

**Notice of Proposed Rulemaking
Department of Environmental Protection
Environmental Quality Board
25 Pa. Code Ch. 252
Environmental Laboratory Accreditation**

Preamble

The Environmental Quality Board (Board) proposes to amend 25 Pa. Code Chapter 252 (relating to environmental laboratory accreditation). The proposal clarifies existing requirements, eliminates unnecessary requirements and proposes additional requirements necessary for laboratory accreditation. The proposal also revises the current fee structure found at 25 Pa. Code § 252.204.

This proposal was adopted by the Board at its meeting of _____.

A. Effective Date

These amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. Contact Persons

For further information contact Aaren S. Alger, Chief, Laboratory Accreditation Program, P.O. Box 1467, Harrisburg, PA 17105-1467, (717) 346-8212, or Scott Perry, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) website <http://www.dep.state.pa.us>.

C. Statutory Authority

This proposed rulemaking is being made under the authority of § 4103 (a) of the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (Title 27 Pa. C.S. §§ 4101 – 4113), which directs the Department to establish an accreditation program for environmental laboratories, § 4104 which directs the Department to establish, administer and enforce an environmental laboratory accreditation program which shall include the standards necessary for a State certification program, § 4105, delegating the Board the power to adopt the regulations of the Department to implement the Act, and § 1920-A of The Administrative Code of 1929 (71 P.S. §510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. Background and Purpose

The regulations governing environmental laboratory accreditation at 25 Pa. Code Chapter 252 became effective on January 28, 2006. While completing the first round of laboratory assessments under these regulations, the Laboratory Accreditation Program discovered various provisions that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. The Laboratory Accreditation Program also determined that several necessary standards for accreditation were missing.

Pursuant to section 4104(6) of the Act, the accreditation fees must be “in an amount sufficient to pay the department’s cost of implementing and administering the accreditation program.” In addition, 25 Pa. Code § 252.204(b) requires the Department to recommend to the Board regulatory changes to the accreditation fees every three years to address any disparity between the program income generated by the fees and program costs. In accordance with this requirement, the Laboratory Accreditation Program performed a workload analysis to evaluate the costs associated with the Program. Based on this workload analysis, the Department determined that the accreditation fees contained in 25 Pa. Code § 252.204 were not sufficient to recover the Department’s costs to implement to the program. These proposed regulations provide a new fee structure to cover the costs of the Laboratory Accreditation Program.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to amend Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. The Department and the LAAC ensured that the interests, concerns, and needs of the regulated community were considered and implemented as appropriate. The LAAC met throughout 2008 to review and comment on the draft Chapter 252 amendments presented by the Department. On December 1, 2008, the LAAC unanimously voted to recommend the Chapter 252 amendments for presentation to the Board.

E. Summary of Regulatory Requirements

Subchapter A.

§ 252.1 The definitions section was changed to eliminate references to the now defunct National Environmental Laboratory Accreditation Conference (NELAC) and replace this term with The NELAC Institute, or TNI. The term accrediting authority was changed to accreditation body. The term “laboratory notebook” was deleted, the definition for nonpotable water was changed, and the term “action level” was added.

§ 252.4 The provision for interim accreditation was deleted.

§ 252.5 The proposed TNI Standard does not include requirements for environmental laboratories to respond to an on-site evaluation and/or submit a corrective action report. The requirement of NELAP laboratories to adhere to the provisions of Subchapter F (relating to onsite assessment requirements) was included. Additionally, clarification was made that laboratories choosing to become accredited in the National Environmental Laboratory

Accreditation Program (NELAP) must comply with the currently approved and effective edition of either the NELAC Standard or TNI Standard, as appropriate.

§ 252.6 The Accreditation-by-Rule section was amended to specify that all laboratories performing testing or analysis for compliance with a Department statute must be registered with the Department in accordance with 27 Pa. C.S. § 4107(a).

Subchapter B.

§ 252.202 The phrase “open or pending” was removed from subsection (b).

§ 252.204 An environmental laboratory will pay an initial application fee and annual renewal fees based on the appropriate accreditation categories sought. Pursuant to the Environmental Laboratory Accreditation Act, the fees provided in this section must be sufficient to pay the Department's cost of implementing and administering the accreditation program including processing applications for certificates of accreditation, the issuance, renewal, modification, or other action relating to the certificate. Laboratories pay fees based on the number and complexity of the categories for which they request accreditation. The cost of each fee category is based on the number of assessor hours necessary to accredit an environmental laboratory for that given category.

In order to appropriately distribute the cost of the implementation of the Laboratory Accreditation Program, the fee structure was amended to include fees for a requested change in administrative information, to perform a supplemental on-site assessment when requested by the applicant laboratory to add Field(s) of Accreditation, and an additional fee for NELAP accreditation. The changes to the fee structure include payment of fees based on the number of matrices requested rather than a fee for a specific type of matrix. This structure also allows for a laboratory performing a combination of matrices to pay a lower fee.

§ 252.205 The term “accrediting authority” was changed to “accreditation body” to be consistent with the terms used by TNI. The requirement for secondarily accredited laboratories to submit copies of their proficiency testing studies was deleted.

Subchapter C.

§ 252.301 Subsection (a) was added to clarify that the Department considers only individuals named on the application for accreditation and approved by the Department as the laboratory supervisor(s) of an environmental laboratory.

§ 252.302 The requirements for a laboratory supervisor of an environmental laboratory performing microbiological testing were amended to require biology credits rather than microbiology.

§ 252.304 The initial demonstration of capability requirements from § 252.307(j) were moved to this section to have the demonstration of capability requirements in one location within the regulation.

§ 252.306 Clarification was made to the requirements for weights and thermometers used in the laboratory. Specific acceptance criteria were added to the verification requirements of volumetric dispensing devices and non-Class A glassware used for sample, reagent, and standard reference material measurements. The requirements of subsection (h) were amended and rearranged to better explain the requirements of reference materials, reagents, media, and laboratory supplies.

§ 252.307 The requirements for the Scope section of the laboratory's standard operating procedures have been expanded. The requirement to list or reference the quantitation range and drinking water MCL(s) or action levels for each Field of Accreditation was added.

Subchapter D.

§ 252.401 Editorial changes and amendments have been made throughout this section. Subsection (a) now lists the items a quality manual must contain. Subsection (b) lists the policies and procedures that must be in the quality manual. These policies and procedures are not different from the previous version of Chapter 252; they were included here for reference and to aid the reader. Subsection (d) now includes the requirement for training in ethical and legal responsibilities within two months of employment for new employees and at least every 14 months thereafter for all employees. Subsection (f) now includes the minimum requirements for handling samples and documenting their receipt by the laboratory. Subsection (j) now includes the minimum requirements for an analytical test report issued by an accredited laboratory. Subsection (k) was added to allow a laboratory operated by a facility, as defined in § 252.1 (Definitions), to produce abbreviated reports. Subsection (m) was amended to include the requirement to qualify any analytical results that do not meet all analytical testing and sample acceptance criteria in addition to quality control measures.

§ 252.402 Editorial changes and amendments were made throughout this section. Subsection (d) now includes the required number of calibration standards that must be used when utilizing a second order calibration curve. Subsection (f) was amended. The requirement to alternate the concentrations of the calibration verification standards throughout the analytical batch has been changed to require verification of the calibration curve with a calibration verification standard at both a high and low concentration with each analytical batch. Subsection (m) was added to specify the requirements a laboratory must undertake when performing manual integrations. Subsection (n) was added to specify the confirmatory requirements a laboratory must undergo when performing organic chromatographic analysis with a detector other than a mass spectrometer. When a laboratory analyzes an environmental sample that has not been previously analyzed by the laboratory or has not previously yielded a detectable result for a particular compound, the laboratory must qualitatively confirm the result using a different detector, chromatographic column, or analytical technique. Subsection (o) was added to point the reader to the documentation requirements of section 252.306.

§ 252.403 Editorial changes were made to correct the subsection designations. Subsection (p) was added to point the reader to the documentation requirements of section 252.306.

§ 252.404 Editorial changes and amendments were made throughout this section. The documentation requirements for equipment, supplies, and reference materials specifically listed in this section were removed and placed in § 252.306. Subsection (c) was amended to allow the use of pressure cookers in limited circumstances. Amendments were made to subsection (g) to add clarification to the requirements for membrane filtration units. Subsection (h) now clearly outlines that the applicant laboratory must perform the positive and negative control checks on the media used in the laboratory and specifies the requirements for maintenance of the control cultures. Subsection (j) was added to point the reader to the documentation requirements of section 252.306.

§ 252.405 Subsection (m) was added to point the reader to the documentation requirements of section 252.306.

Subchapter E.

§ 252.501 Subsection (l) was amended to specify that the environmental laboratory shall have its proficiency testing study results submitted to the Department's Laboratory Accreditation Program.

Subchapter F.

§ 252.601 Subsection (a) was amended to specify that the Department will perform an on-site assessment of a laboratory prior to granting primary accreditation. Subsection (f) was added to supplement the proposed TNI Standard that does not include on-site assessment and corrective action report requirements for laboratories applying for NELAP accreditation. This subsection specifies that NELAP laboratories shall submit a corrective action report to the Department within 30 calendar-days from receipt of the on-site assessment report from the Department. This subsection also states that if TNI develops an alternate timeline for submission of a corrective action report to an accreditation body, the laboratory shall follow the TNI-designated timeframe. All NELAP applicant laboratories would be expected to adhere to the requirements of this section.

Subchapter G.

§ 252.706 Subsection (a) was amended to specify that records must be maintained in an organized fashion in a manner accessible by the Department. This means that the laboratory must have a record keeping system that allows ready access by the Department in a manner that can be readily understood and retrieved upon request.

§ 252.707 Subsection (b) was amended to include to require an accredited laboratory's final report to include the accreditation number of any laboratory performing subcontracted results.

§ 252.708 These regulations incorporate the reporting and notification requirements for the Safe Drinking Water regulations, 25 Pa Code Chapter 109, by reference. Since the Chapter 109 requirements are silent with regard to the time for which a laboratory must validate Safe Drinking Water Act compliance results, amendments to subsection (a) were made to guide an

accredited laboratory in how much time an analytical result can be held before the quality control associated with the analytical and/or preparation batch must be reviewed and validated. Subsection (b) was amended to require laboratories to notify the Department within 20 calendar days of a change in laboratory supervisor. Subsection (e) was added to require an environmental laboratory to promptly notify the Department any time a change in analytical capability occurs for more than 90 days. The Department requires this information to ensure that queries regarding a laboratory's analytical capability to produce accredited testing results can be accurately answered and that the laboratory's scope of accreditation is an accurate reflection of the laboratory's analytical capability. The laboratory's accreditation status would be listed as suspended until capability can be adequately demonstrated in order to justify re-instatement of the affected field(s) of accreditation.

F. Benefits, Costs, and Compliance

Benefits

The most significant benefit of these proposed regulations will be the benefit of a clear, concise, and improved regulation for the regulated community. The proposed amendments will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories.

Improved data quality will allow the Department, the regulated community, and the citizens of the Commonwealth to make better decisions concerning the protection of the environment and the protection of public health, safety, and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws.

Compliance Costs

The direct costs of the proposed regulation will be payment of the required fees. The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that require extensive staff time to accredit such as large commercial laboratories and NELAP laboratories will pay a higher accreditation fee. The proposed regulations contain a fee structure that is responsive to the needs of small laboratories. Categories of testing for basic drinking water parameters and for basic wastewater parameters have been increased by only \$50 per category. These smallest environmental laboratories currently pay \$1200 annually and the proposed fee structure will require an annual fee of \$1250. In addition, changes to the fee structure include payment of fees based on the number of matrices requested rather than a fee for a specific type of matrix. This structure allows for a laboratory performing a combination of matrices to pay a lower fee.

Compliance Assistance Plan

The proposed regulations are minor and in most cases clarify existing requirements or eliminate unnecessary requirements. As such, the Department does not believe that a

compliance assistance plan tailored to the proposed regulations is necessary. However, the Department will continue its ongoing compliance assistance efforts.

The ultimate goal of the compliance assistance effort will be improving an environmental laboratory's ability to produce valid and defensible data for use by the Department, the regulated community, and the public. Several areas where compliance assistance is necessary are general laboratory operation, correct performance of specific test procedures, and documentation of laboratory activities. Compliance assistance in these areas has been made available to all environmental laboratories regardless of size throughout the Commonwealth.

G. Sunset Review

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

H. Regulatory Review

In accordance with section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on _____, the Department submitted a copy of the proposed rulemaking to the Legislative Reference Bureau for publication of notice of proposed rulemaking in the *Pennsylvania Bulletin*, to Independent Regulatory Review Commission (IRRC), and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed regulatory analysis form prepared by the Department. A copy of this material is available to the public upon request.

Under § 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations, or objections on the proposed rulemaking within 30 days of the close of public comment period. The comments, recommendations, or objections shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review by the Department, the General Assembly, and the Governor prior to final publication of these regulations.

I. Public Comments

Written Comments--Interested persons are invited to submit comments, suggestions or objections regarding the proposed rulemaking to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th Floor, 400 Market Street, Harrisburg, PA 17105-2301). Comments submitted by facsimile will not be accepted. The Board must receive comments, suggestions, or objections by <<DATE>>. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by <<DATE>>. The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulations will be considered.

Electronic Comments--Comments may be submitted electronically to the Board at RegComments@state.pa.us and must also be received by the Board by <<DATE>>. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgement of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JOHN HANGER,
Acting Chairperson
Environmental Quality Board