

## **MEMORANDUM**

**DATE:** July 31, 2017

**TO:** All Accredited Environmental Laboratories

FROM: PA-DEP Laboratory Accreditation Program

RE: Environmental Laboratory Accreditation Regulations, Chapter 252

Important accreditation information for your laboratory

The Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 252 as amended, became effective on July 29, 2017, upon publication in the *PA Bulletin*. As an environmental laboratory accredited by the PA Department of Environmental Protection's Laboratory Accreditation Program ("Department"), you are subject to the changes outlined in the regulatory amendments.

The following is a summary of a few of the major changes to the Chapter 252 regulations. Please note that this is a limited summary of the major changes and as an accredited environmental laboratory you are responsible for reading, understanding, and complying with the specific requirements of 25 Pa. Code Chapter 252 as they apply to your laboratory. Do not rely on this summary to determine your laboratory's compliance. A full description and explanation of the changes to 25 Pa. Code Chapter 252 are outlined in Volume 47, Number 30 of the *PA Bulletin* at <a href="https://www.pabulletin.com">www.pabulletin.com</a> under "Environmental Quality Board."

- § 252.5—NELAP Equivalency: NELAP accredited laboratories must adhere to the requirements of this section, which include compliance with Subchapter E (PT), Subchapter F (assessment and corrective action), Subchapter G (miscellaneous), the 2009 TNI Standard requirements, § 252.307 (methodology) and § 252.401 (basic requirements).
- § 252.204—<u>Fees</u>: The fee structure and amounts have changed, the table at the end of this memo outlines the new fees.
- § 252.301 and 302—<u>Laboratory Supervisor</u>: The requirements for a laboratory supervisor, including experience and education have changed. Specifically, the education requirements for a supervisor of BNPW, BDW, Basic Microbiology, and Inorganic Non-Metals have changed from two years of experience to one year; a radiochemistry supervisor may have a combination of 24 semester credits in health physics and chemistry; and there are new requirements for a WETT supervisor. Finally, a supervisor may be absent for up to 21 consecutive days.
- § 252.304—Personnel Requirements: All DOCs (initial and continuing) must be at a concentration in the lower half of the calibration curve or at or below the MCL for SDWA compliance testing, whichever is lower; the laboratory must evaluate the individual recoveries of the DOC samples in addition to the mean recovery; and the %RSD of the DOCs must be <20% unless otherwise specified in the method.
- § 252.306—Equipment, Supplies, and Reference Materials: Various changes and clarifications throughout that relate to documentation and recordkeeping requirements for equipment, standards, reagents, media, and other materials used in the laboratory. There is a new requirement for temperature distribution studies for microbiology incubators in 252.306(j).
- § 252.307—Methodology: The laboratory must maintain sample collection, preservation, and handling instructions and make these available to all sample collection personnel, both laboratory employees and clients/customers. This section outlines what must be included in these instructions.
- § 252.401—<u>Basic Requirements</u>: Test reports must include a unique identifier code, identify all amendments to test reports, and clearly identify opinions and interpretations. The sample receipt protocols in 252.401(f) have been amended. The changes include the requirement to check and document:
  - The pH of all sample containers for WETT and SDWA compliance samples that are not collected by the accredited environmental laboratory performing the analysis.
  - The presence of residual chlorine when its presence would compromise the validity of the test.
- § 252.402—<u>Essential Quality Control Chemistry</u>: Various changes throughout including how to assign acceptance criteria for quality control protocols when the methods do not include the acceptance limits.
- § 252.404—Essential Quality Control Microbiology: Various changes throughout including:

- The requirement of laboratories performing bacteriological water quality test ratio analyses and HPC tests required by 252.404(d)(2) and (3) to be accredited.
- The requirement to perform sterility checks on each lot of Quanti-Tray<sup>™</sup> sample trays.
- o Clarification of documentation and recordkeeping requirements
- Clarification that all sterility checks and positive and negative controls must be conducted AFTER receipt at the laboratory and under the same conditions as routine samples.
- § 252.501—<u>PT Study Requirements</u>: Clarification that the Department will invalidate any PT study that is not handled, managed, analyzed, or reported in accordance with this section.
- § 252.601—<u>Assessment Requirements</u>: Clarification was added to explain that laboratories must remain in compliance at all times and accreditation may be suspended, revoked, or denied at any time. The requirements for a corrective action report were more clearly explained. The Department removed the term "onsite" throughout much of this section and the whole of Chapter 252 to allow for advances in technology and possible off-site assessment options.
- § 252.701, 702, 703, 704—Denial, Suspension, Revocation, and Voluntary Relinquishment: Various changes throughout these sections including that the Department may choose to require specific language in a written notice to customers when a laboratory's accreditation status changes and clarification that the laboratory must maintain test instruments, equipment, supplies, and reference materials that meet the specifications required to produce valid analytical results.
- § 252.705—<u>Use of Accreditation</u>: Minor changes were made throughout this section.
- § 252.706—Recordkeeping: Examples of what records must be maintained and what documentation must be kept to ensure a full and complete record were added to this section.
- § 252.708—Reporting and Notification Requirements: Various edits were made to this section, including:
  - Specific data review and reporting requirements for drinking water samples
  - Requirement to read microbiological sample results within 30 minutes of the end of the incubation period.
  - Requirement that the concentration of the LCS analyzed with any SDWA compliance testing must be at or below the MCL of the contaminant.
  - Explanation that only analytical results that meet all statutory, regulatory, method, and permit requirements may be reported to DWELR unless specifically approved by the Department.

Accreditation Category			Fee
Application Fee – Initial Application for State Accreditation <sup>2</sup>			\$ 1,500
Application Fee – Renewal Application for State Accreditation			\$ 700
Application Fee – Initial Application for NELAP Accreditation <sup>2</sup>			\$ 3,500
Application Fee – Renewal Application for NELAP Accreditation			\$ 2,750
Application Fee – Ownership Transfer or Change			\$ 150
Application Fee – Addition of Fields of Accreditation			\$ 350
Application Fee – Change in Administrative Information			\$ 150
Application Fee – Supplemental Onsite Assessment			\$ 500
Basic Drinking Water Category			\$ 750
Basic Non-Potable Water Category			\$ 850
Whole Effluent Toxicity Testing (WETT)			\$ 950
Accreditation Category – Continued	Fee 1 Matrix	Fee 2 Matrices	Fee 3 Matrices
Asbestos Category	\$ 600	\$ 1,050	\$ 1,450
Basic Microbiology Category – includes fecal coliform, total coliform, <i>E. coli</i> , and HPC	\$ 700	\$ 1,300	\$ 1,800
Complex Microbiology Category	\$ 1,000	\$ 1,900	\$ 2,700
Trace Metal Category	\$ 750	\$ 1,350	\$ 1,900
Inorganic Non-metal Category	\$ 850	\$ 1,550	\$ 2,200
Purgeable Volatile Organic Chemicals	\$ 850	\$ 1,550	\$ 2,150
Extractable and Semi-volatile Organic Chemicals	\$ 1,750	\$ 3,350	\$ 4,800
Dioxin	\$ 850	\$ 1,550	\$ 2,200
Radiochemical Category	\$ 950	\$ 1,800	\$ 2,500