

**Notice of Final-Form Rulemaking**  
**Department of Environmental Protection**  
**Environmental Quality Board**  
**(25 Pa. Code Ch. 252)**  
**(Environmental Laboratory Accreditation)**

The Environmental Quality Board (Board) by this order amends 25 Pa. Code Chapter 252 (relating to environmental laboratory accreditation). The amendments clarify existing requirements, remove or amend overly restrictive and cost-prohibitive requirements, and include additional requirements necessary for laboratory accreditation. The final-form rulemaking also revises the current fee structure found at 25 Pa. Code § 252.204.

This order was adopted by the Board at its meeting of \_\_\_\_\_.

*A. Effective Date*

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

*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 William S. Cumings, Jr., 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 final-form rulemaking is available on the Department of Environmental Protection's (Department) web site at [www.dep.pa.gov](http://www.dep.pa.gov) (Select "Public Participation," then "Environmental Quality Board").

*C. Statutory Authority*

This final-form rulemaking is being made under the authority of 27 Pa. C.S. § 4105(a), which directs the Board to adopt regulations as necessary to implement 27 Pa. C.S. Chapter 41 (relating to Environmental Laboratory Accreditation) (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 and were amended on April 10, 2010. While completing ongoing rounds of laboratory assessments under these regulations, the Laboratory Accreditation Program ("Program") discovered various provisions that are unclear or where the rules are lacking sufficient detail to ensure full compliance with the regulatory requirements or where the standards were overly restrictive and cost-prohibitive. The Program also determined that several

necessary standards for accreditation were lacking. The final-form rulemaking amends various citations within the Scope of the regulations, but the applicable laws and acts within the Scope of the regulations remain unchanged.

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 Program compared the work necessary to perform the functions of the Program to evaluate the costs associated with the Program. Based on this analysis, the Department determined that the accreditation fees contained in 25 Pa. Code § 252.204 are not sufficient to recover the Department’s costs to implement to the program. These final-form 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, with the assistance of the LAAC, ensured that the interests, concerns, and needs of the regulated community were considered and implemented appropriately. The LAAC met throughout 2014, 2015, and 2016 to review and comment on drafts of the proposed and final-form Chapter 252 amendments presented by the Department. The Department also discussed the written comments received during the public comment period during a meeting of the LAAC on December 7, 2016. On December 7, 2016, the LAAC unanimously voted to recommend the final-form Chapter 252 amendments for presentation to the Board.

#### *E. Summary of Changes to the Proposed Rulemaking*

Editorial corrections and amendments were made throughout the final-form rulemaking based on comments received during the public comment period to ensure that the final-form rulemaking meets the requirements of the *Pennsylvania Code & Bulletin Style Manual*. For example, the term “but not limited to” was removed throughout.

#### Subchapter A.

§ 252.3. The applicable statutes for which environmental testing must be conducted by an accredited laboratory are amended to accurately reflect the correct names and citations.

#### Subchapter B.

§§ 252.201 & 252. 203. In the final-form rulemaking, the terms “on forms provided by the Department” were added in response to a comment by the Independent Regulatory Review Commission (IRRC) concerning the format and content of the application requirements that environmental laboratories must submit. The final-form rulemaking adds additional language to § 252.203(d) at the suggestion of IRRC to add clarity to the written client notification requirements for laboratories when the laboratory’s accreditation certificate expires.

Laboratories are required to notify all affected customers of the loss or lapse in accreditation in writing within 48 hours of the certificate expiration. This additional language explains that the Department may choose to require the use of specific language or to require Department approval of the notice before issuance.

#### Subchapter C.

§ 252.304. The requirement for laboratory personnel to meet any more stringent qualification requirements established by method, regulation, or program was added as subsection (a)(4) in response to comments received during the public comment period. The proposed rulemaking included this provision in the laboratory supervisor qualifications section, but, as noted by two commentators, this provision is also applicable to some laboratory personnel.

§ 252.306. The allowance for re-certification of expired standards, reagents and media in § 252.306(h)(6) was removed in the final-form rulemaking based on a comment received from the public. The Department added this provision in 2010, but no laboratory has sought approval from the Department for approval to re-certify expired laboratory materials, thus removal of this provision does not negatively impact the regulated community and will ensure that laboratories use valid standards.

At the suggestion of several public comments, the provision for temperature distribution studies for microbiology incubators in § 252.306(j) was amended to exempt this requirement for circulating water baths. Circulating water baths ensure even temperature distribution throughout the incubator. Distribution studies are not necessary to ensure valid temperature distribution throughout the unit.

§ 252.307. At the suggestion of a commentator, the Department removed the requirement for the laboratory to develop the sample collection and preservation documents from § 252.307(j). The Department does not intend to require a laboratory to develop procedures that might already exist or be available from other organizations provided that the sample collection and preservation instructions meet the requirements of subsections (f) and (g).

#### Subchapter D.

§ 252.401. Significant public comment and discussion during public meetings of the LAAC resulted in the addition to § 252.401(f) requiring that environmental laboratories check and document the pH of every sample container received by the laboratory. Numerous comments and concerns were raised regarding the proposed language, the necessity of the requirements, and the overall cost to the regulated community. After much discussion and consideration, the final-form rulemaking requires that the laboratory check the pH of each sample container for safe drinking water act compliance samples and whole effluent toxicity samples that are not collected by trained, accredited laboratory staff. The Safe Drinking Water Program and the United States Environmental Protection Agency's (EPA) Office of Water consider an improperly preserved sample invalid for compliance purposes. Therefore, unless each sample container used for sample analysis is verified to be at the correct pH, it is not possible to determine if the sample is valid and appropriately collected. This compromise ensures protection of the public health for

drinking water compliance samples but does not place an undue burden, financial or otherwise, on the regulated community testing non-drinking water samples.

§ 252.404. The final-form rulemaking adds necessary clarification to § 252.404(g)(2) to more thoroughly explain that a re-useable membrane filtration funnel must be checked for sterility with a sterility blank after every ten filtrations of a sample aliquot, not after every ten samples. A sample could include numerous dilutions and aliquots. Based on comments received, the Department removed the proposed addition to § 252.404(h)(4) and (5) to allow for the re-certification of expired positive and negative culture controls. As suggested by a commentator, the Department added a provision, § 252.404(h)(7), in the final-form rulemaking to ensure that positive and negative controls are processed under the same conditions as routine environmental samples. The proposed rulemaking added the statement “Department approved” to § 252.404(h)(5) with the intention to require the laboratories to obtain approval for their documented procedures for maintaining culture controls. This statement was determined to be unnecessary because the current regulation outlines the specific requirements for maintaining culture controls. Therefore, the additional language proposed by the Department was removed in this final-form rulemaking.

#### Subchapter F.

§ 252.601. Subsection (h) was amended in the final-form rulemaking in response to a comment from IRRC regarding the Department’s requirements for corrective action based on deficiencies found during an assessment conducted by the Program. The final-form rulemaking clarifies that unless otherwise required or approved by the Department, environmental laboratories shall correct all deficiencies within 120 calendar days of receipt of the assessment report. Assessments occur for various reasons, including on-site assessments, review of a laboratory’s request to add fields of accreditation, change in ownership and laboratory supervisor notices, etc. Laboratories are required to perform corrective actions and submit any requested evidence of correction to the Program to demonstrate compliance with the regulation. Subsection (h) clarifies that the Program can require the laboratory to correct the violation sooner than 120 days or can grant the laboratory additional time for correction based on the provisions of subsection (i).

#### Subchapter G.

§§ 252.702, 252.703 and 252.704. The final-form rulemaking adds additional language to §§ 252.702(d), 252.703(e), and 252.704(c) at the suggestion of IRRC to add clarity to the written client notification requirements for laboratories when a voluntary relinquishment, loss, or lapse in accreditation occurs. Laboratories are required to notify all affected customers of the loss or lapse in accreditation in writing within 72 hours of the change in accreditation status. This additional language explains that the Department may choose to require the use of specific language or to require Department approval of the notice before issuance.

§ 252.706. Based on public comment, the final-form rulemaking removes the signature requirement from subsection (c) to state that the name or initials must be included on the records. Subsection (b)(5) was corrected to note that the results of chemical “or” thermal preservation

verifications or adjustments, or both must be documented. The final-form rulemaking more clearly explains the Department's requirements for historical reconstruction of laboratory activities in subsection (c)(2) when making changes to records. Specifically, the laboratory is expected to document the rationale for any non-typographical correction to records.

#### *F. Summary of Comments and Responses on the Proposed Rulemaking*

The Board approved publication of the proposed rulemaking at its May 17, 2016 meeting. The proposed rulemaking was published at 46 Pa.B. 5088 on August 20, 2016, with a 30-day public comment period. Comments were received from ten commentators, including IRRC.

The majority of the comments received during the public comment period related to requirements for microbiology incubation units, laboratory supervisor qualifications, sample acceptance and sample receipt, expired materials, and a general request for technical guidance documents from the Department to describe and detail compliance options with the new requirements.

Several commentators noted that the Department's proposal to require temperature distribution studies for incubation units used for microbiology testing should be amended. These commentators noted that circulating water baths are equitably distributed by design and should be exempt from the distribution study. The Department agreed with these comments and added language to the final-form rulemaking to exempt circulating water baths from the temperature distribution study.

Commentators stated that it would be helpful to have the Department develop technical guidance for how the Department would recommend compliance with the requirements for microbiology incubators detailed in the proposed rulemaking. The Department plans to develop technical guidance documentation in collaboration with the LAAC. These technical guidance documents will provide more detailed examples and options for how a laboratory might achieve compliance with the regulatory requirements for microbiology incubators regarding temperature distribution studies and the daily temperature monitoring requirements.

Several commentators provided comment regarding the Department's proposal to amend the laboratory supervisor qualification requirements. Some of the commentators expressed concern that the proposed reduction in years of experience for inorganic non-metals, basic water and wastewater, and basic microbiology might weaken the quality of results generated by accredited laboratories. Other commentators expressed support of the Department's proposal and suggested that it will be easier to find qualified laboratory supervisors with the reduction in years of experience. One commentator suggested that the Department should not reduce the years of experience, but should increase the years of experience and minimum number of college semester credit hours for all areas of supervision. The Department carefully considered these comments and determined that the language should remain the same in the final-form rulemaking regarding the qualifications for a laboratory supervisor. The methodologies and analytical technologies contained within the inorganic non-metals, basic microbiology, and basic drinking water and wastewater areas of testing are less complicated and more easily mastered. One year of experience in these areas should be sufficient to obtain mastery in these technical

disciplines and will also enable smaller laboratories to more easily comply with the accreditation regulations, thus reducing the burden on small businesses and publicly owned laboratories. The Department's requirements for laboratory supervisor experience and education for the other areas of laboratory testing, organics, trace metals, and complex microbiology are similar to those established by the National Environmental Laboratory Accreditation Program (NELAP) and the requirements of the final-form rulemaking are adequate to ensure proper experience and education of a laboratory supervisor.

Several commentators expressed concern that the Department's proposal to require that at least four of the minimum required college semester credit hours in biology must be microbiology credits for a microbiology laboratory supervisor is too stringent and not necessary. During meetings of the LAAC, several members of the public in attendance as well as the LAAC members requested that the Department require, that in addition to four credits in microbiology, all laboratory supervisors must have taken a microbiology laboratory course. After consideration of the public comments and after further discussion with the LAAC, the Department determined that requiring four credits of microbiology and not specifically requiring a laboratory course work is an acceptable compromise. Colleges and universities have many courses available online, and four microbiology credits can be obtained in a single course. An individual that proposes to supervise a microbiology laboratory needs the microbiology education obtained during a college-level microbiology course and four credits in microbiology. The techniques and methods included in the basic microbiology category are not limited to Colilert testing, as noted by several commentators. The basic microbiology category includes technologies such as membrane filtration, multiple tube fermentation, and pour plate. These techniques require understanding and proficiency with sterile techniques, positive and negative controls, and specific media preparation and uses. The Department did not make any changes in the microbiology supervisor sections from proposed rulemaking to final-form rulemaking.

Several commentators provided suggestions related to the Department's proposal to require chemical preservation checks of all sample bottles received by the laboratory. The Department had included this provision at the recommendation of the Safe Drinking Water (SDW) Program and the EPA's instruction that an improperly collected sample is invalid and cannot be used for compliance purposes. Through discussions with the regulated community, the Department decided to limit the pH testing requirement to those samples that require a specific pH by method, regulation, or permit, and all SDW compliance samples. This compromise will ensure the protection of the public health but reduce the financial burden for non-drinking water samples. The regulated community participating in the public meeting were amenable to the compromise. The Department also plans to develop technical guidance documents in collaboration with the LAAC to assist the regulated community in understanding the various options available to comply with the sample acceptance and handling requirements of the regulation.

Commentators also stated that the laboratory should not be required to develop sample handling, collection, and preservation instructions if adequate documentation for these activities already exist. The Department agreed with these commentators and amended the final-form rulemaking to clarify that the laboratory must maintain documentation of sample collection and preservation

requirements. The laboratory may choose to develop their own or use currently published materials from another source.

Finally, one commentator asserted that the proposed language to segregate expired chemicals from unexpired chemicals should not be accepted and expired chemicals should be removed from the laboratory and discarded. The commentator also stated that the Department's allowance for re-certification of expired chemicals, materials, and positive and negative controls should be removed from §§ 252.404(h) and 306(h) because the use of expired materials does not improve the quality of the testing results. The proposed language for segregation of expired chemicals was a compromise made between the Department and the LAAC to allow laboratories to maintain expired chemicals for non-compliance purposes but to ensure that they could not be mistaken as acceptable for use for compliance testing. However, the Department agreed with the suggestion to remove the allowance for re-certification of expired materials and removed this provision from the final-form rulemaking.

### *G. Benefits, Costs, and Compliance*

#### *Benefits*

The most significant benefit of this final-form rulemaking is a clear, concise, and improved regulation for the regulated community. The final-form rulemaking 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. All laboratories, particularly small laboratories, will benefit from allowing a laboratory supervisor to be absent for up to 21 days, rather than the current 16 days, and be replaced by a qualified staff member without requiring written notification to the Department. Several of the laboratory supervisor areas of experience qualifications were reduced from two years to one year. The final-form rulemaking removes the requirement for the Department to conduct "on-site" assessments, thus allowing the Department to explore and employ advances in technology to perform off-site assessments which can substantially reduce overall costs to the Program and the regulated laboratories.

The regulation also adds some specific requirements for NELAP laboratories. The current TNI (the NELAC Institute) Standard, which the NELAP laboratories must meet, is silent or lacking in specific requirements for several necessary standards. Requiring that all NELAP laboratories adhere to these regulations and amendments will ensure that all laboratories performing testing or analysis of compliance samples for the Department are meeting the same minimum standard.

Improved data quality will allow the Department, the regulated community, and the citizens of the Commonwealth to make better and more informed 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 which are covered by the regulations.

### *Compliance Costs*

The direct costs of the final-form rulemaking is the payment of the accreditation fees. The Act requires that the fees be set in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These costs 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 renewal fee for State accreditation is increased by \$200 per year while the renewal fee for NELAP applicants is increased by \$750 per year. The renewal application fees increase for all laboratories at a rate of approximately 30%. Each laboratory is also responsible for paying the appropriate category fee associated with its requested scope of accreditation, such as microbiology, trace metals, volatile organics, etc. The total accreditation fee for each laboratory is the renewal application fee plus each appropriate category fee. Each category fee was increased by between \$100-200 depending on the complexity of each category. The fees for medium to large accredited laboratories are likely to increase by approximately 20-30% depending on the requested scope of accreditation.

The final-form rulemaking includes a fee structure that is responsive to the needs of small laboratories. Specifically, increased accreditation costs for smaller laboratories will be minimal as the fees for the Basic Non-Potable Water and Basic Drinking Water fee categories increase by \$300. The current annual fee paid by these environmental laboratories is \$1250.00, and the fee change will 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. In addition, the fee structure includes changes including separation of the microbiology category into “basic” and “complex” to ensure that laboratories that are performing the more complex testing, which requires additional staff time and oversight, cover the costs of the accreditation. There were no public comments expressing objections to these increased fees.

Indirect costs will be related to the individual laboratory’s implementation of the new requirements. Many in the regulated community are already in compliance with the additional requirements itemized in the final-form rulemaking and will not incur any additional costs for implementation. Others will be required to update or develop standard operating procedures and update recordkeeping procedures.

Cost savings will occur in the regulated community because the new and clarified requirements will enable laboratories to better understand the applicable requirements and should reduce the number of violations found during assessments, thus reducing the amount of time and money necessary to correct these violations.

### *Compliance Assistance Plan*

Aside from the fee changes, the major changes that might require additional compliance assistance include the new requirements for sample collection instructions, sample receipt documentation, and microbiology incubator temperature distribution studies. The Department

plans to develop technical guidance in collaboration with the LAAC and the public. The other changes included within the final-form rulemaking are minor and in most cases clarify existing requirements or make current requirements less stringent. As such, the Department does not believe that a compliance assistance plan tailored to these changes is necessary. However, the Department will continue its ongoing compliance assistance efforts with mass email, updates to the website, and other activities.

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.

#### *Paperwork Requirements*

The final-form rulemaking does not include any additional forms, reports, or other paperwork to be submitted.

#### *H. Pollution Prevention*

Not applicable.

#### *I. Sunset Review*

The Board is not establishing a sunset date for these regulations, since they are needed for the Department to carry out its statutory authority. The Department will continue to closely monitor these regulations for their effectiveness and recommend updates to the Board as necessary.

#### *J. Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 29, 2016, the Department submitted a copy of the notice of proposed rulemaking, published at 46 Pa.B. 5088, to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on DATE, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on DATE and approved the final-form rulemaking.

### *K. Findings of the Board*

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law, and all comments were considered.
- (3) This final-form rulemaking does not enlarge the purpose of the proposed rulemaking published at 46 Pa.B. 5088 (August 20, 2016).
- (4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

### *L. Order of the Board*

The Board, acting under the authorizing statutes, orders that:

- (a) The regulations of the Department, 25 Pa. Code Chapter 252, are amended by amending §§ 252.1, 252.3, 252.4-252.6, 252.201, 252.203-252.206, 252.301, 252.302, 252.304, 252.306, 252.307, 252.401, 252.402, 252.404, 252.501, 252.601, 252.701-252.706, 252.708 to read as set forth in Annex A.
- (b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.
- (c) The Chairperson of the Board shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.
- (d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.
- (e) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

PATRICK MCDONNELL  
*Acting Chairperson*