

Laboratory Accreditation

Final Rulemaking

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Background

- **Environmental Laboratory Accreditation Act – June 29, 2002**

§ 4104(1): “The Department shall establish, administer, and enforce an environmental laboratory accreditation program which shall include accreditation standards necessary for a State certification program.”

- **25 Pa Code Chapter 252 – January 28, 2006**

§ 252.2: “The purpose of this chapter is to protect public health, safety, welfare and the environment by ensuring the accuracy, precision and reliability of data generated by laboratories by establishing an accreditation program for environmental laboratories.”

- **Proposed Rulemaking**

- Approved by EQB on April 21, 2009
- Published in PA Bulletin on June 20, 2009
- 30 Day Public Comment Period (closed July 20, 2009)

Public Comments

- **Produced comments from two commentators:**
 - Independent Regulatory Review Commission (IRRC).
 - Accredited Environmental Laboratory
- **Major comments included requests for the Department to:**
 - Clarify the recordkeeping and documentation requirements.
 - Address concerns with regard to the qualifications of a laboratory supervisor.
 - Provide additional training to the regulated community.

Regulation Development

- Laboratory Accreditation Advisory Committee
 - Pennsylvania Water Environment Association (PWEA)
 - Pennsylvania Rural Water Association
 - Small Laboratory
 - Commercial Laboratory
 - Public Water Supply
 - Industrial Laboratory
 - Academic Laboratory
 - Wastewater Treatment Plant Laboratory
 - Environmental Engineering Firm
 - Large NELAP Laboratory
 - General Public
- Unanimous Approval of the Final Rulemaking—
September 10, 2009

Major Amendments to Proposed Rulemaking

- Statement of Proficiency Testing (PT) Requirements
 - Requested by USEPA
 - Reference the current Drinking Water PT Requirements
 - Not different from current expectations for regulated laboratories
- Clarification of Recordkeeping Requirements for Demonstrations of Capability
 - Include specific documentation requirements for laboratories
 - Clarification will help laboratories comply with regulation
 - Not different from current expectations for regulated laboratories

Stakeholders Affected

- No new regulated entities
- 3431 Registered Laboratories
- 420 State Accredited Laboratories
 - 312 Small Laboratories
 - 88 Medium Laboratories
 - 20 Large Laboratories
- 127 NELAP Accredited Laboratories
 - 34 Primary NELAP Laboratories
 - 93 Secondary NELAP Laboratories

Summary of Changes

Additions to the Regulation:

- Sample acceptance and handling requirements
- Analytical test report requirements
- Manual integration and confirmation requirements
- Timeline for reviewing and validating drinking water sample results
- Timeline to notify the Department of a change in analytical capability
- Proficiency Testing Requirements (final)

Summary of Changes

Clarifications to Current Regulation:

- Added clarifying language
 - Registration Requirements
 - Laboratory Supervisor Documentation
 - Procedures for Recordkeeping
 - Quality Manual Requirements
 - Proficiency Testing Reporting Requirements
 - Documentation for Demonstration of Capability (final)
- Re-organized sections of the standard for readability
 - Initial Demonstration of Capability
 - On-Going Demonstration of Capability
 - Microbiology Recordkeeping Requirements

Summary of Changes

Changed several requirements:

- Eliminated the requirement of Secondary NELAP laboratories to submit PT study reports
- Eliminated the requirement to alternate the concentrations of calibration verifications
- Eliminated the requirement to purchase and professionally service autoclave
- Changed acceptance criteria of a thermometer calibration

Summary of Changes

Fees:

- **Environmental Laboratory Accreditation Act – June 29, 2002**
§ 4104(6): “The Department shall have the [power and duty] to require a fee for the processing of an application for a certificate of accreditation, including issuance, renewal, modification or other action relating to the certificate, in an amount sufficient to pay the Department’s costs of implementing and administering the accreditation program.”
- **25 Pa Code Chapter 252 – January 28, 2006**
§ 252.204(b): “At least every 3 years, the Department will recommend regulatory changes to the fees in this section to the EQB to address any disparity between the program income generated by the fees and program costs. The regulatory amendment will be based upon an evaluation of the accreditation program fees income and the Department’s costs of administering the accreditation program.”
- **Workload Analysis**

Summary of Changes

Fee Structure Changes:

- Reorganized the Fee Tables to be more readily understood
- Included option for discounted rate for all laboratories
- Added a NELAP Accreditation Fee
- Added a fee for supplemental on-site assessments
- Added tests to the Basic Non-Potable Water Category

Examples of Laboratory Fees

WWTP Laboratory

Current Fee Structure:

Renewal Application Fee	\$500
Basic NPW Fee	\$700
-Fecal Coliform, BOD, CBOD, NO ₃ , NO ₂ , NH ₃ , TN, TKN, TP, Solids	
Total	\$1200

Proposed Fee Structure:

Renewal Application Fee	\$500
Basic NPW Fee	\$750
-Fecal Coliform (NPW & SCM), BOD, CBOD, NO ₃ , NO ₂ , NH ₃ , TN, TKN, TP, Solids (NPW & SCM)	
Total	\$1250

Difference in Fee = \$50 per year

Examples of Laboratory Fees

Non-Potable Water Laboratory

Current Fee Structure:

Renewal Application Fee	\$500
Micro (NPW)	\$400
Non-Metals+Trace Metals (NPW)	\$900
Volatiles (NPW)	\$500
Total	\$2300

Proposed Fee Structure:

Renewal Application Fee	\$500
Micro (1 Matrix)	\$500
Non-Metals (1 Matrix)	\$550
Trace Metals (1 Matrix)	\$600
Volatiles (1 Matrix)	\$650
Total	\$2800

Difference in Fee = \$500 per year

Examples of Laboratory Fees

Non-Potable Water and Solids Laboratory

Current Fee Structure:

Renewal Application Fee	\$500
Micro (NPW)	\$400
Non-Metals+Trace Metals (NPW)	\$900
Volatiles (NPW)	\$500
Semi-Volatiles (NPW)	\$950
Micro (SCM)	\$450
Non-Metals (SCM)	\$550
Trace Metals (SCM)	\$450
Volatiles (SCM)	\$550
Semi-Volatiles (SCM)	\$1200
Total	\$6450

Proposed Fee Structure:

Renewal Application Fee	\$500
Micro (2 Matrices)	\$950
Non-Metals (2 Matrices)	\$1050
Trace Metals (2 Matrices)	\$1150
Volatiles (2 Matrices)	\$1250
Semi-Volatiles (2 Matrices)	\$2900
Total	\$7800

Difference in Fee = \$1350 per year

Compliance Strategy

- Guidance Documents posted to the website
- Newsletters to the regulated community
- Technical training courses offered throughout the Commonwealth
- Round-Table discussions for regulated community held at DEP Regional Offices
- General e-mail account directly to the Laboratory Accreditation Program
- Dedicated compliance assistance personnel

Recommendation To EQB

Approval Recommended