Virginia Regulatory Town Hall

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Radiological Health
Virginia Administrative Code (VAC) citation	12VAC5-490
Regulation title	Radiation Protection Regulations, Fee Schedule
Action title	Amend fee schedule to add fees to support the radioactive materials licensing and inspection program
Date this document prepared	9/26/08

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations: Fee Schedule (12VAC5-490) to 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.

The Radioactive Materials Program (RMP) was created in the Division of Radiological Health in order for Virginia to become an Agreement State. Currently the RMP is funded through a special fund with financial support from VDH. These regulations would allow the RMP to be self-supporting through the licensing fees applied to those persons holding a radioactive materials license.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On October 17, 2009 the Board of Health voted to adopt the proposed regulation 12VAC5-490-30 and 40.

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 numbers, 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 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.

Refer to the following web sites for viewing the statutory authority cited in Section 32.1-229, and Section 32.1-232.1 of the Code of Virginia:
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229 and
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-232.1.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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 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. On June 18, 2008 the agreement state application was delivered to the NRC. On August 26, 2008 the final conference call with the NRC was held during which the NRC stated that the application was sufficient in nature to proceed with the agreement process. The proposed agreement date is no later than March 31, 2009.

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. Adequate funding is also required to support such a regulatory program.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Section 30 is being created to establish licensing fees for naturally-occurring radioactive materials and Accelerator-produced materials that Virginia currently regulates, which will revert to the NRC in 2009 unless the Commonwealth enters into an agreement with the NRC.

Section 40 is being created to establish the licensing fees for radioactive material users currently regulated by the NRC. These fees will provide sufficient funding to cover the expenses relating to licensing, inspections, investigations, emergency response, and personnel training.

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 to the public is that the radioactive materials licensing and inspection activities will not rely on general funds to support these activities and will financially impact the businesses that directly benefit from the use of radiation. It is also advantageous to businesses currently using radioactive materials under a federal license to pay a lesser fee when the Commonwealth enters into an agreement with the NRC.

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 VDH to eliminate its dependence on its general fund appropriation to support this regulatory program. The proposed fee schedule will also allow the Commonwealth to enter into an agreement with NRC to regulate radioactive materials and be self supporting.

There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

3. Pertinent matters of interest to the regulated community.

The VDH does not anticipate any issues from most of the radioactive materials licensees, since the proposed fee schedule for radioactive materials will be significantly reduced in most cases from the fees the licensees are currently paying to the NRC.

4. Other matters:

In 1995 President Bush signed the Energy Policy Act (EPA) which changed the definition of radioactive material to include naturally-occurring and accelerated-produced material (NARM). By signing the EPA, the NRC will assume full regulatory control of all radioactive material unless a state has entered into an agreement with the NRC. This process will conclude in 2009. Currently 35 states have entered into such an agreement. Virginia, New Jersey and Michigan have signed letters of intent to become Agreement States.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
40		The licensing fee for *category 7A was changed from $10,000 to $7500 and *7D was changed from $3900 to $3750.	When these fees were initially proposed to the BOH in June of 2007 all the fees were less than NRC's. On 2/13/08 the NRC dramatically lowered several fee categories, these included 7A and 7D. This is the main category for medical facilities. The NRC licensing fee for 7A decreased from $15,100 to $10,500 and 7D decreased from $6000 to $3900. Even though the proposed fee of $3750 is not less than 75% of the NRC's fee, it is lower than the NRC's and it is our belief that this fee will be increased by the NRC next year.
40		The amendment fee for *11B was changed from $100 to $0.	Several comments were made regarding charging the licensees a fee to amend their license in addition to an annual fee. It is anticipated that the revenue would have been approximately $20,000, which can be made up elsewhere.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
SANDY WOLFF, SENTARA HEALTHCARE	I seem to recall the proposed fees when agreement state status was initially introduced in 2005 were closer to $600 than $4,000.	Disagree. No one in VDH recalls stating that licensing fees would be around $600. It is VDH's goal to reduce the cost to licensees from their current NRC licensing fees with this proposed schedule. No change.
BROCK CUTCHINS	All fees should be set at current NRC levels or below.	Agree. When the proposed fee schedule was created in 2007 all fees were less than the NRC fee schedule listed in 10 CFR 171.16. The NRC has modified this fee schedule twice since then such that in the proposed regulation all but three fees were less than the NRC. The current opinion is that NRC licensing fees will be raised next year due to Pennsylvania and Virginia becoming Agreement States and transferring over 1,000 licensees from the NRC. Since 2007 when these fees were proposed several changes in licensing have occurred, including the requirement for a pre-licensing visit and further investigation of the applicant. These requirements will take more time and attributes more cost to licensing. Staff recommends lowering the licensing fees for category 7A from $10,000 to $7500 and category 7D from $3900 to $3750.
Health Physics Consultation	1. The fees do not meet the goal of 75% of the current NRC fees.	1. Agree. When the proposed fee schedule was created in 2007 fees were all less than the NRC fee schedule listed in 10 CFR 171.16. The NRC has modified this fee schedule twice since then such that in the proposed regulation all but three fees were less than the NRC. The current opinion is that NRC licensing fees will be raised next year due to Pennsylvania and Virginia becoming Agreement States and transferring over 1,000 licensees from the NRC. Since 2007 when these fees were proposed several

		changes in licensing have occurred, including the requirement for a pre-licensing visit and further investigation of the applicant. These requirements will take more time and attributes more cost to licensing. Staff recommends lowering the licensing fees for category 7A from $10,000 to $7500 and category 7D from $3900 to $3750.
	2. There is no provision for small business entity status. I would hope the state would want to encourage small business as much.	2. Agree there is no provision for small business. VDH did not use the small business entity status that the NRC uses due to the fact that no matter what the size of the company, the workload for VHD does not change. The license review and inspections are identical between a small business and large business. It is our belief that each company should pay for the amount of work required by VDH employees to maintain a radioactive materials license. No change.
	3. The NRC does not charge a $100 amendment fee and I would hope our Agreement State Program could do the same.	3. Agree. Changed the fee to $0.
Rockingham Memorial Letter	1. The fees do not meet the goal of 75% of the current NRC fees.	1. Agree. When the proposed fee schedule was created in 2007 fees were all less than the NRC fee schedule listed in 10 CFR 171.16. The NRC has modified this fee schedule twice since then such that in the proposed regulation all but three fees were less than the NRC. The current opinion is that NRC licensing fees will be raised next year due to Pennsylvania and Virginia becoming Agreement States and transferring over 1,000 licensees from the NRC. Since 2007 when these fees were proposed several changes in licensing have occurred, including the requirement for a pre-licensing visit and further investigation of the applicant. These requirements will take more time and attributes more cost to licensing. Staff recommends lowering the licensing fees for category 7A from $10,000 to $7500 and category 7D from $3900 to $3750.

	2. There is no provision for small business entity status.	2. Agree. VDH did not use the small business entity status that the NRC uses due to the fact that no matter what the size of the company, the workload for VHD does not change. The license review and inspections are identical between a small business and large business. It is our belief that each company should pay for the amount of work required by VDH employees to maintain a radioactive materials license. No change.
	3. The NRC does not charge a $100 amendment fee as proposed by this schedule.	3. Agree. Changed the fee to $0.
Halifax Regional Health System	1. The fee schedule does not reflect the plan of being less than the NRC.	1. Agree. When the proposed fee schedule was created in 2007 fees were all less than the NRC fee schedule listed in 10 CFR 171.16. The NRC has modified this fee schedule twice since then such that in the proposed regulation all but three fees were less than the NRC. The current opinion is that NRC licensing fees will be raised next year due to Pennsylvania and Virginia becoming Agreement States and transferring over 1,000 licensees from the NRC. Since 2007 when these fees were proposed several changes in licensing have occurred, including a requirement for a pre-licensing visit and further investigation of the applicant. These requirements will take more time and attributes more cost to licensing. The fees can be changed to match NRC's but would need to be revisited within two years to ensure we are capturing the true cost of licensing and inspections of each license type. Staff recommends lowering the licensing fees for category 7A from $10,000 to $7500 and category 7D from $3900 to $3750.
	2. The NRC does not charge a $100 amendment fee as proposed by this schedule. It would be incompatible to charge this fee.	2. Agree. Changed the fee to $0.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

<table>
<tr><th>Current section number</th><th>Proposed new section number, if applicable</th><th>Current requirement</th><th>Proposed change and rationale</th></tr>
<tr><td>New Requirement</td><td>12VAC5-490-30</td><td>No Requirement for radioactive material fees.</td><td>Establish the fee schedule for licensing of natural occurring and accelerator produced radioactive materials radioactive material.
Fees are in section 40.

Rationale: These materials are currently regulated by the states until the year 2009, and fees may be collected prior to the agreement with the NRC.</td></tr>
<tr><td>New Requirement</td><td>12VAC5-490-40</td><td>No Requirement for radioactive material fees.</td><td>Establish fee schedule for application and annual fees for licensing of by product, special and source radioactive material.
<table>
<tr><th>Cat</th><th>Specific License Type</th><th>Fee</th></tr>
<tr><td>1</td><td>Special Nuclear Material</td><td></td></tr>
<tr><td>A.</td><td>License for possession and use of SNM in sealed sources contained in devices used in measuring systems</td><td>$1,000</td></tr>
<tr><td>B.</td><td>License for use of SNM to be used as calibration and reference sources</td><td>$500</td></tr>
<tr><td>C.</td><td>SNM - all other, except license authorizing special nuclear material in unsealed form that would constitute a critical mass [Fee waived if facility holds additional license category]</td><td>$2,000</td></tr>
<tr><td>2</td><td>Source Material</td><td></td></tr>
<tr><td>A.</td><td>Source material processing and distribution</td><td>$3,000</td></tr>
</table></td></tr>
</table>

			B.	Source material in shielding [Fee waived if facility holds additional license category]	$200
			C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	$2,000
			3	Byproduct, NARM	
			A.	License of broad scope for processing or manufacturing of items for commercial distribution	$15,000
			B.	License for processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$8,000
			C.	License for commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$4,000
			D.	Other licenses for processing or manufacturing of items for commercial distribution	$4,000
			E.	License for industrial radiography operations performed only in a shielded radiography installation	$3,000
			F.	License for industrial radiography performed only at the address indicated on the license, and at temporary job sites	$4,000
			G.	License for possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield [Fee waived if facility holds additional irradiator license category]	$3,000

			H.	License for possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes. The category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation	$3,000
			I.	License for possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies)of radioactive material in sealed sources for irradiation of materials	$5,000
			J.	License for possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	$15,000
			K.	License to distribute items containing radioactive materials to persons under a general license	$2,000
			L.	License to possess radioactive materials intended for distribution to persons exempt from licensing	$1,000
			M.	License of broad scope for research and development that does not authorize commercial distribution	$7,500
			N.	Other licenses for research and development that do not authorize commercial distribution	$1,500
			O.	License for installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	$1,500
			P.	License for portable gauges	$1,000
			Q.	License for portable x-ray fluorescence analyzer, dewpointer or gas chromatograph	$250
			R.	Leak testing services	$500
			S.	Instrument calibration services	$1,000
			T.	Fixed gauges	$1,000

			U.	All other byproduct, naturally-occurring or accelerator-produced material licenses, except as otherwise noted	$1,500
			4	Waste Processing	
			A.	Commercial waste treatment facilities, including incineration	$200,000
			B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$11,000
			C.	Waste processing - all other, including decontamination service	$5,000
			5	Well Logging	
			A.	License for well logging using sealed sources or sub-surface tracer studies	$3,000
			B.	License for well logging using sealed sources and sub-surface tracer studies	$4,000
			6	Nuclear Laundry	
			A.	License for commercial collection and laundry of items contaminated with radioactive material	$10,000
			7	Medical/Veterinary	
			A.	License for human use of byproduct, source, special nuclear or NARM material in sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	[~~$10,000~~ $7,500]
			B.	License of broad scope for human use of byproduct, source, special nuclear or NARM materials used in medical diagnosis, treatment, research and development (excluding teletherapy or stereotactic radiosurgery devices)	$15,000
			C.	License for mobile nuclear medicine	$2,000
			D.	Medical - all others, including SNM pacemakers and high does rate remote after-loading devices	[~~$4,000~~ $3,750]
			E.	License for veterinary use of radioactive materials	$2,000
			F.	In-Vitro	$1,000
			8	Academic	

A.	License for possession and use of byproduct, naturally-occurring or accelerator produced radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses	$1,000
9	Accelerator	
A.	License for accelerator production of radioisotopes with commercial distribution	$4,000
B.	Accelerator isotope production - all other [Fee waived if facility holds medical broad scope license with no commercial distribution]	$2,000
10	Reciprocity	
A.	Reciprocal recognition of an out-of-state specific license	50% of annual fee of applicable category
11	Amendments	
A.	Request to amend specific license - no license review	$0
B.	Request to amend specific license - license review required	[~~$100~~ $ 0]
C.	Request to terminate license	$200

Rationale: Staff used existing NRC fee structure and fees were reduced for the various categories of licenses in proportion to projected work load to service each category of license. Revenue generated will approximate projected expenditures for the activity. Proposed state fees will be significantly less than NRC's fees.
Based on public comments, staff agreed to reduce fees for category 7A, 7D and eliminate fee for 11B. This was done to meet goal of no fee set greater than the NRC fee schedule.

Regulatory flexibility analysis

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.

These regulations are a fee schedule for entities holding a radioactive materials license with the Commonwealth. The purpose of this regulation is to provide funding for the RMP based solely on these licensing fees.

The only other option is to provide funding for the RMP from general funds. Due to the decrease in general funds available there is no other option for funding the RMP.

Family impact

Please assess the 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.