Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-490
Regulation title	Radiation Protection Regulations: Fee Schedule
Action title	Amend fee schedule to increase X-ray machine registration and inspection fees
Date this document prepared	September 24, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations: Fee Schedule (12 VAC 5- 490) to adopt new X-ray machine registration fees, and to include additional types of X-ray machines in the inspection fee schedule. These proposed regulations are intended to supersede the Radiation Protection Regulations: Fee Schedule, which became effective January 1, 1989.

NOTE: A Notice of Intended Regulatory Action (NOIRA) was published in the Virginia Register on 2/5/2007. That publication provided notice of an intent to propose these regulations, as well as a separate set of amendments that have proceeded separately to a different point in the promulgation process. (This separate set of amendments currently has a Town Hall Action/Stage number of 2191/4281.)

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On October 17, 2008, the Board of Health voted to adopt the proposed regulation 12 VAC 5-490 (Radiation Protection Regulations: Fee Schedule).

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

These regulations are authorized by the Code of Virginia, Sections 32.1-229 et seq. Section 32.1-229.1 requires the Board of Health to establish fee schedules for registration of machines, for inspections of X-ray machines by Department of Health personnel (except for audit inspections initiated by the Department). Section 32.1-229.2 requires the Board of Health to set inspection fees to minimize competition with the private sector and include all reasonable costs.
Refer to the following web sites for viewing these sections of the Code:
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.2

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The proposed regulatory action addresses two sets of fees levied by the X-ray machine program: X-ray machine *registration fees* and X-ray machine *inspection fees*. With respect to the X-ray machine *registration fees*, the existing regulation is being amended due to the increased costs of maintaining a registration program for X-ray machines since publication of the fee schedule with an effective date of January 1, 1989. The *registration fees* need to be adjusted to decrease the growing reliance on general funds to support this activity. The X-ray machine *inspection fees* also need to be modified. There now exist several types of X-ray machines that did not exist in 1989, for which the agency does not have an appropriate *inspection fee*--fees for these machines are now included in the proposed X-ray machine inspection schedule. The personnel and travel cost to the agency for machine inspections have also increased since the fee schedule was established in 1989.

The harmful effects of radiation are well known, as well as the many beneficial applications of radiation in industry and healthcare. Adequate regulatory controls for the useful application of radiation is necessary to protect the health, safety and welfare of citizens. The Commonwealth seeks to fully cover the costs of the X-ray machine program from registration fees by SFY2010.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Section 10 of the Regulations is to be amended to increase the X-ray machine *registration fee* of $15 annually to $50 for those facilities on an annual inspection frequency; to increase the fee of $15 to $50 every three years for those facilities on a three year inspection cycle; and to consider higher registration fees for radiation therapy machines and particle accelerators.

Section 20 of the Regulations is to be amended to revise the X-ray machine *inspection fees* for the various types of X-ray machines based on existing costs to the agency and to develop inspection fees for bone densitometers; combination dental panographic and cephalometric machines; and other X-ray machine types which were not included in the fee schedule.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1. Primary advantages and disadvantages to the public:

The primary advantage to the public is that the X-ray machine registration and inspection activities will rely less on general funds to support these activities and more on the users of the X-ray equipment.

There are no disadvantages to the public in promulgating the proposed fee schedule.

2. Primary advantages and disadvantages to the agency and Commonwealth:

Approving the proposed fee structure will allow the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

3. Other pertinent matters of interest to the regulated community:

X-ray machine registrants have an interest in keeping inspection fees as low as possible.

Private inspectors of X-ray machines have an interest in assuring that inspection fees by agency inspectors do not hurt their business by undercutting the private sector pricing, and the *Code of Virginia* Section 32.1-229.2 requires the agency to establish inspection fees in such a manner so as to minimize competition with the private inspector while recovering costs.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-490-10	X-ray Machine registration Fees	No change	
12VAC5-490-20	X-ray Machine Inspection Fees	No change	

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Dr. Samuel Peters	This seems to be another tax. I don't approve. Don't you have enough money from actual taxes?	Disagree. The legislative intent is for the X-ray machine program to be supported by fees. The existing fee structure only provides 30 percent of the funds needed to support the activity. No change.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
2VAC5-490-10	N/A	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: $15 for each machine and additional tube(s) that have a required annual inspection, collected annually; $15 for each machine and additional tube(s) that have a required	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: ~~$15~~ $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; ~~$15~~ $50 for each machine and additional tube(s) that have a required inspection every three years, collected every three

		inspection every three years, collected every three years.	years.
		All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:	All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:
		$15 for each machine with a maximum beam energy of less than 1 Mev;	~~$15~~ $50 for each machine with a maximum beam energy of less than ~~1 Mev~~ 500 KVp;
		$15 for each machine with a maximum beam energy of 1 Mev or greater.	~~$15~~ $50 for each machine with a maximum beam energy of ~~1 Mev~~ 500 KVp or greater.
		Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.	Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.
			Rationale: Cost of postage, data processing equipment and personnel expenses have increased considerably since the fee schedule was first implemented in 1989. Fees set to generate revenue to support the activity at SFY2008 levels ($400,000) until the next regulatory review cycle in three years.
12VAC5-490-20		Inspection fees. The following fees shall	Inspection fees. The following fees shall be charged for surveys requested by the registrant and

		be charged for surveys requested by the registrant and performed by a Department of Health inspector: Cost Per Type Tube	performed by a Department of Health inspector: Cost Per Type Tube
		General Radiographic(includes: Chiropractic, Mammographic, Podiatric, Veterinary, Cephalometric, and Special Purpose X-ray Systems) $190	General Radiographic (includes: Chiropractic, ~~Mammographic, Podiatric, Veterinary, Cephalometric,~~ and Special Purpose X-ray Systems) $230
		Fluoroscopic, C-arm Fluoroscopic $190	Fluoroscopic, C-arm Fluoroscopic $230
		Combination (General Purpose-Fluoroscopic) $380	Combination (General Purpose-Fluoroscopic) $460
		Dental Intraoral, Cephalometric and Panographic $ 65	Dental Intraoral, ~~Cephalometric~~ and Panographic $ 90 Veterinary $160 Podiatric $ 90 Cephalometric $120 Bone Densitometry $ 90 Combination (Dental Panographic and Cephalometric) $210
		None	Shielding review for dental facilities $250 Shielding review for radiographic,

			chiropractic, veterinary, fluoroscopic, or podiatric facilities $450 Rationale: Personnel and travel expenses have increased since implementation of fee schedule in 1989. VDH has received increasing number of shielding review requests and requires significant staff time.

There are no changes to the proposed regulation resulting from the public comment period.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

1. Approximately two thirds of the facilities are on a three-year registration and inspection cycle rather than an annual registration and inspection cycle. Those facilities on a three-year cycle represent the majority of small businesses.
2. The establishment of schedules or deadlines for compliance with registration or inspection requirements are consistent with other states. Less stringent inspection requirements may result in undetected non-compliances that may adversely affect patient care and safety. Less stringent registration requirements may adversely impact the reliability and value of the X-ray machine database.
3. The fee schedules were kept as simple as possible.
4. Establishment of performance standards in place of operational standards does not appear to be applicable to implementing a fee schedule.
5. Most of the entities this regulation applies to are small businesses. The Code of Virginia does not provide exemptions for the requirements of this regulation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes would not have a direct impact on the institution of the family and family stability.