

Laboratory Accreditation

Proposed Rulemaking

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Background

- **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.”

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 Proposed Rulemaking—
December 11, 2009
- Workload Analysis of the Laboratory Accreditation Program

Objectives

- Add standards for accreditation
- Clarify existing requirements
- Eliminate unnecessary or cost prohibitive requirements
- Amend the fee structure

Stakeholders Affected

- No new regulated entities
- 3431 Registered Laboratories
 - ABR Parameters only, no fees
- 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

Necessary 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

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
- Re-arranged sections of the standard
 - Initial Demonstration of Capability
 - On-Going Demonstration of Capability
 - Microbiology Recordkeeping Requirements

Summary of Changes

Elimination of cost prohibitive requirements:

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

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
- General e-mail account directly to the Laboratory Accreditation Program
- Dedicated compliance assistance personnel

Recommendation To EQB

- 30-day Comment Period
- Approval
Recommended