Comments of the Independent Regulatory Review Commission

Environmental Quality Board Regulation #7-555 (IRRC #3311)

Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices

October 13, 2021

We submit for your consideration the following comments on the proposed rulemaking published in the August 14, 2021 *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 (Board) to respond to all comments received from us or any other source.

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter B. RADIATION-PRODUCING DEVICES

1. Section 225.103. Field radiography. – Protection of the public health, safety and welfare; Clarity.

Subsection (a.6) requires an operator to periodically monitor the area of operation when radiation levels are variable. How frequently should the operator monitor radiation levels? Since the term "periodically" is vague, we ask the Board to clarify this provision to establish a standard that is achievable for the regulated community and protects the public health, safety and welfare.

CHAPTER 227a. RADIATION SAFETY REQUIREMENTS FOR NON-HEALING ARTS RADIATION-PRODUCING DEVICES

Subchapter B. GENERAL TECHNICAL REQUIREMENTS

2. Section 227a.15. Surveys. – Protection of the public health, safety and welfare; Reasonableness; Implementation procedures; Clarity.

Subsection (a)

Subsection (a)(7) requires a survey to be performed when "a personnel monitoring device shows a significant increase, as predetermined by the registrant, over the previous monitoring period or readings approach the limits specified in 10 CFR 20.1201 (relating to occupational dose limits

for adults)." The Board does not explain in the Preamble what constitutes a significant increase in an occupational dose of radiation and why it is reasonable for the registrant to predetermine the amount. We ask the Board to explain how this provision will be implemented and how it protects the public health, safety and welfare. Further, we ask the Board to consider clarifying this provision to establish a standard that is achievable for the regulated community.

Subsection (d)

Subsection (d) provides that a registrant is not required to perform radiation surveys if it "otherwise demonstrates compliance under this chapter to the satisfaction of the Department" of Environmental Protection (Department). How will the Department evaluate the registrant's compliance with Section 219.51 (relating to dose limits for individual members of the public), as required by subsection (a)? We ask the Board to explain how this subsection will be implemented to ensure a registrant is in compliance with radiation dose limits.

3. Section 227a.18. Operating requirements. – Implementation procedures.

Subsection (b)(3) requires a record of a bypass of a safety device or interlock. This provision does not include a record retention requirement. The Board should consider revising this paragraph to include the 5-year record maintenance requirement for consistency with other radiological health regulations.

This comment also applies to Section 227a.51(2) (relating to bomb detection radiation-producing devices).

4. Section 227a.21. Instruction and training. – Implementation procedures; Clarity.

Section 227a.21 states the instruction and training requirements for an individual to operate or maintain a radiation-producing device or enter a shielded room. We have two questions. First, how will an individual be evaluated to determine competence with paragraphs (1) – (6)? Second, will a registrant be required to maintain a record of competence? We ask the Board to explain how this regulation will be implemented. We also ask the Board clarify this section to address these concerns.

5. Section 227a.22. Radiation protection responsibility. – Implementation procedures; Clarity.

Subsection (b)(5) requires the radiation safety officer to maintain "all radiation safety records, including annual audits of the radiation protection program and documentation of its findings." We have two questions. First, does the Department consider all of the records required under Chapter 227a to be "safety records"? Second, what are the requirements of the annual audit of the radiation protection program? We ask the Board clarify this paragraph to address these concerns.

Subchapter C. CLOSED-BEAM RADIATION-PRODUCING DEVICES

6. Section 227a.35. Electron microscope devices. – Implementation procedures; Clarity; Need.

Under subsection (c), an individual may not operate or conduct maintenance on a closed-beam electron microscope until they have received instruction "and demonstrated an understanding of the normal operating procedures necessary to ensure radiation safety." Similar to Comment #4, this regulation does not state how an individual's understanding will be evaluated and if there is a record of competence. Further, is this subsection needed as Section 227a.21 requires instruction, training and competence? We ask the Board to explain how this regulation will be implemented and why it is needed.

Subchapter D. OPEN-BEAM RADIATION-PRODUCING DEVICES

7. Section 227a.40. Safety device. – Protection of the public health, safety and welfare; Reasonableness; Implementation procedures.

Subsection (a)

Subsection (a) requires a registrant to document the justification of the use of an open-beam radiation-producing device. The Board should consider adding this document to the records required to be maintained under subsection (c).

Subsection (b)

Subsection (b) requires a registrant to "consider a safety device" to minimize the chance of a portion of an operator's body from entering into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path. We ask the Board to explain its rationale for requiring a restraint to consider but not require a safety device and why this approach is reasonable. We further ask the Board to explain how this provision protects the health, safety and welfare of operators of these devices.

8. Section 227a.45. Radiation emission limits. – Protection of the public health, safety and welfare; Reasonableness.

Under this section, the registrant sets the radiation emissions limits for an open-beam radiation-producing device. The Preamble does not state why the registrant is given the authority to make this decision. We ask the Board to explain why this provision is reasonable and how it protects the health, safety and welfare of an individual in the area around a device.

9. Section 227a.48. Control of access. – Need.

The first sentence of this section requires an operator to control access to a radiation-producing device at all times during operation when it is not in a restricted area. The second sentence requires an operator to control access at all times during operation when the device is not in a

restricted area and is capable of creating a radiation area or a high radiation area. The broad condition in the first sentence appears to encompass all radiation-producing devices. We ask the Board to explain why the specific restriction on radiation areas in the second sentence is needed.

10. Section 227a.51. Bomb detection radiation-producing devices. – Implementation procedures; Need.

Paragraph (3) specifies that the registrant shall prevent entry when the device is energized during training. The Preamble does not explain how this paragraph will be implemented and why it is needed. We ask the Board to explain the implementation procedures in the Preamble to the final-form regulation.

11. Section 227a.52. Radiation-producing devices used in individual security screening. – Clarity.

Paragraph (4) addresses individual security screening with limited-use systems that are "used with discretion." This phrase lacks the clarity to set a binding norm. We ask the Board to revise this provision to establish a standard that is achievable for the regulated community.

12. Regulatory Analysis Form (RAF) – Economic or fiscal impact.

In response to RAF Questions #19 – 21, the Board states training to operate a radiation-producing device "costs approximately $950." Is this cost estimate for one individual? Further, the response to RAF Question #23 addresses three local governments. However, it does not include an estimate of costs for new registrations or registrants who may utilize additional devices and additional individuals who may need to be trained. We ask the Board to explain if the cost of training is per individual and update the cost estimates accordingly. We also ask the Board to provide an estimate of costs for additional devices and operators in RAF Questions #19 – 21 and 23 or explain why it is not possible to do so.

13. Miscellaneous clarity.

- We identified the following clarity issues in Section 227a.2 (relating to definitions):
    - The term "analytical X-ray equipment" is not used in the regulations. This definition should be deleted under Section 2.11(c) of the *Pennsylvania Code & Bulletin* (*Style Manual*).
    - In the definitions of "general-use system" and "limited-use system," the units of measure for the effective dose should be corrected to microrem and microsievert to reflect the definitions in Suggested State Regulation Section H.4 (relating to definitions).
    - The definitions of "general-use system" and "limited-use system" contain substantive provisions in the second sentences regarding screening an individual and dose limits, respectively. Section 2.11(e) of the *Style Manual* states that

substantive provisions may not be contained in a definition section. We recommend moving these requirements to the body of the regulations.

- In the definition of "handheld radiation-producing device," the acronym "XRF" should be stated in full as it is only used one time.

- In the definition of "limited-use system," the cross-reference to Section 227a.53(e) (relating to radiation-producing devices used in vehicle security screening) should be corrected to Section 227a.53(c).

- In Section 227a.12(a) (relating to labeling), the cross-reference to Section 219.159 (relating to posting of radiation-producing machines) is not needed and should be deleted.

- In Section 227a.15(a)(5) (relating to surveys), subsection (d) should be added to the cross-reference to Section 227a.18(b) (relating to operating requirements).

- In Section 227a.15(c), "assure" should be revised to "ensure."

- The explanation of Section 227a.34 (relating to security screening devices) in the Preamble should be revised to refer to exposures of greater than 0.5 second.

- Section 227a.45 (relating to radiation emission limits) should be revised to refer to ratings established by the "manufacturer."

- The cross-reference in Section 227a.53 to Section 227a.52 (relating to radiation-producing devices used in individual security screening) should be reviewed and revised for consistency. In addition, the explanation of Section 227a.53 in the Preamble should be revised accordingly.