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Proposed Regulation
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	August 9, 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.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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 annual licensing fees. The fee increase is necessary to maintain program solvency so as to provide services and adequate regulatory controls necessary to protect public and worker health, safety and welfare.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CAT – Category
CRCPD - Conference of Radiation Control Program Directors
FDA – United States Food and Drug Administration
FY – Fiscal Year
KY - Kentucky
MQSA - Mammography Quality Standards Act
NC – North Carolina
NRC – Nuclear Regulatory Commission
OFM - Office of Financial Management
ORH - Office of Radiological Health
PA - Pennsylvania
RMP – Radioactive Materials Program
IN - Tennessee
VDH – Virginia Department of Health
VITA – Virginia Information Technology Agency
XRP – X-ray Program

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe 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 proposed regulatory action addresses fees for two program areas, XRP and RMP, and is necessary to maintain program solvency, so as to provide services and adequate regulatory controls necessary to protect public and worker health, safety, and will fix the elimination of general fund support for the programs and the subsequent spend down of surplus fee revenue since 2015. With one exception, 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 cover program and ancillary business expenditures since they were supplemented by general funds that 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, due in part to the overage, the anticipated continuation of general funds, and a petition for small business relief. On 7/12/2017, a change in non-medical X-ray device registration and inspection fees was adopted. This regulatory action was initiated in early 2015, prior to the loss of general fund support, to help offset the cost of administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment – equipment which had not been assessed a registration fee prior to that time.

As mentioned earlier, general funds that were used to support ORH were abolished effective July 1, 2016. The 2015 general fund amount, having been reduced from about $466,000 to $361,000 over several years, constituted 19.3% of ORH's then budgeted resources (revenues) of $1,871,476 and 13.4% of ORH's budgeted expenditures of about $2,700,000. Since that time, the surplus has been used to balance the budget but is projected to be depleted in 2018.

The proposed fee increases were derived based on OFM revenue and expenditure projections through the year 2021 that have been deemed necessary to maintain the programs solvent, as follows:

Program	2017 Revenue	2021 Expenditure Forecast
X-ray	$713,000	$1,064,729
Radioactive Materials	$750,000	$1,248,278

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 responds 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 includes six (6) Compliance/Safety Officers in addition to supervisory and office services personnel who perform registrations, certifications and billing, process and track payments, and provide client contact services. This staff complement, according to the Conference of Radiation Control Program Directors (CRCPD), is performing the workload of a minimum of eight (8) XRP FTEs for an equivalent program (CRCPD, Criteria for and Adequate Radiation Control Program, Appendix C, May 2014).

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 overall fee schedule effective March 4, 2009.

The registration fees need to be adjusted to reflect the elimination of general funds. 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. Virginia's current and proposed X-ray registration fees, in comparison to those charged by other nearby states, appears below.

X-ray Facility	Virginia Current Registration	Virginia Proposed Registration Fee	Virginia Current Inspection Fee	Virginia Proposed Inspection Fee	Virginia Frequency
Chiropractors	$50	$100	$230	$250	Annual
Dentists	$50	$100	$90	$100	3 year
Medical Offices	$50	$100	$230	$250	Annual
Hospitals	$50	$100	Private Inspectors Only	Private Inspectors Only	Annual
Veterinary Offices	$50	$100	$160	$175	3 year
Podiatric Offices	$50	$100	$90	$125	3 year
Therapy <0.9MeV	$50	$100	Private Inspectors Only	Private Inspectors Only	Annual
Therapy > 0.9 MeV	$50	$100	Private Inspectors Only	Private Inspectors Only	Annual
Educational	$50	$100	Instrument Dependent	Instrument Dependent	Annual
Government (Academic)	$50	$100	Instrument Dependent	Instrument Dependent	Annual
Baggage	$20	$40	100	100	5 year
Cabinet/Analytical	$25	$50	150	150	3 year
Industrial	$50	$100	200	200	Annual
Bone Density	$50	$100	$90	90	3 year

X-ray Facility	Tennessee*	Tennessee Frequency	Maryland*	Maryland Frequency	North Carolina* (Initial + $24 to $50/tube)	North Carolina Frequency
Chiropractors	$195	2 years	$222	2 years (Private)	$180	3 year
Dentists	$85	4 years	$80	3 years (State)	$180	5 year
Medical Offices	$286	Annual	$222	2 years (Private)	$180	3 year
Hospitals	$286	Annual	$222	2 years (Private)	$390	3 year
Veterinary Offices	$195	2 years	$222	2 years (State)	$130	4 year
Podiatric Offices	$195	2 years	$222	2 years (Private)	$180	3 year
Therapy <0.9MeV	$390	Annual	$882	Annual (Private)	$400	3 year
Therapy > 0.9 MeV	$2,600	Annual	$882	Annual (Private)	$400	3 year
Educational	$780	2 years	$222	3 years (Private)	$130	4 year

Government (Academic)	$780	2 years	$222	3 years (Private)	$130	4 year
Baggage/Cabinet/ Industrial	$780	2 years	$222	3 Years (Private)	$180	3 year
Bone Density	$195	2 years	$222	2 years (Private)	$180	3 year

*Inspection fees included in registration fee, where conducted by state inspectors.

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. RMP staffing consists of one (1) supervisor who conducts inspections, five (5) program support inspectors, and two (2) Administrative Program Specialists. These personnel 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.

According to the CRCPD, RMP professional/technical personnel requirements should consist of eight (8) to twelve (12) inspectors plus management and administrative support (CRCPD, Criteria for and Adequate Radiation Control Program, Appendix C, May 2014).

This proposal seeks to continue to assess RMP fees equitably across all license categories by using the fee structure adopted in 2009 upon Virginia's becoming an Agreement State, while also incorporating the regulatory changes adopted on November 22, 2012 to accommodate small business relief. Using this approach, revenue generation is estimated to be about $1,248,500 which will approximate OFM's

projected expenditures of about $1,248,300. It is also important to note that this proposal does not suggest establishing an hourly rate for initial license application and amendment reviews as does the NRC, which is currently $263 per hour for such reviews. A comparison of the NRC's existing fees to VDH's proposed fees, as well as a sampling of other Agreement State fees, appears below:

Cat	Specific License Type	NRC FY17 Fee*	VDH Proposed Fee	PA Fee**	TN Fee	KY Fee	NC Fee
1	Special Nuclear Material						
A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	$8,000	$1,700	$3,150			
B.	SNM to be used as calibration and reference sources	$3,000	$900	$8,700			
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]	$8,600	$3,400	$8,700	$7,800		
2	Source Material						
A.	Source material processing and distribution	$8,000	$5,100	$45,100			
B.	Source material in shielding [Fee waived if facility holds additional license category]	$3,300	$300	$1,125	$425		
C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	$9,400	$3,400	$20,100			
3	Byproduct, NARM						
A.	Broad scope for processing or manufacturing of items for commercial distribution	$30,500	$17,000	$12,450	$7,800	$5,200	$2,250
B.	Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$12,900	$9,000	$17,850	$7,800	$5,200	
C.	Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$12,900	$6,800	$10,200	$7,800	$5,200	
D.	Processing or manufacturing of items for commercial distribution	$11,600	$3,400	$12,450		$3,600	$2,250
E.	Industrial radiography operations performed only in a shielded radiography installation	$27,000	$5,100	$21,150	$7,800	$4,000	$2,600
F.	Industrial radiography performed only at the address indicated on the license, and at temporary job sites	$27,000	$6,000	$21,150	$7,800	$4,000	$3,500
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 category]	$10,800	$3,400	$6,300	$1,950	$1,750	$4,500
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	$11,800	$5,100	$11,700	$36,000	$4,200	$4,500
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	$95,700	$5,100	NRC Fee + 10% Application or Renewal	$36,000	$4,200	$8,500

J.	Possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	$95,700	$8,500	$46,800	$36,000	$4,200	$8,500
K.	Distribute items containing radioactive materials to persons under a general license	$4,600	$1,700	$3,750	$36,000		
L.	Possess radioactive materials intended for distribution to persons exempt from licensing	$11,600	$1,700	$16,050	$2,730		
M.	Broad scope for research and development that does not authorize commercial distribution	$16,300	$10,200	$22,600	The sum of all applicable categories	$3,500	$3,000
N.	Research and development that does not authorize commercial distribution	$14,800	$1,700	$8,400	$1,170	$1,250	
O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	$22,100	$1,700	$12,750		$1,200	
P.	Portable gauges	$9,300	$1,300	$4,050	$2,730	$1,300	$425
Q.	Portable x-ray fluorescence analyzer, dewpointer or gas chromatograph	$9,300	$400	$4,050	$850		
R.	Leak testing services	$9,300	$900	$4,050	$850	$1,200	$400
S.	Instrument calibration services	$9,300	$1,700	$4,050	$850	$1,200	$400
T.	Fixed gauges	$9,300	$1,300	$3,150	$1,950	$1,100	$550
U.	All other byproduct, naturally-occurring or accelerator-produced material licenses, except as otherwise noted	$9,300	$2,600	$4,050	Case-by-case basis		$500
4	Waste Processing						
A.	Commercial waste treatment facilities, including incineration		$170,000	Full Cost	$450,000		
B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$20,800	$12,800	$18,000	$14,625	$10,000	
C.	Waste processing - all other, including decontamination service		$8,500	Full Cost	Case-by-case basis	$25,000	
5	Well Logging						
A.	Well logging using sealed sources or sub-surface tracer studies	$16,000	$5,100	$6,600	$5,200	$2,500	
B.	Well logging using sealed sources and sub-surface tracer studies	$16,000	$5,100	Full Cost	$5,200	$2,500	
6	Nuclear Laundry						
A.	Commercial collection and laundry of items contaminated with radioactive material	$38,500	$17,000	$43,200	$14,625	$7,500	
7	Medical/Veterinary						
A.	Human use of sealed sources contained in teletherapy-or stereotactic radiosurgery devices, including mobile therapy	$23,800	$10,200	$7,350	$2,730	$4,000	
B.	Broad scope for human use in medical diagnosis, treatment, research and development (excluding teletherapy or stereotactic radiosurgery devices)	$33,800	$20,400	$43,500	The sum of all applicable categories	$7,500	$5,250
C.	Mobile nuclear medicine	$14,700	$3,400	$7,350	$7,800	$2,500	$1,600
D.	Medical Institutions providing imaging,diagnostic or radionuclide therapy	$14,700	$4,000	$7,350	$1,170	$2,100	$2,900

E.	HDR, Emerging Technologies	$14,700	$6,400	$7,350	$2,730	$4,000	$2,100
F.	Veterinary use of radioactive materials	$9,300	$1,700	NRC Fee + 10% Application or Renewal	$2,730	$2,100	
G.	In-Vitro	$9,300	$1,700	NRC Fee + 10% Application or Renewal		$1,250	
8	Academic						
A.	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 license	$14,800	$1,300	$1,300	$7,800	$1,250	
9	Accelerator						
A.	Accelerator production of radioisotopes with commercial distribution	$32,000	$3,400	NRC Fee + 10% Application or Renewal			
B.	Accelerator isotope production - all other [Fee waived if facility holds medical broad scope license with no commercial distribution]	$32,000	$3,400	NRC Fee + 10% Application or Renewal			
10	Reciprocity						
A.	Reciprocal recognition of an out-of-state specific license		50% of annual fee of applicable category	$2,250			
	* The NRC also charges an initial application fee. Fees for permits, licenses, amendments, renewals, special projects, 10 CFR part 55 re-qualification and replacement examinations and tests, other required reviews, approvals, and inspections will be calculated using the professional staff-hour rate of $263 per hour.			**Small Business Fee: $3,450			

The fee schedule continues to be designed on the premise that all licensees will pay a fair share of the program costs. One fee is set per category of licensee based on time and effort. When the Commonwealth's program was developed, 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 involved. However, a Petition for Rulemaking was submitted to the Virginia Regulatory Town Hall on August 17, 2009 requesting the radioactive material licensing fees be lowered to accommodate this provision to the extent possible. That change took effect on November 22, 2012 and as a result, 19 of 54 licensees were assessed a higher licensing fee by VDH than they paid to the NRC while 35 were lower than the NRC fee. The same category and fee structure applied at that time was followed for this proposal. Using the 2017 NRC small business fees in comparison to the VDH proposed fees, 14 businesses would be charged a fee higher than the NRC small business fee, while 48 would be charged less, as shown below:

#	Name	TYPE	CAT	2017 NRC Small Business Fee	Proposed VA Fee	Difference VA Proposed to NRC
1	Blue Ridge Isotopes, LLC	Nuclear Pharmacy	3B	$ 4,100	$ 9,000	$ 4,900
2	Radiology Services of Northern VA	Nuclear Pharmacy	3B	$ 4,100	$ 9,000	$ 4,900
3	Martin Industrial Testing, Inc.	Industrial Radiography	3F	$ 850	$ 6,000	$ 5,150
4	Hampton Roads Cardiology, PLLC	Medical	7D	$ 850	$ 4,000	$ 3,150
5	Precision Nuclear Diagnostics	Mobile Medical	7C	$ 850	$ 3,400	$ 2,550
6	Advex Corporation	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
7	J Core Drilling, Inc.	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
8	Pole Brothers Imaging Co	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
9	Scientific Technical, Inc.	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
10	Testing Technologies, Inc	Industrial Radiography	3F	$ 4,100	$ 6,000	$ 1,900
11	Well Data Services, Inc.	Well Logger	5B	$ 4,100	$ 5,100	$ 1,000
12	General Health Physics	Calibration	3S	$ 850	$ 1,700	$ 850
13	Wise County Coals, Inc.	Portable Gauge	3P	$ 850	$ 1,300	$ 450
14	Geo Design & Engineering, Inc.	Portable Gauge	3P	$ 850	$ 1,300	$ 450
15	Ajay A. Acharya, M.D., P.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)
16	Blue Ridge Cardiovascular Associates	Medical	7D	$ 4,100	$ 4,000	$ (100)
17	Cardiac & Vascular Care of Virginia, P.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)
18	Cardiology Associated, PC	Medical	7D	$ 4,100	$ 4,000	$ (100)
19	Cardiology of Virginia, Inc.	Medical	7D	$ 4,100	$ 4,000	$ (100)
20	Cardiology Specialists of Virginia, PC	Medical	7D	$ 4,100	$ 4,000	$ (100)
21	Cardiovascular Associates of Charlottesville, PLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
22	Heart Care Associates, P.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)

23	Henrico Cardiology Associates	Medical	7D	$ 4,100	$ 4,000	$ (100)
24	Javed Cardiac Center, PLLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
25	M. Rafiq Zaheer, M.D., F.A.C.C.	Medical	7D	$ 4,100	$ 4,000	$ (100)
26	Medical Associates of Northern VA	Medical	7D	$ 4,100	$ 4,000	$ (100)
27	Northern Virginia Endocrinologists	Medical	7D	$ 4,100	$ 4,000	$ (100)
28	Odyssey Imaging, LLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
29	Prince William Nuclear Cardiology	Medical	7D	$ 4,100	$ 4,000	$ (100)
30	Richmond Cardiology Associates	Medical	7D	$ 4,100	$ 4,000	$ (100)
31	Roanoke Heart Institute, PLC	Medical	7D	$ 4,100	$ 4,000	$ (100)
32	Tidewater Heart Institute	Medical	7D	$ 4,100	$ 4,000	$ (100)
33	Best Medical International, Inc.	Mfg./Dist.	3D	$ 4,100	$ 3,400	$ (700)
34	Blue Ridge Equine Clinic, Inc	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
35	Wm. G. Brewer, DVM	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
36	Health Physics Consultation	Other - Consult	3U	$ 4,100	$ 2,600	$(1,500)
37	Physics Associates	Other - Consult	3U	$ 4,100	$ 2,600	$(1,500)
38	Dilon Technologies, LLC	R&D	3N	$ 4,100	$ 1,700	$(2,400)
39	EPL Pathology, Inc.	Other - Consult	3U	$ 4,100	$ 2,600	$(1,500)
40	Spurlock Equine Associates	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
41	Veterinary Emergency Center, Inc.	Veterinary	7F	$ 4,100	$ 1,700	$(2,400)
42	AlexCom & Associates, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
43	ATCS, P.L.C.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
44	Branscome, Inc	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
45	Commonwealth Environmental Associates, Inc	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
46	Consulting Engineers Corporation	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
47	Dominion Engineering Associates, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
48	Dominion Inspection Co., Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
49	ECS Mid-Atlantic, LLC (Winchester)	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
50	EnCon Consulting Services, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
51	Engineering & Materials Technology, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
52	Engineering and Testing Consultants, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
53	GeoConcepts Engineering, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
54	Geotechnics, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
55	HDH Associates, PC	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
56	Lee Hy Paving Corporation	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
57	NXL Construction Serivces, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)

58	Roofing Consulting Service, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
59	Seal Engineering, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
60	Terra Tech Engineering Service, P.C.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
61	Viola Engineering, PLC	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)
62	Zannino Engineering, Inc.	Portable Gauge	3P	$ 4,100	$ 1,300	$(2,800)

Other Actual and Anticipated Cost Increases:

It is important to note that VDH's Office of Financial Management's (OFM) 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).
e) OFM forecasts X-ray Program expenditures of about $1,065,000 by the year 2021, while revenue is expected to remain constant at about $713,000 unless fees are raised.
f) OFM forecasts RMP expenditures of about $1,250,000 by the year 2021, while revenue is expected to remain constant at about $750,000 unless fees are raised.

OFM also provided information on various cost increases since the RMP fee reduction of 2012 went into effect. Specifically:

a) FY18: 3% legislated raise in staff compensation.
b) FY14: 2% legislated raise in staff compensation.
c) FY13 and FY14: Health insurance employer premium increases each year (individual plan increases vary; average increased in 3-8% range annually).
d) FY11 and FY12: Modest health insurance employer premium increase
e) 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

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

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, and for non-medical X-ray devices.

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 annual fees for entities 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 $750,000 while expenses have averaged about $950,000. This action is

expected to increase the RMP revenue generation to be in line with current and anticipated future 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.

The RMP, through its registration fees, currently provides for about 30% 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 challenge the viability of the office-at-large.

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.

The primary advantage of this change to the public and the regulated community is that registering all X-ray machines allows ORH to maintain an accurate database of the devices, track inspections and ensure that the machines are functioning properly so as to minimize the risk of equipment malfunction and accidental overexposures.

1. Primary advantages and disadvantages to the public:
   The primary advantage to the public is that the X-ray machine registration and inspection fees rely on owners/operators of the X-ray equipment. Similarly, radioactive materials licensing fees rely on the owners/operators of radioactive materials sources and devices.

   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 the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

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

3. Other pertinent matters of interest to the regulated community:

X-ray machine registrants and Radioactive Materials licensees have an interest in keeping inspection fees as low as possible. 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.

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.

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 applicable federal requirements or no requirements that exceed 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.

There are no localities that would be disproportionately affected by this action.

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.

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.

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**	a) Fund Source: X-ray Machines, 02601 and Radioactive Materials Program, 09312. The two programs are not supported by state general funds, but rather by fees collected from X-ray registrations and inspections and RMP licensing fees, respectively. b) Ongoing: Program expenditures are primarily on-going and sometimes increase with salary adjustments such as cost of living raises. OFM forecasts X-ray Program expenditures of about $1,065,000 by the year 2021, while revenue is expected to remain constant at about $713,000. OFM forecasts RMP expenditures of about $1,250,000 by the year 2021, while revenue is expected to remain constant at about $750,000 if unchanged.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no direct charges to the localities for X-ray devices, which are exempt from registration fees for X-ray machines. Nevertheless these facilities are required to register their X-ray machines. For those localities that have radioactive materials licenses, the VDH fee will remain below the NRC's scheduled fee for the equivalent service.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	a) This amendment affects any entity that owns/operates an X-ray device in the Commonwealth. Entities affected by the regulation include: health care facilities ranging from single practitioner to major medical centers; engineering and industrial firms; and security screening. b) This amendment affects any entity that owns/operates/possesses licensed radioactive material/devices regulated by the Commonwealth. Any person required to possess a license for the use of radioactive material must pay an annual 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 other applications.
Agency's best estimate of the number of such entities that will be affected. Please include an	a) X-ray: Currently about 7,000 registrants with approximately 21,000 x-ray tubes; staff inspects

estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	about 1,000 facilities and 2,100 machines per year. The majority of registrants (dental facilities, chiropractic facilities, podiatry offices, medical facilities/offices, veterinary facilities) are assumed to be small businesses while hospitals, of which there are about 100, generally are not. b) Radioactive Materials: Currently there are about 400 specific licensees. The NRC's definition of a small entity is found in 10 CFR 171.16. The Department of Health will not be offering a small business exemption for the licensing of radioactive material; however, accommodations for small businesses were made based upon the amount of work needed for licensing/inspecting a specific type of radioactive material as described on pages 9 – 11 of this proposal.
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 including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) 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.**	a) X-ray Registration Fees: Direct Costs for implementing this regulation will be $100 per X-ray tube annually for those facilities on a one year machine inspection cycle (medical, hospitals, and chiropractic), and every three years for those facilities on a three-year inspection cycle (dental, podiatry, and veterinary). Indirect cost includes the facility staff time to update the database, prepare and submit a registration form, cost of generating a check to VDH in response to a VDH invoice, and postage (approximately $40). b) X-ray Inspection Fees: Direct Costs for implementing this regulation will be dependent on the type of X-ray machine and will range from $100 for a simple dental intra-oral machine to $250 for a moderately complex general purpose machine, to $250 for a complex fluoroscopic X-ray machine The direct cost may be an annual expense or incurred every three years depending on the facility's inspection cycle. X-ray machine facilities may choose to obtain the services of an approve Private Inspector rather than use a VDH inspector. Private inspector fees for services are independently negotiated with each facility, and may be higher or lower than VDH's proposed inspection fees. Indirect costs for the inspection requirement include staff time to schedule either a Private Inspector or a VDH inspector, to submit an Inspector's report to VDH, to keep record of inspection reports and correspondences, and, if a VDH inspector is used, to prepare a check in response to a VDH invoice. RMP: Costs for implementing this regulation for an annual license fee would include the cost of registration depending on the radioactive material category, generating a check to VDH and postage in response to a VDH invoice. In addition to the previous cost estimate for preparing payment,

	there would be additional staff time ranging from an hour to several hours to review applications, prepare, print and approve licenses, etc. These costs are included in the VDH application or renewal fee. It is important to note that this action does not propose establishing an hourly rate for license application and amendment reviews, as does the NRC (NRC 2017 fee is $263 per hour for such reviews). b) There are no costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes.
Beneficial impact the regulation is designed to produce.	Ensure Virginia's X-ray and Radioactive Materials programs meet current standards and practices by generating revenue necessary to maintain an adequately trained and competent workforce to administer and enforce Virginia Radiation Protection Regulations.

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.

Failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide adequate regulatory programs that protect public health and safety with regard to the maintenance and operation of X-ray devices and Radioactive Material devices.

The VDH considered the alternative of not participating in the NRC's Agreement State program; however, significantly higher NRC fees would result in commensurate higher fees to Virginia's licensees.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

1. 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) have been reviewed and approved by the NRC.

2. The establishment of schedules or deadlines for compliance with registration or inspection requirements is consistent with other states. Less stringent X-ray registration and inspection requirements may result in undetected non-compliances that may adversely affect patient care and safety, while less stringent Radioactive Materials registrations may adversely impact the inventory of radioactive materials devices and sources throughout the Commonwealth, and consequently the staff's ability to track users and perform inspections intended to ensure the protection of public health and safety.
3. The fee schedules were kept as simple as possible.
4. Establishment of performance standards in place of operational standards does not appear to be applicable to implementing a fee schedule.
5. Many of the entities this regulation applies to are small businesses. The Code of Virginia does not provide exemptions for the requirements of this regulation.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Not applicable.

Public comment

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

No comments were received following the publication of the NOIRA.

Commenter	Comment	Agency response

Family impact

Please assess the impact of this 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; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-490-10		All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: $50 for each machine and additional tube(s) that have a required annual inspection, collected annually; $60 for each machine and additional tube(s) that have a required inspection every three years, collected every three years. All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee: $50 for each machine with a maximum beam energy of less than 500 KVp; $50 for each machine with a maximum beam energy of 500 KVp or greater. All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: ~~$50~~ $100 for each machine and additional tube(s) that have a required annual inspection, collected annually; ~~$60~~ $100 for each machine and additional tube(s) that have a required inspection every three years, collected every three years. All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee: ~~$50~~ $100 for each machine with a maximum beam energy of less than 500 KVp; ~~$50~~ $100 for each machine with a maximum beam energy of 500 KVp or greater. All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay the following annual registration fee: ~~$20~~ $40 for each machine used for baggage inspection;

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<td>the following annual registration fee:

$20 for each machine used for baggage inspection;

$25 for each machine identified as cabinet or analytical; and

$50 for each machine used for industrial radiography.

Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.</td>
<td>~~$25~~ $50 for each machine identified as cabinet or analytical; and

~~$50~~ $100 for each machine used for industrial radiography.

Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.

Intent/Rationale/Impact: This change would increase registration fees for all x-ray producing devices. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in totality (in 2009), and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.</td>
</tr>
<tr>
<td>12VAC5-490-20</td>
<td></td>
<td>The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:
<table>
<tr><th>Type</th><th>Cost Per Tube</th><th>Inspection Frequency</th></tr>
<tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>$230</td><td>Annually</td></tr>
<tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>$230</td><td>Annually</td></tr>
<tr><td>Combination (General Purpose-Fluoroscopic)</td><td>$460</td><td>Annually</td></tr>
<tr><td>Dental Intraoral and Panographic</td><td>$90</td><td>Every 3 years</td></tr>
<tr><td>Veterinary</td><td>$160</td><td>Every 3 years</td></tr>
<tr><td>Podiatric</td><td>$90</td><td>Every 3 years</td></tr>
<tr><td>Cephalometric</td><td>$120</td><td>Every 3 years</td></tr>
<tr><td>Bone Densitometry</td><td>$90</td><td>Every 3 years</td></tr>
<tr><td>Combination (Dental</td><td>$210</td><td>Every 3 years</td></tr>
</table>
</td>
<td>The following table lists the fees that shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, as well as the required inspection frequencies for each type of X-ray machine:
<table>
<tr><th>Type</th><th>Cost Per Tube</th><th>Inspection Frequency</th></tr>
<tr><td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td><td>~~$230~~ $250</td><td>Annually</td></tr>
<tr><td>Fluoroscopic, C-arm Fluoroscopic</td><td>~~$230~~ $250</td><td>Annually</td></tr>
<tr><td>Combination (General Purpose-Fluoroscopic)</td><td>~~$460~~ $500</td><td>Annually</td></tr>
<tr><td>Dental Intraoral and Panographic</td><td>~~$90~~ $100</td><td>Every 3 years</td></tr>
<tr><td>Veterinary</td><td>~~$160~~ $175</td><td>Every 3 years</td></tr>
<tr><td>Podiatric</td><td>~~$90~~ $125</td><td>Every 3 years</td></tr>
<tr><td>Cephalometric</td><td>~~$120~~ $130</td><td>Every 3 years</td></tr>
<tr><td>Bone Densitometry</td><td>~~$90~~ $100</td><td>Every 3 years</td></tr>
<tr><td>Combination (Dental Panographic and Cephalometric)</td><td>~~$210~~ $230</td><td>Every 3 years</td></tr>
<tr><td>Shielding Review for Dental Facilities</td><td>~~$250~~ $300</td><td>Initial/Prior to use</td></tr>
<tr><td>Shielding Review for Radiographic, Chiropractic, Veterinary,</td><td>~~$450~~ $500</td><td>Initial/prior to use</td></tr>
</table>
</td>
</tr>
</table>

Panographic and Cephalometric)		
Shielding Review for Dental Facilities	$250	Initial/Prior to use
Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	$450	Initial/prior to use
Baggage X-Ray Unit	$100	Every 5 years
Cabinet/Analytical X-ray Unit	$150	Every 3 years
Industrial Radiography X-Ray Unit	$200	Annually

Fluoroscopic, or Podiatric Facilities		
Baggage X-Ray Unit	$100	Every 5 years
Cabinet/Analytical X-ray Unit	$150	Every 3 years
Industrial Radiography X-Ray Unit	$200	Annually

Intent/Rationale/Impact: This change increases x-ray device inspection fees except for non-medical devices (Baggage, Cabinet, Industrial), which were adjusted effective July 2017. Administrative, personnel, travel and other expenses have increased since the overall inspection fee schedule was last revised in 2009 (with the exception of the aforementioned non-medical devices), and the use of general funds to support the X-ray program was eliminated in SFY16.

12VAC5-490-40. Application and licensing fees for radioactive materials licenses.

Application 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
12VAC5-490-40			

Category		Specific License Type	Application & Annual Fee
1		Special Nuclear Material (SNM)	
	A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	$1,000
	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	$2,000

Category		Specific License Type	Application & Annual Fee
1		Special Nuclear Material (SNM)	
	A.	Possession and use of SNM in sealed sources contained in devices used in measuring systems	~~$1,000~~ $1,700
	B.	SNM to be used as calibration and reference sources	~~$500~~ $900
	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~~ $3,400
2		Source Material	

			category)	
2			Source Material	
	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
3			Byproduct, NARM	
	A.		Broad scope for processing or manufacturing of items for commercial distribution	$10,000
	B.		Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$6,000
	C.		Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$4,000
	D.		Processing or manufacturing of items for commercial distribution	$2,000
	E.		Industrial radiography operations performed only in a shielded radiography installation	$3,000
	F.		Industrial radiography performed only at the address indicated on the license, and at temporary job sites	$3,500

	A.	Source material processing and distribution	~~$3,000~~ $5,100
	B.	Source material in shielding (fee waived if facility holds additional license category)	~~$200~~ $300
	C.	Source material - all other, excluding depleted uranium used as shielding or counterweights	~~$2,000~~ $3400
3		Byproduct, NARM	
	A.	Broad scope for processing or manufacturing of items for commercial distribution	~~$10,000~~ $17,000
	B.	Processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	~~$6,000~~ $9,000
	C.	Commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	~~$4,000~~ $6,800
	D.	Processing or manufacturing of items for commercial distribution	~~$2,000~~ $3,400
	E.	Industrial radiography operations performed only in a shielded radiography installation	~~$3,000~~ $5,100
	F.	Industrial radiography performed only at the address indicated on the license, and at temporary job sites	~~$3,500~~ $6,000

			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 category)	$2,000		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 category)	~~$2,000~~ $3,400
			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		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~~ $5,100
			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		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~~ $5,100
			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		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~~ $8,500
			K.	Distribute items containing radioactive materials to persons under a general license	$1,000		K.	Distribute items containing radioactive materials to persons under a general license	~~$1,000~~ $1,700

				L.	Possess radioactive materials intended for distribution to persons exempt from licensing	$1,000			L.	Possess radioactive materials intended for distribution to persons exempt from licensing	~~$1,000~~ $1,700
				M.	Broad scope for research and development that does not authorize commercial distribution	$6,000			M.	Broad scope for research and development that does not authorize commercial distribution	~~$6,000~~ $10,200
				N.	Research and development that do not authorize commercial distribution	$1,000			N.	Research and development that do not authorize commercial distribution	~~$1,000~~ $1,700
				O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	$1,000			O.	Installation, repair, maintenance or other service of devices or items containing radioactive material, excluding waste transportation or broker services	~~$1,000~~ $1,700
				P.	Portable gauges	$750			P.	Portable gauges	~~$750~~ $1,300
				Q.	Portable X-ray fluorescence analyzer (XRF), dewpointer or gas chromatograph	$250			Q.	Portable X-ray fluorescence analyzer (XRF), dewpointer or gas chromatograph	~~$250~~ $400
				R.	Leak testing services	$500			R.	Leak testing services	~~$500~~ $900
				S.	Instrument calibration services	$1,000			S.	Instrument calibration services	~~$1,000~~ $1,700
				T.	Fixed gauges	$750			T.	Fixed gauges	~~$750~~ $1,300
				U.	All other radioactive material licenses, except as otherwise noted	$1,500			U.	All other radioactive material licenses, except as otherwise noted	~~$1,500~~ $2,600
			4		Waste Processing		4			Waste Processing	
				A.	Commercial waste treatment facilities, including incineration	$100,000			A.	Commercial waste treatment facilities, including incineration	~~$100,000~~ $170,000
									B.	All other commercial	~~$7,500~~

			B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$7,500			facilities involving waste compaction, repackaging, storage or transfer	$12,800
			C.	Waste processing - all other, including decontamination service	$5,000		C.	Waste processing - all other, including decontamination service	~~$5,000~~ $8,500
		5		Well Logging		5		Well Logging	
			A.	Sealed sources or subsurface tracer studies	$3,000		A.	Sealed sources or subsurface tracer studies	~~$3,000~~ $5,100
			B.	Sealed sources and subsurface tracer studies	$3,000		B.	Sealed sources and subsurface tracer studies	~~$3,000~~ $5,100
		6		Nuclear Laundry		6		Nuclear Laundry	
			A.	Commercial collection and laundry of items contaminated with radioactive material	$10,000		A.	Commercial collection and laundry of items contaminated with radioactive material	~~$10,000~~ $17,000
		7		Medical/Veterinary		7		Medical/Veterinary	
			A.	Human use of sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	$6,000		A.	Human use of sealed sources contained in teletherapy or stereotactic radiosurgery devices, including mobile therapy	~~$6,000~~ $10,200
			B.	Broad scope for human use of byproduct, source, special nuclear or NARM materials used in medical diagnosis, treatment, research and development (excluding	$12,000		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~~ $20,400
							C.	Mobile nuclear medicine	~~$2,000~~

			teletherapy or stereotactic radiosurgery devices)		
		C.	Mobile nuclear medicine	$2,000	
		D.	Medical Institutions providing imaging, diagnostic or radionuclide therapy.	$2,300	
		E.	Medical institutions using High Dose Remote Afterloaders or Emerging Technologies	$3,750	
		F.	Veterinary use of radioactive materials	$1,000	
		G.	In-Vitro	$1,000	
8			Academic		
		A.	Possession and use of radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses	$750	
9			Accelerator		
		A.	Production of radioisotopes with commercial distribution	$2,000	
		B.	Production - all other (fee waived if facility holds medical broad scope license with no commercial distribution)	$2,000	
10			Reciprocity		
		A.	Reciprocity recognition of an out-of-state specific license	50% of annual fee of applicable category	

			$3,400
	D.	Medical Institutions providing imaging, diagnostic or radionuclide therapy.	~~$2,300~~ $4,000
	E.	Medical institutions using High Dose Remote Afterloaders or Emerging Technologies	~~$3,750~~ $6,400
	F.	Veterinary use of radioactive materials	~~$1,000~~ $1,700
	G.	In-Vitro	~~$1,000~~ $1,700
8		Academic	
	A.	Possession and use of radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses	~~$750~~ $1,300
9		Accelerator	
	A.	Production of radioisotopes with commercial distribution	~~$2,000~~ $3,400
	B.	Production - all other (fee waived if facility holds medical broad scope license with no commercial distribution)	~~$2,000~~ $3,400
10		Reciprocity	
	A.	Reciprocity recognition of an out-of-state specific license	50% of annual fee of applicable category

Rationale: RMP: VDH staff applied an increase of about 70% to the current fee structure which was originally instituted in 2009 and amended in 2012 and based on workload and device type for the various categories of licenses. Revenue generated will approximate projected expenditures for the activity. Proposed fees will remain less than NRC fees in all categories.