

EXECUTIVE SUMMARY

Environmental Laboratory Accreditation Regulation

Amendments to Chapter 252

The Environmental Laboratory Accreditation Regulation in 25 Pa. Code Chapter 252 sets forth the requirements that laboratories must meet to be accredited to perform testing for 12 environmental statutes. While completing the first round of laboratory assessments under the Chapter 252 regulation, effective January 28, 2006, the Laboratory Accreditation Program discovered various portions of the regulation that are unclear or are overly restrictive. Additionally, the current accreditation fees do not adequately fund the Laboratory Accreditation Program as mandated by the Environmental Laboratory Accreditation Act (Act 90 of 2002, 27 Pa C.S. §§ 4101 *et seq*). The fees also fail to equally distribute the cost of the program over the regulated community. Finally, the National Environmental Laboratory Conference (NELAC) has been disbanded and replaced with The NELAC Institute. Therefore, the regulations must be revised to reflect that change.

The purpose of the proposed regulation is fourfold. The first is to add valuable and necessary standards for accreditation. The second is to clarify existing requirements to allow the regulated community to better comply with and understand the Department's regulations. The third is to eliminate unnecessary or cost prohibitive requirements. The fourth is to amend the fee structure in section 252.204(b). Specifically, the proposed rulemaking offers amendments to the following areas of the laboratory accreditation regulations:

- a. Fee Structure
- b. Definitions
- c. NELAP Equivalency
- d. Quality Assurance/Quality Control Procedures
- e. Analytical Procedures
- f. Record Keeping Procedures
- g. Notification Requirements

The proposed amendments to the accreditation regulations do not change the scope of the current regulation. The majority of the proposed changes simply clarify the current regulatory language.

The most significant amendment is the proposed revision to the fee structure. The current fee structure is confusing to laboratories because it offers multiple options for calculating fees based on the type of accreditation sought. The proposed regulation simplifies the fee structure by listing the fees based on the number of requested matrices, rather than basing fees on the type of matrix requested. Additionally, implementation of the National Environmental Laboratory Accreditation Program (NELAP) incurs added costs over those associated with the accreditation program outlined in the Chapter 252 regulation, but the current fee structure does not require NELAP applicant laboratories to pay additional fees. The proposed fee structure would include an additional fee for laboratories requesting NELAP accreditation. The fees for medium to large non-NELAP accredited laboratories are likely to increase by approximately 10-20%. However, increased costs for smaller laboratories will be minimal as the fees for the Basic Non-Potable Water and Basic Drinking Water fee categories are proposed to increase by only \$50. The current annual fee paid by these environmental laboratories is \$1200.00, and the fee change would result in an annual fee of \$1250.00. Laboratories seeking accreditation for these two

categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the draft regulations. The LAAC held meetings on July 9, 2008, September 29, 2008, and December 11, 2008 to review the Department's proposed drafts of the Chapter 252 regulations. The LAAC provided invaluable advice and insight to the Department during these meetings. The Department considered all and agreed to the majority of the recommendations made by the LAAC. On December 11, 2008, the LAAC voted unanimously to recommend the draft Chapter 252 amendments to the EQB for consideration.

The Department recommends a public comment period of 30 days. Because the Laboratory Accreditation Advisory Committee held public meetings during development of the Chapter 252 amendments and these amendments do not impose regulations on new entities, the Department recommends that no public meetings be held.