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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	Establish X-ray Device Private Inspector Fees
Date this document prepared	October 30, 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 (ORH) proposes to amend the Virginia Radiation Protection Regulations Fee Schedule (12VAC5-490) in order to establish fees for the initial registration and subsequent annual renewal of individuals that inspect X-ray devices in the Commonwealth.

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.

NOIRA - Notice of Intended Regulatory Action
ORH - Office of Radiological Health
VDH – Virginia Department of 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 the Code of Virginia § 32.1-229.1, Inspections of X-ray machines required; Radiation Inspection Reports; fees; qualification of inspectors (effective July 1, 2016).

Section 32.1-229.1 authorizes the Board of Health to set annual registration fees for X-ray device Private Inspectors, not to exceed \$150.00 for such registration. Upon approval of the application, the Private Inspector will be included on the Commonwealth’s list of qualified X-ray machine inspector published pursuant to § 32.1-228.1.

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 Virginia Department of Health (VDH), ORH proposes to amend 12VAC5-490, Radiation Protection Fee Schedule, by establishing a new section 12VAC5-490-50, Private Inspector fees. Radiological Control Program regulations, which already require the registration of individuals that inspect X-ray producing devices in the Commonwealth, do not establish fees for their initial registration or annual renewal. Revenue recovery, as is the practice in other states using X-ray device Private Inspectors, will help offset administrative costs associated with document collection, review, approval, the issuance of certificates and the maintenance of an up-to-date Private Inspector directory.

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.

The Virginia Department of Health’s Office of Radiological Health (ORH) proposes to amend the Virginia Radiation Protection Regulations Fee Schedule (12VAC5-490) in order to establish fees for the

registration of individuals that inspect X-ray devices in the Commonwealth. Radiological Control Program regulations currently require the registration of individuals that inspect X-ray producing devices in the Commonwealth. The regulations, though, do not establish fees for their initial registration or annual renewal. Registration fees for X-ray device Private Inspectors are charged in other states to help offset administrative costs associated with document collection, review, approval, the issuance of certificates and the maintenance of an up-to-date Private Inspector directory. These fees will help offset such administrative costs that were once supported using General Funds allocated to ORH but which have since been abolished.

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 of this change to the public and the regulated community is that the establishment of Private Inspector fees will help offset administrative costs that were once paid using General Funds but which have since been abolished.

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:

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.

<p>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</p>	<p>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.</p> <p>b) One-time: There are no one-time expenditures associated with this action. Ongoing: An X-ray program support technician and the X-ray Program Supervisor, compensated using X-ray finds, document the collection, review, approval, issuance of certificates and the maintenance of an up-to-date Private Inspector directory. Office support personnel that perform business functions (collections, deposits, Human Resources, procurement, etc.) are also paid in part from this</p>
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	fund source.
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 individuals / businesses that provide X-ray machine inspection services 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 174 X-ray machine Private Inspectors (as of July 2016) certified to perform inspections in the Commonwealth.
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) The proposed fee for each individual registering or renewing their registration as a Private Inspector is \$150 per year. Reporting, recordkeeping, and other administrative costs for an individual or businesses to comply are limited to the costs of preparing, submitting and recording the payment of the fees. 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. Less stringent inspector registration and certification requirements may adversely impact the accuracy of the X-ray machine database.
2. The establishment of schedules or deadlines for compliance with registration and certification requirements is consistent with other states. Less stringent schedules or deadlines may result in the offering of services by inspectors that have not maintained their training, which may adversely affect x-ray machine inspection results and ultimately, patient care and safety.
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 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.

The Office of Radiological Health did not receive any comments with regard to the “Periodic review and small business impact review” announced in the NOIRA. There were no specific comments as to whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economic performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Public comment

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

Commenter	Comment	Agency response
Bob Gonsoulin	In a few months I likely will be retired and will ask to be placed on	ORH concurs.

	the X-ray inspectors list. It's my opinion that the annual registration fee for X-ray inspectors be set at the maximum possible - \$150/year. I will gladly pay that fee for the privilege of being a private inspector at that time. To lower the fee below the maximum will cause great hardship on the Office of Radiological Health to meet its goal of collecting 100% of its expenses to run the program.	
Lee S. Anthony, Jr. - Physics Associates	I do not oppose the \$150.00 annual registration fee for x-ray device Private Inspectors. However, I also feel that the inspector charges for x-ray device inspections by State employees should be increased to be more in line with Private Inspector charges. The State inspection charges for in town inspections are more appropriate. However, when the State does not charge auto expense and travel time, charges for out of town work are below what they should be.	ORH concurs. The X-ray device inspection fee schedule appears in 12VAC5-490-20. Inspection fees. Changing those fees will have to be addressed using a separate regulatory action at a future date.
David E. Weimer	Question: Can one individual be certified on behalf of all inspectors conducting business for a company or organization?	No. each X-ray inspector must register and be certified in order to legally conduct X-ray device inspections in the Commonwealth.

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.

Radiological Control Program regulations currently require the registration of individuals that inspect X-ray producing devices in the Commonwealth. The regulations, though, do not establish fees for their initial registration or annual renewal. Registration fees for X-ray device Private Inspectors are charged in other states to help offset administrative costs associated with document collection, review, approval; the issuance of certificates; and the maintenance of an up-to-date Private Inspector directory. A fee of \$150 per year is proposed, which will help offset administrative costs that were once supported using General Funds allocated to ORH but which have since been abolished.

The proposed new regulation follows:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
None.	12VAC5-490-50	None.	<p>12VAC5-490-50. Private Inspector registration fees.</p> <p>A. Individuals included on the Commonwealth's list of qualified inspectors of X-ray machines pursuant to 32.1-229.1.D.5 of the Code of Virginia, as of November 1, 2016, shall:</p> <ol style="list-style-type: none"> 1. Pay annually a registration renewal fee of \$150 to the Virginia Department of Health's X-ray Program in order to remain on the list as a qualified inspector of X-ray machines pursuant to 12VAC5-481-340. <p>B. Individuals requesting to be placed on the Commonwealth's list of qualified inspectors of X-ray machines pursuant to 32.1-229.1.D.5 of the Code of Virginia shall:</p> <ol style="list-style-type: none"> 1. Request approval by the Office of Radiological Health to become a qualified inspector of X-ray machines pursuant to 12VAC5-481-340; and 2. Pay an initial registration fee of \$150 to the Virginia Department of Health's X-ray Program, once approved; and 3. Pay annually a registration renewal fee of \$150 to remain on the list as a qualified inspector of X-ray machines pursuant to 12VAC5-481-340. Statutory Authority § 32.1-229.1 of the Code of Virginia <p>Intent/Rationale/Impact: This new regulation would establish annual registration and application change fees for individuals certified to inspect x-ray producing devices in the Commonwealth.</p> <p>Private X-ray device inspectors are already required to register with ORH, but ORH has not, in the past, been authorized to collect a fee to recover administrative costs. Administrative, personnel, travel and other expenses have increased since the fee</p>

			<p>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. The impact to Private Inspectors operating in the Commonwealth will be the registration and/or any applicable inspection category change fees, and any costs associated with preparing and submitting that fee to ORH.</p>
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