

**ENVIRONMENTAL LABORATORY ACCREDITATION REGULATION
COMMENT AND RESPONSE DOCUMENT**

List of Commentators

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COMMENTS AND RESPONSES

Laboratory Supervisor

1. Comment: The current regulations should allow additional time to replace a laboratory supervisor. The revised regulations should extend the time to at least 90 days instead of the current 30 days to find a supervisor. Small wastewater treatment laboratories that do not have several degreed chemists on staff do not have the depth to name a person on staff as a supervisor with the resignation of a supervisor. As the current “grandfathered” supervisors retire and/or seek other positions, it will be harder for the municipal sector to quickly hire qualified applicants. (1)

Response: The regulation requires designation of an alternate laboratory supervisor for temporary absences greater than 16 days but does not require that the Department be notified unless the temporary absence is greater than 30 days. An absence of a laboratory supervisor for greater than 16 days could adversely affect the quality of the data produced by the laboratory, especially in the case of a laboratory that operates 7 days a week. The Department believes that allowing a laboratory to continue to operate unsupervised for longer than 16 days would create a situation that could result in unacceptable data generation.

In the case of permanent changes to a laboratory supervisor, the Department expects the laboratory to provide notification within 20 days of the change. The notification of a permanent change within 20 days allows the Department be made aware earlier in the replacement process and available to offer guidance to the laboratory with regard to the laboratory supervisor qualification requirements.

2. Comment: Consideration should be made to allow supervisors to take a test in the laboratory methods to be certified as a supervisor. The operator certification program does not have anything to do with the current job responsibilities of a laboratory supervisor. There needs to be a way to certify supervisors with a specific laboratory test to allow those with extensive experience to be qualified. (1)

Response: The Department is currently developing the laboratory supervisor sub-classification under the Water and Wastewater Systems Operators’ Certification Act. The provision § 252.302 (h)(2) and (3) is included because the regulations authorizing the sub-classification are also in the regulatory development process and are expected to be completed in the near future.

3. Comment: The current regulations require extensive education for the laboratory supervisor or the operator’s exam. Additional education has been added to § 252.302 to require that supervisors have four semester hours of general microbiology. Now in addition to chemistry credits, supervisors must have educational credits in microbiology. This puts an additional burden on wastewater treatment plants that now have one person in charge of the laboratory. (1)

Response: Section 252.302(d) does not include additional requirements. The Department made the educational requirements more lenient by changing the requirement for semester credit hours in “general microbiology” to “biology.”

Record Retention and Documentation

4. Comment: Several sections of this regulation require record retention or recording of information. However, it is unclear what method of retention or recording the Board requires and the duration of the required retention is not set forth. The final-form regulation should clarify these requirements. (2)

Response: Section 252.706(d) requires that all records that are required by the Chapter 252 regulation be maintained for a minimum of five years. The Department will reinstate the definition for a laboratory notebook and included the phrase “in a laboratory notebook” where the proposed rulemaking deleted these phrases.

5. Comment: § 252.304(b)(3)(vi)(F) This subsection requires labs to retain “all data necessary” to reproduce the initial demonstration of capability. What types of data would meet this requirement? The final-form regulation should clarify the Board’s intent. (1)

Response: The Department will include the specific documentation to be maintained by the laboratory in order to document initial demonstration of capability and demonstrations of continued proficiency. Subsection 252.706(b) requires each “environmental laboratory to maintain records that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples.” The Department added “proficiency test study samples, initial demonstrations of capability and demonstrations of continued proficiency” to this subsection.

General Comments

6. Comment: The quality control requirements in the regulations are extensive. The PADEP should consider additional training to allow the small water and wastewater treatment plants to continue to operate their laboratories. The requirements may be forcing plants to abandon their laboratories and contract work out at a high cost to the utility customers. There needs to be a balance on quality control. There should be consideration for more outreach to help the small laboratories. (1)

Response: Thank you for your suggestion. The Department continues to develop and provide training courses to assist applicant laboratories in remaining compliant with the laboratory accreditation requirements. These courses are approved for continuing education credits for the Operators’ Certification Program. Further opportunities for assistance are available through the Laboratory Accreditation Program’s website, direct contact with the laboratory’s accreditation officer, and the on-site assessment process.

7. Comment: § 252.304(b)(3)(vi)(E) This subsection allows laboratory methods used prior to January 1, 2005 to be exempt from the initial demonstration of capability. How did the Board determine this was an appropriate date? (2)

Response: This language is the same language from the January 28, 2006 version of Chapter 252; it has been re-located to this section to keep all demonstration of capability requirements located in the same section of the regulation. The January 1, 2005 date was chosen because it was one year before the environmental laboratory accreditation rulemaking was originally promulgated.

8. Comment: § 252.304(b)(3)(vi)(G)(I) Under this subsection, a new employee in a work cell must work with an experienced analyst. However, it is not clear how long this must occur. The

final-form regulation should clearly state how long an experienced analyst must work with the new work cell employee. (2)

Response: Clause 252.304(b)(3)(vi)(G)(I) will be deleted.

9. Comment: § 252.304(b)(3)(vi)(G)(II) This subsection mentions “acceptable” quality control performance checks. This term is vague. The final-form regulation should specify what the Board considers “acceptable.” (2)

Response: The term “acceptable” refers to the requirements of the specific method, regulation, laboratory SOP, or client-specific requirement. The next sentence in this clause specifies that the quality control must meet acceptance criteria. “Acceptable quality control” is a term that is well understood by environmental laboratory personnel and must be defined in each laboratory SOP.

10. Comment: § 252.306(f)(9)(i) In this subsection, what does the Board consider an “appropriate” method for checking delivery volumes of mechanical volumetric dispensing devices? This term is vague. The Board should delete this term or set forth the “acceptable” methods. (2)

Response: The phrase, “using an appropriate method,” will be deleted.

11. Comment: § 252.306(h)(6) This subsection refers to a “Department approved procedure” to reevaluate and validate certain materials used past their expiration date. The final-form regulation should set forth this procedure or provide citation to an existing procedure that will be used. (2)

Response: A laboratory would apply for permission by submitting a request in writing to the Department. The Department is not requiring a specific format at this time to allow laboratories the flexibility to use laboratory-developed procedures. The method for validation of an expired chemical would be dependent upon the chemical. The wording will be changed to clarify that it is not a procedure developed by the Department, but a laboratory-developed procedure that is approved by the Department. The Department will notify the laboratory by mail of its decision.