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| <h1 style="margin: 0;">Regulatory Analysis Form</h1> <p style="margin: 0;">(Completed by Promulgating Agency)</p> <p style="margin: 0;">(All Comments submitted on this regulation will appear on IRRC's website)</p> | | <p><i>INDEPENDENT REGULATORY REVIEW COMMISSION</i></p> |
| <p>(1) Agency: Department of Environmental Protection</p> | | <p>IRRC Number:</p> |
| <p>(2) Agency Number: 7 Identification Number: 574</p> | | |
| <p>(3) PA Code Cite: 25 Pa. Code Chapter 218</p> | | |
| <p>(4) Short Title: Radiological Health Fees</p> | | |
| <p>(5) Agency Contacts (List Telephone Number and Email Address): Primary Contact: Laura Griffin, 717-783-8727, laurgriffi@pa.gov Secondary Contact: Jessica Shirley, 717-783-8727, jessshirley@pa.gov</p> | | |
| <p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> Proposed Regulation</p> <p><input type="checkbox"/> Final Regulation</p> <p><input type="checkbox"/> Final Omitted Regulation</p> | | <p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><input type="checkbox"/> Certification by the Attorney General</p> |
| <p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>In order to ensure there is adequate funding for the Department's Radiation Protection Program to continue to provide oversight of radiation safety-related activities, meet the requirements of the Radiation Protection Act, and maintain Pennsylvania's status as a U.S. Nuclear Regulatory Commission Agreement State, this proposed rulemaking would increase the Chapter 218 fees for the Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area by 30% and the Radioactive Materials and Decommissioning program area by 10%. These proposed fee increases would provide sufficient funding to support the program areas through FY 2027-28.</p> | | |
| <p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>The proposed amendments to Chapter 218 are authorized under sections 301, 302 and 401 of the Radiation Protection Act (35 P.S. §§ 7110.301, 7110.302 and 7110.401) and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).</p> | | |
| <p>(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.</p> <p>Yes, Section 401 of the Radiation Protection Act (35 P.S. § 7110.401) requires the Environmental Quality Board (Board) to establish license fees "in an amount at least sufficient to cover the</p> | | |

department's costs of administering the programs." The proposed fee increases are needed to meet these statutory requirements. Section 302 of the Radiation Protection Act requires the Board to review the fee structure every three years to ensure compliance with Section 401 of the Radiation Protection Act (35 P.S. § 7110.302).

(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.

This proposed regulation is needed to ensure there is adequate funding for the Department's Radiation Protection Program to continue to provide oversight of radiation safety-related activities, maintain Pennsylvania's status as a U.S. Nuclear Regulatory Commission Agreement State, and meet the requirements of the Radiation Protection Act.

25 Pa. Code Chapter 218 sets the fee amounts that provide funding for operation of the Department's Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area and the Radioactive Materials and Decommissioning program area. The Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area handles the registration and inspection of X-ray facilities, licensing and inspection of accelerators, and registration of radiation-producing machine service providers. Fees associated with this work have not been increased since 2009 even though costs to administer the program have steadily increased. If fees for radiation-producing machines are not increased, oversight of radiation safety-related activities may be diminished, and the replacement of obsolete survey equipment may be delayed reducing the assurance that regulated activities are being conducted safely.

The Radioactive Materials and Decommissioning program area is responsible for the regulation, licensing, and inspection of radioactive material user operations and for termination of radioactive material licenses. In March 2008, then Governor Rendell signed an Agreement with the Chairman of the U.S. Nuclear Regulatory Commission (NRC) for the Commonwealth to become an Agreement State. This allows the Commonwealth to regulate licensing and inspection of radioactive material users for Pennsylvania entities. These duties are funded through the Chapter 218 license fees. The proposed amendments to the Chapter 218 fees for radioactive material licenses are necessary to assure adequate funding is available for the Commonwealth to carry out its required duties under the Agreement State program. If the Commonwealth was forced to cede its authority to regulate radioactive materials back to the NRC, they would impose higher fees on the regulated community.

Therefore, the Department will benefit from the proposed rulemaking by having the needed revenue to cover the costs of the programs mandated by the Radiation Protection Act and maintain Pennsylvania as an Agreement State. The regulated community, particularly radioactive materials users, will benefit from paying lesser fees compared to what would be required by the NRC should Pennsylvania lose its authority as an Agreement State. Most importantly, the general public will benefit from the proposed rulemaking by the continued safety with the use of radioactive materials, the safety of radiation-producing machines, and additional quality assurance that will be provided by the Department having adequate resources to provide oversight for these operations.

(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.

No provisions 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?

Radiation producing machine registration and radioactive materials license fees vary from state to state. The same categories of fees apply to radioactive materials licensees whether they are based in Pennsylvania, some other Agreement State, or a state regulated by the NRC. The NRC's fee category designations have been adopted by Pennsylvania and other states. However, comparing Pennsylvania's fees with other states' fees is not an apples to apples comparison because each state structures its fees differently. Additionally, the number of employees in the states' programs vary, with different salary scales, medical / dental / retirement benefits, indirect charge-backs (e.g., rent, IT, etc.), equipment, calibration, and other expenses. Pennsylvania assesses an annual fee while some other states assess fees biannually. Some states charge a base license fee and add in inspection fees, may have independent contractors perform work and direct-bill registrants, or have other supplemental fees. Some states fold all their radiation producing machine expenses into a single facility fee, where others (including Pennsylvania) charge a smaller base facility fee and add a "per tube" fee for radiation producing machines. All of these factors make it impossible to draw clear conclusions regarding whether a given fee is higher or lower in Pennsylvania when compared to another state. As one example, a hypothetical dental intraoral device registrant in Texas could pay either more or less in registration fees than a facility in Pennsylvania depending on the number of tubes associated with their device.

The Radiation Protection Act requires the Commonwealth's Radiation Protection Program to cover its costs to implement the programs through fees. Since Pennsylvania became an NRC Agreement State in 2008, the Commonwealth has maintained significantly lower radioactive license fees while providing equal quality and faster turnaround license amendments and renewals, which was noted by the Radiation Protection Advisory Committee (RPAC) Chairman for the record in 2010. The Radiation Protection Program's current fees are substantially lower than the NRC's fee schedule for non-Agreement States by about 50 percent. Even with the increases proposed in this rulemaking, the resulting fees will still be more than 20% less than the NRC's current fees, which the NRC increases every year.

Some additional common fee categories from the NRC's fee tables in 10 CFR Part 170 and 171 (relating to fees for federal facilities, special nuclear materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended; annual fees for reactor licenses and fuel cycle licenses and materials licenses, including holders of certificates of compliance, registrations, and quality assurance program approvals and government agencies licensed by the NRC) have not been added because the Department is not authorized to regulate such operations. The professional hourly rate fee identified by the asterisk in Chapter 218, Appendix A, of the proposed rulemaking is increased from \$225 per hour to \$275 per hour—still below the NRC's fiscal year 2021 hourly rate of \$288 per hour. Reduced Chapter 218 radioactive material licensing fees are also available for small businesses.

Therefore, the proposed fee increases as a result of this rulemaking will not negatively impact Pennsylvania relative to other states.

(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 Pennsylvania regulations will be affected.

(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.)

The proposed amendments to the Chapter 218 fees for radiation-producing machines, vendors, and accelerators and for radioactive materials and decommissioning were reviewed by the Department’s Radiation Protection Advisory Committee (RPAC). The committee represents various stakeholders, including radioactive materials licensees, radiation-producing machine registrants and service providers, and radon service providers, as well as the general public. The Department presented the draft proposed regulation to RPAC on March 3, 2022. RPAC endorsed moving forward with the proposed rulemaking.

(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?

All radiation-producing machines, including accelerators, licensees, and service providers, and radioactive material licensees in this Commonwealth will be affected by the proposed regulation. This includes 10,393 radiation-producing machine registrants; 148 accelerator licensees; 350 service providers; and 682 specific and general radioactive material licensees.

Small businesses covered by the radiological health provisions for radiation-producing machines, accelerators, and service providers in this proposed rulemaking include dentist offices and private medical practices. While the Department does not collect information regarding the size of each business that is an X-ray registrant, licensee, or service provider, the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking. Eighty-five (85) radioactive material licensees qualify as small businesses under the definitions currently in use by the NRC and the Department. (Please see the response to Question 24 for further explanation). Examples of radioactive materials licensees include hospitals (license category 7C “Human Use – Specific License”) and possessors of nuclear density gauges (license category 3P “Other Byproduct Material”).

A 30 percent increase in fees will occur for radiation-producing machine registrants, accelerator licensees, and service providers. The increases are in line with increased personnel costs.

A 10 percent increase in fees will occur for radioactive materials licensees, and the professional hourly rate will be increased by 22 percent. The increases are in line with increased personnel costs.

(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.

All radiation-producing machines, including accelerators, licensees, and service providers, and radioactive material licensees in the Commonwealth will be required to comply with the proposed regulation. This includes 10,393 radiation-producing machine registrants, 148 accelerator licensees, 350 service providers, and 682 specific and general radioactive material licensees. The Department

considered the vast majority of X-ray registrants, licensees and service providers to be small businesses, and eighty-five (85) radioactive material licensees qualify as small businesses under the definitions currently in use by the NRC and the Department.

(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.

All radiation-producing machine registrants, accelerator licensees, and service providers will experience a 30 percent increase in their annual fees, while all radioactive material licensees will experience a 10 percent increase in fees. Considering increases in inflation since the last time these fee categories were increased (2009 for the Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area and 2018 for the Radioactive Materials and Decommissioning program area), the cost of compliance is being increased in line with inflation rates.

These proposed fee increases are needed to ensure there is adequate funding for the Department's Radiation Protection Program to continue to provide oversight of radiation safety-related activities, maintain Pennsylvania's status as a U.S. Nuclear Regulatory Commission Agreement State, and meet the requirements of the Radiation Protection Act.

Therefore, the Department will benefit from the proposed rulemaking by having the needed revenue to cover the costs of the programs mandated by the Radiation Protection Act and maintain Pennsylvania as an Agreement State. The regulated community, particularly radioactive materials users, will benefit from paying lesser fees compared to what would be required by the NRC should Pennsylvania lose its authority as an Agreement State. Most importantly, the general public will benefit from the proposed rulemaking by the continued safety with the use of radioactive materials, the safety of radiation-producing machines, and additional quality assurance that will be provided by the Department having adequate resources to provide oversight for these operations.

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

The proposed increased fees will allow the Department to maintain existing radiation-safety programs at current levels of operation. This includes enabling the Department to continue to fund personnel, purchase upgrades to obsolete survey equipment, and make investments in new personnel training to continue the effective oversight of radiation-producing activities benefitting the health of all Pennsylvanians.

For radiation-producing machine registrants, accelerator licensees, and service providers, fees have not been increased since 2009. During this time, expenses have risen steadily each year, and this proposed fee increase will allow the Department to continue to perform the registration, licensing, and inspection program as required by the Radiation Protection Act.

For radioactive material licensees, Pennsylvania's proposed increased Chapter 218 fees will still be below the amount that would have been charged by the NRC had Pennsylvania not become an Agreement State while ensuring the Department has the necessary funding for the regulation, licensing, and inspection of radioactive material user operations and for termination of radioactive material licenses.

In summary, the benefits of this proposed rulemaking outweigh any cost and adverse effect, because the proposed increase to the Chapter 218 fees will allow the Department to continue to implement existing programs required by law and assure adequate funding is available for the Commonwealth to carry out its duties under NRC's Agreement State program while continuing to protect public health from the harmful effects of overexposure 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.

(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.

All Chapter 218 fees vary by type and complexity of material or modality and were calculated to cover the Department's costs of implementing the programs as required by the Radiation Protection Act. Costs to the regulated community associated with this proposed rulemaking are the increase of the Chapter 218 fees by 30 percent for radiation-producing machine registrants, accelerator licensees, and service providers and by 10 percent for radioactive material licensees. Overall, the proposed rulemaking will increase Chapter 218 fees paid to the Department by approximately \$1,226,000 per year in the radiation-producing machine section and \$430,000 per year in the radioactive materials section. The total increase in fees to the regulated community will be \$1,618,410.

With these fee increases, the radiation-producing machine section would receive a total of \$5,856,000 per year, and the radioactive materials section would receive a total of \$4,944,000 per year.

The Department multiplied the number of entities that will be subject to the increased fees by the dollar amounts of the increased fees to derive the overall estimate.

No other compliance, legal, accounting, or consulting procedure costs or savings are required by this proposed rulemaking.

(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.

Fees for local governments that use licensed radioactive material and radiation-producing machines will increase by 10% and 30% respectively. Approximately nine (9) local governments will experience radioactive material license fee increases, and approximately 70 local governments will experience radiation-producing machine registration increases. The total increase in fees paid to the Department by local governments will be \$23,599 per year (\$22,810 for radiation-producing machines and \$789 for radioactive materials) as a result of this proposed rulemaking.

The Department subtracted the current amount collected from all local government licenses and registrations from the proposed amount that would be collected after the increase goes into effect to derive the overall estimate of the total increase.

No other compliance, legal, accounting, or consulting procedure costs or savings are required by this final-form rulemaking.

(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.

Fees for Commonwealth agencies that use licensed radioactive material and radiation-producing machines would increase by 10% and 30% respectively. Approximately six (6) Commonwealth agencies would experience radioactive material license fee increases, and nine (9) agencies would experience radiation-producing machines registration fee increases. The total increase in fees paid to the Department by Commonwealth agencies will be \$20,026.50 per year (\$17,422.50 for radiation-producing machines and \$2,604 for radioactive materials) as a result of this proposed rulemaking.

The Department subtracted the current amount collected from all Commonwealth agency licenses and registrations from the proposed amount that would be collected after the increase goes into effect to derive the overall estimate of the total increase.

No other compliance, legal, accounting, or consulting procedure costs or savings are required by this final-form rulemaking.

(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 does not require additional recordkeeping or reporting requirements.

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

No, forms are not required for implementation of this proposed regulation.

(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 2021/2022 | FY +1 2022/2023 | FY +2 2023/2024 | FY +3 2024/2025 | FY +4 2025/2026 | FY +5 2026/2027 |
|--------------------------------|---------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| 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 |

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|-----------------------------|---|---|-------------|-------------|-------------|-------------|
| COSTS: | | | | | | |
| Regulated Community | 0 | 0 | \$1,618,410 | \$1,618,410 | \$1,618,410 | \$1,618,410 |
| Local Government | 0 | 0 | \$24,190 | \$24,190 | \$24,190 | \$24,190 |
| State Government | 0 | 0 | \$13,400 | \$13,400 | \$13,400 | \$13,400 |
| Total Costs | 0 | 0 | \$1,656,000 | \$1,656,000 | \$1,656,000 | \$1,656,000 |
| 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.

| Program | FY -3 2018/2019 | FY -2 2019/2020 | FY -1 2020/2021 | Current FY 2021/2022 |
|---------------------------|----------------------------|----------------------------|----------------------------|---------------------------------|
| Radiation Protection Fund | \$11,975,000 | \$12,809,000 | \$12,140,000 | \$15,004,000 |

(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.

Small businesses covered by the radiological health provisions for radiation-producing machines, accelerators, and service providers in this proposed rulemaking include, for example, dentist offices and private medical practices. While the Department does not collect information regarding the size of each business that is an X-ray registrant, licensee, or service provider, the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking.

Reduced radioactive material license fees are available for small businesses (see Chapter 218 Appendix A, categories SB1 and SB2). The Department assumes a portion of radioactive material licensees are small businesses, as defined in Section 3 of the Regulatory Review Act, 71 P.S. § 745.3. This definition references the Code of Federal Regulations (13 CFR Part 121), which defines a small business based on the dollar amount of gross annual receipts generated by the business or the number of employees based upon employment. The gross annual receipts or number of employees required to qualify as a small business is different for each type of entity.

In implementing the program, the Department uses a different definition of “small business” than the CFR definition. Specifically, the Department uses a small business form to collect annual

information from licensees to verify whether they qualify for the reduced Chapter 218 fees. The small business form, which was modeled after NRC's Form 526 (Certification of Small Entity Status), requires the submission of copies of business organization forms and categorizes business as follows:

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| Small Business Less than \$350,000 | \$350,000 to \$5,000,000 |
| Manufacturing Industry Less than 35 Employees | 35 to 500 Employees |
| Small Organization Less than \$350,000 | \$350,000 to \$5,000,000 |
| Small Governmental Jurisdiction Less than 20,000 Population | 20,000 to 50,000 Population |
| Small Education Institution Less than 35 Employees | 35 to 500 Employees |

As an example, a Certification of Small Entity Status form submitted by a radiographic laboratory would have qualified under both the CFR definition of a small business and the Department's definition. This particular lab would qualify under the CFR because its annual gross income was less than \$15,000,000 (see 13 CFR § 121.201 (NAICS Code 541380)) and qualified under the Department's definition because its average gross income over its last 3 years was between \$350,000 and \$5,000,000.

Based upon the Department's definitions, 85 radioactive material licensees in Pennsylvania qualify as small businesses.

- (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.

The proposed rulemaking does not require additional reporting, recordkeeping or other administrative costs for small business compliance.

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

All radiation-producing machine registrants, accelerator licensees, and service providers that are small businesses will experience a 30 percent increase in their annual fees, while all radioactive material licensees that are small businesses will experience a 10 percent increase in fees. Considering increases in inflation since the last time these fee categories were increased (2009 for the Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area and 2018 for the Radioactive Materials and Decommissioning program area), the cost of compliance is being increased in line with inflation rates. Therefore, the Department does not believe that the proposed rulemaking will have an adverse impact on small businesses.

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

There are no less intrusive or less costly methods of achieving the purpose of the regulation.

(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.

Reduced Chapter 218 fees for radioactive materials licensees are already available for small businesses that will be affected by the increased fees in the proposed rulemaking, as reflected in the SB1 and SB2 fee categories at the bottom of Appendix A (Fees for Radioactive Material Licenses). The Department does not collect information regarding the size of each business that is an X-ray registrant, licensee, or service provider, but the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking when calculating proposed fee increases. Therefore, no additional special provisions were developed for this proposed rulemaking.

(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 proposed rulemaking as the Radiation Protection Act (35 P.S. § 7110.401) requires that fees be established to cover the Department's Radiation Protection Program costs.

(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;

Less stringent compliance and reporting requirements are not necessary, because the compliance requirements in the proposed rulemaking are minimal.

b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

Less stringent schedules or deadlines for and the consolidation or simplification of compliance or reporting are not necessary, because the compliance and reporting requirements in the proposed rulemaking are minimal.

c) The consolidation or simplification of compliance or reporting requirements for small businesses;

Less stringent schedules or deadlines for and the consolidation or simplification of compliance or reporting are not necessary, because the compliance and reporting requirements in the proposed rulemaking are minimal.

d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and

The proposed rulemaking does not require design or operation standards.

- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Reduced Chapter 218 fees for radioactive material licensees are already available for small businesses that will be affected by the increased fees in the proposed rulemaking, as reflected in the SB1 and SB2 fee categories at the bottom of Appendix A (Fees for Radioactive Material Licenses). The Department does not collect information regarding the size of each business that is an X-ray registrant, licensee, or service provider, but the Department considered the vast majority of these entities to be small businesses for the purpose of this rulemaking.

(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 the basis for this proposed rulemaking. The Department prepared the “Three-Year Regulatory Fee and Program Cost Analysis Report” (Report) to summarize the Department’s fee collections and program costs by functional area for the past three fiscal years and the next three projected years. The functional areas for purposes of this proposed rulemaking are grouped into three categories: Radiation-producing machines (i.e., Accelerator, X-ray, and Vendors/Service Providers); Radioactive Materials and Decommissioning; and Radon. The conclusion of the Report is that Radioactive Materials and Radiation-producing machines (Chapter 218 fees) require an increase to cover program costs. A copy of the report is attached to this proposed rulemaking.

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

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| A. The length of the public comment period: | <u>30 days</u> |
| B. The date or dates on which any public meetings or hearings will be held: | <u>None scheduled</u> |
| C. The expected date of delivery of the final-form regulation: | <u>Quarter 2, 2023</u> |
| D. The expected effective date of the final-form regulation: | <u>30 days after publication in the <i>Pennsylvania Bulletin</i></u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>30 days after publication in the <i>Pennsylvania Bulletin</i></u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>Not applicable</u> |

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

The Board is not establishing 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.