



pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION



Bureau of Laboratories

Final Rulemaking - Environmental Laboratory Accreditation (25 Pa. Code Chapter 252)

Environmental Quality Board Meeting
April 18, 2017

Tom Wolf, Governor

Patrick McDonnell, Acting Secretary

Background

- Environmental Laboratory Accreditation Act, June 29, 2002, 27 Pa C.S. § 4103(a) – “The department shall establish an accreditation program for environmental laboratories.”
- 25 Pa. Code Chapter 252
 - Promulgated January, 28, 2006
 - Updated April 10, 2010

Regulation Development

- Laboratory Accreditation Advisory Committee (LAAC)
 - PA Water Environment Association (PWEA)
 - PA Rural Water Association
 - Small Environmental Laboratory
 - Commercial Environmental Laboratory
 - Public Water Supply
 - Industrial Laboratory
 - Academic Laboratory
 - Wastewater Treatment Plant Laboratory
 - Environmental Engineering Firm
 - Large NELAP Laboratory
 - General Public

Regulation Development

- Proposed Rulemaking Published August 30, 2016
 - 30-day Public Comment Period
- LAAC met throughout 2014, 2015, and 2016 in public meetings
- LAAC unanimously concurred with DEP's recommendation to move final rule forward for EQB consideration – December 7, 2016

Objectives

- Add necessary standards for accreditation
- Clarify existing requirements
- Amend cost prohibitive requirements
- Amend fee structure

Affected Stakeholders

- Scope of the regulation remains unchanged
 - No new regulated entities
- >4500 registered laboratories
 - Accreditation-By-Rule parameters only, no fees, no applications
- 305 state accredited laboratories
 - 244 small labs
 - 46 medium labs
 - 15 large labs
- 125 National Environmental Laboratory Accreditation Program (NELAP) accredited laboratories
 - 34 primary NELAP labs
 - 91 secondary NELAP labs

Regulatory Comparison

- Federal Regulations for Certification of Drinking Water (DW) labs
 - Regulate compliance testing of Public Water Systems
 - Mandated test method requirements
 - Recommendations by U.S. Environmental Protection Agency (EPA)
- NELAP Accreditation
 - Voluntary accreditation option in PA: DW, Non-Potable Water, Solid/Chemical Materials
 - Reciprocal accreditation from 12 other NELAP-recognized Accreditation Bodies
- National Pollutant Discharge Elimination System (NPDES) and Clean Water Programs
 - Federally mandated test method requirements
- Solid and Chemical Materials
 - Federally recommended test methods

Summary of Changes

- Necessary additions to the regulation:
 - Credit hours for microbiology supervisor
 - Qualifications for Whole Effluent Toxicity Testing supervisor
 - Sample acceptance and handling requirements
 - Analytical test report requirements
 - Temperature distribution studies for incubators
 - Criteria for establishing acceptance limits
 - Explanation of DEP's authority to suspend, revoke, or deny accreditation based on non-compliance found during on-site assessments
 - NELAP equivalency sections
 - Notification requirements for loss or lapse in accreditation

Summary of Changes

- Clarifications to current regulation:
 - Procedures for recordkeeping
 - College-semester credit hours must be from an accredited college or university
 - Requirements for microbiology quality control checks
 - Corrective action report requirements
 - Requirements for evaluating and reporting drinking water compliance testing results

Summary of Changes

- Amendment of Cost Prohibitive Requirements:
 - Reduce amount of hands-on experience requirements for microbiology and inorganic non-metals supervisors
 - Allow college credit hours in health physics for radiochemistry supervisors
 - Allow a lab supervisor to be absent for 21 days instead of limiting to 16 days
 - Define “working-day” for monitoring refrigerators and freezers
 - Allow DEP to develop procedures for offsite assessments
 - Allow DEP to suspend a lab’s accreditation for some violations instead of requiring revocation

Summary of Changes

- Fee structure changes:
 - Increased initial and renewal fees for all laboratories
 - Increased each category fee by \$100-250
 - Added a fee category for complicated microbiology testing
 - Increased the travel reimbursement rate for out-of-state on-site assessments
- Fees Remain the Same from Proposed to Final

Summary of Changes

- Small Publicly Owned Treatment Works Laboratory
 - Current Fee: \$1,250 New Fee: \$1,550
 - Difference = \$300/year
- Medium Laboratory
 - Current Fee: \$4,900 New Fee: \$6,500
 - Difference = \$1,600/year
- Large Laboratory
 - Current Fee: \$12,500 New Fee: \$15,600
 - Difference = \$3,100/year

Public Comments

- 10 commentators, including Independent Regulatory Review Commission (IRRC)
- Requirements for Microbiology Incubator Units
- Laboratory Supervisor Qualifications
- Sample Acceptance, Receipt, and Validation Requirements
- Use of Expired Materials
- Request for Technical Guidance Documents
- No Comments on Proposed Fees

Changes From Proposed Rule

- Allows DEP to mandate specific language for notifications of changes in status
- Labs cannot use materials past their expiration date, cannot revalidate expired materials
- Amended sample validation requirements, pH checks for some samples
- Exempt circulating water baths from temperature study requirements for micro incubators
- Allow labs to use currently published sample collection instructions
- Clarification to corrective action requirements

Implementation Plan

- Effective Upon Publication in PA Bulletin
- Email Notices to all Accredited Laboratories
- Written Notices to all Accredited Laboratories
- Discussion at PA Association of Accredited Laboratories meetings
- Develop Technical Guidance
 - Sample Acceptance, Receipt, and Validation
 - Temperature Requirements for Microbiology Incubators

Recommendation to EQB

DEP is recommending the adoption of this final-form rulemaking.



pennsylvania

DEPARTMENT OF ENVIRONMENTAL PROTECTION



Bureau of Laboratories

Aaren S. Alger

Chief, Laboratory Accreditation Program

aaalger@pa.gov

William Cumings

Bureau of Regulatory Counsel

wcumings@pa.gov