Bureau of Laboratories
Laboratory Accreditation Program

ENVIRONMENTAL LABORATORY ACCREDITATION REGULATION

25 Pa. Code Chapter 252
46 Pa.B. 5088 (August 20, 2016)
Environmental Quality Board Regulation #7-495
(Independent Regulatory Review Commission #3157)

Comment and Response Document

List of Commentators

ID	Name/Address
1	Richard Taylor Valley Forge Sewer Authority 333 Pawling Road Phoenixville, PA 19460
2	Barbara Loner Williamsport Sanitary Authority Laboratories 253 West Fourth Street Williamsport, PA 17701
3	David Brubacker Pure-Test Laboratory 736 E Lincoln Ave Myerstown, PA 17067
4	Glenn DiBernardi 200 Ross Street Plymouth Meeting, PA 19462
5	Larissa Hoover Cranberry Township WWTP 2525 Rochester Rd, Suite 400 Cranberry Township, PA 16066
6	Anngela Chapman 1803 Philadelphia Street Indiana, PA 15701
7	Genie Bausinger Milton Regional Sewer Authority 5585 State Route 405 PO Box 433 Milton, PA 17847
8	Debbie Shockley Allegheny Valley Joint Sewage Authority 24500 State Route 405 Pittsburgh, PA 15238
9	Robert J. Eppinger Philadelphia Water Department 1500 E. Hunting Park Avenue Philadelphia, PA 19124
10	Independent Regulatory Review Commission (IRRC) 333 Market Street, 14th Floor Harrisburg, PA 17101

General Support of Proposed Rulemaking

1. **Comment**: The proposed rulemaking is an improvement to the current regulation in allowing an absence of a laboratory supervisor for 21 consecutive days. (3)

   Response: The Department thanks the commentator for the support of this rulemaking.

2. **Comment**: The Department's addition of the items to be included in a test report, such as unique identifier code and identification of amendments and opinions were an improvement to the current regulation. (9)

   Response: The Department thanks the commentator for the support of this rulemaking.

Application and Supporting Documents

3. **Comment**: The current regulations state that an environmental laboratory seeking accreditation must apply to the Department in "writing on forms provided" by the Department. The regulation is being proposed to replace the phrase with "the format specified" by the Department. The commentator suggested that the Department specify what information must be included in the submissions and stated that § 252.205(a)(2)(iii)(A) also references forms. (10)

   Response: The Department did not intend to remove the requirement for submission of Department-provided application forms that outline the specific items and information to be submitted. §§ 252.201 and 252.203 of the final rulemaking have been amended to return the original language "on forms provided by the Department." The Department makes all forms available to the environmental laboratories, and the forms required to be submitted for compliance with final-form rulemaking are the same as those currently required. The "format specified" language remains in the final-form rulemaking in order to allow for multi-media submission of forms in the future.

Notification Requirements

4. **Comment**: The proposed rulemaking requires a laboratory to notify all customers within 48-hours of an expiration of their accreditation certificate "in a manner approved by the Department." It is recommended that the final rulemaking explain where the laboratory can obtain the information on what is an appropriate manner for providing notice to the customers. (10)

   Response: The Department amended the proposed language to remove "in a manner approved by the Department," and added "The Department may choose to require the laboratory to use specific language in the written notice or to require Department approval of the notice before issuance." Each case of loss of accreditation, including expiration of certificate, lapse in accreditation, suspension, and revocation, are unique to the particular laboratory and cannot be generalized. The revised language will allow the Department to

review the laboratory's proposed written notification or specify that certain language be used depending on the circumstances related to the loss of accreditation.

Microbiology Incubators

5. **Comment**: The revisions to section 252.306(j) regarding temperature distribution studies for incubators used for microbiology testing should be deleted or modified, suggesting that only incubator units that exhibit problems during an assessment should be required to undergo this study. Three commentators suggested that circulating water baths should be exempt from the distribution study. (1, 4, 5, 7, 10)

   Response: The Department has amended the final rulemaking to clarify that circulating water baths do not require the temperature distribution study. All other types of incubators used for microbiology testing can exhibit uneven temperature distribution and those that cannot demonstrate consistent temperature distribution do not meet the regulatory requirements for compliance. It is necessary for the laboratories to proactively evaluate the incubator's temperature distribution to ensure that all samples are properly incubated and the mandated temperatures. To allow laboratories to use malfunctioning incubation units until a Departmental on-site assessment discovers them is not an acceptable alternative.

6. **Comment**: Many laboratories do not staff their labs during holidays and weekends and the requirement to monitor incubators and water baths twice per day, at least four hours apart on these days is too stringent. A single temperature should be sufficient. (8)

   Response: The clarification language provided in the proposed rulemaking of the requirement to monitor and record the temperature of a microbiology incubator twice per day on each day that the incubator is in use is not different than the existing requirement for monitoring microbiology incubators. The laboratory is not required to staff the laboratory to manually make two measurements separated by four hours. The laboratory may employ a continuous monitoring device or a maximum/minimum reading thermometer to monitor the temperatures of microbiology incubators on days when the laboratory does not have staff physically on site.

7. **Comment**: A commentator requested clarification to the Department's use of the term "laboratory" in § 252.306(f)(8)(iv) when referring to a "working day" for all laboratory activities. (9)

   Response: The existing regulations require that the laboratory define its operations, trained laboratory staff, and their responsibilities in its quality manual, or other documentation. The laboratory must document this information as necessary to account for when trained and responsible laboratory staff are working in a laboratory and when a temperature is required to be taken for a non-microbiology incubator, water-bath, heating block or oven.

Request for Guidance Documents

8. **Comment**: Several commentators requested that the Department develop compliance assistance documents related to various requirements of the proposed rulemaking, specifically temperature distribution studies and sample receiving protocols. (2, 6, 7, 9, 10)

   Response: The Department is planning to develop technical guidance in collaboration with the Laboratory Accreditation Advisory Committee (LAAC) for procedures related to sample receiving and temperature distribution studies for microbiology incubators. Additional details were added to the order under "compliance assistance" to explain the Department's plans for preparation of technical guidance documents.

9. **Comment**: Does the Department plan to develop examples of data qualifier opinions and interpretation language that would be acceptable for inclusion in a test report? (9)

   Response: The Department will present this to the LAAC for discussion.

Laboratory Supervisor Qualifications and Requirements

10. **Comment**: The laboratory supervisor qualifications for basic microbiology testing should remain the same, and not specifically require four college semester credit hours in microbiology. (2, 3)

    Response: The proposed rulemaking did not add additional credit hour requirements for microbiology laboratory supervisors, but it does clarify that four of the 16 credit hours in biology must be in microbiology. Several public comments during the LAAC meetings and comments from the LAAC itself requested that the Department require that, in addition to four credits in microbiology, all laboratory supervisors must have taken a microbiology laboratory course. The Department believes that an individual who supervises a microbiology laboratory needs the microbiology education obtained during a college-level microbiology course and believes that four credits in microbiology, not specifically requiring a laboratory course work, is an acceptable compromise.

11. **Comment**: Technical knowledge obtained in a microbiology course is not necessary for a laboratory performing basic microbiology, such as Colilert testing, and requiring four microbiology course credits is unnecessary. (3, 6)

    Response: The techniques and methods included in the basic microbiology category are not limited to Colilert testing, and include 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.

12. **Comment**: Requiring four credit hours in microbiology for a laboratory supervisor for basic microbiology will result in the laboratory community failing to be able to meet these new laboratory supervisor requirements. (3)

Response: Colleges and universities have many courses available on-line and four microbiology credits can be obtained in a single course. The Department has not required a lab be included in the four credits. The Department does not believe that the requirement for four credits in microbiology will diminish laboratory capability.

13. **Comment**: The Department should allow laboratory supervisors to be off-site and use remote electronic access to laboratory data/operations. Additionally, the Department should define 'absence' as 'off-site and not involved in or reviewing lab operations.' (3)

    Response: The Department extended the allowable time that a laboratory supervisor may be absent from 16 to 21 calendar days. Review of data is not the only responsibility of a laboratory supervisor. The laboratory supervisor is required to perform day-to-day supervision of the laboratory staff, operations, training, data generation, data reporting, etc. The Department will explore alternative ways to supervise laboratory staff and discuss these options with the LAAC to determine if a technical guidance document is necessary.

14. **Comment**: The laboratory supervisor provisions should allow for the substitution of years of experience for college credit hours. (6)

    Response: The LAAC and Department explored the option of allowing experience to substitute for college credit hours during the development of the proposed rulemaking in 2008 and again in 2015. Since experience is subjective, the Department, with assistance from the LAAC, was unable to determine how to evaluate experience for equivalency with college semester credits. However, many colleges and universities will evaluate experience and assign a credit value. The Department will accept credit hours assigned by an accredited college or university that are based on the individual's experience.

15. **Comment**: A commentator suggested that the laboratory supervisor provisions are not stringent enough, suggesting that:
    - a master's degree should not be substituted for one year of analytical experience,
    - the experience requirements for all laboratory supervisors should be increased from two years to four years citing that the accreditation requirements are getting more stringent and additional laboratory experience requirements would be a service to a laboratory supervisor,
    - the educational requirements for all laboratory supervisors should be increased to at least 24 semester credit hours of applicable education, and
    - a degree in engineering should be removed as an acceptable form of educational credentials. (9)

    Response: The Department's regulations are similar to those established by the National Environmental Laboratory Accreditation Program and believes the requirements of the rulemaking are adequate to ensure proper experience and education of a laboratory supervisor.

16. **Comment**: The new requirement, "if a method, regulation or program requires more stringent qualifications for education or experience, or both, the laboratory shall meet the more stringent requirements" should be added to § 252.304. (9, 10)

    Response: The Department has amended the final-form rulemaking to include this requirement in the personnel section, § 252.304.

17. **Comment**: The Department should reconsider the proposed change to the minimum number of years of experience for laboratory supervisors of inorganic non-metals, basic microbiology, and basic non-potable water. One commentator requested that the Department explain its rationale for why reducing the years of experience is adequate for the protection of the public and the Commonwealth's natural resources. (9, 10)

    Response: The methodologies and analytical technologies contained within these areas of supervision are less complicated and more easily mastered. The Department believes that one year of experience in these areas is 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.

18. **Comment**: The specific requirements required by the U.S. Environmental Protection Agency (EPA) for the certification of cryptosporidium be listed directly in the Chapter 252 regulation. (10)

    Response: The Department did not include these requirements directly in the Chapter 252 regulation to ensure that, if the EPA changes its requirements, the Department's requirements will not be obsolete or require amendment. The inclusion by reference will ensure that the Department's regulations are up-to-date. The Department will include these requirements in its application instructions to ensure that the applicant laboratories are aware of these requirements before submitting any applications for accreditation.

Volumetric Dispensing Devices

19. **Comment**: One commentator suggested that the removal of the term "mechanical" from § 252.306(f)(9)(i) will put a significant burden on the laboratory to verify non-Class A volumetric dispensing devices. (7)

    Response: The existing Chapter 252 requires that all mechanical volumetric dispensing devices be verified quarterly and any non-Class A volumetric dispensing devices be verified initially before use. The final-form rulemaking increases the requirement to verify all non-Class A glassware annually. This requirement was added to ensure that glassware that was not certified as Class A, which would include measuring devices that are self-marked in the laboratory, continue to meet the requirements of the standards and regulatory methods for volume. This annual verification requirement for non-Class A volumetric dispensing devices is consistent with the existing regulation for annual verification of non-Class A graduated sample containers included in § 252.306(f)(10).

Sample Handling and Receipt Protocols

20. Comment: Laboratories should be allowed to use currently published materials for sample handling, collection, and preservation in lieu of developing their own. (6, 10)

Response: The Department made changes to 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.

21. Comment: A single temperature is taken for sample refrigerators and not every sample bottle contained in the refrigerator, so a representative sample bottle should be allowed to be checked for temperature in a cooler. (8)

Response: The final-form rulemaking does not state that every sample bottle must be checked for thermal preservation. The Department is planning to develop technical guidance relating to sample collection, preservation, receipt, and storage.

22. Comment: Chemistry tests that do not require chemical preservation should not need to be measured for pH at the time of receipt. Also, when methods do not require the pH check of a sample, the pH should not be required to be checked, such as TSS. The cost of testing will likely be increased due to the increased cost associated with verifying the pH of all sample bottles. (8, 9, 10)

Response: Neither the existing regulations nor final-form rulemaking require that the pH of samples be taken at the time of receipt. The laboratory may develop its own procedures for checking and documenting the pH of samples, which may be at the time of receipt or throughout the life of the sample, as appropriate for the test. The Department 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.

23. Comment: A commentator asked for clarification if the Department's "Request to Report Qualified Drinking Water Sample Results – Chemistry" system was the motivation for the proposed rulemaking change to require the pH of all samples be checked. (9)

Response: The Department's proposed rulemaking requirements relating to pH samples were not a result of the qualified drinking water request system.

24. Comment: The requirement in § 252.401(f)(1)(iii) is vague, stating that the laboratory should use the requirements or guidance in the method to determine if a sample needs to be checked for residual chlorine. (9, 10)

Response: The requirement to check samples for the presence of residual chlorine when its presence will compromise the validity of the test is a vital requirement to ensure that the sample results reported to the Department are valid for compliance purposes. The environmental laboratories are responsible for validating the sample upon receipt. A sample that contains chlorine, where chlorine will negatively impact the test, results in an invalid sample for compliance purposes. For example, the presence of chlorine in nitrate, nitrite, and bacteria/microbiological samples will negatively impact the validity of the final result. If a laboratory does not check for the presence of chlorine, it would not know if the sample result was negatively impacted and might report an invalid result for compliance purposes.

The Department worked diligently with the LAAC in crafting the language included in § 252.401(f)(1)(iii). The Department originally suggested that this provision require all samples to be tested for the presence of residual chlorine. However, the LAAC and other members of the public that attended the meetings were opposed to that language. Many tests are not impacted by residual chlorine, so the added cost of testing for residual chlorine would not justified. The LAAC suggested the language included in this provision as an alternative and the Department agreed that it would achieve the goal of ensuring valid final results. The Department did not attempt to list every test that is impacted by the presence of residual chlorine, nor did the LAAC request it, because to do so could unnecessarily limit the Department's enforceability of this requirement. Additionally, a list could quickly become obsolete if new test methods are added to other regulations, permits, or orders that also fall under the scope of the accreditation regulation.

25. Comment: A commentator requested guidance related to the requirements of § 252.307(j)(2), specifically asking if the laboratory is expected to provide written sampling instructions to non-laboratory personnel, or if the laboratory is expected to provide formal, documented training to non-laboratory personnel. (9)

Response: The final-form rulemaking states that the laboratory is to make sample collection and preservation instructions available to customers and clients that collect samples. The rule does not require the laboratory to provide any training to non-laboratory personnel.

26. Comment: All methods require or specify a temperature for sample collection or storage. Some methods do not require thermal preservation of samples, such as metals. The commentator asked if these samples will require a temperature measurement. (9)

Response: Yes, the final-form rulemaking does require a temperature measurement for all samples, but the regulation does not specifically require a temperature measurement of each sample container. The condition of the sample must be checked and documented upon receipt, and temperature of the sample is one of the observations that must be documented. The absence of a thermal preservation requirement for a particular sample or test does not negate the possibility that the samples might not be properly stored. By taking the

temperature of the sample, the observation of the condition of the sample would aid in indicating possible improper handling, inaccurate sample collection information, or other anomalies. The laboratory is responsible for ensuring that all necessary information is available for the data user to determine the validity of the sample results. The condition of the sample is the first step in validation of the final sample result. The Department will develop technical guidance to assist laboratories in meeting the requirements of sample receiving, handling, and storage.

Quality Control Requirements

27. Comment: A commentator requested clarification to § 252.404(d)(7) asking if these new requirements apply to purchased, pre-sterile dilution water for fecal coliform. The commentator requested consideration for laboratories that only test fecal coliform and do not have a history of method blank contamination. (8)

Response: The language in paragraph (7) adds a requirement that the testing be performed by a laboratory accredited for the test being performed.

28. Comment: The language in § 252.404(h)(4) should include language that all positive and negative controls be processed along with an under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure. (9)

Response: The Department added this language in Section 252.404(h)(7) in the final-form rulemaking.

29. Comment: Quality control checks should be performed before analysis of samples, before first use, as contamination identified during use would invalidate an entire sample batch. (9)

Response: The Department agrees with the commentator, but decided not to amend the language of the proposed rulemaking in order to allow laboratories to determine when they perform the quality control.

30. Comment: A commentator requested clarification to § 252.304(b)(3)(vi)(D)(I) asking if the mid-point of the calibration range is acceptable or if the concentration tested must be less than the mid-point. (9)

Response: The final-form rulemaking states that the concentration must be in the lower half of the calibration range. The mid-point is not in the lower half of the calibration range.

31. Comment: The relative standard deviation in § 252.304(b)(3)(vi)(IV) does not provide information relating to the measurement's accuracy. (9)

Response: The commentator is correct. The rulemaking includes a statement in § 252.304(b)(3)(vi)(III) which requires laboratories to evaluate the individual recoveries in addition to the mean recovery of the control samples used when performing the demonstration of capability.

Handling of Expired Reagent, Standard, Media, and Reference Materials

32. Comment: 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. (9)

Response: The proposed language for segregation of expired chemicals was a compromise made by the Department in collaboration with 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.

33. Comment: 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). (9)

Response: The Department agrees with the commentator's suggestion to remove the language allowing for re-certification of expired materials and this provision has been removed in the final rulemaking.

34. Comment: The Department should explain how the approval referenced in § 252.404(h)(4) and (5) can be obtained or where information regarding the approval process can be found. (10)

Response: The Department removed the allowance for re-certification of expired materials at the suggestion of another commentator.

Recordkeeping

35. Comment: Are scanned records equivalent to original paper records? (9)

Response: A scanned record is an acceptable equivalent to original paper records. The Department requires that the laboratory ensure that all records, electronic or hard-copy, be maintained in a manner that ensures all changes and amendments are tracked and that all revisions are stored in a manner that is retrievable and meets the requirements of the Act and Chapter 252.

36. Comment: Section 252.706(c)(1) and (2) as written require initials or signature. The Department should consider removing the "signature" requirement and replacing with "printed name" or other identification because signatures are often not legible. (9)

Response: The Department agrees with the commentator and the final-form rulemaking was changed to remove the written "signature" requirement.

37. Comment: A commentator asked how to document changes in electronic records as required by § 252.706(c)(2). Electronic records can be changed and the original entry deleted without being traced. (9)

Response: The language as written in the proposed rulemaking is not different than the language of the existing regulation. The proposed rulemaking separated this requirement into a separate sub-section. The Department requires that all changes to any record, electronic or otherwise, be tracked. The laboratory is responsible for keeping records that track all changes to records.

Data Usability

38. Comment: The language in § 252.402(f)(8)(i) and (ii) should be maintained because this is the criteria for accepting results associated with unacceptable calibration verifications. If it is the Department's concern that labs may continually operate with unacceptable calibration, then the Department should add clarifying language. (9)

Response: The Department removed this language because Chapter 252 provides a list of requirements for the environmental laboratories generating compliance data for any of the 12 statutes listed in § 252.3. The acceptability and usability of the data is not the responsibility of the laboratory. This section of the regulation was often referenced by the laboratories as rationale for not identifying quality control failures, mistakenly believing that this section exempted the use of data qualifiers. The Department's removal of this language does not change the Department's authority or responsibility for evaluating the usability of data.

Assessment and Corrective Action Requirements

39. Comment: The proposed rulemaking explains time frames for correcting deficiencies. Proposed § 252.601(h)(1) requires laboratories to correct all deficiencies within 120 days of receipt of the assessment report, but proposed § 252.601(h)(2) requires the laboratory to implement and maintain the corrective actions within the time frames specified by the Department. Further, these sections are confusing and unclear when deficiencies must be corrected. In what other manner would DEP mandate corrective action? (10)

Response: The final-form rulemaking was revised to remove the conflicting language and states "Unless otherwise required or approved by the Department, deficiencies shall be corrected within 120 calendar days of the assessment report." This allows the Department to determine if the violation is more severe and requires correction in less than 120 calendar days or if the violation is less severe and the laboratory can be allowed an extension for correction as allowed in § 252.601(i). Corrective action is required through a corrective action report after an on-site assessment, data audit, application review, complaint investigation, or other material review conducted by the Program. The Department's findings are usually described in an assessment report, which would trigger the requirements of § 252.601 for corrective action. Corrective action is required whenever the laboratory fails to meet the requirements of the regulation. The consequences and rationale for Department action are outlined in subchapter G (relating to miscellaneous provisions).

General Comments

40. Comment: The Department did not propose to amend § 252.3 (relating to scope), but that several of the references contained within § 252.3 are out of date. (10)

Response: The Department reviewed the citations contained within § 252.3 and made the necessary corrections to update these references.

41. Comment: Two commentators included several suggestions for editorial changes to be consistent with the *Pennsylvania Code & Bulletin Style Manual* and other editorial suggestions. (9, 10)

Response: The Department reviewed the regulation and editorial comments and made changes where applicable and necessary.

42. Comment: The Regulatory Analysis Form (RAF) should be more detailed in response to question #12 regarding how the final rulemaking compares to other states regulations and how it will impact PA's ability to compete with other states. (10)

Response: Additional detail is provided in the RAF for item #12.

General Comments Not Related to the Proposed Rulemaking

43. Comment: The Department's laboratory accreditation personnel do not meet the requirements of a Chapter 252 laboratory supervisor and laboratory assessments are conducted by unqualified laboratory assessors. (3)

Response: The Department ensures that its laboratory accreditation officers are trained in accordance with the EPA's requirements for SDWA Certification Officers and the National Environmental Laboratory Accreditation Program's (NELAP) requirements for accreditation officers and all laboratory accreditation staff meet the minimum education and experience requirements of the State Civil Service Commission for Chemist 2 and Microbiologist 2 job classifications.

44. Comment: A proposed list of data qualifiers from PA-DEP should be discussed more formally during the LAAC meetings. Does the Department intend to standardize data qualifier language? (9)

Response: The Department has commenced working with the LAAC to standardize data qualifier language. That endeavor will continue after the technical guidance documents are developed for sample receiving and microbiology incubator studies.

45. Comment: The Department should use the 2012 MUR format for referencing methods using an approval year instead of the edition, stating that this would make all laboratory documentation consistent from internal documentation through to, and including, the sample data reporting to external customers. (9)

Response: The Department uses the edition number, when appropriate, to identify SDWA mandated methods where the edition number is necessary to determine which method technology is used in the laboratory. The Department does not specifically require an edition or approval year when identifying test results to customers or clients.