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Notice of Intended Regulatory Action (NOIRA)
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 Fee Schedule
Date this document prepared	March 19, 2015

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.*

Subject matter and intent

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment (Baggage, Cabinet, Analytical, and Industrial equipment). The regulations, though, do not establish a fee for registration of this equipment, do not establish a fee that would allow an Office of Radiological Health (ORH) inspector to perform an inspection of this equipment, and do not establish associated inspection frequencies. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states. 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.

Legal basis

These regulations are authorized by the Code of Virginia Sections 32.1-229 et seq.
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.

Refer to the following web site for viewing the statutory authority cited in Section 32.1-229.1 of the Code of Virginia:

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1

Purpose

The Virginia Department of Health (VDH), ORH 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.

Substance

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment, i.e., equipment that is not used in the healing arts. This equipment includes Baggage, Cabinet and Analytical, and Industrial X-ray machines. However, associated registration and inspection fees and inspection frequencies have not been established. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states. The potential for accidents associated with equipment not used in the healing arts exists and has in fact occurred. Accordingly, regulatory attention needs to be applied to promote the safety of non-medical X-ray equipment use. This action proposes to modify registration fees for non-medical devices that are inspected on a three-year frequency, proposes to institute registration and inspection fees for non-medical X-ray equipment, and proposes to establish associated inspection frequencies. The fees will help offset administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment that were once absorbed from general funds allocated to ORH and which have since been abolished. Specifically:

- The current fee for each machine and additional tube(s) that have 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.
- The following inspection fees and required inspection frequencies are proposed for all operators or owners of baggage, cabinet or 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.

Alternatives

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 model regulations or additional requirements to address concerns that may be unique within the Commonwealth.

Public participation

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, (804)864-8170 (Office Phone), (804)864-8175 (fax), 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.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Periodic review/small business impact review announcement

In addition, pursuant to Executive Order 17 (2014) and § 2.2-4007.1 of the Code of Virginia, the agency is conducting a periodic review and small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical 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.

Periodic review and small business impact review report of findings

If this NOIRA is the result of a periodic review/small business impact review, use this NOIRA to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) 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.

This NOIRA is not the result of a periodic review/small business impact review

Commenter	Comment	Agency response