# Executive Summary
## Amendments to 25 Pa. Code Chapter 252
## Environmental Laboratory Accreditation

The Department of Environmental Protection (Department) recommends final-form amendments to 25 Pa. Code Chapter 252 (relating to environmental laboratory accreditation). The final-form amendments clarify the current regulatory requirements and the amendments add several necessary standards for accreditation. The final-form amendments also amend the current fee structure to ensure that the accreditation fees assessed to applicant laboratories cover the costs of the Program.

**Purpose of the Final-Form Rulemaking**

This final-form rulemaking amends the Environmental Laboratory Accreditation Regulations in 25 Pa. Code Chapter 252 which set forth the requirements that laboratories must meet to be accredited to perform testing for 12 environmental statutes. While completing ongoing rounds of laboratory assessments under the Chapter 252 regulation, last amended April 10, 2010, the Laboratory Accreditation Program learned that various portions of the regulations needed clarification, were overly restrictive, or were cost prohibitive. Additionally, the existing accreditation fees do not adequately fund the Laboratory Accreditation Program as mandated by 27 Pa. C.S. Chapter 41 (relating to the Environmental Laboratory Accreditation) (Act 90 of 2002).

The purpose of the final-form 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 remove unnecessary or cost prohibitive requirements. The fourth is to amend the fee structure in section 252.204(b).

**Summary of the Final-Form Rulemaking**

The final-form rulemaking amends the following areas of the laboratory accreditation regulations: fee structure; definitions; NELAP equivalency; laboratory supervisor qualifications; quality assurance/quality control procedures; analytical procedures; record keeping procedures; and notification requirements.

The most significant amendment is the revision to the fee structure. The existing fee structure does not ensure that the costs of administering the accreditation program are covered by the fees collected from the accredited laboratories. The amended fee structure accounts for the number of laboratories currently seeking accreditation, the size of the laboratory's scope of accreditation, and the amount of time and cost associated with administering the accreditation program. In 2014, the Laboratory Accreditation Program began providing accreditation services for cryptosporidium, which imposes additional costs not recovered by the fees promulgated in 2010. The fee structure separates the basic microbiology category from complex microbiology and assesses two different fees based on the complexity of the accreditation activities.

In 2010, the renewal application fee for each laboratory accredited in the State program was not increased; the individual category fees were increased based on the workload and other expenses

associated with these accreditations. The overall cost of the Program has increased due, in most part, to operating costs associated with fixed expenses such as salary and benefits and rent. Since these costs are fixed and do not relate specifically to any one laboratory or accreditation task, to equally distribute the costs of the accreditation program based on the workload associated with the two accreditation types (State and NELAP), the renewal fee for State accreditation is increased by $200/year while the renewal fee for NELAP applicants is increased by $750/year. In addition to the renewal application fees, each laboratory will pay for the appropriate category for which accreditation is sought. The accreditation fees for medium to large accredited laboratories are likely to increase by approximately 20-30%. However, accreditation category costs for smaller laboratories will be minimal as the fees for the Basic Non-Potable Water and Basic Drinking Water fee categories will increase by $300. The current annual fee paid by these environmental laboratories is $1250.00, and the fee change would result in an annual fee of $1550.00. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories.

Other amendments include clarifications of existing requirements, such as:

- Performing temperature distribution studies for microbiology incubators,
- Maintaining sample collection and handling procedures/instructions for sample collectors,
- Verifying and documenting the condition of the sample upon receipt,
- Explaining that the Department will not accept proficiency test study results that are not performed in accordance with Chapter 252 requirements, and
- The Department's authority to suspend, revoke, or deny accreditation based on non-compliance found during an on-site assessment.

The final-form regulations remove or amend several overly restrictive or cost prohibitive requirements, such as:

- Reduction in the amount of hands-on analytical experience that is necessary for a laboratory supervisor for basic microbiology, basic non-potable water, and inorganic non-metals,
- Allowance for college semester credit hours in health physics and chemistry instead of limiting credits in chemistry for radiochemistry laboratory supervisors,
- Allowance for the Department to develop procedures and practices to conduct laboratory assessments offsite and use other technological advances instead of requiring all assessments to occur onsite at the laboratory,
- Allowance for the Department to suspend a laboratory's accreditation for violations relating to assessment requirements instead of requiring revocation of the laboratory's accreditation

Finally, the final-form rule adds sections to the NELAP Equivalency portion of section 252.5 to ensure that all laboratories generating compliance data for the Department are doing so under the same requirements, specifically, the requirements for sample collection, acceptance, and handling.

**Affected Parties**

Those persons, groups, or entities affected by this regulation include any person, facility, or group that performs testing or analysis on drinking water, non-potable water, and/or solid and chemical material environmental samples required for compliance with 12 enumerated environmental statutes. This regulation lists the 12 specific statutes, which are the same as those included in the scope of the regulation at initial promulgation of the Chapter 252 regulations in 2006. Approximately 5,000 laboratories are regulated under Chapter 252, but the number of entities that will be required to change procedures due to the proposed changes is approximately 450. The technical expertise, experience with regulatory programs, and size of the facilities affected by these regulations vary greatly. The majority of the regulatory amendments include clarifications to the current requirements rather than wholly new requirements. The smallest facilities are expected to have the least amount of technical expertise and have been and will continue to be the primary focus of compliance assistance efforts.

**Advisory Groups**

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the proposed and final-form regulations. The LAAC held public meetings on December 11, 2014, March 11, 2015, June 24, 2015, September 30, 2015, and December 2, 2015 to review the Department's proposed drafts of the Chapter 252 regulations. The LAAC met again on December 7, 2016 to discuss the public comments from the proposed rulemaking and the Department's draft final-form regulations. The LAAC and other members of the public provided advice and insight to the Department during these meetings. The Department considered all feedback and agreed to the majority of the recommendations made by the LAAC. On December 7, 2016, the LAAC voted unanimously to recommend that the final Chapter 252 amendments move forward to the EQB for consideration.

**Public Comments**

The proposed rulemaking was published on August 20, 2016, opening the public comment period. The Department received approximately 45 comments from 10 individuals. The majority of comments related to laboratory supervisor qualifications, microbiology incubator requirements, and sample receipt protocols.