ~~proficiency testing~~accreditation will be suspended when a laboratory fails to comply with Subchapter 9 Section 3: failing to maintain a history of at least two acceptable PT studies out of the most recent three. The suspension will be temporary lasting no more than six months or when the accreditation expires whichever is longer. The laboratory must notify the Laboratory Accreditation Program of its intent to regain accreditation through submission of a corrective action plan and regaining acceptable proficiency testing performance. Once accreditation for a field of ~~proficiency testing~~accreditation has been lost, the procedures for initial or interim accreditation shall apply.

**252:307-9-9. Supplemental PT testing**

A laboratory may elect to participate in PT testing more frequently than required by the semiannual schedule. Any additional tests performed by a laboratory must be submitted to DEQ in the same manner as required tests. Additional PT tests are counted and scored the same way as required tests, and must be at least seven (7) calendar days apart from the closing date of one study to the opening date of another study for the same analyte and matrix.

**252:307-9-10. Corrective action**

When a laboratory receives an evaluation of not acceptable for any FoA, the laboratory 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 (CAP). The CAP shall be submitted to ~~the~~ DEQ within forty-five (45) days of the PT report issuance.

**252:307-9-11. Alternate PT provider**

~~The~~ DEQ may designate an alternative proficiency testing provider if it determines such designation is appropriate.

**252:307-9-12. Analyte absence**

If a laboratory is requesting accreditation for an analyte and matrix combination that does not have a PT available through an NELAP-approved or DEQ-approved PT provider, the laboratory may qualify for accreditation through acceptable PT performance of similar parameters. This is specifically achieved through successful analysis in two out of three PTs for at least seventy-five percent (75%) of all analytes that the laboratory is seeking accreditation for that are of the same matrix and in the same accreditation category. This process does not affect the accreditation status of the parameters that do have PTs available. Those parameters are evaluated in accordance with the other sections of this subchapter.

## PART 7. RECORD KEEPING AND REPORTING

**252:307-9-60. Required records**

All required laboratory records must be written in a clear and unambiguous manner, be readily available for reference or inspection, and shall include:

(1) **Records of accreditation.** The laboratory shall keep the following records on file at its main facility.

(A) Scope of accreditation and the application on which it is based;

(B) Copies of final reports and quality documents associated with reported data submitted to ~~the~~ DEQ or clients;

(C) Internal audits and quality assurance plans; also

(D) Each laboratory shall maintain on file the list of analytes for which it is accredited, and shall provide a copy of the list upon request.

(2) **Quality manual~~,~~.** ~~which is addressed in~~Refer to **252:307-9-42**;

(3) **Bench records.** All raw data, whether hard copy or electronic data associated with testing, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records); date, time, analyst, method, amounts (volume and weights), clean up, separation protocols, incubation periods, calculations, sample matrix, and sample identification.
(4) **Calibration data.** Calibration criteria, frequency and acceptance criteria including the curve or coefficient of the linear equation ~~which~~that describes the calibration curve; measure of relative error; concentration/response data (or relative response data) for standards; percent recovery of all calibration checks (MRL, PSC initial) standard and the date it was analytically determined; percent recovery of the continuing calibration check standard; and laboratory sample identification of the samples run with the curve.
(5) **Sample history and associated data.** All data is to be clearly and unambiguously documented so that all steps of the method are indicated. This shall include but is not limited to the following: Date, analyst, type of extraction or digestion for each sample, and laboratory sample identification.
(6) **Surrogate and tracer records.** Surrogates or tracers, when required, are chosen to reflect the chemistries of the targeted components of the method and are added prior to sample preparation/extraction. The laboratory shall document the amount of surrogate or tracer spiked, percent recovery of each surrogate, date, analyst, and laboratory sample identification. The results are compared to the acceptance criteria as published in the method. If there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits.
(7) **Maintenance logs.** Maintenance logs shall be kept for each instrument, to include dates and description of repairs, preventive maintenance, malfunctions, and other actions or events affecting performance. All instruments not in service must be tagged out of service. Maintenance logs shall also be kept for all devices that are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf [Registered Trademark] or automatic dilutor/dispensing devices), if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. Each balance shall be annually serviced and calibrated by a recognized accredited metrological service.
(8) **Corrective action procedures.** Procedures for evaluating, documenting and reporting corrective action used for audits, PT failures, out-of-control situations and in response to enforcement actions.
(9) **Quality protocols.** Procedures for monitoring the validity of the environmental testing and the resulting data shall be recorded in such a way that trends are detectable, and statistical techniques shall be applied to the reviewing of the results. All laboratories shall have documentation for positive and negative controls, variability, repeatability, and accuracy of the method.
(10) **Chain of custody and sample accession.** Procedural plans for sample login, unique sample identification (all sample containers), date, time, source of sample (including name, location (location code) and sample matrix), preservative used, analysis required, name of collectors and any pertinent field data.
(11) **Spike duplicates and spike-duplicate data.** The laboratory shall document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of quality system matrix-specific quality control samples, and are designed as data quality indicators for a specific sample using the designated method. Information shall include but is not limited to: date, analyst, laboratory sample number, amount spiked, percent recovery, percent of difference, and makeup and concentration in the spiking solution.
(12) **Electronic data.** All electronic data including security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries shall be preserved.
(13) **Sensitivity, LOD/LOQ.** Procedures used for determining limits of detection and quantitation shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained. LOQ shall be verified annually within the established control limits.

## SUBCHAPTER 11. SECONDARY ACCREDITATION

**252:307-11-1. DEQ as a secondary accreditation body**

(a) ~~The~~ DEQ shall grant accreditation to laboratories accredited by any other TNI primary accreditation body in accordance with 27A O.S.§ 2-4-306 on a laboratory-by-laboratory basis. No additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of testing for which the laboratory holds primary TNI accreditation shall be required.
(b) When granting secondary accreditation to a laboratory, ~~the~~ DEQ shall grant accreditation:

(1) for only the fields of testing, methods and analytes for which the laboratory holds current accreditation from a primary AB, and that fall within the scope of this Chapter; and
(2) issue certificates to the applicant laboratory within 30 calendar days of receipt of the laboratory's application unless potential noncompliance with TNI standards is noted.

**252:307-11-2. Potential noncompliance when DEQ is secondary AB**

(a) If ~~the~~ DEQ notes any potential noncompliance with the TNI standards by a laboratory during the initial application process for secondary accreditation, ~~the~~ DEQ shall immediately notify, in writing, the applicable TNI-recognized primary AB.
(b) The applicant laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated.
(c) The notification must cite the applicable sections within the TNI standards for which noncompliance by the laboratory has been noted.
(d) If the alleged noncompliance is noted during the initial application process for secondary accreditation, final action on the application shall not be taken until the alleged noncompliance issue has been resolved.
(e) If the alleged nonconformance is noted after the secondary accreditation has been granted, the laboratory shall maintain its current secondary accreditation status until the alleged noncompliance issue has been resolved.

**252:307-11-3. Potential noncompliance when DEQ is primary AB**

(a) When ~~the~~ DEQ receives notification of potential noncompliance from a secondary AB, it shall review and investigate the alleged noncompliance and take appropriate action in accordance with 252:307-5-4, including the addition of any change of accreditation status in the TNI

National Environmental Laboratory Accreditation Database.

(b) Within 20 days of the notification of potential noncompliance from a secondary AB, ~~the~~ DEQ shall respond in writing with a copy to the secondary AB, providing the following information:

(1) an initial report of the findings;

(2) a description of the actions to be taken; and

(3) a schedule for implementation of corrective action, if necessary.