

Regulatory Analysis Form		This space for use by IRRC
(1) Agency Department of Environmental Protection Bureau of Radiation Protection		2001 SEP 21 PM 5:35
(2) I.D. Number (Governor's Office Use) 7-363		IRRC Number: 2175
(3) Short Title Radiological Health Amendments – Chapter 218 (Fees)		
(4) PA Code Cite 25 Pa. Code Chapter 218	(5) Agency Contacts & Telephone Numbers Primary Contact: Sharon F. Trostle, 783-1303 Secondary Contact: Barbara Sexton, 783-1303	
(6) Type of Rulemaking (Check One) <input type="checkbox"/> Proposed Rulemaking <input checked="" type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Final Order, Proposed Rulemaking Omitted	(7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: By the Attorney General <input type="checkbox"/> Yes: By the Governor	
(8) Briefly explain the regulation in clear and nontechnical language. These revisions to Chapter 218 update fees for registration of radiation-producing machines and licenses for naturally-occurring and accelerator-produced radioactive material (NARM), establish license fees for particle accelerators, and establish fees for licenses now administered by the U. S. Nuclear Regulatory Commission (NRC) that will be transferred to the Department when the Commonwealth becomes an Agreement State. The present fees for registration of radiation-producing machines and licenses for use of NARM were last revised in 1992 and no longer cover the costs of the program. Revisions to the regulations in 1998 established a licensing program for particle accelerators. This is a more complicated program than registration and will cost considerably more to conduct. Finally, before the Commonwealth becomes an NRC Agreement State, appropriate fees to conduct a full regulatory program for about 740 new licensees must be established. Because many of the NRC licensees conduct much larger and more complicated operations than those conducted under the currently existing NARM licenses, both licensing and inspection will be more complex and require more resources per license. Due to the Commonwealth's lower overhead and labor rates, the proposed fees will generally be about 30 percent less than currently charged by the NRC and will not exceed NRC fees now paid by the licensees in any case.		
(9) State the statutory authority for the regulation and any relevant state or federal court decisions. Sections 301 and 302 of the Radiation Protection Act (35 P.S. Secs. 7110.301, 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 Environmental Quality Board 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).		

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. As noted in (9) above, various sections of the Radiation Control Act require the Department to set and collect fees sufficient to cover the costs of conducting the radiation protection programs required by the Act and by 25 PA Code, Chapters 215-240. Additionally, Governor Tom Ridge, in his letter of December 6, 1995, notified the U. S. Nuclear Regulatory Commission of the Commonwealth of Pennsylvania's intent to apply for full agreement regulatory authority pursuant to Section 274 of the Atomic Energy Act. As noted in (9) above, the assumption of this regulatory authority is authorized in the Radiation Control Act.

To conduct the regulatory program that will be required to meet the responsibilities of being an NRC Agreement State will require substantially greater resources per license than presently generated from the existing NARM licenses. Two of the limiting factors in assuming this authority are adoption of regulations consistent with NRC regulations (passed in final-form at the June 2001 EQB meeting) and development of a fee structure adequate to support the expanded radioactive materials licensing and inspection program needed.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The Radiation Control Act requires the Department to conduct the radiation protection program, utilizing fees charged under the same authority, to reduce risk to the public from exposure to radiation.

The amendments to Chapter 218 will permit the Department to carry out the existing programs for registration of radiation-producing machines, accelerator licensing, and NARM licensing and inspection activities until the transfer of responsibility for NRC licenses occurs. When the Agreement State authority is granted, and thereafter, the new fee categories will fund the combined program.

Many current NRC licensees also hold PA NARM licenses and registrations of radiation-producing machines. In addition to reducing the total materials licensing fees paid by a licensee, combining licensing of NARM and by-product material into one program will simplify the administrative burden and cost of compliance by licensees because their whole program will be under one set of regulations and only subject to inspection by one agency.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

If the fee structure is not adjusted, the Department will not be able to meet its legal obligations, particularly with regard to inspections of radiation-producing machines and radioactive materials licenses.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The amendments to Chapter 218 will affect approximately 11,000 X-Ray registrants, 250 accelerator licensees, 430 NARM licensees and 740 NRC licensees.

The NRC licensees, particularly those who also hold NARM licenses, will benefit from reduced costs of licensing and compliance in comparison with the present situation. The public in general, particularly users of medical facilities, will benefit from the reduced likelihood of unnecessary radiation exposure associated with improperly used radiation producing machines and sources.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effect as completely as possible and approximate the number of people who will be adversely affected.)

In terms of risk, nobody is adversely affected by these amendments.

The fees paid by 11,000 holders of registrations for X-Ray machines will increase by an average of 40% to account for increases in inspector salaries and equipment costs since 1992. Fees for licenses of particle accelerators are being established at this time. The decision to license, rather than register, accelerators was based on Department experience with inspection of installation and use of these machines. They are much more complicated than lower energy X-Ray machines and present greater difficulty in ensuring safety of patient, staff and the public. The proposed fees are based on experience providing inspections and management/legal time spent on compliance enforcement. The fees for 430 NARM licensees are initially being increased by the same percentage as X-Ray registration fees. The proposed state fees for NRC licenses will be about 70% of the current federal fee. If an NRC licensee also holds a NARM license, the licenses will be combined when DEP assumes the NRC authority, and only the higher fee charged. NARM licensees who do not hold NRC licenses will pay more after Agreement State authority is established because the "NARM only" licenses will cease to exist. The Department estimates that there are 50-100 such licensees.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

X-Ray machine registrants – 11,000, mostly medical and industrial users.

Accelerator Licensees – 250 (but increasing rapidly).

NARM Licensees – 430

NRC Licensees (fees effective after agreement state authority is granted) – estimated at 740.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The amendments were developed with the assistance of the Radiation Protection Advisory Committee comprised of 15 expert representatives of various radiation protection and user groups. Groups represented include: (1) American Associations of Physicists in Medicine (AAPM), Delaware Valley Chapter; (2) AAPM, Penn-Ohio Chapter; (3) Appalachian Compact Users of Radioactive Isotopes (ACURI); (4) Health Physics Society (HPS), Delaware Valley Society for Radiation Safety; (5) HPS, Susquehanna Valley Chapter; (6) HPS, Western PA. Chapter; (7) PA Chiropractic Association; (8) PA College of Nuclear Medicine; (9) PA Dental Association; (10) PA Osteopathic Medical Society; (11) PA Podiatric Medicine Association; (12) PA Radiological Society; (13) PA Society of Radiological Technologists; (14) PA Veterinary Medicine Association; and (15) Independent consultant in industrial uses of radiation.

(17) 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.

The financial effects of these amendments will vary widely with the type of registrant or licensee and were recited in (14) above. Fees for current holders of NRC radioactive materials licenses will almost always be 30% less than they are presently paying. The exact total amount will depend on the specific type of licenses in the state, and we won't have that information until the Department obtains the records from the NRC. Because inspectors are always accompanied by a facility staff person, large facilities like major hospitals should realize substantial savings in compliance costs, in addition to the reduced license fees, by a reduction in the number of inspections and records required. Owners of about 250 particle accelerators will face an increase in costs to support the State's licensing and inspection program that experience has proven necessary and is now required by Chapter 228. The exact amount of the increase will depend on the type of accelerator being licensed and how many similar units are possessed by the licensee. The use of consultants is already widespread, particularly for accelerators and smaller facilities that do not have qualified in-house medical physics staff. This probably won't change appreciably. Additional legal costs would not be required unless enforcement actions are instituted. In recent years, such actions have almost always been associated with medical accelerators.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

It is not possible to estimate the applicability of the proposed fees to local governments at this time. Numerous licenses contain the name of a municipality or county in their name but the only way of determining ownership would be through a manual file review of 13,000 files for present registrants and licensees. Such a review of the NRC licenses will not be possible until the files are in the Department's possession after Agreement State status is achieved.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting or consulting procedures which may be required.

The effects of these amendments will be to provide about \$0.5 million additional funding to support the X-Ray program, about \$230,000 to support the accelerator licensing and inspection program, and about \$100,000 additional funding to support NARM licensing and inspection. These funds will compensate for the present excess of costs over income in those programs. The Department expects only minor increases in cost in the X-Ray program once accelerator activities are separately funded, about 3 FTE increase for accelerator licensing and inspections, and a yet-to-be determined increase in costs of radioactive material licensing and inspections.

The FY2000 income to the NRC from the licenses that the Department will be assuming is reported at \$2.93 million. Because the NRC fees are required by law to cover the entire costs of operating the agency, including international activities, congressional activities, research and many other items not related to license administration, there is no direct connection between the fees charged and the services rendered to a licensee. The NRC licenses the Department will be acquiring tend to be larger and more complicated than NARM licenses and will have to be administered per NRC requirements, which require inspections more often than NARM licenses and more staff time to accomplish. An additional issue in setting fees for a license category is that educational institutions are generally exempted and small businesses are charged reduced fees. In establishing the proposed fee structure, the Department employed a consultant familiar with NRC activities to investigate the NRC fees and the licenses the Department will be acquiring. It was determined that setting Department fees at 70% of the NRC fees and subsuming the existing NARM licenses into the NRC licenses is a reasonable starting point, subject to revision after operating experience is gained. The fees arrived at by this approach are basically adjusted to reflect DEP labor and overhead rates, and are in the middle range of fees set by existing agreement states. The gross increased resources annually would be about \$2 million and a net increase of about \$1.7 million when the amount of fees currently collected for NARM licenses combined with the NRC licenses is subtracted.

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

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Local Government	0	0	0	0	0	0
State Government	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Total Savings	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
COSTS:						
Regulated Community	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Local Government	0	0	0	0	0	0
State Government	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Total Costs	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
REVENUE LOSSES:						
Regulated Community	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Local Government	0	0	0	0	0	0
State Government	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Total Revenue Losses	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a

(20a) Explain how the cost estimates listed above were derived.

The effect of these amendments on license costs is expected to be highly variable as previously noted. For the regulated community, the effect will range from substantial savings on the part of licensees now holding both NRC and state licenses, to, in the case of owners of accelerators, an increase in costs per accelerator that depends on the type, number and use of machines being licensed.

Local governments have no regulatory responsibility in this area and, unless they hold registrations or licenses, should not be affected.

The fiscal implications to state government are discussed in (19) above. For existing X-Ray registrants and NARM licensees, as well as the accelerator registrants being converted to licenses, it is anticipated that income will roughly equal costs for several years. With the assistance of a consultant, who interviewed NRC accounting personnel, the Department derived a formula to estimate what PA fees should be for present NRC license categories. The formula is:

$$\text{PA Annual Fee} = 0.7[\text{NRC Annual Fee} + 0.1 \text{ NRC Application Fee}]$$

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(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-3	FY-2	FY-1	Current FY
X-ray reg/testing	1,403,178	1,613,178	1,584,093	342,295(1 st Qtr)
RAM Lic/Inspect.	216,402	313,041	245,770	18,407
NRC Fees	Unknown	Unknown	Unknown	Est. 2,930,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

These data reflect the total costs of the present X-ray and accelerator registration and inspection programs and the NARM licensing and inspection program. As previously noted, the effect of these proposed amendments will be highly variable, depending on the combinations of licenses and registrations held. Taken separately, X-ray registrants will see an average of 40% increase in fees. Most holders of NRC licenses will see about a 30% decrease in fees when assumed by the Commonwealth. Further, license fees will not increase annually, as the NRC has done. Holders of NARM licenses will see an average of 40% fee increase until the Agreement State authority is achieved. At that time, if they hold an NRC license, the NARM license will be combined with the NRC license at a substantial reduction of total fees. At that time, the separate categories for NARM licenses will be terminated and combined into the corresponding NRC category. Costs for licensees holding only NARM licenses will increase to the equivalent byproduct material license fee at that time.

The benefit to the Commonwealth, other governmental entities, and the public lies in the provision of a unified program of radiation protection covering all radiation sources, except parts of the nuclear fuel cycle, nuclear power plants, and the nuclear weapons program which will continue to be regulated by the NRC or other Federal agencies. Control of radiation is brought closer to local rule.

Users of radioactive material will benefit by having one regulator, lower compliance costs, and, generally, lower licensing expenses.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

None were considered. See (23)

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The only viable alternative regulatory scheme is for the Commonwealth to stop efforts toward becoming a NRC Agreement state and to continue the dual regulatory system currently in effect. This alternative was dismissed because: (1) acquiring the NRC regulatory authority for radioactive materials is a purpose of the Radiation Control Act; (2) Governor Ridge committed us to this path in 1995 by his letter to the NRC; and (3) it is a significant advantage to the regulated community to combine radioactive materials licensing and inspections into one program rather than the present two programs.

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(24) 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 regulation.

Yes. All state regulations regarding X-ray machines and accelerators are more stringent than federal regulations because the federal government (FDA), with the exception of mammography, only approves the design of such machines. All regulation of their use in medicine and industry is done by the states. PA regulations conform in most respects to the Suggested State Regulations of the Conference of Radiation Control Program Directors (CRCPD). Fees are comparable to other states with similar programs.

The proposed fees for NRC licenses being transferred to the Commonwealth average about 70% of the FY2000 NRC fees.

(25) How does the regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The fees being proposed vary somewhat in fine detail, but are generally comparable to those charged by other states.

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

These amendments are a complete revision of Chapter 218 (Fees) and directly affect only existing DEP programs plus incorporation of radioactive materials licenses presently regulated by the NRC. Other agencies will be affected only if they hold DEP registrations or licenses or NRC licenses.

Impact on other State agencies will be negligible, if any.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No.

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(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Not to any great extent. The Department already uses forms similar to the NRC forms and the reports required are similar. The license application forms for accelerators are in the final stages of development.

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

Reduced fees have been provided for small businesses and not-for-profit organizations in accordance with a similar approach that the NRC currently uses (see Appendix A footnotes 5 and 6).

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

These fees will be effective when published in the *PA Bulletin* as final rulemaking. For X-Ray machines, the new fees will appear on renewal invoices sent two months prior to the registration anniversary date. The same is true of existing NARM licenses. It is anticipated that existing registrations for accelerators will be converted to licenses by the time these fees are in effect. The new fees will be invoiced on renewal. The present NRC licenses will be converted to PA licenses on the license anniversary date and the PA fee invoiced at that time. This will probably occur late in the year 2002.

(31) Provide the schedule for continual review of the regulation.

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

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(Pursuant to Commonwealth Documents Law)

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DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. #7-363

DATE OF ADOPTION: 9-18-01

BY: David E. Hess

TITLE: DAVID E. HESS, CHAIRMAN
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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ORDER ADOPTING REGULATIONS

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Radiological Health Amendments - Fees

25 Pa. Code, Chapter 218

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

Sec.

218.1. Purpose and scope.

PAYMENT OF FEES

218.11. Registration, renewal of registration and license fees.

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

GENERAL

§ 218.1. Purpose and scope.

(a) This chapter establishes fees for registration and licensing and provides for their payment.

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

(1) Is required to register or renew registration for radiation-producing machines under Chapter 216 (relating to registration of radiation-producing machines).

(2) Is an applicant for or holder of a radioactive material license issued under Chapter 217 (relating to licensing of radioactive material).

(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.]

(Editor's Note: The following text is new and is printed in regular type to enhance readability.)

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

(b) A registrant filing an initial registration under § 216.2 (relating to registration) or an application for renewal of a certificate of registration under § 216.4 (relating to renewal of certificate of registration) shall remit the appropriate fee calculated by using the

information on the registration or application form and the fee schedule in subsection (a). Fees for any initial registration under § 216.2 are payable upon the filing of the registration. Fees for the renewal of a certificate of registration are payable upon the submission of an application for a renewal of a certificate of registration. If the number of tubes increases after an initial registration or after an application for renewal has been filed with the Department, no additional fee is required until the time of the next registration. Likewise, if the number of tubes decreases during the year, no refund will be made for that year.

(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.]

(1) 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.

[(2) *Exceptions.* This subsection does not apply to the low-level radioactive waste disposal facility operating license.]

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

(1) 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.

(2) Accelerators used for ion implantation - \$500 plus \$50 for each additional unit at the same site.

(3) 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) If the registration involves more than one of the facilities in subsection (a), or if a license involves more than one of the categories in subsection (c), the highest applicable fee applies.

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

- (a) A registrant or licensee who fails to pay an annual fee required under this chapter shall be subject to the civil and criminal penalties provided under the act.
- (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: This table is new and is printed in regular type to enhance readability.)

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

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.

3O	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
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

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 less than \$5 million; Small Government Jurisdictions (including publicly supported, non-medical educational institutions) with a population between 20,000 and 50,000; and non-medical educational institutions that are not state or 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 35 employees and less than \$350,000 in Gross Annual Receipts; Small Government Jurisdictions (including publicly supported non-medical educational institutions) with a population less than 20,000; and non-medical educational institutions that are not state or publicly supported and have less than 35 employees.

NOTICE OF FINAL RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL
QUALITY BOARD
[25 PA. CODE CHAPTER 218]
Radiological Health

ORDER

The Environmental Quality Board (Board) by this order amends 25 PA Code, Chapter 218, relating to fees, 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 Pennsylvania attains Agreement State status from the NRC.

This order was adopted by the Board at its meeting of September 18, 2001.

A. *Effective Date.*

These amendments are effective upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. *Contact Persons.*

For further information, the contact persons are L. Ray Urciuolo, Chief, Licensing Section, Radiation Control Division, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-3720; and Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, Rachel Carson State Office Building, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This proposal is available electronically through the DEP Web site (<http://www.dep.state.pa.us>).

C. *Statutory Authority.*

This final rulemaking is being made under the authority of 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, management, regulation and inspection of radiation sources and radiation source users, and delegate to the Board the power to adopt the regulations of the Department to implement the act.

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

D. Background and Summary.

The Radiation Control Act requires the Department to establish fees in amounts at least sufficient to cover the costs of the radiation protection program mandated by that 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, Chapter 228 (relating to radiation safety requirements for particle accelerators) was amended 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 Pennsylvania that are now administered by the U. S. Nuclear Regulatory Commission, the Department 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, where there is no reasonable way of establishing fixed fees.

Therefore, Chapter 218 is being amended 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 percent, an amount sufficient to ensure income adequate to fund those programs;
- (2) establishing fees for licensing of particle accelerators; and
- (3) establishing annual fees for radioactive material licenses located in Pennsylvania 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.

As required by section 301(c)(14) of the act (35 P. S. § 7110.301), the Department provided the Radiation Protection Advisory Committee (Committee) with an opportunity to review the final amendments and to advise the Department prior to submittal to the Board. On May 17, 2001, the Committee met and reviewed the draft final rulemaking. The chairperson announced by letter dated May 17, 2001, the Committee's concurrence to send the final rulemaking to the Board.

E. Summary of Regulatory Requirements.

A description of the amendments is provided below:

GENERAL

§ 218.1. Purpose and Scope.

A new subsection (b)(3) is added to include holders of and applicants for accelerator licenses to the list of persons subject to the provisions of 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 percent 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, is deleted as it is no longer needed.

Existing subsections (d), (e), and (f) are renumbered as (e), (f), and (g), respectively, and a new subsection (d) is added to institute license fees for several classes of accelerators. 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), and to recognize the various fee schedules in 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 Section 218.11(c), which specified fees for NARM licenses, and establishes fees for licenses that will be transferred to Pennsylvania when regulatory authority for most types of radioactive material is transferred from the NRC.

F. Summary of Comments and Responses on the Proposed Rulemaking.

The notice of proposed rulemaking was published at 31 Pa.B. 943 (February 17, 2001) and included a 30-day comment period that ended on March 19, 2001. The Board received no comments from the public, Independent Regulatory Review Commission, or the legislative committees concerning the proposed rulemaking. Therefore, no Comment/Response document was prepared.

G. Benefits, Costs and Compliance.

Executive Order 1996-1 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 the 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 below.

Compliance Costs

The compliance costs under the proposed amendments will vary with the type of license and/or registration held. X-ray registrants and NARM licensees will incur a fee increase on average of about 40 percent. License fees for former NRC radioactive materials licenses will decrease by about 30 percent 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 radioactive materials (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 a significant increase in fees, the exact amount of which will be determined by the type and number of such machines that they possess. The EQB instituted the change to licensing because of the complexity and potential hazards associated with accelerator 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 amendments. Once Agreement State authority is approved, which is anticipated in 2002, and the NRC licenses are converted to state licenses, over a period of a year, licensees will have significantly less paperwork.

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 February 6, 2001, the Department submitted a copy of the notice of proposed rulemaking, published at 31 Pa.B. 943, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment. There were no comments received from the public, IRRC or the Committees on the proposed rulemaking.

Under Section 5.1(d) of the Regulatory Review Act (71 P.S. 745.5a(d)), on _____, these final-form regulations were deemed approved by the House and Senate Committees. Under Section 5.1(e) of the Regulatory Review Act, IRRC met on _____ and approved the final-form regulations.

J. *Findings of the Board.*

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated thereunder at *1 Pennsylvania Code* §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law, and no comments were received.
- (3) These regulations do not enlarge the purpose of the proposal published at *31 Pennsylvania Bulletin* 943 (February 17, 2001).
- (4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

K. Order of the Board.

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department of Environmental Protection, *25 Pennsylvania Code*, Chapters 218, are amended by amending the aforesaid chapter to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Chairman of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of the Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairman shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resource and Energy Committees as required by law.

(d) The Chairman of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately.

BY:

DAVID E. HESS
Chairman
Environmental Quality Board

FEE REPORT FORM
Licensing of Radioactive Materials

Environmental Protection/Radiation Protection
 Agency

December 28, 2000
 Date

L. Ray Urciuolo
 Contact Person

(717) 787-3720
 Phone Number

	<u>Prior Year</u>	<u>Current Year</u>	<u>First Future Year Projected</u>	<u>Second Future Year Projected</u>
FEE COLLECTIONS:				
Current	\$269,990	\$241,000	\$ 337,400	
Proposed			\$ 337,400 when regs final	~\$2,000,000 when A.S. status effective.

FEE TITLE AND RATE:

Current: Licenses for use of naturally-occurring and accelerator-produced radioactive material and certain source material. Depending on quantity, type of use, hazard, etc., licenses are assigned to three categories in § 218.11(c)(1) with annual fees of \$1,530, \$125, or \$600. In CY2000 there were 29 Category 1 Licenses, 42 Category 2 Licenses, and 304 Category 3 Licenses with fees totaling \$241,000.

Proposed: There will be a 2-step modification and increase in fees. When this regulation modification is effective initially, fees for the existing NARM licenses will be increased by about 40% to offset the increases in salaries and equipment since the fees were set in 1992. Beginning on the date that PA becomes an Agreement State for the Nuclear Regulatory Commission, likely to occur sometime in 2002, the NRC license classification system will be adopted and fees charged as shown in the attached table. The fees for individual licensees will change on the anniversary of the current NRC or PA license. For licensees holding both types of license, the licenses will be combined, with a single annual fee, when the first license comes up for renewal.

FEE OBJECTIVE: Completely cover the costs of licensing and inspecting about 1250 radioactive materials licenses for use of NARM and, upon attaining Agreement State status, byproduct materials. Program elements are the Radioactive Materials Licensing Section, Radiation Control Division, BRP, which is located in the Rachel Carson Building, and inspection staff in DEP Regional Offices in Conshohocken, Harrisburg, and Pittsburgh. Supervisory and management staff are at each location. Substantial specialized training of inspectors is required to meet NRC requirements. This training is about half completed for existing staff. The program has to maintain an inventory of specialized radiation survey and analytical equipment for field work, and the Department supports a sophisticated radiation laboratory to support environmental surveillance and materials license inspections. Both will need increase of capability as the NRC's responsibilities are transferred.

**FEE RELATED ACTIVITIES
AND COSTS**

1. Detailed review of license proposals including facility design, operating procedures and radiation safety procedures for the proposed license
2. Inspections of the facility within the first year of licensing to ensure that the design and procedures are followed.
3. Periodical and on-demand inspections throughout operational life. Inspection intervals of 1-7 years, depending upon NRC Priority class.
4. Technical and legal investigation as needed.
5. Special staff training.
6. Supervisory and management time.

ANALYSIS: The Department presently has 375 NARM licenses in effect. These licenses are renewed on a 5-year cycle and inspected on a 4-year interval. Annual fees are charged in the 3 categories as indicated. No separate application/renewal fee is charged. As licenses are renewed, we are shifting to a 10-year cycle to correspond with the NRC. The new fee structure will include over 30 fee categories, taken from the NRC structure, but will not include a separate licensing/renewal fee that the NRC charges. We will have about 1,250 combined materials licenses under the new system. Until we receive the license files from the NRC, it is not feasible to determine exactly how many licenses of each category we will have. The new fee structure also includes provision for special fees for not for profit and small businesses based on size and income. An extremely important feature is provision for full cost recovery for work done in connection with certain types of licenses (e.g., decommissioning, restoration etc.) for which the DEP presently must provide staff oversight but lacks means to recover our costs.

Many of the new, combined licenses will involve larger and more complex operations than our current NARM licenses and, even though more than half of the NARM license holders also hold NRC licenses, our experience with licensing and inspecting NARM licenses is not a reliable guide to the effort required to handle the combined licenses. With the assistance of a consultant experienced with NRC practices and accounting for relative overhead costs, DEP determined that an annual licensing fee of 70% of the total NRC charges over a 10-year cycle would be a reasonable starting point with the intent of reviewing the fees in four years. (PA Annual Fee = 0.7 (NRC Annual Fee + 0.1 NRC Renewal Fee). The NRC revises their fees annually. We used the FY2000 fees as the basis. The NRC collected about \$2.7 million from PA materials licensees in FY2000 which would equate to about \$1.9 million in our system (less the loss of income from NARM licenses being combined with NRC licenses), if all licenses were transferred and the categories didn't change.

RECOMMENDATION

AND COMMENT: Approve the final regulations. The Radiation Protection Advisory Committee (RPAC), which includes radiation safety staff from medical and industrial materials licensees, examined the amendments in detail and recommended their adoption.

APPENDIX A

FEES FOR RADIOACTIVE MATERIAL LICENSES

FEE CATEG ORY	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
3O	Radiography	10,850

* * * *

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 license that are not included in this table will be calculated as follows:

$$\text{PA Fee} = 0.7(\text{NRC Annual Fee} + 0.10 \text{ NRC Application/Renewal fee}).$$

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.

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 (ex Teletherapy)	4,300
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 for full cost items	50/hr.

* * * *

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; Small Government Jurisdictions (including publicly supported, non-medical educational institutions, with a population between 20,000 and 50,000; and non-medical Educational Institutions that are not state or 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 35 employees; Small Government Jurisdictions (including publicly supported non-medical educational institutions, with a population less than 20,000; and non-medical Educational Institutions that are not state or publicly supported and have less than 35 employees.

FEE REPORT FORM – Accelerator Licensing

Environmental Protection/Radiation Protection	December 27, 2000
Agency	Date
L. Ray Urciuolo	
Contact Person	
(717) 787-3720	
Phone Number	

<u>Prior</u>	<u>Current</u>	<u>First Future</u>	<u>Second Future</u>
<u>Year</u>	<u>Year</u>	<u>Year</u>	<u>Year</u>
		<u>Projected</u>	<u>Projected</u>

FEE COLLECTIONS:

Current	\$4,775	\$4,775		
Proposed			\$212,250	\$212,250

Actual fee collections will be highly dependent on expanding use in radiation oncology. A table is appended that summarizes estimated collections based on currently active installations.

FEE TITLE AND RATE:

- | | |
|----------|---|
| Current | Not specifically identified in current fee structure. Accelerators are registered and invoiced as X-Ray tubes at \$25/tube. |
| Proposed | Establishment of a new Chapter 228, relating to Radiation Safety Requirements for Particle Accelerators, by the Environmental Quality Board requires that particle accelerators be licensed by the Department and that fees be established. This is the first revision of Chapter 218, relating to fees, since Chapter 228 became effective. Based on DEP experience in evaluating accelerator installations and the level of effort experienced in inspections and compliance activities, the Department is proposing annual fees of \$1,500 for the first accelerator and \$500 for each additional unit at the same facility. Lower fees of \$500 for the first unit and \$50 for additional units are proposed for accelerators used for ion implantation (not involving deliberate human exposure). Accelerators operating at energies above 50 MeV are essentially "one of a kind" units and require proportionately more effort to evaluate. For these units, the Department recommends full cost recovery at the currently established hourly rate. The rate recommended in this revision is \$50 per hour. |

FEE OBJECTIVE: To recoup the Department's costs in reviewing new license applications and renewals, inspect the facilities and conduct necessary compliance activities.

FEE RELATED ACTIVITIES AND COSTS

1. Detailed review of proposed design, operating procedures and radiation safety procedures for the proposed installation.
2. Inspections of the facility before, during, and after construction to ensure that the design and procedures are followed.
3. Periodical and on demand inspections throughout operational life.
4. Technical and legal investigation as needed.
5. Special staff training.
6. Supervisory and management time.

ANALYSIS: The use of particle accelerators in medicine, especially cancer treatment, and industry has been increasing rapidly in recent years. Unlike X-ray machines which in general are standardized in design, installation, and operation, accelerators require more regulatory attention during the design and pre-operational and early post-operational stages, require much more attention to shielding design and testing, and need more frequent inspection. These concerns led to the adoption of Chapter 228 almost 3 years ago.

RECOMMENDATION

AND COMMENT: Approve the final regulations. The Radiation Protection Advisory Committee (RPAC), which includes several operators of accelerators in its membership, reviewed the proposed fees and felt they were reasonable.

Summary of collections based on proposed annual fees for particle accelerator licenses

		Medical	Non Medical
Current Fees		161 @ \$25 = \$4,025	30 @ \$25= \$750
New Fees	1 unit	64 @ \$1,500 = \$96,500	9 @ \$1,500 = \$13,500
	2 units	31 @ \$2,000 = 62,000	2 @ 2,000 = 4,000
	3 units	7 @ \$2,500 = 17,500	1 @ 2,500 = 2,500
	4 units	2 @ \$3,000 = 6,000	2 @ 3,000 = 6,000
	5 units	0	0
	6 units	1 @ \$4,000 = 4,000	1 @ 750 ¹ = 750 (ION)
Subtotal		\$185,500	\$26,750
Total			\$212, 250

* * * *

¹ Ion implant machines

FEE REPORT FORM – Registration of X-Ray Machines

Environmental Protection/Radiation Protection
Agency

December 27, 2000
Date

L. Ray Urciuolo
Contact Person

(717) 787-3720
Phone Number

	<u>Prior Year</u>	<u>Current Year</u>	<u>First Future Year Projected</u>	<u>Second Future Year Projected</u>
FEE COLLECTIONS:				
Current	\$1,655,520	\$1,763,920	\$1,763,920	
Proposed			\$2,537,905	\$2,537,905

FEE TITLE AND RATE:

- Current X-ray Machine Registration Fees
- Proposed X-Ray Machine Registration Fees.

See attached summary table for details.

FEE OBJECTIVE: Per Radiation Control Act, establish and collect fees sufficient to cover costs of registering and periodically inspecting radiation-producing machines and establishing, reviewing, and revising regulations for the safe use of such equipment.

- FEE RELATED ACTIVITIES AND COSTS**
1. Devise and operate a system of registration for X-Ray Machines.
 2. Establish appropriate regulations for use of X-Ray Machines including recommended radiation safety procedures.
 3. Periodically and on demand inspect facilities for compliance with regulations.
 4. Technical and legal investigation as needed.
 5. Special staff training.
 6. Supervisory and management time.

ANALYSIS: The use of X-Ray machines is ubiquitous and expanding in all forms of medical practice. Certain areas of interventional practice, involving protracted use of fluoroscopes on a patient to guide treatment inside the body, have emerged as needing particular care to protect both patient and practitioner. In certain cases, notably mammography, special care is needed to ensure diagnostic accuracy. The current fees and staff supported by them, no longer support the level of inspection program needed. It is noted that these fees were established in 1992, that staff salaries have increased at the rate of about 5% annually (totaling about 40%), and that the cost of acquiring and, especially maintaining calibration of, appropriate instrumentation has increased equivalently in this period.

RECOMMENDATION

AND COMMENT: Approve the final regulations. The Radiation Protection Advisory Committee (RPAC), which includes practitioners of medical disciplines that use X-Ray machines, medical physicists, health physicists, medical technologists and industrial users, examined the amendments in detail and recommended their adoption.

Summary of Current and Proposed Annual Fees for Registration of X-Ray Machines

Type of Facility	Current Annual		Current			CY2000 Fee Collection	Prop. Annual Admin. Fee	Prop. Annual Fee Per Tube	Estimated Annual Fee Collection with Proposed Fees
	Registration Fees (incl. 1 X-ray tube)	Current Annual Fee for Each Additional Tube	Number of Facilities	Number of Extra Tubes	Total Number of Tubes				
Chiropractor	\$175	\$25	1,135	886	2,021	\$220,775	250	\$35	\$354,485
Clinic	175	25	322	602	924	72,120	250	35	112,840
Dentist	75	25	5,424	13,973	19,397	756,120	70	35	1,058,575
Home	175	25	14	28	42	3,150	250	35	4,970
Hospital	520	25	236	5,717	5,953	268,730	520	35	331,075
Industry	175	25	424	1,263	1,687	106,350	250	35	165,045
Medical Doctor	175	25	792	1,244	2,036	170,000	250	35	269,260
Osteopath	175	25	77	88	165	15,675	250	35	25,025
Other Medical	175	25	43	248	291	13,725	250	35	20,935
Other Non-Med	175	25	17	35	52	3,850	250	35	6,070
Podiatrist	75	25	601	224	825	50,675	70	35	70,945
Prison	175	25	23	46	69	5,175	250	35	8,165
School	175	25	53	452	505	20,725	250	35	30,925
Veterinarian	75	25	652	318	970	56,850	70	35	79,590
TOTALS						\$1,763,920			\$2,537,905



Pennsylvania Department of Environmental Protection

Rachel Carson State Office Building
P.O. Box 2063
Harrisburg, PA 17105-2063
September 21, 2001

The Secretary

Phone: 717-787-2814
E-Mail: DavidHess@state.pa.us

Mr. Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown #2
333 Market Street
Harrisburg, PA 17120

RE: Final Rulemaking: Radiological Health (Fees – Ch. 218) (#7-363)

Dear Bob:

Pursuant to Section 5.1(a) of the Regulatory Review Act, enclosed is a copy of a final-form regulation for review by the Commission. This final rulemaking was approved by the Environmental Quality Board (EQB) on September 18, 2001.

This final rulemaking contains a revised fee structure for registrations, licenses, and inspections of radiation-producing machines and radioactive material. Current fees no longer cover these activities, which are required by regulation. In addition, DEP's responsibilities will expand to include more complex licensing and inspection when Pennsylvania becomes an Agreement State. With Agreement State status, DEP will assume responsibility for licensing and oversight of decommissioning of a number of sites formerly licensed by the Nuclear Regulatory Commission (NRC). Authority for actual cost recovery is established in these amendments.

The proposed rulemaking was adopted by the EQB on January 16, 2001, and published February 17, 2001. There were no comments received during the 30-day public comment period; therefore, no changes have been made in the final rulemaking. The RPAC endorsed the final rulemaking on May 17, 2001.

The Department will provide the Commission with any assistance required to facilitate a thorough review of this final-form regulation. Section 5.1(e) of the Act provides that the Commission shall, within ten days after the expiration of the committee review period, approve or disapprove the final-form regulation.

Mr. Robert E. Nyce

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September 21, 2001

For additional information, please contact Sharon Trostle, Regulatory Coordinator, at 787-4526.

Sincerely,

A handwritten signature in black ink, appearing to read "David E. Hess". The signature is fluid and cursive, with a prominent initial "D" and a stylized "H".

David E. Hess
Secretary

Enclosures

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

I.D. NUMBER: 7-363
SUBJECT: Radiological Health Amendments - Fees
AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- Proposed Regulation
- X 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

2001 OCT 1 PM 5:57
REGULATORY REVIEW ACT

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/21/01	<i>Kay O'Brien</i>	HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
9/21/01	<i>Pat Larrather</i>	SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
9/21/01	<i>Elena Pagan</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

