

<p><b>Regulatory Analysis Form</b> (Completed by Promulgating Agency)</p> <p><small>(All Comments submitted on this regulation will appear on IRRC's website)</small></p>	<p style="text-align: center;"><b>INDEPENDENT REGULATORY REVIEW COMMISSION RECEIVED</b></p> <p style="text-align: center;">AUG 10 2022</p> <p style="text-align: center;">Independent Regulatory Review Commission</p> <p>IRRC Number: 3352</p>
<p>(1) Agency: Department of Environmental Protection</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, 717-772-3277, laurgriffi@pa.gov                  Secondary Contact: Kate Cole, 717-787-8649, kacole@pa.gov</p>	
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> Proposed Regulation  <input type="checkbox"/> Final Regulation  <input type="checkbox"/> Final Omitted Regulation</p>	<p><input type="checkbox"/> Emergency Certification Regulation;  <input type="checkbox"/> Certification by the Governor  <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
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated Community</b>	0	0	0	0	0	0
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	0	0	0	0	0
<b>Total Savings</b>	0	0	0	0	0	0

<b>COSTS:</b>						
<b>Regulated Community</b>	0	0	\$1,618,410	\$1,618,410	\$1,618,410	\$1,618,410
<b>Local Government</b>	0	0	\$24,190	\$24,190	\$24,190	\$24,190
<b>State Government</b>	0	0	\$13,400	\$13,400	\$13,400	\$13,400
<b>Total Costs</b>	0	0	\$1,656,000	\$1,656,000	\$1,656,000	\$1,656,000
<b>REVENUE LOSSES:</b>						
<b>Regulated Community</b>	0	0	0	0	0	0
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	0	0	0	0	0
<b>Total Revenue Losses</b>	0	0	0	0	0	0

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

<b>Program</b>	<b>FY -3 2018/2019</b>	<b>FY -2 2019/2020</b>	<b>FY -1 2020/2021</b>	<b>Current FY 2021/2022</b>
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:

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:

- |   |  |
|---|--|
| 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.

**RADIATION PROTECTION PROGRAM  
THREE-YEAR REGULATORY FEE AND PROGRAM COST ANALYSIS REPORT  
TO THE ENVIRONMENTAL QUALITY BOARD**

---

The Department of Environmental Protection (DEP or Department) Radiation Protection Program (RPP) was established to carry out the comprehensive program of radiation protection in the Commonwealth of Pennsylvania (Commonwealth) as required by the Radiation Protection Act, 35 P.S. §§ 7110.101—7110.703 (RPA). Section 401 of the RPA (35 P.S. § 7110.401) and Section 8 of the Radon Certification Act, 63 P.S. § 2008, require that fees be established to cover DEP's RPP costs. The RPP includes the functions of both the Central Office Bureau of Radiation Protection (BRP) and the Regional Offices.

As required by 25 Pa. Code § 218.11(i) and Chapter 240, Appendix A, DEP prepared an updated Three-Year Regulatory Fee and Program Cost Analysis Report (Report) for the period of 2018-2021 to present to the Environmental Quality Board. The three RPP areas this cost analysis addresses are: Accelerator, Radiation-Producing Machines, and Vendors/Service Providers; Radioactive Materials and Decommissioning; and Radon. The last fee increase for Accelerator, Radiation-Producing Machines and Vendors/Service Providers was proposed in 2006 and effective in 2009. The last fee increase for Radioactive Materials, Decommissioning and Radon was proposed in 2015 and effective in 2018.

The purpose of this report is to review the adequacy of fees based on projected RPP costs through FY2027-2028. Following is a summary of the RPP fee collections and program costs by functional area.

**ACCELERATOR, X-RAY AND VENDORS/SERVICE PROVIDERS**

**BACKGROUND**

Through a staff of 71 located in the central and regional offices, the RPP's Radiation Control Division administers the radiation-producing machine registration and inspection program, the Mammography Quality Standards Act program, the particle accelerator licensing and inspection program, and the vendor/service provider registration program.

**Radiation-Producing Machine Registration and Inspection Program**

The Radiation Control Division is responsible for the registration and inspection of over 11,000 facilities possessing about 33,000 X-ray units. These facilities include hospitals, clinics, and medical and dental offices.

In order to ensure that patients, personnel, and the environment are protected and that operators are properly trained, quality control is performed, and radiation equipment and facilities meet current protection standards, the Department has a goal to routinely inspect all facilities at least once every four years or as necessary to ascertain compliance or non-compliance with applicable regulations. Major facilities may be inspected every two to three years. Approximately 2,800 site inspections are conducted each year.

Users of radiation-producing machines are required to register with the Division, indicate the number and type of units possessed, and designate an individual responsible for radiation safety. Users pay registration fees based on the type of facility and the number of X-ray units they have. The fee amounts

are listed in 25 Pa. Code § 218.11(a) (relating to registration, renewal of registration, and license fees) and are provided in Appendix A of this report. The Division oversees the production and issuance of associated registration certificates, renewal letters, and invoices and the collection of initial and annual fees.

#### Mammography Quality Standards Act Activities

The federal Mammography Quality Standards Act (MQSA) was signed into law on Oct. 27, 1992. The MQSA ensures that women and men receive high-quality mammography services for early breast cancer detection through the establishment of a federal certification and inspection program. The Act authorizes the U.S. Food and Drug Administration (USFDA) to obtain state and local assistance in enforcing the MQSA requirements, including annual inspections of all certified mammography facilities. DEP, under a \$588,000 reimbursement contract with the USFDA, conducts inspections of each of the Commonwealth's more than 300 facilities which perform mammographic X-ray procedures. This contract is modified most years due to the changing number of facilities. The average amount is \$575,000. These inspections are conducted on a schedule prescribed by the USFDA. This schedule calls for a facility to be inspected once every 12 months.

#### Accelerator Licensing and Inspection

The Commonwealth requires licensing of all particle accelerators within the Commonwealth for industrial use, research, or medical purposes. A person who intends to purchase, construct, or acquire an accelerator must notify the Department of this intent by filing the appropriate application for a specific license within 30 days after the initial order is issued to obtain any or all parts of the accelerator. Annual fees for licensed particle accelerators are listed in 25 Pa. Code § 218.11(d) and are provided in Appendix A of this report. About 150 facilities have approximately 250 licensed accelerators within the Commonwealth.

#### Vendor/Service Provider Registration

The Commonwealth administers a registration program for vendors/service providers who sell, lease, install and/or service radiation-producing machines. Commonwealth regulations require that each vendor/service provider doing business within the Commonwealth must be registered prior to providing such services. To register, each vendor/service provider must complete a registration application and return that application with the associated fee to BRP. The registration is renewable for 12-month periods following submission of the applicable fee as listed in 25 Pa. Code § 218.11(k) and provided in Appendix A of this report. Registration of machine vendors ensures the Department will be notified of the location and owner of new X-ray equipment installations.

### **REVENUE TREND AND PROJECTION**

The combined revenue from these RPP areas has been relatively stable. However, implementation costs are expected to continue to increase. This analysis assumes the purchase of new X-ray testing equipment, and a 3% increase in all operational costs annually for future years, and a 4.75% increase in personnel costs per the contract agreement.

**COMMENT**

The RPP has conducted a detailed fiscal analysis of these program areas. Based on current fee collections and existing available funds in these program areas, this analysis indicates with existing reserve funds and current fees, the fund balance will be negative in FY 2023-24 for radiation-producing machine and vendor registrations and accelerator license categories.

**Accelerator, X-ray and Vendors/Service Providers\***

	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28
Beginning Balance	\$2,302	\$2,338	**\$2,848	\$2,445	\$1,915	\$1,284	-\$588	-\$1,742	-\$3,160	-\$4,854
Fee Collection	\$4,449	\$4,200	\$4,208	\$4,200	\$4,200	\$4,200	\$4,200	\$4,200	\$4,200	\$4,200
Fines and Penalties	\$89	\$69	\$68	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MQSA Contract	\$530	\$575	\$229	\$588	\$575	\$575	\$575	\$575	\$575	\$575
Total Revenue	\$5,068	\$4,844	\$4,505	\$4,788	\$4,775	\$4,775	\$4,775	\$4,775	\$4,775	\$4,775
Program Costs	\$5,033	\$5,142	\$4,908	\$5,318	\$5,406	\$5,568	\$5,735	\$5,907	\$6,095	\$6,267
Ending Balance	\$2,338	\$2,040	\$2,445	\$1,915	\$1,284	-\$588	-\$1,742	-\$3,160	-\$4,854	-\$6,837

\*All figures in thousands of dollars.

\*\*Funds were moved from Radioactive Materials and Decommissioning to help support the Radiation-Producing Machines area due to its decreasing revenue.

**RADIOACTIVE MATERIALS & DECOMMISSIONING**

**BACKGROUND**

DEP’s Radiation Control Division is also responsible for the regulation, licensing, and inspection of radioactive material user operations and, along with the Decommissioning Section of the Decommissioning and Surveillance Division, is responsible for termination of radioactive material licenses (e.g., for by-product, source, and special nuclear material).

**Radioactive Material Licensing and Inspection**

Users of all by-product, source, and special nuclear material are required to obtain a license from DEP prior to obtaining those radioactive materials. This material is used in hospitals, colleges, and industries for medical, research, and industrial purposes. The Department issues specific, general, and reciprocity licenses for the use of radioactive material in the Commonwealth. The objective of the licensing program is to ensure radioactive material is used safely, disposed of properly, and facilities are free from contamination when licensed operations are terminated. Annual license fees for radioactive material arc

listed in 25 Pa. Code Chapter 218, Appendix A (relating to fees for radioactive material licenses) and provided in Appendix A of this report.

### Decommissioning

The Decommissioning Section performs technical reviews of decontamination and decommissioning (D&D) activities for radioactive materials licensees and non-licensed radiologically contaminated sites in accordance with appropriate Commonwealth regulations. Typical reviews include site characterization plans, health and safety plans, decommissioning plans, survey reports, and the evaluation of decommissioning funding plans and financial assurance mechanisms. The Decommissioning Section also performs on-site reviews and inspections of D&D activities for occupational, public, and environmental radiation protection concerns. These activities include performing confirmatory surveys and sampling to ensure the cleanup levels established for the site have been met. This Section would also perform independent oversight and sampling at decommissioning nuclear power plant sites (e.g., TMI Unit 2). This work is performed at full cost recovery.

### **REVENUE TREND AND PROJECTION**

Fee collections for radioactive material licensing have been trending down since the national economic recession of 2008. BRP expects the COVID-19 pandemic will also impact this RPP area. Universities and industries that use radioactive material have been consolidating or finding other operational methods that do not require a license, and many licensees have opted to be licensed under a small business fee category at a lower cost, which is specified in 25 Pa. Code Chapter 218, Appendix A.

Actual RPP personnel costs (salaries and benefits) have increased approximately 14% since the last fee increase in 2018, while fees have remained fixed. This analysis assumes a 3% increase in all operational costs annually for future years, and a 4.75% increase in personnel costs per Pennsylvania's union-covered employee contract agreement.

Work in the Decommissioning Program is driven by industry trends, federal funding, and ongoing discovery of contaminated sites. Most work performed by the Decommissioning Program is subject to full cost recovery from the facility owner. Currently, the DEP hourly rate charge for these activities is \$225. Costs of decommissioning activities at sites where no responsible party exists are paid from the Radiation Protection Fund.

### **COMMENT**

The RPP has conducted a detailed fiscal analysis of these program areas. This analysis indicates with existing reserve funds and current fees, the fund balance will be negative in FY 2024-25 in the Radioactive Materials and Decommissioning area.

### Radioactive Materials Licensing\*

	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28
Beginning Balance	\$3,285	\$3,904	**\$2,848	\$2,918	\$2,295	\$1,646	\$824	-\$180	-\$1,373	-\$2,765
Fee Collection	\$4,413	\$3,877	\$3,204	\$3,200	\$3,200	\$3,200	\$3,200	\$3,200	\$3,200	\$3,200
Fines and Penalties	\$133	\$73	\$37	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Revenue	\$4,546	\$3,950	\$3,241	\$3,200	\$3,200	\$3,200	\$3,200	\$3,200	\$3,200	\$3,200
Program Costs	\$3,928	\$3,910	\$3,171	\$3,823	\$3,849	\$3,964	\$4,083	\$4,206	\$4,332	\$4,462
Ending Balance	\$3,904	\$3,944	\$2,918	\$2,295	\$1,646	\$824	-\$180	-\$1,373	-\$2,765	-\$4,364

\*All figures in thousands of dollars.

\*\*Funds were moved from Radioactive Materials and Decommissioning to help support the Radiation-producing Machines and Radon areas due to their decreasing revenue.

### RADON

#### BACKGROUND

Pennsylvania has some of the highest indoor air radon levels in the country, and perhaps the world. According to the National Academy of Sciences and US Environmental Protection Agency (EPA), radon is the second leading cause of lung cancer. The Department's Radon Program is one of the most robust in the nation and provides a variety of regulatory and public service activities. These activities include:

- Implementing the EPA State Indoor Radon Grant (SIRG) (e.g., education and outreach through public service announcements (PSA); grants to universities; outreach to builders, realtors, and the medical community; and, free test kits to mothers of newborns).
- Certifying radon laboratories, mitigators, and testers.
- Performing routine inspections of mitigation installations, mitigation offices, testing, and laboratory facilities.
- Performing blind testing on radon-detection devices.
- Providing diagnostic services to homeowners and mitigators on difficult-to-remediate houses.
- Performing "targeted" surveys in areas of high radon activity through the American Lung Association.
- Assisting homeowners and mitigators with difficult to remediate buildings.
- Providing free confirmatory testing to homeowners who have installed active mitigation systems and to homes with radon levels greater than 100 pCi/L.

- Developing and maintaining databases for calculations, tracking data, and surveys; maintaining and configuring DEP databases with the Bureau of Information Technology for certification tracking.
- Providing a wide variety of public information services to increase awareness of the radon issue and encouraging testing and mitigation.
- Providing unbiased and expert advice on all aspects of radon to the general public.
- Performing radon-related research projects and contributing technical information to the radon industry.
- Serving on radon-related national committees.

## **REVENUE TREND AND PROJECTION**

The Department performs significant outreach and PSAs that encourage homeowners to test and mitigate. This creates interdependency between outreach and revenue, allowing the program to maintain stability in certification fee revenue from radon laboratories, mitigators and testers. Historically, certification fee revenue has not covered Radon Program costs. Current certification fee amounts are listed in 25 Pa. Code Chapter 240, Appendix A (relating to radon certification fee schedule) and are provided in Appendix A of this report. Grant funding from the EPA SIRG provides a small percentage of revenue to offset administrative costs, but the Radon Program has always been barely self-sustaining.

SIRG funds have been about \$429,000 annually in recent years, which is utilized mainly for staff training, PSAs, equipment and supplies, home shows, and some support of salaries and benefits. It also provides funds to the American Lung Association for radon outreach. With tight federal budgets, the SIRG funding cannot be relied upon as a stable funding source and it can cease at any time; therefore, only the current contract is depicted in the table below.

## **RECOMMENDATION AND COMMENT**

The RPP has conducted a detailed fiscal analysis of this program area. This analysis indicates with existing reserves fund and fees, the Radon program area is sufficiently funded.

The table below provides revenue and program cost projections:

### Radon Program\*

	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28
Beginning Balance	\$2,388	\$2,505	\$2,849 <sup>+</sup>	\$2,845	\$2,643	\$2,452	\$2,201	\$1,889	\$1,524	\$1,106
Fee Collection	\$360	\$241	\$370	\$300	\$300	\$300	\$300	\$300	\$300	\$300
Installation Fee <sup>#</sup>	\$592	\$671	\$609	\$600	\$600	\$600	\$600	\$600	\$600	\$600
Fines and Penalties	\$14	\$12	\$19	\$0	\$0	\$0	\$0	\$0	\$0	\$0
SIRG <sup>^</sup>	\$353	\$385	\$468	\$429	\$429	\$429	\$0	\$0	\$0	\$0
Total Revenue	\$1,319	\$1,309	\$1,466	\$1,329	\$1,329	\$1,329	\$1,329	\$1,329	\$1,329	\$1,329
Program Costs	\$1,152	\$1,252	\$1,470	\$1,531	\$1,520	\$1,566	\$1,613	\$1,661	\$1,711	\$1,762
Ending Balance	\$2,505	\$2,562	\$2,845	\$2,643	\$2,452	\$2,201	\$1,889	\$1,524	\$1,106	\$631

\*All figures in thousands of dollars.

<sup>#</sup>\$50 fee for each mitigation installation

<sup>^</sup>State Indoor Radon Grant (SIRG)

<sup>+</sup>Funds were moved from Radioactive Materials and Decommissioning to help support the Radon area due to its decreasing revenue.

### SUMMARY OF RECOMMENDATIONS

#### Accelerator, Radiation-Producing Machines, and Vendors/Service Providers

Based on current fee collections and existing available funds in these program areas, this analysis indicates that in FY 2023-24 there will not be sufficient revenue for the radiation-producing machine and vendor registrations and accelerator license categories. The program also determined the chiropractor category should be moved from the category of "Other" to the same category of "Dentists, Podiatrists, and Veterinarians" as their equipment is more in-line with that category. The RPP recommends proposing a future rulemaking to increase fees to adequately fund this program area and correct the fee category for chiropractors.

#### Radioactive Materials and Decommissioning

This analysis indicates that in FY 2024-25 there will not be sufficient revenue for license categories in the Radioactive Materials area and the Decommissioning hourly rate. The RPP recommends proposing a future rulemaking to increase fees to adequately fund this program area.

#### Radon

This analysis indicates that after FY 2027-28 there will be sufficient revenue to maintain the current Radon Program and no rulemaking to adjust fees for Radon will be necessary at this time.

**APPENDIX A**  
**Current Radiation Protection Program Fee Amounts**

**Radiation-Producing Machine Registration and Inspection Program:**

<b>Fee Type</b>	<b>Fee Amount</b>	<b>Regulatory Citation</b>
Dentists, podiatrists, veterinarians	Annual Administrative Fee: \$100 Annual Fee per Device: \$50	25 Pa. Code § 218.11(a)
Hospitals	Annual Administrative Fee: \$725 Annual Fee per Device: \$50	25 Pa. Code § 218.11(a)
Other Facilities	Annual Administrative Fee: \$350 Annual Fee per Device: \$50	25 Pa. Code § 218.11(a)

**Accelerator Licensing and Inspection:**

<b>Fee Type</b>	<b>Fee Amount</b>	<b>Regulatory Citation</b>
Accelerators, below 50 MeV, other than for ion implantation	\$2,100 for the first accelerator at a facility  \$700 for each additional unit at the same facility	25 Pa. Code § 218.11(d)(1)
Accelerators used for ion implantation	\$700 for the first accelerator at a facility  \$70 for each additional unit at the same facility	25 Pa. Code § 218.11(d)(2)
Accelerators 50 MeV and above	Minimum annual fee of \$2,100 for the first accelerator at the facility  \$700 for each additional unit at the same facility  Additional invoices will be issued by the Department at regular intervals at least quarterly when net costs are incurred above the minimum annual fee.	25 Pa. Code § 218.11(d)(3)

**Vendor/Service Provider Registration:**

<b>Fee Type</b>	<b>Fee Amount</b>	<b>Regulatory Citation</b>
Annual registration fee	\$140	25 Pa. Code § 218.11(k)

**Radioactive Material Licensing and Inspection:**

<b>Fee Type</b>	<b>Fee Amount</b>	<b>Regulatory Citation</b>
Special Nuclear Material Sealed Source Gauges (X-Ray Fluorescence)	Annual Fee: \$3,150	25 Pa. Code Chapter 218, Appendix A
Special Nuclear Material—Other	Annual Fee: \$8,700	25 Pa. Code Chapter 218, Appendix A
Source Material—Metal Extraction	Annual Fee: \$45,100	25 Pa. Code Chapter 218, Appendix A
Removal of Radioactive Contaminants from Drinking Water	Annual Fee: \$16,800	25 Pa. Code Chapter 218, Appendix A
Source Material as Shielding	Annual Fee: \$1,125	25 Pa. Code Chapter 218, Appendix A
Source Material—Other (not 11c2)	Annual Fee: \$20,100	25 Pa. Code Chapter 218, Appendix A
Manufacturing & Distribution Commercial Broad Scope—10 CFR 30, 33	Annual Fee: \$43,650	25 Pa. Code Chapter 218, Appendix A
Manufacturing, Refurbishing & Distribution Commercial Specific License—10 CFR 30	Annual Fee: \$12,450	25 Pa. Code Chapter 218, Appendix A
Manufacturing & Distribution Pharmaceuticals—10 CFR 32.72—32.74	Annual Fee: \$17,850	25 Pa. Code Chapter 218, Appendix A
Pharmaceuticals—Distribution Only—10 CFR 32.7x	Annual Fee: \$10,200	25 Pa. Code Chapter 218, Appendix A
Irradiator—Shielded Source	Annual Fee: \$6,300	25 Pa. Code Chapter 218, Appendix A
Irradiator—Unshielded <10kCi	Annual Fee: \$11,700	25 Pa. Code Chapter 218, Appendix A
Irradiator—Unshielded ≥10kCi	Annual Fee: \$46,800	25 Pa. Code Chapter 218, Appendix A
Distribution As Exempt—No Review of Device	Annual Fee: \$16,050	25 Pa. Code Chapter 218, Appendix A
Distribution—SSD Devices to Part 31 GLs	Annual Fee: \$3,750	25 Pa. Code Chapter 218, Appendix A
Distribution—No Review-Exempt Sealed Source	Annual Fee: \$2,850	25 Pa. Code Chapter 218, Appendix A
Research & Development Broad Scope	Annual Fee: \$22,650	25 Pa. Code Chapter 218, Appendix A
Research & Development	Annual Fee: \$8,400	25 Pa. Code Chapter 218, Appendix A
Services other than Leak Testing, Waste Disposal or Calibration	Annual Fee: \$12,750	25 Pa. Code Chapter 218, Appendix A
Radiography	Annual Fee: \$21,150	25 Pa. Code Chapter 218, Appendix A

Other Byproduct Material	Annual Fee: \$4,050	25 Pa. Code Chapter 218, Appendix A
Generally licensed devices under § 217.143 (relating to certain measuring, gauging or controlling devices)	Annual Fee: \$480	25 Pa. Code Chapter 218, Appendix A
Greater than the General License Limits in 10 CFR 31.12(a)(3), (4) or (5) but not more than ten times those Limits	Annual Fee: \$3,150	25 Pa. Code Chapter 218, Appendix A
Greater than ten times the General License Limits in 10 CFR 31.12(a)(3), (4) or (5)	Annual Fee: \$4,050	25 Pa. Code Chapter 218, Appendix A
Manufacturing & Distribution Pharmaceuticals—Accelerator Produced Only	Annual Fee: \$17,700	25 Pa. Code Chapter 218, Appendix A
Waste Storage, Processing or Disposal	Annual Fee: Full Cost	25 Pa. Code Chapter 218, Appendix A
Waste Packaging or Repackaging	Annual Fee: \$18,000	25 Pa. Code Chapter 218, Appendix A
Waste Receipt of Prepackaged for Disposal	Annual Fee: \$13,800	25 Pa. Code Chapter 218, Appendix A
Well Logging & Non Field Flood Tracers	Annual Fee: \$6,600	25 Pa. Code Chapter 218, Appendix A
Well Logging Field Flood Tracer Studies	Annual Fee: Full Cost	25 Pa. Code Chapter 218, Appendix A
Nuclear Laundry	Annual Fee: \$43,200	25 Pa. Code Chapter 218, Appendix A
Human Use—Teletherapy	Annual Fee: \$20,550	25 Pa. Code Chapter 218, Appendix A
Human Use—Broad Scope (except Teletherapy)	Annual Fee: \$36,250	25 Pa. Code Chapter 218, Appendix A
Human Use (except Teletherapy)	Annual Fee: \$7,350	25 Pa. Code Chapter 218, Appendix A
Specifically licensed sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	Annual Fee: \$3,150	25 Pa. Code Chapter 218, Appendix A
Decontamination, Decommissioning, Reclamation or Site Restoration	Annual Fee: Full Cost	25 Pa. Code Chapter 218, Appendix A
Reciprocity (180 days/year)	Annual Fee: \$2,250	25 Pa. Code Chapter 218, Appendix A
Small Business—Category 1	Annual Fee: \$3,450	25 Pa. Code Chapter 218, Appendix A
Small Business—Category 2	Annual Fee: \$750	25 Pa. Code Chapter 218, Appendix A

Radon Certification:

<b>Fee Type</b>	<b>Fee Amount</b>	<b>Regulatory Citation</b>
Testing Individual	\$525 every 2 years	25 Pa. Code Chapter 240, Appendix A
Testing Employee	\$150 every 2 years	25 Pa. Code Chapter 240, Appendix A
Testing Firm	\$1,050 every 2 years	25 Pa. Code Chapter 240, Appendix A
Mitigation Individual	\$450 every 2 years	25 Pa. Code Chapter 240, Appendix A
Mitigation Firm	\$1,050 every 2 years	25 Pa. Code Chapter 240, Appendix A
Laboratory Individual	\$600 every 2 years	25 Pa. Code Chapter 240, Appendix A
Laboratory Firm	\$1,125 every 2 years	25 Pa. Code Chapter 240, Appendix A
Primary Testing Device Listing	\$150 every 2 years	25 Pa. Code Chapter 240, Appendix A
Course Provider	\$565 every 2 years	25 Pa. Code Chapter 240, Appendix A
Late Application Renewal	\$150	25 Pa. Code Chapter 240, Appendix A
Late 45-Day Reporting	\$150	25 Pa. Code Chapter 240, Appendix A
Radon Mitigation System Fee	\$50 for each radon mitigation system installed or activated	25 Pa. Code Chapter 240, Appendix A



**FACE SHEET  
FOR FILING DOCUMENTS  
WITH THE LEGISLATIVE REFERENCE  
BUREAU**

**(Pursuant to Commonwealth Documents Law)**

**RECEIVED**

**AUG 10 2022**

**Independent Regulatory  
Review Commission**

**DO NOT WRITE IN THIS SPACE**

Copy below is hereby approved as to form and legality.  
Attorney General

By: **Amy M.  
Elliott**  
(Deputy Attorney General)

**7/26/2022**  
DATE OF APPROVAL

Check if applicable  
Copy not approved. Objections attached.

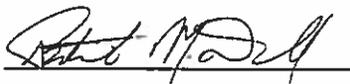
Copy below is hereby certified to be true and  
correct copy of a document issued, prescribed or  
promulgated by:

**DEPARTMENT OF ENVIRONMENTAL  
PROTECTION  
ENVIRONMENTAL QUALITY BOARD**

(AGENCY)

DOCUMENT/FISCAL NOTE NO. **7-574**

DATE OF ADOPTION **June 14, 2022**

BY 

TITLE **PATRICK MCDONNELL  
CHAIRPERSON**

EXECUTIVE OFFICER CHAIRPERSON OR SECRETARY

Copy below is hereby approved as to form and legality  
Executive or Independent Agencies

BY 

**June 27, 2022**  
DATE OF APPROVAL

(Deputy General Counsel)  
(Chief Counsel - Independent Agency)  
(Strike inapplicable title)

Check if applicable. No Attorney General Approval  
or objection within 30 days after submission.

**NOTICE OF PROPOSED RULEMAKING**

**DEPARTMENT OF ENVIRONMENTAL PROTECTION  
ENVIRONMENTAL QUALITY BOARD**

**Radiological Health Fees**

**25 Pa. Code Chapter 218**



**PROPOSED RULEMAKING  
ENVIRONMENTAL QUALITY BOARD  
[ 25 PA. CODE CH. 218]**

**Radiological Health Fees**

The Environmental Quality Board (Board) proposes to amend Chapter 218 (relating to fees) to update the regulations to read as set forth in Annex A. The proposed amendments to Chapter 218 increase the annual fees for radiation-producing machine and service provider (vendor) registrations, accelerator licenses, and radioactive material licenses, and increases the hourly rate professional fee associated with certain full cost recovery licenses.

This proposed rulemaking was adopted by the Board at its meeting on June 14, 2022.

*A. Effective Date*

This proposed rulemaking will be effective 30 days after publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

*B. Contact Persons*

For further information, contact John Chipppo, Chief, Division of Radiation Control, P.O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 783-9730; or Christopher Minott, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 783-8075. Persons with a disability may use the Pennsylvania Hamilton Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposed rulemaking is available on the Department of Environmental Protection's (Department) web site at [www.dep.pa.gov](http://www.dep.pa.gov) (Select "Public Participation," then "Environmental Quality Board" and then navigate to the Board meeting of June 14, 2022).

*C. Statutory Authority*

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).

*D. Background and Purpose*

The Department of Environmental Protection's Radiation Protection Program (RPP) was established to carry out the comprehensive program of radiation protection in this Commonwealth as required by the Radiation Protection Act (RPA) (35 P.S. §§ 7110.101—7110.703). Section 401 of the RPA (35 P.S. § 7110.401) and section 8 of the Radon Certification Act (63 P.S. § 2008) require that fees be established to cover the Department's RPP costs. Section 302(b) of the RPA (35 P.S. § 7110.302(b)) requires the Board to review the radiation protection fee structure every 3 years.

On February 15, 2022, the Department presented its Three-Year Regulatory Fee and Program Cost Analysis Report (Report) in accordance with § 218.11(l) (relating to registration, renewal of registration and license fees) and Chapter 240, Appendix A (relating to radon certification fee schedule) to the Board. The Report covered the period of 2018-2021 and analyzed costs for three RPP areas, including Accelerator, Radiation-Producing Machines, and Vendors/Service Providers; Radioactive Materials and Decommissioning; and Radon.

*Accelerator, Radiation-Producing Machines, and Vendors/Service Providers Analysis*

Through a staff of 71 located in the Department's central and regional offices, the RPP's Radiation Control Division administers the radiation-producing machine registration and inspection program, the Mammography Quality Standards Act program, the particle accelerator licensing and inspection program, and the vendor/service provider registration program.

The Radiation Control Division is responsible for the registration and inspection of over 11,000 facilities possessing about 33,000 X-ray units. These facilities include hospitals, clinics, and medical and dental offices. Users of radiation-producing machines are required to register with the Radiation Control Division, indicate the number and type of units possessed, and designate an individual responsible for radiation safety. Users pay registration fees based on the type of facility and the number of X-ray units they have. The fee amounts are listed in § 218.11(a).

The federal Mammography Quality Standards Act (MQSA) (42 U.S.C.A. § 263b) was signed into law on October 27, 1992. The MQSA ensures that women and men receive high-quality mammography services for early breast cancer detection through the establishment of a federal certification and inspection program. The Act authorizes the United States Food and Drug Administration (USFDA) to obtain state and local assistance in enforcing the MQSA requirements, including annual inspections of all certified mammography facilities. The Department, under a \$588,000 reimbursement contract with the USFDA, conducts inspections of each of this Commonwealth's more than 300 facilities which perform mammographic X-ray procedures. This contract is modified most years due to the changing number of facilities. The average amount is \$575,000.

The Department requires licensing of all particle accelerators within this Commonwealth for industrial use, research, or medical purposes. A person who intends to purchase, construct, or acquire an accelerator shall notify the Department of this intent by filing the appropriate application for a specific license within 30 days after the initial order is issued to obtain any or all parts of the accelerator. Annual fees for licensed particle accelerators are listed in § 218.11(d). About 150 facilities have approximately 250 licensed accelerators within this Commonwealth.

The Department also administers a registration program for vendors/service providers who sell, lease, install and/or service radiation-producing machines. Department regulations require that each vendor/service provider doing business within this Commonwealth must be registered prior to providing such services. To register, each vendor/service provider must complete a registration application and return that application with the associated fee to BRP. The registration is renewable for 12-month periods following submission of the applicable fee as listed in § 218.11(k).

In analyzing the annual costs and revenue associated with the Accelerator, Radiation-Producing Machines and Vendors/Service Providers RPP fee category, the Department found that despite substantial increases in personnel and program costs, the Chapter 218 fees, which support the registration of radiation-producing machines and vendors/service providers and the licensing of accelerators, have not been revised since 2009. As a result, the Radiation Protection Fund is decreasing annually in operating reserves, and the fund balance will be negative in fiscal year (FY) 2023-24. Without a fee increase, the Department will be required to curtail spending for needed equipment, infrastructure upgrades, and training and hiring of qualified personnel.

#### *Radioactive Materials and Decommissioning Analysis*

The RPP's Radiation Control Division is also responsible for the regulation, licensing, and inspection of radioactive material user operations and, along with the Decommissioning Section of the Decommissioning and Surveillance Division, is responsible for termination of radioactive material licenses (such as for by-product, source and special nuclear material).

Users of all by-product, source and special nuclear material are required to obtain a license from the Department prior to obtaining those radioactive materials. This material is used in hospitals, colleges and industries for medical, research and industrial purposes. The Department issues specific, general and reciprocity licenses for the use of radioactive material in this Commonwealth. The objective of the licensing program is to ensure radioactive material is used safely, disposed of properly and facilities are free from contamination when licensed operations are terminated. Annual license fees for radioactive material are listed in Chapter 218, Appendix A (relating to fees for radioactive material licenses).

The Decommissioning Section performs technical reviews of decontamination and decommissioning (D&D) activities for radioactive materials licensees and non-licensed radiologically contaminated sites in accordance with appropriate Commonwealth regulations. Typical reviews include site characterization plans, health and safety plans, decommissioning plans, survey reports, and the evaluation of decommissioning funding plans and financial assurance mechanisms. The Decommissioning Section also performs on-site reviews and inspections of D&D activities for occupational, public and environmental radiation protection concerns. These activities include performing confirmatory surveys and sampling to ensure the cleanup levels established for the site have been met. The Decommissioning Section would also perform independent oversight and sampling at decommissioning nuclear power plant sites (for example, TMI Unit 2). This work is performed at full cost recovery.

Fee collections for radioactive material licensing have been trending down since the National economic recession of 2008. Universities and industries that use radioactive material have been consolidating or finding other operational methods that do not require a license. Many licensees have opted to be licensed under a small business fee category at a lower cost, which is specified in Chapter 218, Appendix A. During this same time, actual RPP personnel costs (salaries and benefits) have increased approximately 14% since the last fee increase for this fee area took effect in 2018.

The Department's fiscal analysis showed that with existing reserve funds and current fees, the fund balance will be negative in FY 2024-25 for the Radioactive Materials and Decommissioning area.

#### *Radon Analysis*

This Commonwealth has some of the highest indoor air radon levels in the country, and perhaps the world. According to the National Academy of Sciences and the United States Environmental Protection Agency (EPA), radon is the second leading cause of lung cancer. The Department's Radon Program is one of the most robust in the nation and provides a variety of regulatory and public service activities. These activities include, but are not limited to, implementing the EPA State Indoor Radon Grant (SIRG); certifying radon laboratories/mitigators/and testers; performing inspections of mitigation installations, mitigation offices, testing and laboratory facilities; assisting homeowners and mitigators with difficult to remediate buildings; providing free confirmatory testing to homeowners who have installed active mitigation systems and to homes with radon levels greater than 100 pCi/L; and providing a wide variety of public information services to increase awareness of the radon issue and encouraging testing and mitigation.

The Department receives funding for its Radon Program through a certification fee on radon laboratories, mitigators and testers. Additionally, grant funding from the EPA SIRG provides a small percentage of revenue to offset administrative costs. SIRG funds have been about \$429,000 annually in recent years, which is utilized mainly for staff training, public services announcements, equipment and supplies, home shows and some support of salaries and benefits.

The Department's fiscal analysis indicated that there is currently sufficient revenue to maintain the Radon Program until FY 2027-28.

#### *Summary of RPP Funding Needs*

Based on the findings of the Report, the Board proposes this rulemaking to address the discrepancy between anticipated fees and needed revenue for the Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area and the Radioactive Materials and Decommissioning program area.

In March 2008, then-Governor Rendell signed an agreement with the Chairperson of the United States Nuclear Regulatory Commission (NRC) for the Commonwealth to become an Agreement State. This allows the Department to oversee and regulate licensure of radioactive materials for entities in this Commonwealth. These duties are funded through the Chapter 218 fees. As part of the agreement, the Commonwealth committed to implementing a radiation protection program comparable to the NRC's program and ensured that Department regulations would be compatible with NRC regulations.

The proposed amendments to the Chapter 218 fees for radiation-producing machines, vendors, and accelerators are necessary to ensure adequate funding is available for the Commonwealth to carry out its duties under the RPA. 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 duties under the Agreement State program. If the Commonwealth

were forced to cede its authority to regulate radioactive materials back to the NRC, the regulated community would experience higher costs per NRC's fee regulations.

In order to ensure there is adequate funding for these program areas and for the Commonwealth to maintain its status as an NRC Agreement State, the Board proposes to increase the fees associated with the Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area by 30% to provide sufficient revenue through FY 2027-28 and to increase fees associated with the Radioactive Materials and Decommissioning program area by 10% to ensure sufficient funding through FY 2027-28.

### *Outreach*

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

### *E. Summary of Regulatory Requirements*

#### *§ 218.11. Registration, renewal of registration and license fees.*

In subsection (a), the annual administrative fees and annual fees per x-ray tube or radiation generating device for radiation-producing machines are proposed to be increased by approximately 30% in order to provide adequate funding to support the oversight of x-ray machines in hospitals, dental offices, veterinary clinics and other facilities. Additionally, the Board proposes to move "Chiropractors" out of the "Other" fee category and have them instead pay the same annual administrative fees and annual fees per x-ray tube or radiation generating device as "Dentists, Podiatrists, and Veterinarians." This change is proposed as chiropractors' equipment is more in-line with the equipment used by dentists, podiatrists and veterinarians.

In subsection (d)(1), the fee amounts for accelerators, below 50 MeV, other than for ion implantation are proposed to be increased by 30% from \$2,100 to \$2,730 for the first accelerator at a facility and from \$700 to \$910 for each additional unit at the facility.

In subsection (d)(2), the fee amounts for accelerators used for ion implantation are proposed to be increased by 30% from \$700 to \$910 and from \$70 to \$90 for each additional unit at the same facility.

In subsection (d)(3), the fee amounts associated with accelerators 50 MeV and above are proposed to be increased by 30%. This includes the hourly rate considered for staff time to review license applications and to conduct inspections being increased from \$150 per hour to \$195 per hour; the minimum annual fee being increased from \$2,100 to \$2,730 for the first accelerator at a facility; and the fee for each additional unit being increased from \$700 to \$910.

In subsection (i), the annual fee amounts for electronic brachytherapy devices are proposed to be increased by 30% from \$1,000 to \$1,300 for the first unit at a facility and from \$100 to \$130 for each additional unit at the facility.

In subsection (k), the annual registration fee for radiation-producing machine service providers is proposed to be increased by 30% from \$140 to \$180.

#### *Chapter 218, Appendix A. Fees for radioactive material licenses*

The Board is proposing to increase the 39 different fee categories for radioactive material licenses by 10% based on the findings of the Report to ensure adequate funding is available for the Commonwealth to carry out its duties under the Agreement State program.

Additionally, the professional hourly rate fee, identified by the asterisk in this proposed rulemaking, is proposed to be increased from \$225 per hour to \$275 per hour, which is below the NRC's current Fiscal Year 2021 hourly rate of \$288 per hour. This hourly rate is applicable to fee categories 4A (Waste Storage, Processing or Disposal), 5B (Well Logging Field Flood Tracer Studies) and 14 (Decontamination, Decommissioning, Reclamation or Site Restoration).

#### *F. Benefits, Costs and Compliance*

##### *Benefits*

The proposed Chapter 218 fee increases for radioactive material licenses are necessary to ensure that adequate funding is available for the Commonwealth to carry out its duties under the Agreement State program and the Radiation Protection Act. If the Commonwealth were forced to cede its authority to regulate radioactive materials back to the NRC, the regulated community would be subject to higher NRC fees. Radioactive material controls under the Agreement State program guard against the potential for unnecessary public radiation exposure from the use of radioactive material benefitting the health of all residents in this Commonwealth.

The proposed Chapter 218 fees for registration of X-ray facilities, licensing of accelerators, and registration of vendors have not been increased since 2009, although costs 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.

For these reasons, the Department will benefit from this proposed rulemaking by having the needed additional revenue to cover the costs of the programs mandated by the Radiation Protection Act, and the general public will benefit from this 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.

##### *Compliance costs*

The cost of compliance with the proposed fee amendments for the Accelerator, Radiation-Producing Machines, and Vendors/Service Providers program area are proposed to increase by 30% to provide sufficient revenue through FY 2027-28. The cost of compliance with the

proposed fee amendments for the Radioactive Materials and Decommissioning program area are proposed to increase by 10% to ensure sufficient funding through FY 2027-28. 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.

#### *Compliance assistance plan*

The Department will notify the regulated community to expect higher fees by informing RPAC, issuing an Information Notice to relevant licensees and publishing notification in the *Pennsylvania Bulletin*.

#### *Paperwork requirements*

This proposed rulemaking does not require additional recordkeeping or reporting requirements as a result of the fee increases in Chapters 218.

#### *G. Pollution Prevention*

The Pollution Prevention Act of 1990 (42 U.S.C.A. §§ 13101—13109) established a National policy that promotes pollution prevention as the preferred means for achieving state environmental protection goals. The Department encourages pollution prevention, which is the reduction or elimination of pollution at its source, through the substitution of environmentally friendly materials, more efficient use of raw materials and the incorporation of energy efficiency strategies. Pollution prevention practices can provide greater environmental protection with greater efficiency because they can result in significant cost savings to facilities that permanently achieve or move beyond compliance.

This proposed rulemaking is designed to support the safe and effective use of licensed radioactive materials and radiation-producing machines to protect the health and safety of residents in this Commonwealth. Failure to increase fees may have a direct effect on the Department's ability to implement radiological pollution prevention.

#### *H. Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

#### *I. Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on August 10, 2022, the Department submitted a copy of this proposed rulemaking and a copy of the Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to this proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5(b)) which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

*J. Public Comments*

Interested persons are invited to submit written comments, suggestions, support or objections regarding this proposed rulemaking to the Board. Comments, suggestions, support or objections must be received by the Board by September 26, 2022.

Comments may be submitted to the Board online, by e-mail, by mail or express mail as follows:

Comments may be submitted to the Board online by accessing the Board's online comment system at <http://www.ahs.dep.pa.gov/eComment>.

Comments may be submitted to the Board by e-mail at [RegComments@pa.gov](mailto:RegComments@pa.gov). A subject heading of this proposed rulemaking and a return name and address must be included in each transmission.

If an acknowledgement of comments submitted online or by e-mail is not received by the sender within 2 working days, the comments should be retransmitted to the Board to ensure receipt. Comments submitted by facsimile will not be accepted.

Written comments should be mailed to the Environmental Quality Board, P.O. Box 8477, Harrisburg, PA 17105-8477. Express mail should be sent to the Environmental Quality Board, Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301.

RAMEZ ZIADEH, P.E.,  
*Acting Chairperson*

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 218. FEES

PAYMENT OF FEES

§ 218.11. Registration, renewal of registration and license fees.

(a) Annual registration fees for radiation-producing machines are the sum of an annual administrative fee and an annual fee for each X-ray tube or radiation generating device and shall be paid as follows:

Type Facility	Annual Administrative Fee	Annual Fee per X-ray Tube or Radiation Generating Device
Dentists, podiatrists, veterinarians, <u>chiropractors</u>	<del>[\$100]</del> <u>\$130</u>	<del>[\$50]</del> <u>\$65</u>
Hospitals	<del>[\$725]</del> <u>\$940</u>	<del>[\$50]</del> <u>\$65</u>
Other Facilities	<del>[\$350]</del> <u>\$455</u>	<del>[\$50]</del> <u>\$65</u>

\* \* \* \* \*

(d) Particle accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Annual fees are as follows:

(1) Accelerators, below 50 MeV, other than for ion implantation—~~[\$2,100]~~ \$2,730 for the first accelerator at the facility plus ~~[\$700]~~ \$910 for each additional unit at that facility.

(2) Accelerators used for ion implantation—~~[\$700]~~ \$910 plus ~~[\$70]~~ \$90 for each additional unit at the same facility.

(3) Accelerators 50 MeV and above—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is ~~[\$150]~~ \$195 per hour). For the purpose of anticipating costs and compliance with subsections I and (f), a minimum annual fee of ~~[\$2,100]~~ \$2,730 for the first accelerator at the facility plus ~~[\$700]~~ \$910 for each additional unit is established. Additional invoices will be issued by the Department at regular intervals at least quarterly when net costs are incurred above the minimum annual fee.

\* \* \* \* \*

(i) Electronic brachytherapy devices are licensed under Chapter 221 (relating to X-rays in the healing arts). The annual fee is [~~\$1,000~~] \$1,300 for the first unit (controller) at the facility plus [~~\$100~~] \$130 for each additional unit at that facility.

\* \* \* \* \*

(k) A radiation-producing machine service provider shall pay an annual registration fee of [~~\$140~~] \$180.

\* \* \* \* \*

## APPENDIX A

### Fees for Radioactive Material Licenses

<i>Fee Category<sup>5,6</sup></i>	<i>Description</i>	<i>Annual Fee (\$)<sup>1,2,3,4,7</sup></i>
1C	Special Nuclear Material Sealed Source Gauges (X-Ray Fluorescence)	[ <del>3,150</del> ] <u>3,465</u>
1D	Special Nuclear Material—Other	[ <del>8,700</del> ] <u>9,570</u>
2A(2)(c)	Source Material—Metal Extraction	[ <del>45,100</del> ] <u>49,610</u>
2A5	Removal of Radioactive Contaminants from Drinking Water	[ <del>16,800</del> ] <u>18,480</u>
2B	Source Material as Shielding	[ <del>1,125</del> ] <u>1,240</u>
2C	Source Material—Other (not 11c2)	[ <del>20,100</del> ] <u>22,110</u>
3A	Manufacturing & Distribution Commercial Broad Scope—10 CFR 30, 33	[ <del>43,650</del> ] <u>48,015</u>
3B	Manufacturing, Refurbishing & Distribution Commercial Specific License— 10 CFR 30	[ <del>12,450</del> ] <u>13,695</u>
3C	Manufacturing & Distribution Pharmaceuticals—10 CFR 32.72—32.74	[ <del>17,850</del> ] <u>19,635</u>
3D	Pharmaceuticals—Distribution Only—10 CFR 32.7x	[ <del>10,200</del> ] <u>11,220</u>
3E	Irradiator—Shielded Source	[ <del>6,300</del> ] <u>6,930</u>
3F	Irradiator—Unshielded < 10kCi	[ <del>11,700</del> ] <u>12,870</u>
3G	Irradiator—Unshielded >= 10kCi	[ <del>46,800</del> ] <u>51,480</u>
3I	Distribution As Exempt—No Review of Device	[ <del>16,050</del> ] <u>17,655</u>
3J	Distribution—SSD Devices to Part 31 GLs	[ <del>3,750</del> ] <u>4,125</u>
3K	Distribution—No Review-Exempt Sealed Source	[ <del>2,850</del> ] <u>3,135</u>
3L	Research & Development Broad Scope	[ <del>22,650</del> ] <u>24,915</u>
3M	Research & Development	[ <del>8,400</del> ] <u>9,240</u>
3N	Services other than Leak Testing, Waste Disposal or Calibration	[ <del>12,750</del> ] <u>14,025</u>
3O	Radiography	[ <del>21,150</del> ] <u>23,265</u>
3P	Other Byproduct Material	[ <del>4,050</del> ] <u>4,455</u>
3Q	Generally licensed devices under § 217.143 (relating to certain measuring, gauging or controlling devices)	[ <del>480</del> ] <u>530</u>

3R1	Greater than the General License Limits in 10 CFR 31.12(a)(3), (4) or (5) but not more than ten times those Limits	[3,150] <u>3,465</u>
3R2	Greater than ten times the General License Limits in 10 CFR 31.12(a)(3), (4) or (5)	[4,050] <u>4,455</u>
3S	Manufacturing & Distribution Pharmaceuticals—Accelerator Produced Only	[17,700] <u>19,470</u>
4A	Waste Storage, Processing or Disposal	Full Cost *
4B	Waste Packaging or Repackaging	[18,000] <u>19,800</u>
4C	Waste Receipt of Prepackaged for Disposal	[13,800] <u>15,180</u>
5A	Well Logging & Non Field Flood Tracers	[6,600] <u>7,260</u>
5B	Well Logging Field Flood Tracer Studies	Full Cost *
6A	Nuclear Laundry	[43,200] <u>47,520</u>
7A	Human Use—Teletherapy	[20,550] <u>22,605</u>
7B	Human Use—Broad Scope (except Teletherapy)	[36,250] <u>39,875</u>
7C	Human Use (except Teletherapy)	[7,350] <u>8,085</u>
8A	Specifically licensed sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	[3,150] <u>3,465</u>
14	Decontamination, Decommissioning, Reclamation or Site Restoration	Full Cost *
16	Reciprocity (180 days/year)	[2,250] <u>2,475</u>
SB1 <sup>5</sup>	Small Business— Category 1	[3,450] <u>3,795</u>
SB2 <sup>6</sup>	Small Business— Category 2	[750] <u>825</u>

<sup>1</sup> A license may include as many as four noncontiguous sites at the base fee. Sites that are within 5 miles of the main radiation safety office where the license records are kept will be considered contiguous. An additional fee of 25% of the base fee will be added for each noncontiguous site above four.

<sup>2</sup> All fees will be effective upon publication of the final rules in the *Pennsylvania Bulletin*. Existing NARM licenses will be changed to the corresponding category of byproduct material license in Appendix A upon publication of the final rule.

<sup>3</sup> Annual fees for categories of NRC licenses that are not included in this table will be calculated as follows: PA Fee = (NRC Annual Fee + 0.10 NRC Application or Renewal fee).

<sup>4</sup> Annual fees charged to holders of transferred NRC licenses with multiple sites will not exceed the fees charged by the NRC for the same licenses that are in effect in the year of transfer, provided the number of noncontiguous sites does not increase.

<sup>5</sup> Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of more than \$350,000 and less than \$5 million; Manufacturing Entities that have an average of 35—500 employees with Gross Annual Receipts of more than \$350,000 and less than \$5 million; Small Government Jurisdictions (including publicly supported,

nonmedical educational institutions) with a population between 20,000 and 50,000; and nonmedical Educational Institutions that are not state or publicly supported and have 35—500 employees.

<sup>6</sup> Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of less than \$350,000; Manufacturing Entities that have an average of less than 35 employees and less than \$350,000 in Gross Annual Receipts; Small Government Jurisdictions (including publicly supported nonmedical educational institutions) with a population less than 20,000; and nonmedical Educational Institutions that are not state or publicly supported and have less than 35 employees.

<sup>7</sup> Full cost recovery licensees and licensees required to provide financial assurance for decommissioning are not eligible for reduced fees under category SBI or SB2.

\* Full cost recovery consists of a professional fee, to cover the activities and support of Department personnel, and any other additional incidental charges incurred, such as related contracted services or laboratory costs. The professional fee component (Hourly Rate) is [~~\$225~~] \$275 per hour. Other costs are recovered at 100% of actual cost. Invoices shall be issued by the Department at regular intervals but at least quarterly when net costs are incurred.



**pennsylvania**  
DEPARTMENT OF ENVIRONMENTAL  
PROTECTION

August 10, 2022

David Sumner  
Executive Director  
Independent Regulatory Review Commission  
333 Market Street, 14th Floor  
Harrisburg, PA 17120

Re: Proposed Rulemaking: Radiological Health Fees (#7-574)

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed a copy of the Radiological Health Fees proposed rulemaking for review by the Independent Regulatory Review Commission (Commission). This proposal is scheduled for publication in the *Pennsylvania Bulletin* on August 27, 2022, with a 30-day public comment period. The Environmental Quality Board adopted this proposal on June 14, 2022.

This rulemaking proposes to increase the annual fees for radiation-producing machine and service provider (vendor) registrations, accelerator licenses, and radioactive material licenses, and increases the hourly rate professional fee associated with certain full cost recovery licenses.

As set forth in the Regulatory Review Act, the Department will consider any comments and recommendations made by the Commission, as well as the House and Senate Environmental Resources and Energy Committees and the public, prior to final adoption of the enclosed rulemaking.

Please contact me by e-mail at [laurgriffi@pa.gov](mailto:laurgriffi@pa.gov) or by telephone at 717.772.3277 if you have any questions or need additional information.

Sincerely,

A handwritten signature in cursive script that reads "Laura E. Griffin".

Laura Griffin  
Regulatory Coordinator

Enclosures



**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

**I.D. NUMBER:** 7-574  
**SUBJECT:** Radiological Health Fees  
**AGENCY:** DEPARTMENT OF ENVIRONMENTAL PROTECTION  
 ENVIRONMENTAL QUALITY BOARD

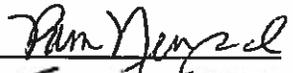
**RECEIVED**

AUG 10 2022

Independent Regulatory  
Review Commission

- TYPE OF REGULATION**
- X Proposed Regulation
  - Final Regulation
  - Final Regulation with Notice of Proposed Rulemaking Omitted
  - 120-day Emergency Certification of the Attorney General
  - 120-day Emergency Certification of the Governor
  - Delivery of Tolled Regulation
    - a. With Revisions
    - b. Without Revisions

**FILING OF REGULATION**

<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
		<i>HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES &amp; ENERGY</i>
8/10/22		MAJORITY CHAIR <u>Representative Daryl Metcalfe</u>
8/30/22		MINORITY CHAIR <u>Representative Greg Vitali</u>
		<i>SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES &amp; ENERGY</i>
8/10/22	electronic submittal	MAJORITY CHAIR <u>Senator Gene Yaw</u>
8/10/22	electronic submittal	MINORITY CHAIR <u>Senator Carolyn Comitta</u>
_____	_____	<i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>
_____	_____	<i>ATTORNEY GENERAL (for Final Omitted only)</i>
8/10/22	electronic submittal	<i>LEGISLATIVE REFERENCE BUREAU (for Proposed only)</i>



**Madison Brame**

---

**From:** Eyster, Emily  
**Sent:** Wednesday, August 10, 2022 11:01 AM  
**To:** Troutman, Nick; Griffin, Laura  
**Cc:** Chalfant, Brian; Reiley, Robert A.; Nezat, Taylor; Hartman, Michael; Rodriguez, Amanda  
**Subject:** Re: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

Received. Thank you!

Emily Eyster  
Legislative Director, Office of Senator Carolyn T. Comitta  
Executive Director, Senate Environmental Resources and Energy Committee  
Cell: (717) 756-4702  
Phone: (717) 787-5709  
[www.pasenate.com](http://www.pasenate.com)

**RECEIVED**

AUG 10 2022

Independent Regulatory  
Review Commission

---

**From:** Troutman, Nick <ntroutman@pasen.gov>  
**Sent:** Wednesday, August 10, 2022 10:59 AM  
**To:** Griffin, Laura <laurgriffi@pa.gov>; Eyster, Emily <Emily.Eyster@pasenate.com>  
**Cc:** Chalfant, Brian <bchalfant@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Nezat, Taylor <tnezat@pa.gov>; Hartman, Michael <michael.hartman@pasenate.com>; Rodriguez, Amanda <amarodrigu@pa.gov>  
**Subject:** RE: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

■ EXTERNAL EMAIL ■

---

Received. Thanks Laura

-Nick

---

**From:** Griffin, Laura <laurgriffi@pa.gov>  
**Sent:** Wednesday, August 10, 2022 10:48 AM  
**To:** Troutman, Nick <ntroutman@pasen.gov>; Eyster, Emily <Emily.Eyster@pasenate.com>  
**Cc:** Chalfant, Brian <bchalfant@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Nezat, Taylor <tnezat@pa.gov>; michael.hartman@pasenate.com; Rodriguez, Amanda <amarodrigu@pa.gov>  
**Subject:** Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)  
**Importance:** High

● CAUTION : External Email ●

Good morning,

Pursuant to Section 5(a) of the Regulatory Review Act, please find attached the Radiological Health Fees Proposed Rulemaking (#7-574) for review by the Senate Environmental Resources and Energy Committee. The

rulemaking documents are attached in a compressed folder and the cover letters for Senators Yaw and Comitta are attached separately.

The transmittal sheet confirming receipt of the rulemaking by the House Environmental Resources and Energy Committee this morning.

Please confirm receipt of this rulemaking by replying to all recipients.

Thank you,  
Laura

**Laura Griffin** | Regulatory Coordinator

*she/her/hers*

Department of Environmental Protection | Policy Office

Rachel Carson State Office Building

400 Market Street | Harrisburg, PA

Phone: 717.772.3277 | Fax: 717.783.8926

Email: [laurgriffi@pa.gov](mailto:laurgriffi@pa.gov)

[www.dep.pa.gov](http://www.dep.pa.gov)

Connect with DEP on: [Twitter](#) | [Facebook](#) | [LinkedIn](#) | [YouTube](#) | [Instagram](#)

This message and any attachment may contain privileged or confidential information intended solely for the use of the person to whom it is addressed. If the reader is not the intended recipient then be advised that forwarding, communicating, disseminating, copying or using this message or its attachments is strictly prohibited. If you receive this message in error, please notify the sender immediately and delete the information without saving any copies.

## Madison Brame

---

**From:** Bulletin <bulletin@palrb.us>  
**Sent:** Wednesday, August 10, 2022 11:58 AM  
**To:** Griffin, Laura; Code&Bulletin  
**Cc:** Rodriguez, Amanda  
**Subject:** [External] RE: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

*ATTENTION: This email message is from an external sender. Do not open links or attachments from unknown senders. To report suspicious email, use the [Report Phishing button in Outlook](#).*

Good afternoon Laura,

Thank you for sending this Proposed Rulemaking. Someone from our office will contact you regarding publication in the *Pennsylvania Bulletin*.

Take care,

Ernest L. Engvall | Legal Assistant  
[eengvall@palrb.us](mailto:eengvall@palrb.us) | 717.783.1531  
Legislative Reference Bureau  
Code and Bulletin Office

**RECEIVED**

**AUG 10 2022**

**Independent Regulatory  
Review Commission**

---

**From:** Griffin, Laura <laurgriffi@pa.gov>  
**Sent:** Wednesday, August 10, 2022 11:40 AM  
**To:** Code&Bulletin <codeandbulletin@palrb.us>; Bulletin <bulletin@palrb.us>  
**Cc:** Leah Brown <lbrown@palrb.us>; A.J. Mendelsohn <amendelsohn@palrb.us>; Adeline E. Gaydosh <agaydosh@palrb.us>; Rodriguez, Amanda <amarodrigu@pa.gov>  
**Subject:** Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)  
**Importance:** High

Good morning,

Please see the attached documents, including Word versions of the Preamble and Annex A, for Proposed Rulemaking – Radiological Health Fees (#7-574), for publication on **August 27, 2022**.

A cover letter and the transmittal sheet confirming receipt of the rulemaking by the House and Senate ERE Committees is attached.

Please confirm that you received the rulemaking documents for publication.

Thank you!  
Laura

**Laura Griffin** | Regulatory Coordinator  
*she/her/hers*  
Department of Environmental Protection | Policy Office  
Rachel Carson State Office Building

400 Market Street | Harrisburg, PA  
Phone: 717.772.3277 | Fax: 717.783.8926  
Email: [laurgriffi@pa.gov](mailto:laurgriffi@pa.gov)  
[www.dep.pa.gov](http://www.dep.pa.gov)

Connect with DEP on: [Twitter](#) | [Facebook](#) | [LinkedIn](#) | [YouTube](#) | [Instagram](#)

## Madison Brame

---

**From:** Bulletin <bulletin@palrb.us>  
**Sent:** Wednesday, August 10, 2022 12:12 PM  
**To:** Griffin, Laura; Code&Bulletin  
**Cc:** Rodriguez, Amanda; Leah Brown; Adeline E. Gaydosh  
**Subject:** RE: [External] RE: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

Thank you, Laura.

Ernest

---

**From:** Griffin, Laura <laurgriffi@pa.gov>  
**Sent:** Wednesday, August 10, 2022 12:09 PM  
**To:** Bulletin <bulletin@palrb.us>; Code&Bulletin <codeandbulletin@palrb.us>  
**Cc:** Rodriguez, Amanda <amarodrigu@pa.gov>; Leah Brown <lbrown@palrb.us>; Adeline E. Gaydosh <agaydosh@palrb.us>  
**Subject:** RE: [External] RE: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

Good afternoon Ernest,

Please find attached the emails from the Senate ERE Committee Chairs acknowledging receipt of proposed rulemaking #7-574. I forgot to attach them to the initial email.

Thank you,  
Laura

**Laura Griffin** | Regulatory Coordinator  
*she/her/hers*  
Department of Environmental Protection | Policy Office  
Rachel Carson State Office Building  
400 Market Street | Harrisburg, PA  
Phone: 717.772.3277 | Fax: 717.783.8926  
Email: [laurgriffi@pa.gov](mailto:laurgriffi@pa.gov)  
[www.dep.pa.gov](http://www.dep.pa.gov)

**RECEIVED**

**AUG 10 2022**

**Independent Regulatory  
Review Commission**

Connect with DEP on: [Twitter](#) | [Facebook](#) | [LinkedIn](#) | [YouTube](#) | [Instagram](#)

---

**From:** Bulletin <bulletin@palrb.us>  
**Sent:** Wednesday, August 10, 2022 11:58 AM  
**To:** Griffin, Laura <laurgriffi@pa.gov>; Code&Bulletin <codeandbulletin@palrb.us>  
**Cc:** Rodriguez, Amanda <amarodrigu@pa.gov>  
**Subject:** [External] RE: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

**ATTENTION:** This email message is from an external sender. Do not open links or attachments from unknown senders. To report suspicious email, use the [Report Phishing button in Outlook](#).

Good afternoon Laura,

Thank you for sending this Proposed Rulemaking. Someone from our office will contact you regarding publication in the *Pennsylvania Bulletin*.

Take care,

**Ernest L. Engvall | Legal Assistant**  
[eengvall@palrb.us](mailto:eengvall@palrb.us) | 717.783.1531  
Legislative Reference Bureau  
*Code and Bulletin Office*

---

**From:** Griffin, Laura <[laurgriffi@pa.gov](mailto:laurgriffi@pa.gov)>  
**Sent:** Wednesday, August 10, 2022 11:40 AM  
**To:** Code&Bulletin <[codeandbulletin@palrb.us](mailto:codeandbulletin@palrb.us)>; Bulletin <[bulletin@palrb.us](mailto:bulletin@palrb.us)>  
**Cc:** Leah Brown <[lbrown@palrb.us](mailto:lbrown@palrb.us)>; A.J. Mendelsohn <[amendelsohn@palrb.us](mailto:amendelsohn@palrb.us)>; Adeline E. Gaydosh <[agaydosh@palrb.us](mailto:agaydosh@palrb.us)>; Rodriguez, Amanda <[amarodrigu@pa.gov](mailto:amarodrigu@pa.gov)>  
**Subject:** Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)  
**Importance:** High

Good morning,

Please see the attached documents, including Word versions of the Preamble and Annex A, for Proposed Rulemaking – Radiological Health Fees (#7-574), for publication on **August 27, 2022**.

A cover letter and the transmittal sheet confirming receipt of the rulemaking by the House and Senate ERE Committees is attached.

Please confirm that you received the rulemaking documents for publication.

Thank you!  
Laura

**Laura Griffin | Regulatory Coordinator**  
*she/her/hers*  
Department of Environmental Protection | Policy Office  
Rachel Carson State Office Building  
400 Market Street | Harrisburg, PA  
Phone: 717.772.3277 | Fax: 717.783.8926  
Email: [laurgriffi@pa.gov](mailto:laurgriffi@pa.gov)  
[www.dep.pa.gov](http://www.dep.pa.gov)

Connect with DEP on: [Twitter](#) | [Facebook](#) | [LinkedIn](#) | [YouTube](#) | [Instagram](#)

**Madison Brame**

---

**From:** Troutman, Nick  
**Sent:** Wednesday, August 10, 2022 10:59 AM  
**To:** Griffin, Laura; Eyster, Emily  
**Cc:** Chalfant, Brian; Reiley, Robert A.; Nezat, Taylor; Hartman, Michael; Rodriguez, Amanda  
**Subject:** RE: Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)

Received. Thanks Laura

-Nick

**RECEIVED**

**AUG 10 2022**

**Independent Regulatory  
Review Commission**

---

**From:** Griffin, Laura <laurgriffi@pa.gov>  
**Sent:** Wednesday, August 10, 2022 10:48 AM  
**To:** Troutman, Nick <ntroutman@pasen.gov>; Eyster, Emily <Emily.Eyster@pasenate.com>  
**Cc:** Chalfant, Brian <bchalfant@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Nezat, Taylor <tnezat@pa.gov>; michael.hartman@pasenate.com; Rodriguez, Amanda <amarodrigu@pa.gov>  
**Subject:** Delivery of Proposed Rulemaking - Radiological Health Fees (7-574)  
**Importance:** High

Ⓞ CAUTION : External Email Ⓞ

Good morning,

Pursuant to Section 5(a) of the Regulatory Review Act, please find attached the Radiological Health Fees Proposed Rulemaking (#7-574) for review by the Senate Environmental Resources and Energy Committee. The rulemaking documents are attached in a compressed folder and the cover letters for Senators Yaw and Comitta are attached separately.

The transmittal sheet confirming receipt of the rulemaking by the House Environmental Resources and Energy Committee this morning.

Please confirm receipt of this rulemaking by replying to all recipients.

Thank you,  
Laura

**Laura Griffin** | Regulatory Coordinator  
*she/her/hers*  
Department of Environmental Protection | Policy Office  
Rachel Carson State Office Building  
400 Market Street | Harrisburg, PA  
Phone: 717.772.3277 | Fax: 717.783.8926  
Email: [laurgriffi@pa.gov](mailto:laurgriffi@pa.gov)  
[www.dep.pa.gov](http://www.dep.pa.gov)

Connect with DEP on: [Twitter](#) | [Facebook](#) | [LinkedIn](#) | [YouTube](#) | [Instagram](#)

