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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	X-ray and Radioactive Materials Fee Schedule Revisions
Date this document prepared	March 17, 2017

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

The Virginia Department of Health's (VDH) Office of Radiological Health (ORH) is requesting a revision to 12VAC5-490 in order to amend the fee schedule used by the X-ray Program (XRP) for device registrations and inspections, and to amend the fee schedule used by the Radioactive Materials Program (RMP) for charging initial license application and annual licensing fees. The XRP and RMP are fully supported by these fees, which have not increased since 2009 and need to be increased for the reasons listed herein.

Legal basis

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

- Section 32.1-229 authorizes the Board of Health to establish fee schedules, which shall not exceed comparable U.S. Nuclear Regulatory Commission (NRC) 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 VDH personnel; however, no fee shall be charged for inspections initiated by VDH.
- 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 websites for viewing the statutory authority cited in §§ 32.1-229, 32.1-229.1, 32.1-229.2 and 32.1-232.1of the Code of Virginia:
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-229/
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-229.1/
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-229.2/
http://law.lis.virginia.gov/vacode/title32.1/chapter6/section32.1-232.1/

Purpose

The proposed regulatory action addresses fees for two program areas, XRP and RMP, and is necessary to maintain program solvency given the elimination of general fund support for the programs and the subsequent spend down of surplus fee revenue since 2015. Fees for these programs have not increased since 2009, when X-ray fees were adjusted and the RMP was established along with commensurate fees necessary for program operations. At that time, fees were sufficient to accommodate program and ancillary business functions as they were supplemented by general funds which were allocated to ORH (then Division of Radiological Health). In fact, the fees generated a surplus. As a result, a 20% decrease in RMP fees went into effect in 2012, in part due to the overage combined with the anticipated continuation of general funds.

As mentioned earlier, general funds that were used to support ORH were abolished in 2015. At that time, the general fund amount of $361,366 constituted 19.3% of ORH's budgeted resources (revenues) of $1,871,476 and 13.4% of ORH's budgeted expenditures of $2,693,345. Since that time, the surplus has been used to accommodate the balance and is projected to be depleted in 2018.

Potential concerns may be expressed by private X-ray device inspectors whose fees are independent of VDH's inspection fees and are negotiated between individual private inspectors and the registrants. Virginia Code § 32.1-229.2 requires the agency to establish inspection fees to minimize competition with the private inspector and recover its costs. X-ray machine registrants may also express concerns that the proposed inspection fees are excessive. As this proposal is advanced, fees required by other states will be examined to provide a comparative analysis.

Similarly, VDH may anticipate objection from the radioactive materials licensees due to a proposed increase, even though the proposed fee schedule for radioactive materials will remain below the NRC's fees for equivalent (non-Agreement State) services. In addition, VDH intends to continue to provide fee exemptions and reductions for certain government and small business entities.

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

X-ray Program
The XRP is responsible for the registration and inspection of x-ray producing devices in the Commonwealth, in which there are approximately 7,000 registrants with approximately 22,300 x-ray tubes. The XRP is also responsible for FDA Mammography Quality Standards Act (MQSA) facility inspections; performs inspection reviews, correspondence, enforcement and other associated activities; employs staff that maintain specialized training and certifications necessary to conduct XRP activities;

reviews the academic and occupational credentials of and certifies private inspectors authorized to conduct business in the Commonwealth, reviews their inspection reports for accuracy; and respond to incidents and emergencies requiring radiological technical expertise and dose characterization. Staff members are emergency response trained, maintain training to perform exposure assessment and participate in radiological drills and exercises with federal, state and local stakeholders and responders.

Current XRP staffing consists of one (1) Program Director and six (6) Compliance/Safety Officers in addition to two (2) Program Support Technicians and one (1) contract Office Services Specialist who perform registrations, certifications and billing, process and track payments, and provide client contact services. However, a minimum of eight (8) XRP management and inspection full time equivalents, in addition to the aforementioned program support staff, should be allocated in the Commonwealth for a properly aligned X-ray control program as recommended by the Conference of Radiation Control Program Directors (CRCPD).

It is important to note that Radiological Control Program regulations currently require the registration of medical and non-medical X-ray equipment (baggage, cabinet, analytical, and industrial equipment), but ORH does not conduct non-medical X-ray equipment inspections due to resource constraints. Accordingly, an Analytical/Industrial X-ray inspector position should be established and funded to oversee the tracking and inspections of the approximate 1,500 non-medical X-ray devices throughout the Commonwealth.

The proposed regulatory action will address two sets of fees levied by the XRP: X-ray machine registration fees and X-ray machine inspection fees. With respect to the X-ray machine registration fees, the existing regulation is proposed to be amended due to the increased costs of maintaining a registration program for X-ray producing devices since publication of the fee schedule effective March 4, 2009. The registration fees need to be adjusted to reflect the elimination of general funds in 2015 and the consequent spend down of the surplus fee revenue. The X-ray machine inspection fees also need to be modified to accommodate increased personnel, overhead and travel costs to the agency since 2009 and which are projected to continue to increase in the coming years.

It is important to note that a proposed X-ray fee action is currently in progress for selected x-ray devices and inspection costs. This fee action was initiated prior to the 2015 elimination of general funds and may be insufficient and will continue to be examined as this proposal moves forward. The fee action that is currently underway, Non-Medical X-Ray Device Registration and Inspection Fee Schedule (Action 4371 / Stage 7476) may be found on the Virginia Regulatory Town Hall at http://townhall.virginia.gov/L/ViewStage.cfm?stageid=7476.

Radioactive Materials Program

Virginia entered into an agreement with the NRC on March 31, 2009 to assume the responsibilities of regulating the use of radioactive materials in Virginia. 12VAC5-490 was promulgated at that time to supply the monetary means for supporting the RMP by charging application and annual licensing fees.

The RMP is tasked with performing detailed technical reviews of license applications submitted for possession, use, manufacture, and distribution of radioactive materials, as well as any other associated activities requiring licensing by regulations (e.g., decontamination services) prior to approval for possession and/or operation. Contacts with applicants during the review process are documented through review letters and memoranda. For major operations, facilities subject to increased controls or applicants with no previous history with the RMP, pre-licensing visits to examine facilities and equipment may be in order. Procedures are in place to promote thoroughness, technical quality and uniformity. The RMP requires license amendments for any significant change in authorized radioactive materials, uses and operations and an amendment review is equivalent to the license application review. A complete technical review and reauthorization of active licenses comparable to the original licensing process are also conducted at a frequency based on the type of facility, materials and/or activities authorized. The program requires the registration of certain devices containing large quantity or otherwise hazardous sealed sources of radioactive material that are generally licensed under its regulations and also requires evidence of financial assurance/surety for large quantity licensees with substantial potential for

contamination of facilities, equipment, and the environment, or which possess large quantities of radioactive material requiring disposal. Inspections are conducted to evaluate compliance with regulatory standards, and inspection reports are generated that follow a uniform format and allow for timely (no later than 30 days after inspection) communication of results to the licensee. These reports summarize the inspection scope, include measurement data with appropriate interpretation, clearly list and categorize as to the severity each item of noncompliance, set a reasonable date for correction of each item, and require a plan for corrective action that includes submission of evidence that corrections have been performed and are effective.

The RMP licenses and inspects approximately 400 specific licensees. The RMP also tracks over 2,900 general licensees which possess over 34,000 general licensed devices; however, general licensees are not subject to inspection. The RMP professional/technical personnel requirements for licensing, inspection, and enforcement should be about 1.0 to 1.5 FTE per 50 licenses as recommended by the CRCPD. Additional professional/technical staff would be required for unusually large and time consuming licenses such as a major manufacturer, waste processor, or uranium mining and milling, and sources subject to Increased Controls. Programs should also consider adding 0.5 to 2 FTE for rule development, incident response and investigations to reflect the impact on normal licensing and inspection activities. Using this formula, RMP staffing should consist of eight (8) to twelve (12) inspectors plus management and administrative support.

However, actual RMP staffing consists of only one (1) supervisor who conducts inspections, and five (5) program support inspectors. Additionally, two (2) Administrative Program Specialists maintain the RMP's databases on licensure and inspections; prepare and distribute statistical and informational reports, including monthly reports on the number of inspections (due, past due and conducted), license applications, amendments, license actions overdue, violations, denials, etc.; receive and process the daily mail including license applications, amendments and renewals, inspection letters and licensing fees; mail out licensing bills, inspection letters, renewal applications and general information to licensees; contact licensees by phone regarding licensing fees and renewals; and maintain the licensing file system including file numbers, licenses, inspection reports, billing notices and other materials.

Other Actual and Anticipated Cost Increases:

It is important to note that VDH's Office of Financial Management's expenditure budget forecast assumes no reductions in staff/operating costs and the following future cost impact assumptions through 2021:

a) Health Insurance: Likely 8% increase in FY18 (based on statewide central appropriation planning in Appropriation Act).
b) Health Insurance: Additional conservative individual FY19-FY21 increases of 5%, 2% and 2%.
c) VITA: Annual conservative 1% increase in each FY.
d) State Compensation: Conservative 3% annual salary cost impact factored in FY18 and beyond (FY18 and future FYs speculative).

VDH's Office of Financial Management also provided information on various cost increases since the RMP fee reduction of 2012 went into effect. Specifically:

a) FY14: 2% legislated raise in staff compensation.
b) FY13 and FY14: Health insurance employer premium increases each year (individual plan increases vary; average increased in 3-8% range annually).
c) FY11 and FY12: Modest health insurance employer premium increase
d) There were additional net contributions required of agency non-general funds/cash balances that were used to support the Virginia Retirement System's pension liability.

Substance

Section 10 of the Regulations is proposed to be amended to increase the X-ray machine registration fee for operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing

radiation as well as operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts that are capable of producing radiation.

Section 20 of the Regulations is proposed to be amended to increase fees charged for surveys (inspections) requested by a registrant and performed by a VDH inspector.

Section 40 of the Regulations is proposed to revise the application fee for a radioactive materials license and annual fees for persons issued a radioactive materials license pursuant to 12VAC5-481, as necessary, to support the licensing and inspection program under the Commonwealth's authority as a NRC Agreement State. Since the 2012 revision, fee collection by the RMP has averaged about $800,000 while expenses have averaged about $950,000. This action is expected to increase the RMP revenue generation to be in line with the anticipated expenditures.

The Atomic Energy Act of 1954, as amended, provides the statutory basis by which the NRC relinquishes portions of its regulatory authority to license and regulate radioactive material to a state that agrees to accept that responsibility. Through the Agreement State program, 37 states, including Virginia, have signed formal agreements for inspection and enforcement authority with the NRC. The NRC retains an oversight role and periodically reviews Agreement State programs for continued adequacy to protect public health and safety through their Integrated Materials Performance Evaluation Program (IMPEP). All IMPEP reviews use common performance indicators in the assessment. For most IMPEP reviews, no action other than issuance of the final report is needed. In cases where additional action is needed, the NRC may consider monitoring, heightened oversight, probation, suspension or termination. Suspension and termination are considered when a program is deemed inadequate to protect public health and safety. In these situations, the state's authority is revoked and reverts back to the NRC, and the state's revenue stream normally generated by program fees would be eliminated.

In November 2014, the NRC's IMPEP review team evaluated Virginia's RMP and found "the Program experienced a backlog in inspections due, in part, to having a shortage of qualified staff to complete inspections within the required timeframe." Since that time, the RMP has hired and trained two new inspectors and completed the overdue inspection backlog, thus avoiding monitoring, probation or forfeiture. The NRC warned, however, that a loss of even one inspector could create an environment for recurrence due to the absence of staffing depth. The NRC also noted that the administrative assistant responsible for maintaining the database had been filled three times since 2010 and was vacant again at the time of the review. ORH explained that efforts would be undertaken to request the conversion of that position to a Full-Time Equivalent, which was granted in 2015 and subsequently filled.

It is important to note that the RMP, through its registration fees, currently provides for about 40% of ORH's overall revenue and supports Administration, the RMP Supervisor, RMP Inspectors and Business staff salaries, as well as some office-wide equipment purchases and emergency response capabilities. A loss of the RMP and the revenue it generates, even temporarily, would be catastrophic and would challenge the viability of the office-at-large.

Alternatives

One potential alternative is to supplement XRP and RMP fees with general funds. However, this does not appear to be possible due to ORH having no general fund accounts and the lowering of state revenue collections requiring recent budget reductions from state agencies.

The second alternative is to lessen the number of program staff. However, this would not constitute a sound business decision for the XRP as the program currently has seven (7) professional/technical FTEs, which is below the CRCPD guidance for a properly aligned XRP consisting of eight (8) XRP management and inspection FTEs, in addition to management and administrative support. Similarly, this is not a reasonable alternative for the RMP as there are six (6) professional/technical FTEs and one (1) administrative FTE. This is below CRCPD guidance for a properly aligned radiological materials control

program which should consist of 10 FTEs, plus management and administrative support, considering the number of Virginia's specific, general and reciprocity licensees.

Neither of the two alternatives is desirable, thus the fee increase is the best choice to maintain the XRP as well as the RMP and associated Agreement State status.

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

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 **Steve Harrison, Virginia Department of Health, Office of Radiological Health, 109 Governor Street, Room 736, Richmond, VA 23219; Office Phone: (804) 864-8151; Fax: (804) 864-8175; email: steve.harrison@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.

The Radiation Advisory Board will be convened and asked to assist in decision-making with regard to proposing fee changes.