



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5 - 490
<b>Regulation title</b>	Radiation Protection Regulations: Fee Schedule
<b>Action title</b>	Amend fee schedule to include fees to support radioactive materials licensing and inspection program.
<b>Date this document prepared</b>	June 12, 2007

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

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.*

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations: Fee Schedule (12 VAC 5- 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. 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., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

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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.

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>, respectively.

The radioactive materials licensing and inspection fees are less than comparable federal fees.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

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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. The NRC will not enter into an agreement until the state demonstrates its ability to fiscally support this activity.

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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

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Section 30 is being created to establish licensing fees for natural 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

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### 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 sufficient.

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

### 4. 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.

### 5. 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 34 states have entered into such an agreement. Pennsylvania, Virginia and New Jersey have signed letters of intent to become Agreement States.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which are 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.*

These annual licensing fees are based upon the NRC fees listed in 10 CFR Part 171. The difference in fees ranges from 25% to 85% less than the NRC's. The application fee will be the same as a license fee.

**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.*

None

**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.*

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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](mailto: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 date of the public comment period.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<b>Projected cost to the state to implement and</b>	Funding for the Radioactive Materials Program is
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<p><b>enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>being provided by the Department of Health from special funds. When Virginia is granted Agreement State status by the NRC, the program will become self-sufficient based on the application and licensing fees and will be deposited in a special fund to support the program.</p>
<p><b>Projected cost of the regulation on localities</b></p>	<p>For those localities that have NRC radioactive materials licenses the fee should be less than what they are now paying the NRC.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b></p>	<p>Any person required to possess a license for the use of radioactive material will pay an application/licensing fee to the Department of Health. The licensing fees are based upon the type of material use. Diversity of uses of radioactive material covers medicine, academia, industry, and mining.</p>
<p><b>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.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Currently there are approximately 350 NRC licensees that will become Virginia licensees after the agreement is approved. Of the 350, approximately 25 are considered small entity by the NRC. The NRC’s definition of a small entity is found in 10 CFR 171.16.</p> <p>Currently there are 228 NARM licensees, of which approximately 75 do not possess an NRC license.</p> <p>The Department of Health will not be offering a small business exemption for the licensing of radioactive material.</p>
<p><b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>Costs for implementing this regulation for an annual license fee would include the cost of generating a check to VDH and postage in response to a VDH invoice, probably less than \$5.00. The cost of submitting an application will vary considering the complexity of the proposed licensing active. In addition to the previous cost estimate for preparing payment, there would be additional staff time ranging from an hour to several hours. These licensees are currently incurring these costs when preparing a license application and licensing fee payment to the NRC.</p>

**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.*

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 had considered the alternative of not participating in the NRC Agreement State program; however, the higher cost of the federal program results in higher fees to Virginia's licensees.

**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.*

The regulations for licensing and inspecting of radioactive material must at a minimum be equal to the regulations of the NRC as listed in 10 CFR. The NRC uses a compatibility program that delineates the flexibility of each 10 CFR regulation. The Commonwealth's regulations (12 VAC 5-481) will be reviewed and approved by the NRC before Virginia becomes an Agreement State.

**Public comment**

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

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
Pamela Gebhart-Cline, MSFEd,RT (R) (M)-Riverside School of Health Careers	I do not know what the current fee schedule is nor do I know what the range is proposed however I request that you give special consideration to academic settings. If a school has an energized lab or radioactive substances for educational purposes only (not those shared by institutions that provide patient care and are reimbursed for the same) it is my belief that schools should pay less due to the nature of their business.	Staff agrees. Proposed fee schedule includes a fee category for academic use that is in keeping with the time required for this type of license.

**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.

**Detail of changes**

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale			
New Requirement	12VAC5-490-30	No Requirement for radioactive material fees.	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.			
New Requirement	12VAC5-490-40	No Requirement for radioactive material fees.	Establish fee schedule for application and annual fees for licensing of by product, special and source radioactive material.			
			Cat	Specific License Type	Fee	
			1	Special Nuclear Material		

			A.	License for possession and use of SNM in sealed sources contained in devices used in measuring systems	\$1,000	
			B.	License for use of SNM to be used as calibration and reference sources	\$500	
			C.	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]	\$2,000	
			<b>2</b>	<b>Source Material</b>		
			A.	Source material processing and distribution	\$3,000	
			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	
			<b>3</b>	<b>Byproduct, NARM</b>		
			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	
			<b>4 Waste Processing</b>		
			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	
			<b>5 Well Logging</b>		
			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	
			<b>6 Nuclear Laundry</b>		
			A. License for commercial collection and laundry of items contaminated with radioactive material	\$10,000	
			<b>7 Medical/Veterinary</b>		
			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	
			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	

			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		
			C.	Request to terminate license	\$200		
		<p>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.</p>					