pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Bureau of Radiation Protection

COMMENT AND RESPONSE DOCUMENT

Radiation Safety Requirements for Non-Healing Arts Radiation Producing Devices

25 Pa. Code Chapters 225, 227, 227a and 228
51 Pa.B. 4845 (August 14, 2021)
Environmental Quality Board Regulation #7-555
(Independent Regulatory Review Commission #3311)

INTRODUCTION

On May 19, 2021, the Environmental Quality Board (Board or EQB) adopted a proposed rulemaking amending 25 Pa. Code Chapters 225, 227, 227a, and 228 to establish and maintain adequate radiation protection standards and oversight of non-medical X-ray operations and emerging technologies in the industrial field. The proposed amendments are based on standards for radiation-producing devices set by recognized accrediting bodies and national organizations. Specifically, the proposed amendments incorporate the Suggested State Regulations (SSR) Part H and the training requirements in SSR Part E that were developed by the Conference of Radiation Control Program Directors (CRCPD). The American National Standards Association was consulted in developing these amendments. The amendment to Chapter 228 is proposed to update a definition to match the U.S. Nuclear Regulatory Commission's terminology.

The proposed rulemaking was published in the *Pennsylvania Bulletin* on August 14, 2021 (51 Pa.B. 4845) for a 30-day public comment period that closed on September 13, 2021. Comments were received from one public commentator. The Independent Regulatory Review Commission (IRRC) also submitted comments on the proposed rulemaking.

This Comment and Response Document provides responses to all comments received. Copies of all public comments received by the Board are posted on the Department's e-Comment website at https://www.ahs.dep.pa.gov/eComment/. Additionally, copies of all comments are available on IRRC's website at http://www.irrc.state.pa.us by searching for Regulation # 7-555 or IRRC #3311.

LIST OF COMMENTATORS ON THE PROPOSED RULEMAKING

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1. William Hoake Boalsburg, PA 16827
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List of Acronyms used in this Comment and Response Document

ANSI – American National Standards Institute
CFR – Code of Federal Regulations
Mrem – millirem
µSv – microsievert
RAF – Regulatory Analysis Form
RSO – Radiation Safety Officer
XRF – X-ray Fluorescence

COMMENTS AND RESPONSES

1. Comment: Regarding § 227a.52 on radiation-producing devices used in individual security screening, a commentator states that paragraph 3 is confusing and should be rewritten to be consistent with ANSI N43.17-2009. Specifically, the commentator recommends the following:

1. For general use systems:
   a. The reference effective dose from a single screening shall not exceed 25 microrem (0.25 µSv).
   b. The reference effective dose received by an individual shall not exceed 25 mrem (250 µSv) in one year.
2. For limited use systems:
   a. The reference effective dose from a single screening shall not exceed 1 mrem (10 µSv)
   b. The reference effective dose received by an individual shall not exceed shall not exceed 25 mrem (250 µSv) in one year.
   c. Documented procedures must be in place to ensure that not individual exceeds 25 mrem (250 µSv) in one year.
3. The statement in paragraph 3 "when equipment is capable of operation greater than 25 rem in a 12-month period at the facility" appears to be an error. The commentator can find no reference to this in either ANSI or the suggested state regulations.
4. Regarding the training requirements for RSOs in paragraph 4, the commentator believes the 8-hour requirement is excessive. The RSO on these units do not perform surveys, dose calculations, dosimetry, etc. In the commentator's experience, 4 hours of training is appropriate with emphasis on regulatory compliance and record keeping requirements. The commentator suggests that an RSO be required to take the 2-hour operator radiation safety class and in addition a 4-hour RSO class. (1)

Response: Regarding the amendments to § 227a.52 paragraphs 3 and 4 for general use systems and limited use systems, the Department acknowledges that the units of measurement referenced are not consistent with the ANSI standards. However, the units were changed from the ANSI standards for consistency with the Commonwealth's radiological health regulations and the U.S. Nuclear Regulatory Commission's regulations, who use conventional units first. Therefore, the final-form rulemaking has not been modified as suggested by the commentator.

Regarding the commentator's note about an error in the Preamble to the proposed rulemaking discussing paragraph 3 of § 227a.52, the Department reviewed the paragraph and agrees. Therefore, the Preamble for the final-form rulemaking has been corrected by removing the "in a 12-month period at the facility" language.

Lastly, the Department acknowledges the comment regarding the number of training hours for radiation safety officers (RSO). However, based on the Department's experience with facilities using individual screening devices, individuals receiving this training are unlikely to have prior experience or knowledge in radiation safety as these machines are used in settings where employees have not traditionally used radiation-producing devices, such as prisons and drug rehabilitation centers to search for contraband. Thus, individuals, such as corrections officers,

need a longer timeframe for training to understand the concepts and can protect the health and safety of all individuals involved. Therefore, no changes were made to the training requirements in the final-form rulemaking.

2. Comment: IRRC comments that in § 225.103 on field radiography, subsection (a.6) requires an operator to periodically monitor the area of operation when radiation levels are variable. IRRC asks how frequently the operator should monitor radiation levels. Since the term "periodically" is vague, IRRC asks 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. (2)

Response: After review, the Department finds the sentence regarding periodic monitoring is unnecessary and duplicative of the first sentence as a survey is required to be done for each new operating condition. Therefore, it has been deleted in the final-form rulemaking.

3. Comment: IRRC comments that in § 227a.15 on surveys, 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, IRRC asks the Board to consider clarifying this provision to establish a standard that is achievable for the regulated community. (2)

Response: For the final-form rulemaking, the Department deleted "significant" and "predetermined by the registrant" and revised the language used in this subsection to specify a radiation exposure of more than 25 percent of the annual occupational dose limit would trigger the need for a survey to be performed. This is an increase that would note something is wrong with the equipment that may not be apparent except through this dosimetry and would ensure the individual would not exceed the annual occupational dose limit.

4. Comment: IRRC also comments that in § 227a.15 on surveys, 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 § 219.51 (relating to dose limits for individual members of the public), as required by subsection (a)? IRRC asks the Board to explain how this subsection will be implemented to ensure a registrant is in compliance with radiation dose limits. (2)

Response: Evaluating compliance in this scenario would be accomplished by reviewing historical radiation survey results, shielding calculations, personnel dosimetry reports, area monitoring, and manufacturer literature. This information could, in some instances, provide enough information for the Department to determine a radiation-producing device complies with dose limits for individual members of the public without the registrant having to perform a radiation survey.

5. Comment: IRRC comments that in § 227a.18 on operating requirements, 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. (2)

Response: The five-year retention period language has been added to § 227a.18(b)(3) in the final-form rulemaking.

6. Comment: IRRC notes that § 227a.21 states the instruction and training requirements for an individual to operate or maintain a radiation-producing device or enter a shielded room. IRRC inquires how an individual will be evaluated to determine competence with paragraphs (1) – (6) and how a registrant will be required to maintain a record of competence. IRRC asks the Board to explain how this regulation will be implemented and to clarify this section to address these concerns. (2)

Response: Standard actions in the Radiation Protection program's inspection procedures are to review training records of the registrant or licensee. The sentence "Before an individual may operate or maintain a radiation-producing device or enter a shielded room, the individual shall receive instruction in and shall demonstrate competence as to the following:" was revised to "Before an individual may operate or maintain a radiation-producing device or enter a shielded room, the individual shall receive instruction in and shall demonstrate competence **through a performance evaluation by the registrant,** as to the following:" to clarify that an individual will be evaluated through a performance evaluation by the registrant to determine competence with paragraphs (1) – (6). As noted in this section, records related to an operator's training and instruction are required to be maintained onsite and made available for review by the Department for 5 years.

7. Comment: IRRC notes that in § 227a.22 on radiation protection responsibility, 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." IRRC asks if the Department considers all of the records required under Chapter 227a to be "safety records" and what the requirements are for the annual audit of the radiation protection program. IRRC asks the Board to clarify this paragraph to address these concerns. (2)

Response: Subsection (b)(5) of the final-form rulemaking has been revised to clarify which records must be retained and to reference the federal regulation containing the annual review requirements. The annual review requirement is a federal requirement incorporated by reference in the Department's regulations. *See* 10 CFR 20.1101(c) (relating to Radiation Protection Programs; incorporated by reference in 25 Pa. Code § 219.5. Subsection (b)(5) now reads "**Retaining** all records **required to show compliance with this section**, including annual **reviews** of the radiation protection program **content and implementation** and **the** documentation of its findings, **as required in § 219.5 (relating to incorporation by reference) and incorporating by reference 10 CFR 20.1101(c) (relating to radiation protection programs)**, and making the records available for review by the Department for 5 years."

8. Comment: IRRC notes subsection (c) of § 227a.35 on electron microscope devices states that 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. IRRC questions if this subsection is needed as § 227a.21 requires instruction, training and competence and asks the Board to explain how this regulation will be implemented and why it is needed. (2)

Response: The Department agrees that this requirement is duplicative of § 227a.21. Therefore, subsection (c) of § 227a.35 has been deleted from the final-form rulemaking.

9. Comment: IRRC comments § 227a.40(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). (2)

Response: The first sentence of § 227a.40(c) in the final-form rulemaking has been revised to read "If the registrant's use of an open-beam radiation-producing device does not permit the use of a safety device to minimize the chance of direct body exposure, the registrant shall maintain a written record of **the justification required in subsection (a), and** a description of the various safety devices that have been evaluated and reasons the devices cannot be used."

10. Comment: IRRC notes § 227a.40(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. IRRC asks the Board to explain its rationale for requiring a registrant to consider but not require a safety device and why this approach is reasonable. IRRC further asks the Board to explain how this provision protects the health, safety and welfare of operators of these devices. (2)

Response: In some circumstances, use of a safety device with an open-beam radiation-producing device is impractical because it will prevent the device from taking an accurate image or analysis of metals. In these circumstances, the device can still be operated in a manner that protects the health, safety, and welfare of operators, without a safety device, as long as the device is operated according to policies and procedures designed to minimize the possibility of unnecessary exposure. As examples, operator training can include instructions that the operator never use their hand or any other body part to hold a sample, and not to point the radiation-producing device at another person. Subsection (c) requires that an operator document the safety devices it considered for the open-beam radiation producing device and the reasons the safety devices could not be used. Subsection (d) requires that an operator document the policies and procedures they will require, in the absence of a safety device, to ensure the radiation-producing device is operated safely.

11. Comment: IRRC comments that § 227a.45 allows the registrant to set the radiation emissions limits for an open-beam radiation-producing device. IRRC notes the Preamble does not state why the registrant is given the authority to make this decision and asks 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. (2)

Response: The words "set by the registrant and" have been deleted in the final-form rulemaking and replaced with the radiation emissions limits that must be met for any specified tube rating should be established by the tube manufacturer.

12. Comment: IRRC comments that in § 227a.48, the first sentence 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. IRRC asks the Board to explain why the specific restriction on radiation areas in the second sentence is needed. (2)

Response: The Department agrees with this comment, and the second sentence has been deleted in the final-form rulemaking.

13. Comment: IRRC comments that paragraph (3) of § 227a.51 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. IRRC asks the Board to explain the implementation procedures in the Preamble to the final-form regulation. (2)

Response: The Department agrees with this comment, and the words "during training" were deleted from the final-form rulemaking. This requirement is always necessary, not just during training, to ensure no unnecessary exposures to radiation occurs and to protect the workers and anyone else nearby from exposure to radiation. It will be implemented by physical controls that the registrant uses, such as barriers, doors or warning signs, which can all be verified upon inspection.

14. Comment: IRRC notes that § 227a.51(2) requires a registrant to maintain a use log for each bomb detection radiation-producing device. 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. (2)

Response: The 5-year retention period language has been added to § 227a.51(2) of the final-form rulemaking.

15. Comment: IRRC notes that paragraph (4) of § 227a.52 addresses individual security screening with limited-use systems that are "used with discretion." This phrase lacks the clarity to set a binding norm. IRRC asks the Board to revise this provision to establish a standard that is achievable for the regulated community. (2)

Response: Paragraph (4) has been clarified by deleting "and is used with discretion" and adding the following sentence: "The number of scans per individual must be tracked to ensure the dose does not exceed the limit referenced in paragraph (5)."

16. Comment: IRRC comments that 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. IRRC asks the Board to explain if the cost of training is per individual and update the cost estimates accordingly, as well as 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. (2)

Response: The training cost is for the Radiation Safety Officer (RSO), and there is one RSO per registrant. This has been clarified in the RAF. There is no additional training cost for additional devices. The RSO training cost would apply any time there is a change of the facility's RSO and cannot be predicted by the Department. The operators are trained by the RSO. Therefore, the cost estimate of $950 in the RAF is accurate. Subsequent to delivery of the proposed rulemaking package to IRRC on July 14, 2021, the three local governments identified in the response to RAF Questions #20 and #23 have completed the RSO training. The cost estimates for those two questions have been updated accordingly.

17. Comment: IRRC comments in § 227a.2 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). (2)

Response: The term and definition of "analytical X-ray equipment" has been deleted in the final-form rulemaking.

18. Comment: IRRC comments in § 227a.2, for 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). (2)

Response: The units of measure in these definitions have been corrected in the final-form rulemaking.

19. Comment: IRRC comments that the definitions of "general-use system" and "limited-use system" in § 227a.2 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. IRRC recommends moving these requirements to the body of the regulations. (2)

Response: The Department agrees that the sentences IRRC identified are substantive provisions that should not be included in definitions. "Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year" has been deleted from the definition of "general-use system." This provision is redundant and unnecessary because

§ 227a.52(3) already provides the restriction of an effective dose limit of 25 µrem (0.25 µSv) for a single complete screening when using a general-use system.

"A limited-use system requires additional controls and documentation to ensure that annual individual dose limits required under § 227a.53(c) (relating to radiation-producing devices used in vehicle security screening) are not exceeded" has been deleted from the definition of "limited-use system." The requirement to track the number of scans to ensure dose limits in § 227a.53(c) are not exceeded has been added to § 227a.52(4).

20. Comment: IRRC comments that in § 227a.2 in the definition of "handheld radiation-producing device," the acronym "XRF" should be stated in full as it is only used one time. (2)

Response: This acronym is now spelled out in the final-form rulemaking.

21. Comment: IRRC comments that in § 227a.2 in the definition of "limited-use system," the cross-reference to § 227a.53(e) (relating to radiation-producing devices used in vehicle security screening) should be corrected to § 227a.53(c). (2)

Response: The Department agrees with this comment. However, the sentence containing the incorrect cross-reference has since been deleted from the definition of "limited-use system" in response to IRRC's other comment on this definition. Please see Comment #19.

22. Comment: IRRC comments that in § 227a.12(a) (relating to labeling), the cross-reference to § 219.159 (relating to posting of radiation-producing machines) is not needed and should be deleted. (2)

Response: This cross-reference has been deleted from the final-form rulemaking.

23. Comment: IRRC comments that in § 227a.15(a)(5) (relating to surveys), subsection (d) should be added to the cross-reference to § 227a.18(b) (relating to operating requirements). (2)

Response: The § 227a.18(d) cross-reference is not necessary as § 227a.18(b) is sufficient to require a survey for bypassing a safety device or interlock.

24. Comment: IRRC suggests that in § 227a.15(c), "assure" should be revised to "ensure." (2)

Response: This has been corrected in the final-form rulemaking.

25. Comment: IRRC suggests that the explanation of § 227a.34 (relating to security screening devices) in the Preamble should be revised to refer to exposures of greater than 0.5 second. (2)

Response: The Preamble has been revised to correct the explanation of § 227a.34(1).

26. Comment: IRRC notes that § 227a.45 (relating to radiation emission limits) should be revised to refer to ratings established by the "manufacturer." (2)

Response: "Manufacture" has been corrected to "manufacturer" in the final-form rulemaking.

27. Comment: IRRC comments that the cross-reference in § 227a.53 to § 227a.52 (relating to radiation-producing devices used in individual security screening) should be reviewed and revised for consistency. In addition, the explanation of § 227a.53 in the Preamble should be revised accordingly. (2)

Response: The terms "as general use or limited-use systems" have been deleted from subsection 227a.53(a) in the final-form rulemaking and, as a result, the cross-reference to § 227a.52 does not need to be corrected.