Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency: Department of Environmental Protection

(2) Agency Number: 7

Identification Number: 555

IRRC Number**:**

(3) PA Code Cite: 25 Pa. Code Article V. Radiological Health Chapters 225, 227, 227a, and 228

(4) Short Title: Radiation Safety Requirements for Non-Healing Arts Radiation Producing Devices

(5) Agency Contacts (List Telephone Number and Email Address):

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(6) Type of Rulemaking (check applicable box):

- ☒ Proposed Regulation
- ☐ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Chapter 227a regulations are intended to address developments in radiation technology in industrial types of radiation-producing devices, which have occurred since the regulations covering these devices were last updated in 2009. Since that time, there have been advances in technology and use of X-rays and other ionizing radiation for non-medical radiography. Parts of Chapter 225 are proposed to be moved to Chapter 227a to separate field radiography and non-medical X-ray operations. Also, the definition of "accelerators" in Chapter 228 is being amended to reflect the U.S. Nuclear Regulatory Commission's definition.

The proposed amendments are based on 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).

(8) State the statutory authority for the regulation. Include specific statutory citation.

The proposed amendments to Chapters 225, 227, 228, and a new Chapter 227a, are authorized under the following:

- Section 301(c) of the Radiation Protection Act, 35 P.S. § 7110.301(c), which requires the Department to develop and conduct comprehensive programs addressing the "registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users."

- Section 302 of the Radiation Protection Act, 35 P.S. § 7110.302, which requires the Environmental Quality Board (Board) to "adopt the rules and regulations of the department to accomplish the purposes and carry out the provisions of [the] act."

- Section 1920-A of the Administrative Code, 71 P.S. § 510-20, which authorizes the Board to promulgate rules and regulations necessary for the performance of the work of the Department.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

This regulation is not mandated by any federal or state law, court order, or federal regulation, and there are no relevant state or federal court decisions. However, the proposed amendments incorporate SSR Part H and the training requirements in SSR Part E that were developed by the Conference of Radiation Control Program Directors (CRCPD). Moreover, it will better align the state regulations with the federal requirements under 10 CFR Part 34.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The proposed rulemaking provides an opportunity to update and further clarify and fortify requirements in the regulations for non-medical X-ray equipment used in research and industry and to provide for requirements of new equipment that may be marketed in the future.

As set forth in the proposed rulemaking, users of non-medical radiation-producing devices would be required to comply with radiation protection standards that would not only protect and benefit employees but would also protect and benefit the general public from overexposures to radiation. The proposed rulemaking would ensure that operators of these devices are trained properly so that both the public and the operator are adequately protected from overexposures to radiation.

The regulated community and all citizens of the Commonwealth will benefit from these proposed regulations. For example, personnel at the approximately 90 prisons, 120 schools, 1,040 industrial establishments, and 130 county offices and other non-medical offices registered with the Department perform numerous scans per day resulting in thousands of scans being done annually, and the proposed regulations would ensure anyone involved in these scans are protected from overexposures to radiation. Overexposure to radiation can cause a wide range of potential negative health impacts, such as skin burns, radiation sickness, cancer, and death in the most extreme cases.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no provisions that are more stringent than the federal standards.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

This proposal will not put Pennsylvania at a competitive disadvantage. Instead, it will align Pennsylvania's regulations better with federal regulations (e.g., 10 CFR Part 34) and also national suggested guidance for states (e.g., SSR Part H and Part E) produced by the CRCPD working groups.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No other state regulations will be affected. The Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147 (35 P.S. §§ 7110.101—7110.703) gives full authority to DEP regarding radiation protection.

Section 306 of the Act, Conflicting laws, provides:

Ordinances, resolutions or regulations now or hereafter in effect of the governing body of any agency or political subdivision of this Commonwealth relating to radiation or radiation sources shall be superseded by this act if such ordinances or regulations are not in substantial conformity with this act and any rules and regulations issued hereunder.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

As required by section 301(c)(14) of the Radiation Protection Act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed rulemaking and to advise the Department prior to submittal of the proposed regulation to the Board. Members represent professional health physics and medical physics organizations, environmental, health, science, engineering, business or public interest groups. One member of the committee is the Executive Director of the Citizens Advisory Council to the Department of Environmental Protection representing the general public.

RPAC reviewed the proposed regulations on October 10, 2019, and appointed a subcommittee comprised of professionals in this specific industry. The subcommittee held two conference calls from October 2019 through February 2020. RPAC again reviewed the package with the revisions made as a result of the recommendations of the subcommittee on March 19, 2020. At the conclusion of the July 9, 2020 meeting, RPAC voted to concur with the Department's recommendation that the proposed rulemaking move forward in the regulatory process.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The proposed regulations affect approximately 1,400 radiation-producing device registrants. We estimate approximately 600 of these registrants are small businesses in industries including food manufacturers, primary metal manufacturers, fabricated metal product manufacturers, machinery manufacturers, computer and electronic product manufacturers, and other miscellaneous manufacturers.

In addition to the above stated types of businesses, registrants include government offices such as prisons and courthouses, universities, and research laboratories.

Three local government registrants for radiation-producing devices used in individual security screening will additionally be affected by the proposed rulemaking due to new requirements to provide training on the use of equipment to staff that do not have formal training or knowledge in radiological sciences or radiation safety. These are the registrants of radiation-producing devices used in individual security screening as described in § 227a.52.

Many of the registrants already meet the requirements under the current regulations. These current requirements are being moved into a new Chapter, Chapter 227a. The requirements were rewritten and rearranged in order to incorporate SSR Part H and Part E, and to clarify all the requirements. The proposed requirements reflect current industry practices, as discovered through Department inspections and through conversations with RPAC members. Therefore, the proposed regulations are not expected to impose additional requirements on those registrants.

This proposed rulemaking would not only protect and benefit employees but would also protect and benefit the general public from overexposures to radiation. The proposed rulemaking would ensure that operators of these devices are trained properly so that both the public and the operator are adequately protected from overexposures to radiation.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

Currently, there are approximately 1,400 radiation-producing device registrants that would be required to comply with the proposed regulations. Approximately 600 of these registrants are considered small businesses and include food manufacturers, primary metal manufacturers, fabricated metal product manufacturers, machinery manufacturers, computer and electronic product manufacturers, and other miscellaneous manufacturers. In addition to the previously stated types of businesses, some registrants are also government offices such as prisons and courthouses, universities, and research laboratories.

All future registrants of non-healing arts radiation-producing devices will also be required to comply.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The benefit of the amendments to the radiological health regulations include the requirement for users of radiation-producing devices to comply with radiation protection standards that would not only protect employees but would also protect the general public from overexposures to radiation. The proposed rulemaking would ensure that training is provided to operators of these radiation-producing devices, and the operators and the public are adequately protected from the harmful effects of overexposure to radiation.

Overall, there are no financial, economic, or social impacts expected as a result of the proposed rulemaking. There are no changes to the fee schedule in Chapter 218 in this proposed rulemaking, and the new technologies listed in the proposed rulemaking are already complying with these proposed amendments and fees as required by the general administrative provisions of § 215.22 (relating to prohibited uses) . A small number of registrants may experience additional costs due to the new proposed training requirements. These training requirements are added due to operators of certain technologies not having the knowledge or training in any radiation protection practices. Those in need of this training are registrants of radiation-producing devices used in individual security screening as described in § 227a.52. The current number of these registrants is three local government registrants.

There are no social impacts associated with the proposed rulemaking.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

There are no adverse effects associated with the proposed rulemaking.

The benefits of the proposed rulemaking include protecting employees and the general public from overexposures to radiation by requiring compliance with radiation protection standards. The proposed rulemaking would ensure that training is provided to operators of these radiation-producing devices. The benefit of maintaining adequate radiation protection standards outweigh the cost that a small percentage of registrants may encounter when providing training to the operators of the devices.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Members of the regulated community that currently have radiation-producing devices used in individual security screenings are already in compliance and will incur no new costs. Any new registrant hoping to use a radiation-producing device in individual screenings would be required to obtain training to operate the device, which costs approximately $950 per registrant. This cost was derived by using an estimate by one of the installers that currently provides the training to these operators.

There will be no savings to the regulated community associated with compliance.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are three (3) local governments that have yet to provide the training required as part of compliance with the proposed regulation. Based on the estimate that this training will cost $950 per registrant, compliance will cost the three local governments approximately $2,850 in total. If a local government that does not currently have a radiation-producing device used in individual security screenings elects to use such devices in the future, then that local government's staff will be required to obtain training to operate the device, which again costs approximately $950.

There will be no savings to local governments associated with compliance.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

State agencies that currently have radiation-producing devices used in individual security screenings are already in compliance and will incur no new costs. If a state agency that does not currently have a radiation-producing device used in individual security screenings elects to use such devices in the future, then that agency's staff will be required to obtain training to operate the device, which costs approximately $950.

There will not be savings to state government associated with compliance.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The proposed rulemaking would change various records retention requirements to a five-year record retention period. This change was made in order to promote consistency throughout the radiological health regulations. These records do not need to be in paper format and may be stored electronically.

(22a) Are forms required for implementation of the regulation?

No.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

There are no forms required to implement the regulation.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2020/21	FY +1 2021/22	FY +2 2022/23	FY +3 2023/24	FY +4 2024/25	FY +5 2025/26
SAVINGS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	$2,850	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	$2,850	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

This amendment will have no effect on program expenditures. The DEP Radiation Protection Fund covers all areas of Radioactive Material, Environmental Surveillance, X-Ray / Accelerators, Nuclear Safety and Radon. Decommissioning is also covered to the extent cleanup costs cannot be recovered from responsible parties and are not eligible for funding through other special funds administered by the Department.

Program	FY -3 2017-18	FY -2 2018-19	FY -1 2019-20	Current FY 2020-21
Radiation Protection Fund	$11,639,000	$11,975,000	$12,809,000	$14,936,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

There are approximately 600 small businesses subject to these regulations.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

There is no added reporting, recordkeeping or other administrative requirements that would have a cost.

(c) A statement of probable effect on impacted small businesses.

There are presently no small businesses that are predicted to be affected or adversely impacted by these proposed regulations as they are already in compliance as required by the general administrative provisions of § 215.22 (relating to prohibited uses). If a small business that does not currently have a radiation-producing device used in individual security screenings elects to use such a device in the future, then that business's staff will be required to obtain training to operate the device, the impact of which would be a one-time cost for the small business of approximately $950.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

There is no less intrusive or less costly alternative method of achieving the purpose of the proposed regulations. Much of this proposed regulation is moving current requirements to a different chapter. The requirements were rewritten and rearranged in order to incorporate SSR Part H and Part E, and to clarify all the requirements. The regulated community suggested creating this new chapter would help them to more clearly understand their regulatory obligations. The added requirement in this proposal is for a new technology, radiation-producing devices used in individual security screening, is already being regulated administratively by the program under the Department's general authority in § 215.22 (relating to prohibited uses) and is just being codified in this chapter specifically regulating non-healing arts radiation-producing devices. The additional training for operators of this technology is necessary, as these operators do not have any knowledge or experience in radiation protection.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

The Department does not anticipate any impacts from this proposed rulemaking to minorities, the elderly, small businesses or farmers that would necessitate special provisions By adding the requirements for the radiation-producing devices used in individual security screening with defined operator training requirements, the proposed regulations will help ensure protection of the public from unnecessary radiation exposure. Therefore, no special provisions have been developed.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory provisions have been considered or rejected for the radiological health amendments since the majority of the amendments are current industry radiation protection practices and are based on SSRs produced by the Conference of Radiation Control Program Directors working groups.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Performance standards for small businesses were not considered to replace design or operation standards required by the proposed rulemaking because the radiation risk level remains the same for small businesses which operate radiation-producing devices. The exemption of small businesses from all or any part of the requirements contained in the proposed rulemaking was also not considered for this same reason.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

Data is not the basis for this regulation. Suggested State Regulations Part H and E were the basis for this proposed rulemaking. They are attached to this package.

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period:	30 days
B. The date or dates on which any public meetings or hearings will be held:	None scheduled
C. The expected date of delivery of the final-form regulation:	Quarter 4, 2021
D. The expected effective date of the final-form regulation:	90 days after publication in the *PA Bulletin*
E. The expected date by which compliance with the final-form regulation will be required:	90 days after publication in the *PA Bulletin*
F. The expected date by which required permits, licenses or other approvals must be obtained:	Not applicable

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Board is not proposing a sunset date for these regulations since they are needed for the Department to carry out its statutory authority. The Department will continue to closely monitor these regulations for their effectiveness and recommend updates to the Board as necessary.