Comments of the Independent Regulatory Review Commission

Environmental Quality Board Regulation #7-499 (IRRC #3169)

Radiological Health

July 26, 2017

We submit for your consideration the following comments on the proposed rulemaking published in the May 13, 2017 *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 (RRA) (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. **General – Economic impact; Protection of the public health; Less intrusive alternatives for small business; Implementation procedures; Reasonableness; Feasibility; Need; Possible conflict with existing regulations; Clarity.**

Advances in equipment technology

The Preamble states the EQB has not updated its regulations since 2009. Allegheny Health Network commented that "the rapid technological changes occurring in diagnostic images, including computerization and automation, require additional flexibility in these proposed regulations to allow appropriate responses to these ever accelerating changes and improvements." Allegheny Health Network suggests relying more on the Qualified Medical Physicist (QMP) expertise and is concerned that detailed regulations will quickly become outdated and irrelevant. Another comment describes equipment that self-calibrates. In other instances, commentators describe computer controlled technology that incorporates internal controls to shut down the equipment if it is not used safely. In light of the public comments, we are concerned that, despite an allowance for exemptions such as Section 215.31, portions of the proposed regulatory scheme will quickly become outdated. We recommend that the EQB reconsider the regulatory scheme of using prescriptive requirements and, where possible and appropriate, provide flexibility to accommodate advances in technology that are presently occurring and are certain to occur in the future. The EQB should also consider whether more reliance on the QMP might better accommodate advances in technology and better implement safety.

Department of Health regulations

Regulatory Analysis Form (RAF) 13 asks the promulgating agency: "Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations." The response to RAF 13 explains the Department of Environmental

Protection's (Department) authority and states that "The Department of Health may have regulations regarding radiation. However, DEP's radiological health regulations would supersede them." Why didn't the response include citations to the Department of Health regulations that address radiology including 28 Pa. Code Chapters 127 (relating to radiology services) and 565 (relating to laboratory and radiology services)? While RAF 13 explains that the Department's regulation would supersede Department of Health regulations, the regulated community must comply with both regulations. How was the development of this regulation coordinated with the Department of Health to make sure there are no conflicts? We recommend that the EQB provide in the final regulation submittal an explanation of how it coordinated its regulation with the Department of Health regulations to make sure there are no conflicts for the regulated community.

Definitions

Commentators identified several terms that are defined, but not used in the regulation. As an example, our search for the defined phrase "Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures" did not find this term used in the body of either the proposed regulation or the existing regulation. In other instances, such as the terms "ALARA – as low as reasonably achievable" and "Blind study" defined in Section 240.3, these terms are only used once in the proposed regulation (Sections 240.305 and 240.203(a)(5), respectively). It would be clearer to include an explanation of these terms in those sections rather than defining them in Section 240.3. Therefore, we ask the EQB to review all of the proposed definitions to eliminate terms not used in the body of the regulation, make sure defined terms are used consistently in the body of the regulation, and consider whether definitions are needed for terms in instances where the terms are only used once.

Preamble

In our review of regulations, we refer to the Preamble for an explanation of the amendments, including the need for the amendment. The Preamble to the proposed regulation does not include all amendments and also does not explain why certain amendments are needed. For the final regulation, the Preamble should be amended to include these explanations.

Compliance costs

The Preamble explains costs imposed by the regulation including costs relating to Qualified Medical Professionals and radon certification. However, the response to RAF 18 states there are no costs or adverse effects associated with the proposed rulemaking. How are these explanations consistent with each other? Furthermore, commentators believe the proposed regulation imposes operational costs, supervisory costs and compliance costs relating to outdated regulations. We ask the EQB to review and amend the responses in the Preamble and the RAF for the final regulation.

Business days

Several provisions require notice to the Department within a specific time period such as five days or 10 days. Commentators asked that these time periods be business days rather than calendar days. We agree.

2. Section 219.3. Definitions. – Clarity.

Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures

If this definition is retained in the final regulation, we have two comments. First, Paragraph (i) specifies a dose of "3 Gy (300 rad)." Commentators questioned this dose and believe it is too low. The EQB should explain why 3 Gy is the appropriate dose.

Second, this definition uses the phrase "unintended dose." The phrase "unintended dose" is defined in Section 221.2. Should this definition also be included in Section 219.3?

3. Section 219.229. Other medical reports. – Clarity.

Subsection (b)

The phrase "medical event" is used in this subsection. However, it is not clear what constitutes a "medical event" that would require reporting. Should this subsection use the defined term "Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures"?

4. Section 221.2. Definitions. – Protection of the public health.

QMP - Qualified medical physicist

The American Association of Physicists in Medicine (AAPM) commented that this definition is insufficient to ensure that individuals providing the designated medical physics services are qualified to do so. AAPM provides suggestions for amending the definition. We recommend that the EQB consider incorporating AAPM's suggested revisions into the final regulation, or explain why it is not in the public interest to do so.

5. Section 221.11. Registration responsibilities. – Clarity; Protection of the public health.

Paragraphs (b)(1) and (2) require continuing education, but the regulation does not specify the number of hours. We recommend adding the required number of hours in the final regulation.

6. Section 221.16. Training, competency and continuing education. – Clarity; Protection of the public health.

Subparagraphs (b)(1)(i) and (ii) require continuing education, but the regulation does not specify the number of hours. We recommend adding the required number of hours in the final regulation.

7. Section 240.2. Scope. – Protection of the public health; Clarity; Reasonableness; Implementation procedures.

The Preamble explains that there are two proposed amendments to this section:

> Proposed amendments to § 240.2 (relating to scope) revise certification exceptions from the building that the person occupies to the building in which the

person resides for clarity. A new certification exception is proposed to be added to clarify existing requirements for employees of local governments and schools who perform radon testing.

Several public comments were submitted on this section. Some comments addressed proposed amendments and some addressed existing language that was not proposed for revision. For example, S.W.A.T. Environmental of Pennsylvania believes existing language in Paragraph (a)(2) violates the statute and does not adequately protect the public health. A.B.E. Radiation Measurements Laboratory's comments address concerns with amendments to Sections (a)(4), (a)(4)(ii) and (a)(5).

There appears to be concerns and confusion with Section 240.2, which sets the scope for all of Chapter 240, relating to Radon Certification. We recommend that the EQB review this entire section and work with the regulated community to clarify the scope of Chapter 240.

8. Section 240.3. Definitions. – Clarity; Reasonableness.

ALARA – as low as reasonably achievable

The definition of this term is vague and unreasonable because it sets a standard of "making every reasonable effort" to limit exposure and "taking into account economic considerations and other societal concerns." These phrases are subjective and do not set a clear standard for compliance. What would meet the standard of every reasonable effort? What economic considerations must be considered? What constitutes a societal concern that must be considered? As noted above under Comment 1, it may be clearer to delete ALARA from Section 240.3 and specify the practices that must be followed in Section 240.305, which appears to be the only section of the regulation where ALARA is referenced.

9. Section 240.101. Requirements for radon testing certification. – Need; Reasonableness; Economic impact.

Subsection (b)

This subsection is amended from allowing "at least one person certified to test" to "one individual certified to test." Commentators explained the new language presents problems when a single person is not available due to illness, quitting or retirement. We agree that the new language is unnecessarily restrictive. We recommend maintaining the existing language. Alternatively, the EQB should explain the need for, reasonableness and economic impact of precluding a firm from employing more than one individual who is certified to test. This same concern applies to similar amendments or language proposed for Subsections (b) in Sections 240.102, 240.121 and 240.122.

10. Section 240.102. Prerequisites for radon testing certification. – Need; Reasonableness; Economic impact; Less costly and less intrusive alternatives.

Need for and less intrusive alternatives to requiring written approval from the Department

We have several concerns with this section of the regulation as set forth in the following discussion. Our concerns relate to the following criteria found in the RRA:

- Economic impact including:
    - Adverse effects on prices of services, and
    - Costs to the private sector;
- Need for the regulation;
- Reasonableness of requirements; and
- Whether a less costly or less intrusive alternative method of achieving the same goal of the regulation has been considered for regulations impacting small business.

We ask the EQB to carefully consider these criteria in its responses to the comments on this section, as well as similar provisions in Sections 240.112 and 240.122 cited at the conclusion of this comment.

Subparagraph (b)(1)(ii)

This provision states certification is void: ". . . until the Department approves in writing the firm owner's written and signed request for a certified individual to be in responsible charge of that firm's radon testing activities." The proposed amendment replaces a relatively simple notice to the Department with an indefinite time period during which the firm would be out of business while waiting for written approval from the Department. The Preamble description does not include this proposed amendment. Therefore, the EQB has not provided an explanation of the need for the amendments and it is not clear whether the economic impact of this amendment is included in the EQB's cost analysis of this regulation.

In determining whether the regulation is in the public interest, the criteria in the RRA require us to consider whether a less costly and less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business. A firm may lose its certified individual on very short notice and may find a new certified individual quickly. Under existing regulation, this process could potentially be completed in a day, particularly because it is in the firm's business interest to do so. The regulation fails to specify a time period for the Department to respond. For these reasons, we recommend deleting this amendment. Alternatively, the EQB should explain the costs imposed by the amendment, how those costs are justified and how it considered less costly and less intrusive alternatives, including retaining the existing regulation.

Paragraph (b)(2)

This paragraph adds a new requirement that the firm's certified individual may not also be a testing firm employee. What is the reason for this requirement? The Preamble does not include this addition and therefore does not explain the need for it. A commentator questioned why this provision was added. We agree that the EQB has not provided an explanation of the need for, reasonableness and economic impact of adding this provision. We recommend deleting it unless the EQB can provide justification for adding it.

Paragraph (b)(3)

This provision requires a notice by the firm's certified individual to invalidate an employee's Department listing. Why wouldn't notice be the responsibility of the firm owner?

Paragraph (b)(4)

This paragraph states a testing firm may list a maximum of five testing firm employees at one time. The Preamble states this limit is to "ensure adequate responsible charge by the certified individual." We agree with several commentators who do not believe the EQB has provided adequate support for the need for, reasonableness and economic impact of this provision. Therefore, we recommend deleting this provision. Alternatively, if the EQB retains a limit in the final regulation, it should explain its authority to impose a limit, provide support for the need for a limit including supporting data, explain how the limit was determined, provide an analysis of the economic impact of the limit on businesses, and explain why the limit is in the public interest.

Paragraph (b)(7)

Should the Department's written approval be to the firm's owner rather than the firm's certified individual?

Subsections 240.112(b) relating to radon mitigation certification and 240.122(b) relating to laboratory certification

These concerns with Subsection 240.102(b) also apply to similar requirements in Subsections 240.112(b)(1)(ii), (2), (3), (5) and (7), relating to radon mitigation certification and 240.122(b)(1)(ii), (2), (3) and (6) relating to laboratory certification.

11. Section 240.103. Radon testing application contents. – Need.

Paragraph (a)(3)

This paragraph requires the applicant's date of birth. Commentators questioned the need for the date of birth. We also question how the Department will use the applicant's date of birth. Is the intent to limit the age of an applicant? The EQB should explain the need for this requirement. The same questions apply to Paragraphs 240.113(a)(3) and 240.123(a)(3).

12. Section 240.306. Continuing education program. – Clarity; Need; Reasonableness; Economic impact.

A commentator questions the last sentence of this section which states continuing education hours may only be used for one certification period for each certification activity. If a person is certified as both a tester and a laboratory, are 16 or 32 hours of continuing education required? The explanation of this amendment is not clear in the Preamble. We recommend that the EQB clearly establish in the regulation the number of continuing education hours required. Furthermore, if it is the EQB's intent to require 32 hours for those certified in two areas, the EQB should explain why the continuing education hours should not apply to both certifications.

13. Section 240.308. Radon mitigation standards. – Reasonableness; Feasibility; Clarity.

Subsection (a)

We have three concerns. First, this subsection states a terminal discharge must meet "all" of the seven requirements listed. However, the requirements then describe different discharge scenarios, such as vent pipes attached to the side of the building and vent pipes that penetrate the roof. Would a vent pipe typically be attached to the side of a building and penetrate the roof? If not, the discharge would not meet "all" of the seven requirements. We recommend rephrasing Subsection (a).

Second, Paragraph (6) requires a termination point to be 10 feet or more horizontally from a vertical wall that extends above the roof. Could the termination point also comply by extending above the vertical wall that extends above the roof?

Third, Subsection (a) uses the term "conditioned spaces," whereas Subsection (b) uses the term "heated or cooled space of a building." Is there a difference? If so, the EQB should explain the difference in the regulation. If not, the same terminology should be used in both subsections.

Subsection (c)

In Subparagraph (3)(i) should the word "cost" be used rather than "penalty"?

In Subparagraph (3)(ii) would the "efficiency" of the radon mitigation system be decreased or the "effectiveness"?

14. Section 240.309. Testing protocols. – Clarity.

Clause (a)(4)(v)(G)

This provision states the mitigation system must be functioning during the test period. A commentator questioned what to do if the mitigation system isn't working. The final regulation should address the situation where a mitigation system is not working.

Subparagraph (a)(6)(i)

This subparagraph requires testing devices to be "secured against movement by employing anti-tampering methods." This requirement is vague and it is not clear what actions would be required to comply. This provision should be rewritten to provide clear direction on how to comply.

15. Miscellaneous clarity.

- Should the definition of "General supervision" in Section 221.2 state "by a licensed practitioner" rather than "of a licensed practitioner"?

- In Paragraphs 221.65(1) and (3), the phrasing of the exemption is not clear. Would these paragraphs be clearer by stating "the CT system is exempt from Section...."?

- Paragraph 221.204(c)(1) requires surveys in certain circumstances. A timeframe to complete the surveys should be added.

- Should Section 223.22 also include research on animals?