TITLE 252. DEPARTMENT OF ENVIRONMENTAL QUALITY
CHAPTER 307. TNI LABORATORY ACCREDITATION

SUBCHAPTER 1. INTRODUCTION

252:307-1-4. Incorporation by reference

(a) **TNI Standard.** ~~Except as provided in subsection (c),~~ 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 ~~September 8, 2009~~ 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 methods are hereby incorporated by reference:

(1) "Guidelines Establishing Test Procedures for the Analysis of Pollutants," 40 CFR Part 136, ~~published July 1, 2018~~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,~~ and~~ VI, and VII. See further SW-846-ON-LINE;

(3) "Methodologies set forth in the National Primary Drinking Water Regulations," 40 CFR Part 141 published ~~July 1, 2018~~ 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).

~~(c) **Excluded provisions.** In Volume 1, Module 1 of the TNI Standard, subsections 4.1.3 and 4.2.1a) are not incorporated by reference~~.

(d) **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.

(e) **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.

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 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 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 LAP into disrepute.

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 including arrangements for observing accredited activities when requested and practicable 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

~~Except as provided in 252:307-1-4(c), a~~ The laboratory must meet the PT requirements for initial and continued accreditation as specified in the TNI Standard for each field of proficiency testing 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 within the most recent three rounds attempted. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least ~~15~~7 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule shall be regarded as a failed study on the last day of the seventh (7^{th}) month. Initial or continuing PT studies must meet all applicable criteria described in this Chapter and the TNI Standard.

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

A laboratory's accreditation for a field of proficiency testing 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 ~~less~~longer. The laboratory must notify the Laboratory Accreditation Program of its intent to regain accreditation through submission of a corrective action plan. Once accreditation for a field of proficiency testing 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 ~~fifteen (15)~~seven (7) calendar days apart.

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 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 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.