



Notice of Intended Regulatory Action (NOIRA) 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 and include fees to support radioactive materials licensing inspection program.
Date this document prepared	August 22, 2006

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended 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, include additional types of X-ray machines in the inspection fee schedule, and adopt a fee structure to support the radioactive materials licensing and inspection program for those materials the U.S. Nuclear Regulatory Commission (NRC) intends to transfer to the Commonwealth by agreement. These proposed regulations are intended to supercede the Radiation Protection Regulations: Fee Schedule, which became effective January 1, 1989.

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 number(s), 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 authorizes the Board of Health to establish fee schedules, which shall not exceed comparable federal Nuclear Regulatory Commission fees, for the licensure and inspection of radioactive materials.

Section 32.1-232.1 establishes a special trust fund for Radioactive Materials Facility Licensure and Inspection fees.

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; however, no fee shall be charged for 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 the statutory authority cited in Section 32.1-229, Section 32.1-232.1, Section 32.1-229.1, and Section 32.1-229.2 of the Code of Virginia:

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229>,

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-232.1>,

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

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.2>, respectively.

The radioactive materials licensing and inspection fees are less than comparable federal fees and consistent with other adjacent states' fee schedule.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The proposed regulatory action addresses two program activities, the X-ray machine registration and inspection activity, and the radioactive materials licensing and inspection activity. With respect to the X-ray machine activity, 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 exists several types of X-ray machines without an appropriate inspection fee that did not exist in 1989 and need to be included in the X-ray machine inspection schedule. The personnel and travel cost to the agency for these inspections have also increased since the fee schedule was established in 1989.

With respect to the radioactive materials licensing and inspection activity, additional sections are required to implement a fee schedule to support a radioactive materials licensing and inspections program for certain radioactive materials the federal government currently implements. During the 1999 session of the General Assembly, legislation was passed that authorized implementation of a fee schedule to support a radioactive materials licensing and inspections program for the radioactive materials the federal government currently regulates, and created a special fund for the fees collected. This fee schedule will not be implemented until the Governor enters into an agreement with the U.S. Nuclear Regulatory Commission (NRC) for the regulation of these materials. The Governor sent a letter of intent in December 2005 to the NRC requesting an agreement. The NRC will not enter into an agreement until the state demonstrates its ability to fiscally support this activity. The NRC may also require the agency to implement fees for financial assurance, bonding, decommissioning, and civil penalties.

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 and adequate funding is required to support such a regulatory program.

Potential issues expected are concerns from the private inspectors whose fees are independent of VDH's inspection fees and are negotiated between individual private inspectors and the registrants. The VDH has received comments from the private inspectors that the inspection fees are too low. The *Code of Virginia* Section 32.1-229.2 requires the agency to establish inspection fees to minimize competition with the private inspector and recover its costs. On the other hand, the X-ray machine registrants may have concerns that the proposed inspection fees are excessive.

The VDH does not anticipate any issues from the radioactive materials licensees, since the proposed fee schedule for radioactive materials will be significantly reduced from the fees the licensees are currently paying to the NRC. In addition, VDH intends to provide fee exemptions and reductions for certain government and small business entities similar to those of the NRC.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Section 10 of the Regulations is to be amended to increase the X-ray machine registration fee of \$15 annually for those facilities on an annual inspection frequency; increase the fee of \$15 every three years to those facilities on a three year inspection cycle, or consider charging a lesser fee annually; and 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 develop inspection fees for bone densitometers; combination dental panoramic and cephalometric machines; and other X-ray machine types which were not included in the fee schedule.

News sections beginning with section 30 of the Regulations will adopt a fee schedule to support a licensing and inspection program for those materials that would transfer to the Commonwealth in an agreement with the U.S. NRC. The proposed fee structure will be similar to that of the NRC and the proposed fees for each category of license will be set at 65 – 75 percent of the current NRC fee schedule and is also dependent on the number of NRC licenses that are projected to transfer to the Commonwealth in an agreement with the NRC. In addition, the NRC agreement will require provisions for financial assurance and bonding, decommissioning, civil penalty schedule, and reciprocity fees. The proposed fee schedule for radioactive materials licensing will provide fee exemptions and reductions for certain government and small business entities similar to those of the NRC.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

Abolishing the regulation, or failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide adequate funding to support a regulatory program that protects public health and safety.

The VDH has provided the most cost-effective X-ray machine registration program by eliminating redundant notices to the registrants, and sought federal grants or contracts which provided VDH staff with federally loaned equipment to conduct state inspections. However, federal contracts and grants have been either eliminated or reduced. General funds have provided funding for increased personnel expenses; however, the general funds have not been in keeping with increasing non personnel expenses such as postage, data processing equipment, and radiation inspection equipment.

The VDH had considered the alternative of not participating in the NRC Agreement State program; however, the higher cost of the federal program results in a greater regulatory burden and higher fees to Virginia’s licensees.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) 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 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to: Les Foldesi, Director, Division of Radiological Health, VDH 109 Governor Street, Room 732, Richmond , VA 23219, Phone (804) 864-8151, FAX (804) 864-8155, (e-mail: Les.Foldesi@vdh.virginia.gov). Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The Radiation Advisory Board will assist VDH with development of the fee schedule.

Family impact

Assess the potential 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.