



Fast Track Proposed Regulation Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-490
Regulation title	VIRGINIA RADIATION PROTECTION REGULATIONS: FEE SCHEDULE
Action title	Licensing Fee Schedule Reduction
Date this document prepared	April 29, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The Virginia Department of Health (VDH) intends to amend 12VAC5-490, Radiation Protection Regulations: Fee Schedule, which supports the VDH Radioactive Materials Program (RMP) for those materials the U. S. Nuclear Regulatory Commission (NRC) transferred to the Commonwealth by agreement.

Currently under 12VAC5-490-40, there are 42 different categories of license fees for 428 total licensees. This proposed amendment will:

1. Lower the fee in 22 of the 42 categories. As a result of this, 54 current licensees who were originally charged a reduced licensure fee for small businesses by the NRC, will be affected:
 - 35 of the 54 licensees will pay the same or lower fee to VDH than what they paid the NRC;
 - 19 of the 54 licensees will pay more to VDH than what they paid the NRC, however;
 - 17 of the 19 will pay less to VDH than under the current fee schedule;
 - 2 of the 19 will pay the same as under the current fee schedule.

2. Repeal Section 12VAC5-490-30, which was used for the Naturally Occurring and Accelerated Radioactive Material (NARM) licensees prior to the agreement. These licensees are now covered by the fee schedule in Section 12VAC5-490-40.
3. Remove fee Category 11 in Section 12VAC5-490-40, which was used for licensing amendments and terminations. This cost will be covered as part of the annual licensing fee.

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 April 12, 2011, the Commissioner of the Virginia Department of Health approved the proposed Fast Track amendment to 12VAC5-490-30 and 12VAC5-490-40.

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 General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of 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 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 the regulation 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 fee schedule was designed on the premise that all licensees will pay their fair share of the program costs, and one fee would be set per category of licensee based on time and effort. In developing the Commonwealth's program, the NRC fee schedule was referenced and then adjusted for expected time and effort involved in RMP staff managing each license category. Unlike the NRC program, the RMP did not include a reduced rate for small business licensees as the size of the business (i.e., licensee) did not correlate with the time and effort required by RMP to administer the program.

The NRC delegated responsibility to the Commonwealth for licensure and inspection of radioactive materials on March 31, 2009. On that date there were 106 licensees designated as an NRC-Small

Business (SB). Subsequently 66 of the 106 SBs were charged a higher licensure fee by VDH than they had previously paid to the NRC. Through attrition, mergers, etc., the group of 66 has dropped to 54.

One licensee submitted a Petition for Rulemaking to the Virginia Regulatory Town Hall on August 17, 2009, requesting the radioactive material licensing fees be lowered. By the time the public comment period ended on October 5, 2009, 18 comments had been received. VDH responded to the petition on February 1, 2010, indicating a regulatory action would be initiated.

The proposed amendment to the regulation changes the fee in 22 licensure categories reducing the fee for some licensees while maintaining equity within each category.

Among the 54 remaining licensees, 35 will pay the same or lower fees to VDH than what they paid the NRC while 19 licensees will pay a higher licensing fee to VDH than they paid to the NRC, ranging from \$250 to \$3,700 more. However, of these 19 licensees, 17 will pay a lower fee to VDH than under the current fee schedule while 2 will continue to pay the same amount to VDH.

18 comments were received via the Town Hall concerning the petition for rulemaking. Based on VDH's analysis, only 4 of the commenters will pay a higher fee to VDH than they previously paid to the NRC. However, all 4 will pay less to VDH as a result of the proposed amendments than they are required to pay under the current regulations.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

A fast track process for this amendment is necessary to provide the requested financial relief to the affected licensees as soon as possible.

Substance

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

This amendment repeals Section 30 which was used for the Naturally Occurring and Accelerated Radioactive Material (NARM) licensees prior to the agreement. These licensees are now covered by the fee schedule in Section 40.

The proposal for Section 40 amends the licensing category 7D titled "Medical Institutions Providing Imaging, Diagnostic or Radionuclide Therapy," and lowers the fee to \$2,300 which matches the 2009 NRC small business fee these licensees paid to the NRC. The proposal also creates a new medical licensing category 7E titled "Medical Institutions Using a High Dose Remote Afterloader (HDR) or Emerging Technologies," to be used for medical therapy licensees. It lowers 21 other fee categories.

This amendment removes the fee category 11, which was used for licensing amendments and terminations. This cost can be covered by the annual licensing fee paid.

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 but rather the costs of the regulatory program will be fully borne by the licensees.. It is also advantageous to businesses currently using radioactive materials to pay a lesser fee, where possible.

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 amended fee structure will allow 35 of the 54 active “small business” licensees to pay the same amount or less than what they paid to the NRC prior to March 31, 2009. The amended fee structure will also reduce the annual license fee for 17 of the active “small business” licensees.

There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule. The proposed RMP fee schedule is sufficient to support the program.

3. Pertinent matters of interest to the regulated community.

VDH staff anticipates that the 19 licensees who will still pay a higher licensing fee to VDH than what they paid the NRC may have a negative comment on the fee. The reason they will still pay a higher fee is due to the type of work these businesses perform with the radioactive material, regardless of the size of the business. If this fast track action receives objections from 10 or more public comments then the fee amendment would be processed as a standard rulemaking which would take longer to complete. This would lengthen the period of time during which the licensees would continue to pay a higher fee.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is 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.

There are no requirements in the proposed regulation that are more restrictive than the applicable federal requirements.

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

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.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	The funding for this activity is currently supported by licensing fees from the radioactive material users.
Projected cost of the new regulations or changes to existing regulations on localities.	\$0
Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.	This amendment affects businesses that hold a radioactive materials license with VDH.
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. Small business means a business entity,	Of the initial 106 “small business” licensees, there are 54 active licensees paying VDH more than what they paid the NRC. This amendment will reduce these fees to the same or less for 35 of the

<p>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>54 licensees while lowering the difference for 17 of the remaining 19.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>This fee code is an annual licensing invoice. Licensees previously paid the NRC this invoice. Since Virginia became an agreement state on March 31, 2009 this invoice is paid to VDH. There are no other projected costs with this amendment.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Lower the annual licensing fee in 22 categories.</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.

There are no other alternatives that would lessen the financial risk to 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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

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

~~12VAC5-490-30. Application and licensing fees for naturally occurring and accelerator-produced radioactive materials.~~

~~The application and licensing fees to receive, possess, use, transfer, own or acquire naturally occurring and accelerator-produced radioactive materials license pursuant to 12VAC5-481 are listed in 12VAC5-490-40.~~

~~12VAC5-490-40. Application and licensing fees for byproduct, source, and special nuclear radioactive materials licenses.~~

~~The application and licensing fees to receive, possess, use, transfer, own or acquire byproduct materials, source and special nuclear materials shall not become effective until 30 days after publication in the Virginia Register of a notice of an agreement executed by the Commonwealth of Virginia and the federal government under the provisions of § 274b of the Atomic Energy Act of 1954, as amended (73 Statute 689). Application The application fee for a radioactive materials license and annual fees for persons issued a radioactive materials license pursuant to 12VAC5-481 are listed in the following table:~~

Current section number	Proposed new section number, if applicable	Current requirement			Proposed change and rationale		
		Category	Specific License Type	Application & Annual Fee	Category	Specific License Type	Application & Annual Fee
		1	Special Nuclear Material (SNM)		1	Special Nuclear Material (SNM)	
		A.	License for possession and use of SNM in sealed sources contained in	\$1,000	A.	Possession and use of SNM in sealed sources contained in devices used in	\$1,000

		devices used in measuring systems				measuring systems		
	B.	License for use of SNM to be used as calibration and reference sources	\$500			B.	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			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
	2	Source Material				2	Source Material	
	A.	Source material processing and distribution	\$3,000			A.	Source material processing and distribution	\$3,000
	B.	Source material in shielding (fee waived if facility holds additional license category)	\$200			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			C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	\$2,000
	3	Byproduct, NARM				3	Byproduct, NARM	
	A.	License of broad scope for processing or manufacturing of items for commercial distribution	\$15,000			A.	Broad scope for processing or manufacturing of items for commercial distribution	\$10,000
	B.	License for processing or manufacturing and	\$8,000			B.	Processing or manufacturing and commercial	\$6,000

			commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices				distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	
		C.	License for commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	\$4,000		C.	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		D.	Processing or manufacturing of items for commercial distribution	\$2,000
		E.	License for industrial radiography operations performed only in a shielded radiography installation	\$3,000		E.	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		F.	Industrial radiography performed only at the address indicated on the license, and at temporary job sites	\$3,500
		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	\$3,000		G.	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	\$2,000

			holds additional irradiator license category)				category)		
		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			H.	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			I.	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)	\$3,000
		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			J.	Possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	\$5,000
		K.	License to distribute items containing radioactive materials to persons under a	\$2,000					

		general license			
	L.	License to possess radioactive materials intended for distribution to persons exempt from licensing	\$1,000		K. Distribute items containing radioactive materials to persons under a general license \$1,000
	M.	License of broad scope for research and development that does not authorize commercial distribution	\$7,500		L. Possess radioactive materials intended for distribution to persons exempt from licensing \$1,000
	N.	Other licenses for research and development that do not authorize commercial distribution	\$1,500		M. Broad scope for research and development that does not authorize commercial distribution \$6,000
	O.	License for installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	\$1,500		N. Research and development that do not authorize commercial distribution \$1,000
	P.	License for portable gauges	\$1,000		O. Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services \$1,000
	Q.	License for portable X-ray fluorescence analyzer, dewpointer or gas chromatograph	\$250		P. Portable gauges \$750
	R.	Leak testing services	\$500		Q. Portable X-ray fluorescence analyzer (XRF), dewpointer or gas chromatograph \$250
	S.	Instrument calibration services	\$1,000		R. Leak testing services \$500
	T.	Fixed gauges	\$1,000		

			U.	All other byproduct, naturally occurring or accelerator-produced material licenses, except as otherwise noted	\$1,500			S.	Instrument calibration services	\$1,000
								T.	Fixed gauges	\$750
		4		Waste Processing				U.	All other radioactive material licenses, except as otherwise noted	\$1,500
			A.	Commercial waste treatment facilities, including incineration	\$200,000					
			B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	\$11,000		4		Waste Processing	
			C.	Waste processing - all other, including decontamination service	\$5,000			A.	Commercial waste treatment facilities, including incineration	\$100,000
		5		Well Logging				B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	\$7,500
			A.	License for well logging using sealed sources or subsurface tracer studies	\$3,000			C.	Waste processing - all other, including decontamination service	\$5,000
			B.	License for well logging using sealed sources and subsurface tracer studies	\$4,000		5		Well Logging	
		6		Nuclear Laundry				A.	Sealed sources or subsurface tracer studies	\$3,000
			A.	License for commercial collection and laundry of items contaminated with radioactive material	\$10,000			B.	Sealed sources and subsurface tracer studies	\$3,000
		7		Medical/Veterinary			6		Nuclear Laundry	
								A.	Commercial collection and laundry of items contaminated with	\$10,000

		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	\$7,500			radioactive material	
		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	7		Medical/Veterinary	
		C.	License for mobile nuclear medicine	\$2,000		A.	Human use of sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	\$6,000
		D.	Medical - all others, including SNM pacemakers and high dose rate remote afterloading devices	\$3,750		B.	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)	\$12,000
		E.	License for veterinary use of radioactive materials	\$2,000		C.	Mobile nuclear medicine	\$2,000
		F.	In-vitro	\$1,000		D.	Medical Institutions providing imaging, diagnostic or radionuclide therapy.	\$2,300
	8		Academic			E.	Medical institutions using High Dose Remote Afterloaders or Emerging Technologies	\$3,750
		A.	License for possession and use of byproduct, naturally	\$1,000		F.	Veterinary use of radioactive materials	\$1,000
						G.	In-Vitro	\$1,000

			C.	Request to terminate license	\$200	
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