

**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 _____, 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 (Select "Public Participation," then "Environmental Quality Board" and then navigate to the Board meeting of _____, 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 (date), 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 **(date)**.

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. 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.

PATRICK McDONNELL,
Chairperson