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Proposed 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	January 28, 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 (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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

- Amends 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
NOIRA - Notice of Intended Regulatory Action
ORH - Office of Radiological Health

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. A more detailed discussion is provided in the "Detail of changes" section below.

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:

- $20 for each machine used for baggage inspection;
- $25 for each machine identified as cabinet or analytical; and
- $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:

- Baggage X-Ray Unit: $100 per inspection, inspected every 5 years;
- Cabinet/Analytical X-ray Unit: $150 per inspection, inspected every 3 years;
- 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 the X-ray machine registration and inspection fees rely on owners/operators 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 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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal; the costs and benefits of the alternatives stated in this background document or other alternatives; and, the potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail, email, or fax to **Stan Orchel, Jr., Virginia Department of Health, Office of Radiological Health, 109 Governor Street, Room 733, Richmond, VA 23219; Office Phone: (804) 864-8170; Fax: (804) 864-8175; email: stan.orchel@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) Fund Source: X-ray Machines, 0200. The X-ray program is not supported by state general funds, but rather by fees collected from x-ray device registrations and inspections. Program expenditures are primarily on-going and sometimes increase with salary adjustments such as cost of living raises. b) One-time: The purchase of one X-ray inspection device, including an annual calibration and repair service agreement at about $20,000, with which to conduct inspections. Ongoing: An X-ray program staff member will be needed to track device registrations, conduct inspections (when not conducted by Private Inspectors), issue certificates, etc. at a cost of about $75,000/year (average for Radiation Safety Specialists including salary, benefits and office/administrative overhead).
Projected cost of the new regulations or changes to existing regulations on localities.	$0. There are no direct charges to the localities, which are exempt from registration fees for X-ray machines. Nevertheless these facilities are required to register their X-ray machines. The indirect cost would include postage and staff time (approximately 15 minutes) to complete the registration form.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	This amendment affects anyone who uses an X-ray device in the Commonwealth.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 630 non-medical facilities with 1,597 X-ray machines. Approximately 190 facilities are state or local government entities. Approximately 110 facilities might be classified as small business.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	a) X-ray machines are already required to be registered. • 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. • Proposed annual fees for non-medical device registrations are: 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 • Proposed fees for non-medical device inspections, if conducted by VDH staff, are: 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; ○ Industrial Radiography X-Ray Unit: $200 per inspection, inspected annually. b) None.
Beneficial impact the regulation is designed to produce.	Ensure Virginia's X-ray regulations meet current standards and practices.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

Failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide an adequate regulatory program that protects public health and safety with regard to the maintenance and operation of non-medical X-ray devices. VDH will consider recommendations from the Radiation Advisory Board and the regulated community for alternative means of meeting the intent of the regulations or additional requirements to address concerns that may be unique within the Commonwealth.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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. Small businesses represent many of those facilities on a three-year cycle.
2. The establishment of schedules or deadlines for compliance with registration or inspection requirements is 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. Many of the entities this regulation applies to are small businesses. The Code of Virginia does not provide exemptions for the requirements of this regulation.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Not applicable.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments received.

Commenter	Comment	Agency response

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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-490-10		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: $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; $50 for each machine and additional tube(s) that have a required inspection every three years, collected every three 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: $50 for each machine with a maximum beam energy of less than 500 KVp; $50 for each machine with a maximum beam energy of 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.	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: $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; ~~$50~~ *$60* for each machine and additional tube(s) that have a required inspection every three years, collected every three 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: $50 for each machine with a maximum beam energy of less than 500 KVp; $50 for each machine with a maximum beam energy of 500 KVp or greater. *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:* *$20 for each machine used for baggage inspection;* *$25 for each machine identified as cabinet or analytical; and* *$50 for each machine used for industrial radiography.* 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. **Intent/Rationale/Impact**: This change would increase fees for x-ray producing devices that are required to be registered

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<tr><td></td><td></td><td></td><td>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.</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>12VAC5-490-20</td><td></td><td>The following fees shall be charged for surveys requested by the registrant and performed by a Department of Health inspector:

<table><tr><th>Type</th><th>Cost Per Tube</th></tr><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></table></td><td>The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:

<table><tr><th>Type</th><th>Cost Per Tube</th><th>Inspection Frequency</th></tr><tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>$230</td><td>Annually</td></tr><tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>$230</td><td>Annually</td></tr><tr><td>Combination (General Purpose-Fluoroscopic)</td><td>$460</td><td>Annually</td></tr><tr><td>Dental Intraoral and Panographic</td><td>$90</td><td>Every 3 years</td></tr><tr><td>Veterinary</td><td>$160</td><td>Every 3 years</td></tr><tr><td>Podiatric</td><td>$90</td><td>Every 3 years</td></tr><tr><td>Cephalometric</td><td>$120</td><td>Every 3 years</td></tr><tr><td>Bone Densitometry</td><td>$90</td><td>Every 3 years</td></tr><tr><td>Combination (Dental Panographic and Cephalometric)</td><td>$210</td><td>Every 3 years</td></tr><tr><td>Shielding Review for Dental Facilities</td><td>$250</td><td>Initial/Prior to use</td></tr><tr><td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td><td>$450</td><td>Initial/prior to use</td></tr><tr><td>Baggage X-Ray Unit</td><td>$100</td><td>Every 5 years</td></tr><tr><td>Cabinet/Analytical X-ray Unit</td><td>$150</td><td>Every 3 years</td></tr><tr><td>Industrial Radiography X-Ray Unit</td><td>$200</td><td>Annually</td></tr></table>
Intent/Rationale/Impact: This change would add the inspection frequency for x-</td></tr>
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			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.