

Comments of the Independent Regulatory Review Commission



Environmental Quality Board Regulation #7-495 (IRRC #3157)

Environmental Laboratory Accreditation

October 19, 2016

We submit for your consideration the following comments on the proposed rulemaking published in the August 20, 2016 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Environmental Quality Board (EQB) to respond to all comments received from us or any other source.

1. Determining whether the regulation is in the public interest.

Section 5.2 of the RRA (71 P.S. § 745.5b) directs this Commission to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impact and reasonableness. The Commission also considers the information a promulgating agency is required to provide under § 745.5(a) in the regulatory analysis form (RAF).

RAF question #12 asks how this regulation compares to other states and how this will affect Pennsylvania's ability to compete with other states. EQB's response to the first part of question #12 states that the proposed amendments are in line with other states. We ask EQB to provide a more detailed explanation of how this regulation compares to other states that surround the Commonwealth.

2. Section 252.201. Application and supporting documents. – Implementation procedures; Clarity.

Under Subsection (a), an environmental laboratory seeking accreditation must apply to the Department of Environmental Protection (DEP) in "writing on forms provided" by DEP. EQB is proposing to replace that phrase with the phrase "the format specified" by DEP. EQB explains that this change will allow for advances in technology and submission of electronic applications. EQB is also proposing to delete references to forms in the following sections: §§ 252.203(a), 252.702(d), 252.703(e), and 252.704 (c). We recommend that the final-form regulation specify what information must be included in submissions to DEP. This will assist the regulated community in complying with the regulation. We also note that § 252.205(a)(2)(iii)(A), a subsection that is not being amended, includes a reference to "forms." For consistency throughout Chapter 252, should this provision also be amended?

3. Section 252.203. Accreditation renewal. – Clarity.

Subsection (d) is new language that requires a laboratory with an expired certification to notify their customers within 48-hours “in a manner approved by the Department” that their accreditation has lapsed. Similar to our concern above, we recommend that the final-form regulation specify where a laboratory can obtain information on what is an appropriate manner for providing the required notice to its customers.

4. Section 252.302. Qualifications of the laboratory supervisor. – Protection of the public health, safety and welfare and the effect on this Commonwealth’s natural resources; Clarity.

EQB is proposing to reduce the years of experience requirement for laboratory supervisors from two years to one year under several provisions of this section. A commentator has requested that EQB retain the existing language found in the regulation. We ask EQB to explain its rationale for this change and why it believes the reduced years of experience is adequate for the protection of the public and the Commonwealth’s natural resources.

In addition, new language is being added as Subsection (m). It reads as follows: “If a method, regulation or program requires more stringent qualifications for education or experience, or both, the laboratory shall meet the more stringent requirement.” The Preamble to the proposal explains that this language is needed because the Environmental Protection Agency (EPA) granted DEP primacy for the certification of cryptosporidium, and EPA mandates specific experience for analysts performing testing of cryptosporidium that are not listed in Chapter 252. To improve the clarity of the regulation, we recommend that the final-form regulation specify the requirement for more stringent standards relates specifically to EPA requirements for analysts performing testing for cryptosporidium.

Finally, a commentator has suggested that the language of Subsection (m) should also be included under § 252.304 (relating to personnel requirements). We ask EQB to consider this suggestion as it develops the final-form regulation.

5. Section 252.306. Equipment, supplies and reference materials. – Implementation procedures.

Subsection (j) establishes a new requirement to perform temperature distribution studies for microbiology incubators. Commentators have raised three issues relating to this subsection and how it will be implemented. First, they ask if this subsection applies to circulating water baths. Second they suggest that more guidance is needed on how to develop the incubator distribution study. Third, under Subparagraph (1)(iii), they suggest that the regulation specify what an acceptable time frame for incubator temperature recovery would be. To assist the regulated community in complying with the regulation, we ask EQB to address these concerns in the Preamble to the final-form regulation.

6. Section 252.307. Methodology. – Implementation procedures.

Subsection (j) establishes a new requirement for laboratories to develop and maintain instructions for sample collection and preservation. A commentator has asked if instructions that already have been developed and published by another entity, such as the EPA, could be used to satisfy this requirement. Would instructions that have already been developed by a third party that meet the standards of this subsection be acceptable? If so, we suggest that EQB add language to the final-form regulation that allow for the use documents that have already been developed.

7. Subsection 252.401. Basic requirements. – Need.

Under Subsection (f), environmental laboratories must establish procedures for handling environmental samples. The proposed rulemaking adds detail on how the samples shall be handled and checked. Commentators have questioned the need to test pH levels under (f)(1)(ii) and the rationale for checking for residual chlorine under (f)(i)(iii). What is the need for checking environmental samples in this manner? The rationale for these tests should be explained in the Preamble to the final-form regulation.

8. Subsection 252.404. Essential quality control requirement – microbiology. – Clarity.

Subsection (g) requires environmental laboratories to demonstrate that certain equipment and material has not been contaminated. Subsections (h)(4) and (h)(5) are being amended to require DEP approval for certain actions. To improve the clarity of the regulation, we suggest that the final-form regulation explain how the approval can be obtained or where information regarding the approval process can be found.

9. Section 252.601. Assessment requirements. – Implementation procedures; Clarity.

Subsection (h) explains time frames associated with correcting deficiencies found by DEP during an assessment. Subsection (h)(1) requires environmental laboratories to “correct” all deficiencies within 120 calendar days of receipt of the assessment report. Subsection (h)(2) requires an environmental laboratory to “implement and maintain” the corrective actions within time frames specified in the corrective action report or as mandated by DEP. We have two concerns. First, it is unclear what the time frame for correcting deficiencies are under Subsections (h)(1) and (h)(2). Must deficiencies be corrected within 120 days or within time frames specified in the corrective action report or as mandated by DEP? This should be clarified in the final-form regulation. Second, outside of a corrective action report, in what other manner would DEP mandate corrective action? We ask EQB to explain this in the Preamble to the final-form regulation.

10. Miscellaneous clarity.

- Section 252.3 (relating to scope) is not being amended by this proposal. However, we note that the passage of Act 13 of 2012 has made the citation to the Oil and Gas Act

found at § 252.3(a)(1) incorrect. We encourage EQB to review the 12 environmental statutes listed in § 252.3 to ensure the accuracy of the statutory citations.

- The phrase “including, but not limited to” is used in the following sections of the proposal: §§ 252.306(f)(9)(i), 252.402(c)(4), and 252.404(j). Section 6.16 of the *Pennsylvania Code & Bulletin Style Manual* recommends that the term “includes” or “including” be used instead of the phrase “including, not limited to.”