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Final Regulation Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-490
Regulation title(s)	Virginia Radiation Protection Regulations: Fee Schedule
Action title	Modify radiation protection X-ray device registration and inspection fees.
Date this document prepared	12/13/2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The Virginia Department of Health's Office of Radiological Health proposes to amend 12VAC5-490, Radiation Protection Fee Schedule. Specifically, this amendment:

- Revises registration fees for equipment inspected every three years;
- Adds three (3) categories and associated fees for the registration of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
 - Baggage, Cabinet and Analytical, and Industrial X-ray equipment.
- Adds three (3) categories and associated fees for the inspection of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
 - Baggage, Cabinet and Analytical, and Industrial X-ray Equipment.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

KVp – Peak tube potential; the maximum value of the potential difference across the x-ray tube during an exposure
ORH - Office of Radiological Health

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.

Final amendments to the Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490) were approved by the Board of Health on March 16, 2017.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

These regulations are authorized by §§ 32.1-229 et seq. of the Code of Virginia. Section 32.1-229.1 authorizes the Board of Health to set fees for X-ray equipment and requires the Board of Health to promulgate regulations for the registration, inspection, and certification 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.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment (Baggage, Cabinet, Analytical, and Industrial equipment) but do not establish a fee for registration of this equipment, do not establish a fee for the Office of Radiological Health (ORH) to inspect

this equipment, and do not specify associated inspection frequencies. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states.

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 are necessary to protect the health, safety and welfare of citizens. The potential exists for accidents associated with this equipment, which have in fact occurred. Accordingly, regulatory attention needs to be applied to promote the safety of non-medical X-ray equipment. These fees will help offset the cost of administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment. These costs were once absorbed from general funds allocated to ORH, but those general funds have since been abolished.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

In Section 10 of the Regulations, the fee for each machine and additional tube(s) that has an inspection frequency of every three years is proposed to increase from \$50 to \$60, collected every three years.

The following annual registration fees are proposed for all operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation:

- o \$20 for each machine used for baggage inspection;
- o \$25 for each machine identified as cabinet or analytical; and
- o \$50 for each machine used for industrial radiography.

Section 20 of the Regulations is proposed to be amended to add the following inspection fees and required inspection frequencies for operators or owners of baggage, cabinet, analytical, or industrial X-ray machines capable of producing radiation:

- o Baggage X-Ray Unit: \$100 per inspection, inspected every 5 years;
- o Cabinet/Analytical X-ray Unit: \$150 per inspection, inspected every 3 years;
- o Industrial Radiography X-Ray Unit: \$200 per inspection, inspected annually.

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.

The primary advantage of this change to the public and the regulated community is that registering all X-ray machines allows ORH to maintain an accurate database of the devices, track inspections and ensure that the machines are functioning properly so as to minimize the risk of equipment malfunction and accidental overexposures.

1. Primary advantages and disadvantages to the public:
The primary advantage to the public is that it will ensure the safe operation of non-medical x-ray equipment through the institution of an effective registration and inspection program.

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 ensuring that inspection fees by agency inspectors do not hurt their business by undercutting the private sector pricing, and Virginia Code § 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.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements or no requirements that exceed applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities that would be disproportionately affected by this action.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

No changes were made since the proposed stage.

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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Kevin Donaldson, General Electric	Fees reasonable for X-ray registration. We use 2 cabinet X-rays in our manufacturing facility and the fees seem appropriate and reasonable. No objections.	Concur.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-490-10		<p>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:</p> <p>\$50 for each machine and additional tube(s) that have a required annual inspection, collected annually;</p> <p>\$50 for each machine and additional tube(s) that have a required inspection every three</p>	<p>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:</p> <p>\$50 for each machine and additional tube(s) that have a required annual inspection, collected annually;</p> <p>\$50 \$60 for each machine and additional tube(s) that have a required inspection every three years, collected every three years.</p>

		<p>years, collected every three years.</p> <p>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:</p> <p>\$50 for each machine with a maximum beam energy of less than 500 KVp;</p> <p>\$50 for each machine with a maximum beam energy of 500 KVp or greater.</p> <p>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.</p>	<p>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:</p> <p>\$50 for each machine with a maximum beam energy of less than 500 KVp;</p> <p>\$50 for each machine with a maximum beam energy of 500 KVp or greater.</p> <p><u>All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay the following annual registration fee:</u></p> <p><u>\$20 for each machine used for baggage inspection;</u></p> <p><u>\$25 for each machine identified as cabinet or analytical; and</u></p> <p><u>\$50 for each machine used for industrial radiography.</u></p> <p>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.</p> <p>Intent/Rationale/Impact: This change would increase fees for x-ray producing devices that are required to be registered every three years; and levy fees to register non-medical x-ray producing devices. Owners of x-ray producing devices are already required to register the equipment with ORH, but ORH has not, in the past, been authorized to collect a fee to cover administrative costs. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.</p>
<p>12VAC5-490-20</p>		<p>The following fees shall be charged for surveys requested by the registrant and performed by a Department of Health inspector:</p>	<p>The following <u>table lists the</u> fees <u>that</u> shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, <u>as well</u></p>

	<table border="1"> <thead> <tr> <th>Type</th> <th>Cost Per Tube</th> </tr> </thead> <tbody> <tr> <td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td> <td>\$230</td> </tr> <tr> <td>Fluoroscopic, C-arm Fluoroscopic</td> <td>\$230</td> </tr> <tr> <td>Combination (General Purpose-Fluoroscopic)</td> <td>\$460</td> </tr> <tr> <td>Dental Intraoral and Panographic</td> <td>\$90</td> </tr> <tr> <td>Veterinary</td> <td>\$160</td> </tr> <tr> <td>Podiatric</td> <td>\$90</td> </tr> <tr> <td>Cephalometric</td> <td>\$120</td> </tr> <tr> <td>Bone Densitometry</td> <td>\$90</td> </tr> <tr> <td>Combination (Dental Panographic and Cephalometric)</td> <td>\$210</td> </tr> <tr> <td>Shielding Review for Dental Facilities</td> <td>\$250</td> </tr> <tr> <td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td> <td>\$450</td> </tr> </tbody> </table>	Type	Cost Per Tube	General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	\$230	Fluoroscopic, C-arm Fluoroscopic	\$230	Combination (General Purpose-Fluoroscopic)	\$460	Dental Intraoral and Panographic	\$90	Veterinary	\$160	Podiatric	\$90	Cephalometric	\$120	Bone Densitometry	\$90	Combination (Dental Panographic and Cephalometric)	\$210	Shielding Review for Dental Facilities	\$250	Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	\$450	<p><i>as the required inspection frequencies for each type of X-ray machine:</i></p> <table border="1"> <thead> <tr> <th>Type</th> <th>Cost Per Tube</th> <th><u>Inspection Frequency</u></th> </tr> </thead> <tbody> <tr> <td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td> <td>\$230</td> <td><u>Annually</u></td> </tr> <tr> <td>Fluoroscopic, C-arm Fluoroscopic</td> <td>\$230</td> <td><u>Annually</u></td> </tr> <tr> <td>Combination (General Purpose-Fluoroscopic)</td> <td>\$460</td> <td><u>Annually</u></td> </tr> <tr> <td>Dental Intraoral and Panographic</td> <td>\$90</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Veterinary</td> <td>\$160</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Podiatric</td> <td>\$90</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Cephalometric</td> <td>\$120</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Bone Densitometry</td> <td>\$90</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Combination (Dental Panographic and Cephalometric)</td> <td>\$210</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Shielding Review for Dental Facilities</td> <td>\$250</td> <td><u>Initial/Prior to use</u></td> </tr> <tr> <td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td> <td>\$450</td> <td><u>Initial/prior to use</u></td> </tr> <tr> <td><u>Baggage X-Ray Unit</u></td> <td><u>\$100</u></td> <td><u>Every 5 years</u></td> </tr> <tr> <td><u>Cabinet/Analytical X-ray Unit</u></td> <td><u>\$150</u></td> <td><u>Every 3 years</u></td> </tr> <tr> <td><u>Industrial Radiography X-Ray Unit</u></td> <td><u>\$200</u></td> <td><u>Annually</u></td> </tr> </tbody> </table> <p>Intent/Rationale/Impact: This change would add the inspection frequency for x-ray producing devices that appear elsewhere in regulations so that they are consolidated into one table; and, adds inspection fees and frequencies for non-medical x-ray producing devices. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.</p>	Type	Cost Per Tube	<u>Inspection Frequency</u>	General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	\$230	<u>Annually</u>	Fluoroscopic, C-arm Fluoroscopic	\$230	<u>Annually</u>	Combination (General Purpose-Fluoroscopic)	\$460	<u>Annually</u>	Dental Intraoral and Panographic	\$90	<u>Every 3 years</u>	Veterinary	\$160	<u>Every 3 years</u>	Podiatric	\$90	<u>Every 3 years</u>	Cephalometric	\$120	<u>Every 3 years</u>	Bone Densitometry	\$90	<u>Every 3 years</u>	Combination (Dental Panographic and Cephalometric)	\$210	<u>Every 3 years</u>	Shielding Review for Dental Facilities	\$250	<u>Initial/Prior to use</u>	Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	\$450	<u>Initial/prior to use</u>	<u>Baggage X-Ray Unit</u>	<u>\$100</u>	<u>Every 5 years</u>	<u>Cabinet/Analytical X-ray Unit</u>	<u>\$150</u>	<u>Every 3 years</u>	<u>Industrial Radiography X-Ray Unit</u>	<u>\$200</u>	<u>Annually</u>
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