PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 218] Fees

The Environmental Quality Board (EQB) proposes to amend Chapter 218 (relating to fees) for three purposes: to adjust existing fees for registration of X-ray machines for inflation since last revised; to establish fees for accelerator licensing; and to establish fees for radioactive material licenses now administered by the Nuclear Regulatory Commission (NRC) that will be transferred to the Department of Environmental Protection (Department) when the Commonwealth attains Agreement State Status from the NRC.

This proposal was adopted by the EQB at its meeting on January 16, 2001.

A. Effective Date

These amendments will become effective immediately upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. Contact Persons

For further information, the contact persons are William Kirk, Chief, Radiation Control Division, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-2480; and Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, RCSOB, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposal appears in Section I of this preamble. Persons with a disability may use the AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the DEP website (http://www.dep.state.pa.us).

C. Statutory Authority

These amendments are proposed under the authority of the following statutes: sections 301 and 302 of the Radiation Protection Act (act) (35 P. S. §§ 7110.301 and 7110.302) which, respectively, direct the Department to develop and conduct comprehensive programs for the registration, licensing, control, regulation and inspection of radiation sources and radiation source users, and delegates to the EQB the power to adopt the regulations of the Department to implement the act. Section 401 of the act requires the Department to set reasonable annual fees for the registration of radiation sources and licensing of source users in amounts at least sufficient to cover the costs of administering the programs. Section 102(6) provides for assumption of licensing and regulatory responsibility for radioactive materials from the Federal Government. Section 302(b) provides that the EQB or its successor shall review the fee structure authorized by sections 401 and 402(b).

Section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), which authorizes and directs the EQB to adopt regulations necessary for the proper performance of the work of the Department.

D. Background and Purpose

The act requires the Department to establish fees in amounts at least sufficient to cover the costs of the radiation protection program mandated by the act. The present fees were established in 1992 and have not been revised since that time, despite a substantial increase in inspector salaries and equipment costs. In the last fiscal year, receipts from registrations and licenses fell short of the costs to operate the program. Further, in 1998, the EQB amended Chapter 228 (relating to radiation safety requirements for particle accelerators) to provide that accelerators be licensed, with review of the proposed installation, use and radiation safety program, rather than simply being registered like X-ray machines. In addition to the costs of license application review, experience in recent years has demonstrated that the cost to the Department of inspections and enforcement for accelerators is greater than for X-ray installations. Finally, before the Commonwealth can acquire the authority and responsibility for the radioactive materials licenses in this Commonwealth that are now administered by the NRC, the Commission must have a fee structure in place to fund the effort. It is particularly important that the authority be established for "full cost" recovery for certain types of licenses, notably low level radioactive waste and decommissioning licenses, when there is no reasonable way of establishing set fees.

Therefore, amendments are proposed to Chapter 218 for the purposes of:

- (1) Increasing annual fees for registration of X-ray machines and for licenses to possess and use naturally occurring and accelerator-produced radioactive material (NARM) by an overall average of 40%, an amount sufficient to ensure income adequate to fund those programs.
- (2) Establishing fees for licensing of particle accelerators.
- (3) Establishing annual fees for radioactive material licenses located in this Commonwealth and now administered by the NRC. These fees will not be effective until the Commonwealth is granted Agreement State authority by the NRC under section 274 of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2021).

As required by section 301(c)(14) of the act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed amendments and to advise the Department prior to submittal to the EQB. On October 19, 2000, the RPAC met and reviewed the proposed amendments. The Chairperson announced by letter dated November 20, 2000, the Committee's concurrence to forward the proposed amendments to the EQB.

E. Summary of Regulatory Requirements

A description of the proposed amendments is provided as follows:

Chapter 218. Fees.

§ 218.1. Purpose and scope.

A new subsection (b)(3) is being included to add holders of and applicants for accelerator licenses to the list of persons subject to this chapter.

PAYMENT OF FEES

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

Subsection (a) is rewritten to remove accelerators from the category of radiation-producing machines and to revise the fee structure for X-ray machines. The existing fee structure contains a registration fee that includes the first tube and a fee of \$25 for each additional tube. Fees will now consist of the sum of an annual administrative fee for each registrant plus a \$35 fee for each tube possessed. The fees are presented in a table. Overall, fees are increased by an average of 40% to compensate for increased staff salaries since 1992 when they were established

Subsection (c) is revised to provide for fees for the NRC licenses that will be transferred to the Commonwealth upon achievement of Agreement State status. Because there are many types of licenses recognized by the NRC for which the Commonwealth does not have separate categories, the fees are tabulated in a new Appendix A. The lead sentence is revised by deleting "this subsection" and adding "Appendix A." Existing paragraph (1) and subparagraphs (i), (ii) and (iii) have been deleted. A new paragraph (1) is added to specify that no refunds will be made if a license is terminated. New paragraph (2) provides for changes in license category to take place on the anniversary date of the license. Existing paragraph (2), pertaining to exceptions, was deleted as it is no longer needed.

Subsections (d), (e) and (f) are renumbered to (e), (f) and (g), respectively, and a new subsection (d) is added to institute license fees for several classes of accelerator. These fees are proportional to the complexity and potential for radiation safety problems of the accelerators.

Language was added to renumbered subsection (e) to include reciprocity as a license category requiring advance payment of fees, to include the fees instituted in new subsection (d) in those to be invoiced, and to recognize the various fee schedules in the revised Chapter 218.

Language was also added to renumbered subsection (f) to recognize the new fee schedules. Other than renumbering, no change was made to subsection (g).

§ 218.12. Failure by registrant or licensee to pay required fee.

Subsection (b) was revised to provide that failure to pay X-ray registration fees shall be cause for revocation of the registration. The subsection already provides for revocation of licenses for nonpayment of fees.

Appendix A

Appendix A is new and both replaces former language of § 218.11(c), which specified fees for NARM licenses, and establishes fees for licenses that will be transferred to the state when regulatory authority for most types of radioactive material is transferred from the NRC.

F. Benefits, Costs and Compliance

Executive Order 1996-1 "Regulatory Review and Promulgation," requires a cost/benefit analysis of the proposed amendments.

Benefits

Receipt of fees necessary to cover the costs of the radiation protection program will preserve the current program for the benefit of the people of this Commonwealth. Holders of radioactive materials licenses will benefit from simplification of compliance costs associated with the present dual regulation and by generally reduced fees as noted.

Compliance Costs

The compliance costs under the proposed amendments will vary with the type of license or registration, or both, held. X-ray registrants and NARM licensees will incur a fee increase on average of about 40%. License fees for former NRC radioactive materials licenses will decrease by about 30% from FY2000 NRC fees, and somewhat more if they also hold a NARM license which will be combined with the NRC license at the fee for the NRC license. These holders of both types of RAM licenses will also experience substantial savings by no longer being required to follow two sets of regulations and be inspected by two regulators.

Holders of accelerator registrations being converted to licenses will incur an important increase in fees, the exact amount of which will be determined by the type and number of the machines that they possess. The EQB instituted the change to licensing because of the complexity and potential hazards associated with their use. License review, facility inspection and enforcement activities require considerably more time than regulation of X-ray machines, and the proposed fees reflect that fact.

Compliance Assistance Plan

Compliance assistance requirements are expected to be negligible because, other than changes in the amount of fees, and, for former NRC licensees, to whom they are paid, and the elimination of one set of inspectors, no changes in operating requirements are involved. Outreach and assistance will be provided by regional inspectors and technical staff in the Radiation Control Division.

Paperwork Requirements

No additional paperwork will be required under these proposals. Once Agreement State authority is approved, anticipated in 2002, and the NRC licenses converted to state licenses, over a period of a year, licensees will have significantly less paperwork.

G. Sunset Review

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

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Department submitted a copy of the proposed amendments on February 6, 2001, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has objections to any portion of the proposed amendments, it will notify the Department within 10 days following the close of the Committees' review period. The notification shall specify the regulatory review criteria that have not been met by that portion of the proposed amendments to which an objection is made. The Regulatory Review Act specifies detailed procedures for

review by the Department, the Governor and the General Assembly before final publication of the amendments.

I. Public Comments

Written Comments—Interested persons are invited to submit comments, suggestions or objections regarding the proposed amendments to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by March 19, 2001. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed 1 page in length and must be received by March 19, 2001. The 1-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulation will be considered.

Electronic Comments—Comments may be submitted electronically to the Board at RegComments@dep.state.pa.us and must also be received by the Board by March 19, 2001. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgment of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JAMES M. SEIF, Chairperson

Fiscal Note: 7-363. No fiscal impact; (8) recommends adoption.

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 GENERAL

§ 218.1. Purpose and scope.

* * * * *

(b) Except as otherwise specifically provided, this chapter applies to a person who:

(3) Is an applicant for or holder of an accelerator license issued under Chapter 228 (relating to radiation safety requirements for particle accelerators).

PAYMENT OF FEES

- § 218.11. Registration, renewal of registration and license fees.
- (a) Annual registration fees for radiation producing machines [are], other than accelerators, are the sum of an annual administrative fee and an annual fee for each tube as follows:
- [(1) For dental, podiatric and veterinary facilities—\$75 for the first X-ray tube, plus \$25 for each additional tube.
- (2) For hospital facilities—\$520 for the first X-ray tube, plus \$25 for each additional tube.

(3) For other facilities—\$175 for the first X-ray tube, plus \$25 for each additional tube.

Type Facility	Annual Administrative Fee	Annual Fee per Tube
Dentists, podiatrists, veterinarians	\$70	\$35
Hospitals	\$520	\$35
Other Facilities	\$250	\$35

(c) Annual license fees for radioactive material are set forth in [this subsection] Appendix A.

(1) **Fees.**

- (i) Licenses for radiography under § 217.65; radiopharmacy under §§ 217.90 and 217.91; manufacturing and distribution under §§ 217.81—217.89, 217.92 and 217.93; and, broad scope under §§ 217.71—217.73 (Category 1)—\$1,530.
- (ii) Licenses for source material used as shielding; special nuclear material used in gauges; radioactive material used in static eliminators, smoke detectors, fixed gauges and dew point measurers or used for calibration or civil defense activities and radioactive material maintained in storage (Category 2)—\$125.
- (iii) For other licenses not listed under this subsection (Category 3)—\$600.
- (2) Exceptions. This subsection does not apply to the low-level radioactive waste disposal facility operating license.

No refund will be made for termination of a license.

- (2) If, by amendment or otherwise, a license changes to another fee category, the fee for the new category will take effect on the anniversary date of the license.
- (d) Particle accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Fees are as follows:
- (i) Accelerators, below 50 MeV, other than for ion implantation—\$1,500 for the first accelerator at the site plus \$500 for each additional unit of the same general type at that site.
- (ii) Accelerators used for ion implantation—\$500 plus \$50 for each additional unit at the same site.
- (iii) Accelerators above 50 MeV—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is given in Appendix A).
- [(d)] (e) An initial application for a license or reciprocity shall be accompanied by a check payable to the Department in accordance with the fee schedules in [subsection] subsections (c) and (d). Thereafter, the Department will issue an annual [license] fee invoice in accordance with the appropriate fee schedule at least 2 months prior to the [last day of] license expiration [month based on the fee schedule in

subsection (c)]. Fees are payable by the last day of the license expiration month as shown on the license fee invoice.

[(e)] (f) The Department will not accept an initial application for a license prior to payment of the fees required by [subsection] subsections (c) and (d).

[(f)](g) * * *

§ 218.12. Failure by registrant or licensee to pay required fee.

* * * *

(b) Nonpayment of fees required by this chapter shall be cause for revocation of licenses **or registrations** issued by the Department under the act.

APPENDIX A

Fees for Radioactive Material Licenses

(Editor's note: Appendix A is new, but to enhance readability has been printed in regular type.)

Fee Category	Description	Proposed Pa Annual Fee (\$) ^{1,2,3,4}
1C	SNM Sealed Source Gauges (XRF)	875
1D	SNM—Other	2,475
2B	Source Material as Shielding	450
2C	Source Material—Other (not 11e2)	8,650
3A1	MFR & Distr. Commercial Broad Scope 30, 33	19,875
3A2	MFR & Distr. Commercial Broad Scope—NARM Only	4,000
3B1	MFR & Distr. Commercial Specific Lic. 30	4,650
3B2	MFR & Distr. Commercial Specific Lic.—NARM Only	2,000
3C1	MFR & Distr. Pharmaceuticals 32.72-32.74	11,650
3C2	MFR & Distr. Pharmaceuticals—NARM Only	4,000
3D1	Pharmaceuticals—Distribution Only 32.7x	2,825
3D2	Pharmaceuticals—Distribution Only—NARM Only	2,000
3E	Irradiator—Shielded Source	2,575
3F	Irradiator—Unshielded < 10kCi	4,300
3G	Irradiator—Unshielded ≥ 10kCi	10,750
3I	Distr. As Exempt—No Review of Device	3,525
3J	Distr.—SSD Devices to Part 31 GLs	1,550
3K	Distr.—No Review-Exempt Sealed Source	1,300
3L1	R & D Broad Scope	8,300
3L2	R & D Broad Scope—NARM Only	2,000
3M1	R & D	3,650
3M2	R & D—NARM Only	750
3N	Services Not Leak Test, Waste Disp. Calib.	3,875
30	Radiography	10,850
3P1	Other Byproduct	1,900
3P2	NARM Licenses not covered elsewhere	750
4A	Waste Storage, Processing, or Disposal	Full Cost
4B	Waste Packaging or Repackaging	8,175
4C	Waste Receipt of Prepackaged for Disposal	6,125
5A	Well Logging & Non Field Flood Tracers	7,500
5B	Well Logging Field Flood Tracer Studies	Full Cost
6A	Nuclear Laundry	14,250
7A	Human Use—Teletherapy	11,275
7B1	Human Use—Broad Scope (except Teletherapy)	19,975
7B2	Human Use—Broad Scope (except Teletherapy)—NARM Only	2,000
7C1	Human Use—Specific (except Teletherapy)	4,300

Fee Category	Description	Proposed Pa Annual Fee (\$) ^{1,2,3,4}
7C2	Human Use—Specific License (except Teletherapy)-NARM Only	750
8A1	Civil Defense	875
8A2	Specifically licensed NARM sources used in static eliminators, non-exempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses, or in storage.	200
14	Decontamination, Decommissioning, Restoration, Special	Full Cost
16A	Reciprocity (180 days/year)	900
16B	Reciprocity—NARM (180 days/year)	300
SB1 ⁵	Small Business—Category 1	2,100
SB2 ⁶	Small Business—Category 2	400
PF	Professional Fees (Hourly Rate) for full cost items	\$50 per hour

¹ A license may include as many as four non-contiguous sites at the base fee. Sites that are within 5 miles of the main Radiation Safety Office where the license records are kept

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¹ A license may include as many as four non-contiguous 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.

² All fees for NARM licenses will be effective upon publication of the final rules in the *Pennsylvania Bulletin*. The fees for NRC licenses that are transferred to the Commonwealth will be effective on the next license anniversary date. NARM licenses will be changed to the corresponding category of by-product material license on the next license anniversary date after achievement of Agreement State status and fees adjusted at that time. The NARM license categories will cease to exist one year after Agreement State status is achieved.

³ Annual fees for Categories of NRC licenses that are not included in this table will be calculated as follows: PA Fee = 0.7 (NRC Annual Fee + 0.10 NRC Application or Renewal fee).

⁴ 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 in the year of transfer, provided the number of non-contiguous sites remains constant.

⁵ 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 non-medical Educational Institutions that are not state or publicly supported, non-medical educational institutions with Gross Annual Receipts of less than \$350,000; Manufacturing Entities that have an average of less than \$350,000 in Gross Annual Receipts; Small Government Jurisdictions (including publicly supported and have 35–500 employees.

⁶ 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 \$350,000 in Gross Annual Receipts; Small