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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

March 24, 2005

Honorable Kathleen A. McGinty, Chairperson
Environmental Quality Board
Rachel Carson State Office Building
400 Market Street, 16th Floor
Harrisburg, PA 17101

Re: Regulation #7-392 (IRRC #2454)
Environmental Quality Board
Environmental Laboratory Accreditation

Dear Chairperson McGinty:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

Mary S. Wyatte
Acting Executive Director/Chief Counsel

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Enclosure
cc: Honorable Mary Jo White, Chairman, Senate Environmental Resources and Energy Committee
Honorable Raphael J. Musto, Minority Chairman, Senate Environmental Resources and Energy Committee
Honorable Camille George, Democratic Chairman, House Environmental Resources and Energy Committee
Honorable William F. Adolph, Jr., Majority Chairman, House Environmental Resources and Energy Committee

Comments of the Independent Regulatory Review Commission

on

Environmental Quality Board Regulation #7-392 (IRRC #2454)

Environmental Laboratory Accreditation

March 24, 2005

We submit for your consideration the following comments that include references to the criteria in the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Environmental Quality Board (EQB) must respond to these comments when it submits the final-form regulation. The public comment period for this regulation closed on February 22, 2005. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

GENERAL

1. Use of the Consumer Price Index to adjust fees. – Statutory authority; Consistency with statute and Reasonableness.

Under 27 Pa.C.S. § 4104(6), the Department of Environmental Protection (Department) has the power and duty to:

> Require a fee for the processing of an application for a certificate of accreditation, including the issuance, renewal, modification or other action relating to the certificate, **in an amount sufficient to pay the department's cost of implementing and administering the accreditation program.** (Emphasis added.)

To fulfill this obligation, the EQB proposes Section 252.204(a) (relating to fees) to establish base fees. Under Section 252.204(b), these base fees will then be adjusted every three years by applying the applicable Consumer Price Index (CPI).

We do not see the nexus between the statutory requirement to charge fees "sufficient to pay the department's cost" and the CPI mechanism in the proposed regulation. Therefore, we object to this proposal for the following reasons:

- The regulation does not allow for consideration of actual program costs to determine the fees charged to the regulated community.

- The regulation would circumvent the opportunity for affected parties to comment on fee changes.

- The regulation assumes that all 34 fees will increase at the same rate.

- There is no corrective mechanism for insufficient or excess revenues. How will the Department maintain its obligation to administer and enforce the laboratory accreditation program if the CPI adjusted fees do not cover the program costs? Conversely, what will be done if the CPI adjusted fees produce excess revenue?

We recommend the EQB delete this provision and replace it with a fee adjustment mechanism that reflects actual or projected program costs. If the EQB maintains the proposed CPI mechanism, it must provide convincing data to establish that the CPI mechanism will closely track the direct costs experienced by the Department, as required by 27 Pa.C.S. § 4104(6).

Section 252.206(4) (relating to out-of-state onsite reimbursement) also uses the CPI to adjust the $50 per hour rate for assessor's travel time. For the reasons discussed above, we question why the CPI is used rather than the direct experience of wages and benefits.

2. Unique needs. – Consistency with statute and Setting lesser standards for individuals or small businesses.

The statute at 27 Pa.C.S. § 4105(d) states,

> Unique needs. To the extent possible, the Environmental Quality Board shall establish requirements and procedures that address the unique needs of small businesses, municipalities, municipal authorities and in-house laboratories.

In the Preamble, the EQB states,

> To the extent possible, the unique needs of small businesses, municipalities, municipal authorities and in-house laboratories (collectively referred to as "small laboratories") have been considered and addressed throughout this proposed rulemaking where compatible with the goals of creating an effective and sensible environmental laboratory accreditation program.

Nonetheless, commentators requested changes to the regulation to accommodate small businesses, municipalities, municipal authorities and in-house laboratories. Throughout our comments on specific provisions, we have acknowledged public comment related to the statutory provision of "unique needs." The concerns include the fee structure, accreditation-by-rule, need for accreditation of certain testing and personnel requirements. In the final-form regulation, the EQB should explain how the "unique needs" provision of the statute was applied in development of the regulatory requirements.

3. Coordination of regulatory initiatives. – Consistency with existing regulations and Implementation procedures.

The Regulatory Analysis Form submitted with this proposed regulation states that laboratory certification requirements found in Subchapter H of 25 Pa. Code Chapter 109 will be deleted and moved to this regulatory package. However, this proposed rulemaking does not include deletion of the Chapter 109 requirements.

Additionally, Section 252.302 lists among the qualifications for laboratory supervisor, in Subsections (h)(2) and (3), certification under the Water and Wastewater Systems Operators' Certification Act. However, the Department has acknowledged that the certification program is only in the development stage, and is not ready to be proposed as a regulation. Commentators have justifiably objected to a requirement that is not yet in place.

The Department has stated that both the Chapter 109 revisions and the upcoming certification for water or wastewater subclassification are not yet ready for proposal but are expected to be submitted in the near future. We request that the EQB coordinate these regulatory initiatives and put them in place at the same time. The other regulatory packages should be proposed before this regulation is submitted in final-form. Unless these provisions are all implemented contemporaneously, the result will be redundant, confusing and conflicting requirements.

Subchapter A. GENERAL PROVISIONS

4. Section 252.1. Definitions. – Consistency with statute and Setting lesser standards for individuals or small businesses.

Laboratory supervisor

The definition in the regulation does not include the term "analytical" used in 27 Pa.C.S. § 4102. The regulation should read, ". . . and reporting of analytical data."

5. Section 252.3. Scope. – Clarity.

Commentators seek clarification concerning the applicability of this regulation to laboratory work performed to meet requirements that are not listed in this section. These include programs run by the Environmental Protection Agency, the federal Clean Water Act, the Clean Air Act and Pennsylvania's Air Pollution Control Act. The regulation should include a clear understanding of what laboratory work falls within the scope of this regulation.

6. Section 252.5. NELAP equivalency. – Reasonableness.

In addition to NELAP accreditation programs, the Act (27 Pa.C.S. § 4104(1)) also states; "The program may also include any other specific broad-based Federal or State accreditation program for certification." How does the Department plan to evaluate other accreditation programs which meet the statutory criteria?

7. Section 252.6. Accreditation-by-rule. – Need; Reasonableness; Setting lesser standards for individuals or small businesses and Clarity.

In-house laboratories and small laboratories

There was a wide range of public comment on accreditation-by-rule. Commentators:

- Question the need for in-house laboratories to be accredited-by-rule for internal procedures. They cite quality assurance and other testing that is not done with the purpose of complying with environmental regulations.

- Believe this section does not include testing that should qualify for accreditation-by-rule, such as testing to maintain NPDES discharge permits.

- Express concern that small laboratories may be overly burdened by fees and should qualify for accreditation-by-rule.

- Question why the regulation grants accreditation-by-rule broadly to drinking water laboratories meeting the requirements specified in 25 Pa. Code Chapter 109.704, but in contrast grants accreditation-by-rule to a limited number of wastewater laboratories.

In development of the final-form regulation, the EQB should explain how the parameters selected for accreditation-by-rule are appropriate.

Subsection (a) Purpose.

Paragraph (1) requires conformance with "promulgated methods and guidelines established by the Department." Paragraph (2) requires handling "in accordance with guidelines governing quality control established by the Department." What are these guidelines and where can they be found? The regulation should include these guidelines or provide a specific reference to them.

Subsection (d) Industrial wastewater treatment facility laboratory.

This subsection, by referencing Subsection (a), cross references Section 252.707 which addresses a written plan for record maintenance or transfer if a laboratory transfers ownership or terminates operations. The statute specifies: "Records required under this chapter shall be maintained for five years unless otherwise specified in regulation." (See 27 Pa.C.S. § 4111) Commentators request that accredited-by-rule laboratories and in-house laboratories only be required to maintain records in accordance with applicable permits, some of which may only require retention for three years. We agree that records should only be retained as long as they are needed or required by statute. The EQB should review this requirement and allow shorter record retention where feasible.

Also, commentators questioned whether this should apply to a laboratory that was accredited-by-rule or for a support facility at a power plant that is subsequently closed. Is it necessary to retain records under these circumstances?

Subsection (d) Industrial wastewater treatment facility laboratory.
Subsection (e) Wastewater facility laboratory.

Subsection (d) states environmental laboratories operated by an industrial wastewater facility "will be deemed to be accredited under this chapter to perform testing or analysis **not mandated by the Department** and those tests identified in subsection (f)." (Emphasis added.) Similar language is used in Subsection (e) for wastewater facility laboratories. Commentators are concerned that these provisions would encompass testing and analysis that does not fall under the category of an environmental laboratory. We agree that these provisions are written broadly. Why does the Department need to accredit-by-rule testing and analysis "not mandated by the Department"?

Subsection (f) Other testing and analysis.

This subsection lists 25 tests and analyses that will be deemed accredited under this chapter. Commentators have noted additional items that should also be included in this list, such as "BOD," "COD," "TDS," "TSS," "TKN," "nitrite" and "phosphate detection." The EQB should review this list and consider these tests and analyses.

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

9. Section 252.201. Application and supporting documents. – Consistency with statute; Need and Reasonableness.

Time of application

Under 27 Pa.C.S. § 4107(b) of the statute, "All environmental laboratories shall apply for accreditation within six months after the Environmental Quality Board establishes an accreditation requirement by regulation for a type of laboratory." Why wasn't this statutory provision included in the regulation? How will laboratories be notified of this requirement?

Subsection (d)

The EQB should explain the need to accredit mobile laboratories separately. If one entity owns several mobile laboratories that perform the same testing, will the EQB consider mobile laboratories to be accredited as a group? Additionally, must mobile laboratories maintain a laboratory supervisor for each mobile laboratory?

10. Section 252.204. Fees. – Consistency with statute and Setting lesser standards for individuals or small businesses.

Subsection (a) of the regulation assigns the same fee regardless of the size of a laboratory. The proportional impact of the fee may be more onerous on a small laboratory compared to a larger laboratory. Does the EQB anticipate its costs relating to applications will be similar regardless of the laboratory size? Also, the EQB should consider whether the fees should be amended to correspond to various sized laboratories.

The regulation also imposes the same $700 fee for "Application fee – initial and renewal" of accreditation. Why are these fees the same? It would appear that the Department would incur more costs reviewing an initial application compared to a renewal.

11. Section 252.206. Out-of-state onsite reimbursement. – Costs to the private sector and Clarity.

Paragraph (3) of this section establishes a reimbursement of "Travel time for each assessor at a rate of $50/hour." It is not clear what specific hours this reimbursement is intended to cover. The regulation should specify to what aspects of travel this rate applies.

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

12. Section 252.301. Laboratory supervisor. – Reasonableness and Clarity.

Subsection (a)

This subsection requires that testing, analysis and reporting of data "shall be under the direct supervision of a laboratory supervisor." What constitutes "direct supervision" in this subsection? Also, how does the direct supervision requirement apply to environmental laboratories maintained on separate premises as specified in Section 252.201(c)?

Subsection (f)

This subsection triggers temporary measures when a laboratory supervisor is absent for 15 calendar days. We agree with commentators that the 15-day trigger point would unnecessarily include a typical two week vacation (i.e., 16 days if weekends are included). This provision should be amended to a time period longer than 15 days.

13. Section 252.304. Personnel requirements. – Economic impact; Need and Clarity.

Subsection (a) General requirements for technical staff.

Paragraph (1) states, "An environmental laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions." How will a laboratory know when it has satisfied this requirement? How will the requirement be enforced?

Subsection (b) Laboratory management responsibilities.

Paragraph (3)(vii) requires "A demonstration of continued proficiency by at least one of the following every 12 months for each method that relates to the employee's job responsibilities: . . . ." Commentators believe this will be costly and was not properly reflected in the projected costs of this regulation. One commentator cites an example where seven employees run more than seven tests on a regular basis. Another commentator believes this provision is unnecessary unless there is a change in method or instrumentation, or the laboratory performs unsatisfactorily. The EQB should explain the need for a requirement this stringent and costly.

Paragraphs (4) and (8) are vague requirements for documentation. Both should be expanded to describe what documentation is required.

14. Section 252.306. Equipment, supplies and reference materials. – Need; Reasonableness and Clarity.

Calibration requirements

Commentators have suggested that the constant calibration and measurement of laboratory equipment required in this section is unmanageable and excessive. Are these detailed equipment

requirements needed in regulation? How does the Department intend to enforce them? Also, will this section allow for advancement in technology?

Subsection (f)

Paragraph (4)(vii) requires a "qualified person" to service and calibrate analytical balances. Who is considered a "qualified person"?

Paragraph (11) uses the term "visual comparison devices." This term should be defined.

15. Section 252.307. Methodology. – Clarity.

Analytical method

Numerous provisions in this section and Subchapter D refer to "the method." These provisions should reference the "analytical method" developed to meet the requirements of this section.

Subsection (c)

Under this subsection, a laboratory may apply to the Department for permission to use an alternative or experimental procedure. How will a laboratory apply to or appeal a decision by the Department under this subsection? What process will the Department use to establish criteria for validating the method in Paragraph (4)? Finally, how will laboratories be notified of the Department's decision?

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

16. Section 252.401. Basic requirements. – Clarity.

Subsection (i)(4) includes the phrase, "out-of-control situations." What constitutes an "out-of-control" situation?

17. Section 252.403. Essential quality control requirements - toxicity testing. – Clarity.

Subsection (c)

This subsection states, "An environmental laboratory that measures toxicity or bioaccumulation of contaminants shall comply with guidance issued by the Department regarding counting of neonates, algae cells and weighing of fish for selected endpoints." The regulation should cross reference the guidance document.

Subsection (m)

Paragraph (1) references "refrigerator-sized incubators." To improve clarity, the incubators size requirements should be clearer, such as a measurement in cubic feet.

18. Section 252.405. Essential quality control requirement - radiochemistry. – Clarity.

Subsection (d)(8) states, "Acceptance criteria for instrument suitability verification standards **in the method or regulation shall be followed.**" (Emphasis added.) Are there any situations where the method or regulation would differ?

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

19. Section 252.501. Proficiency test study requirements. – Clarity.

Subsection (a)

This subsection states the Department will publish a list of fields of accreditation for which proficiency test studies are available. Where and how often will these lists be published? The regulation should state where an environmental laboratory can find an updated list of proficiency test studies for fields of accreditation.

Subsection (k)

This subsection sets the standard of "if an environmental laboratory **fails** to successfully analyze a proficiency test study . . . ." (Emphasis added.) What constitutes a failure? For example, if a laboratory successfully completes several analyses, but fails on one, is this considered an overall failure?

Subchapter G. MISCELLANEOUS PROVISIONS

20. Section 252.707. Recordkeeping. – Consistency with statute and Clarity.

Subsection (c) requires that record be retained "for a minimum of 5 years **unless otherwise specified.**" (Emphasis added.) However, 27 Pa.C.S. § 4111 states, "Records required under this chapter shall be maintained for five years **unless otherwise specified in regulation.**" (Emphasis added.) The law contemplates that the Department will specify in this proposal another timeframe that records must be kept. Therefore, the phrase "unless otherwise specified" should be deleted, unless other timeframes are specified in the regulation.

21. Section 252.709. Reporting and notification requirements. – Reasonableness and Clarity.

Subsection (b) requires the following:

> An environmental laboratory shall notify the Department, in writing, within 30 calendar days of changes in laboratory supervisors, analysts, supervisor or analyst assignments, testing or analysis equipment and facilities which affect accredited fields of accreditation.

Commentators believe this provision may produce more reporting than intended. For example, this provision could be interpreted to require reporting of every change in personnel or even the use of a new thermometer. The EQB should clarify these reporting requirements.

22. Miscellaneous clarity issues.

- The term "confirmation" is defined in Section 252.1. However, we could not find this term used within the regulation. Is this definition needed?

- The terms "MCL," "Matrix spike," "Mobile laboratory" and "Relative standard deviation" are defined in Section 252.1, but each term is used only once in the body of the regulation. The EQB should review these definitions to determine whether it may be clearer to define them in the portions of the regulation where they are used, rather in the definitions section.

- As printed in the *Pennsylvania Bulletin*, Paragraph (4) of Section 252.206 refers to "the fee imposed under subsection (c)." Was the intent to reference the fee in Paragraph (3) rather than Subsection (c)?

- The word "are" should be inserted between "areas" and "as" in Section 252.404(d).

Facsimile Cover Sheet

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Date: **March 24, 2005**
Pages: **11**

Comments: We are submitting the Independent Regulatory Review Commission's comments on the Environmental Quality Board's regulation #7-392 (IRRC #2454). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Debra McCauley **Date:** 3/24/05

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