Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-480
Regulation title	Radiation Protection Regulations
Action title	Promulgation of final regulation
Date this document prepared	April 24, 2006

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Virginia Department of Health (VDH) intends to abolish the existing Radiation Protection Regulations (12 VAC 5- 480) and promulgate new regulations (12 VAC 5-481) containing current radiological health standards, including federal standards, state legislation. These proposed regulations are intended to supercede the Radiation Protection Regulations, which became effective July 6, 1988.

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 21, 2006, the State Board of Health voted to adopt the proposed regulation 12 VAC 5-481 (Radiation Protection Regulations) and concurrent repeal of the existing regulation 12 VAC 5 –480.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

These regulations are authorized by the Code of Virginia Sections 32.1-229 et seq.
Section 32.1-229 authorizes the Board of Health to require the licensure and inspection of radioactive materials facilities, and mandates inspections of mammography facilities.
Section 32.1-229.1 requires the Board of Health to promulgate regulations for the registration, inspection, and certification of X-ray machines; and set the criteria for Private Inspectors.
Refer to the following web sites for viewing the statutory authority cited in Section 32.1-229 and Section 32.1-229.1 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+32.1-229.1
Where applicable the radiation protections standards, the standards for X-ray machine performance, and radioactive material licensing is identical to the existing federal minimum requirements. The proposed regulation for mammography facility inspections and patient notification of poor quality mammograms exceeds federal requirements in order to comply with recent state legislation. The state requirements allow unannounced inspections, the federal regulations do not allow unannounced inspections. The Code of Virginia requires patients to be notified within two business days of a poor quality mammogram, the federal regulations allow up to 30 days for facilities to notify their patients.
The Office of the Attorney General issued a statement that the proposed Radiation Protection Regulations were reviewed and that the Department possesses the authority to promulgate these regulations pursuant to Chapter 6, Article 8 of Title 32.1 of the Code of Virginia.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The existing regulation is being replaced in its entirety due to the numerous changes in radiation protection practices since publication of its effective date on July 6, 1988. The harmful effects of radiation are well known, as well as, the many beneficial applications of radiation in industry and healthcare. Adequate regulatory controls for the useful application of radiation are necessary to protect the health, safety, and welfare of citizens. The goals of promulgating the proposed regulation are: to provide the Commonwealth's citizens the same level of protection from radiation exposure as other citizens in the nation or those employed at federal facilities in the Commonwealth; to reduce unnecessary exposure to radiation; and to improve the diagnostic quality of clinical imaging, and accurate delivery of therapeutic doses of radiation to patients. One of the biggest problems with the use of radiation in the healing arts is the need for accurate and reproducible delivery of radiation to film or other imaging devices for successful clinical diagnosis, or delivery of therapeutic radiation doses to patients for successful treatment. The proposed regulation incorporates current performance standards to address this problem.

Substance

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

The major changes that the proposed regulation includes those regarding:

1. U.S. Nuclear Regulatory Commission's (NRC) implemented major changes to the Radiation Protection Standards (Title 10 Code of Federal Regulations Part 21) in 1992, and again in 2001.
2. Congress passed the Mammography Quality Standards Act of 1992 (MQSA) which provided dual regulatory authority to state and federal governments for the regulation of mammography facilities. The MQSA regulations were implemented in 1994 and revised in 2001. The existing regulation does not have standards specific to mammography machines, nor qualifications for Private Inspectors consistent with the federal regulations.
3. The Suggested State Regulations (SSRs) published by the Conference of Radiation Control Program Directors form the basis for VDH's Radiation Protection Regulations and have been revised several times since 1988 to include standards for new X-ray equipment, exposure limits and improve image quality. The SSRs also include revisions for radioactive materials licensing comparable to revised federal standards.
4. Mammography Legislation- The General Assembly passed legislation (House Bills 1487 and 1488-Devolites) in the 2000 session that requires VDH to conduct inspections of mammography machines, and requires facilities to inform patients before leaving the facility whether the image quality is adequate before leaving the facility, respectively. The existing regulations do not have performance standards specific to mammography machines.
5. Radioactive Materials Legislation- The General Assembly passed legislation (House Bill 2655-Katzen) in the 1999 session that authorizes VDH to impose civil penalties on licensees who violate the conditions of their license or the regulation.

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 advantage of the proposed regulation is that businesses regulated by both federal agencies and VDH will operate under identical standards, which will eliminate some confusion, particularly with respect to occupational worker standards, and X-ray machine performance standards. Another advantage for healthcare professionals and patients is the expectation that the application of radiation will meet nationally recognized performance standards and improve the quality of healthcare.

The advantage of the proposed regulation to the agency is that fewer interpretations of the regulation will be needed for the new radiation machines or materials that were developed since the promulgation of the existing regulation and not addressed. Another advantage is that agency staff will no longer need to take additional time to explain regulatory differences to facilities that are dually regulated by another federal agency.

There are no disadvantages to the public or the Commonwealth in promulgating the proposed regulation.

Changes made since the proposed stage

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

Section Number	Requirement at Proposed stage	What has changed	Rationale for change
10	Definitions	"mAa" changed to "mA" "radiation detector" deleted second definition. "teletherapy physicist" changed "the" to "a".	Typographical error "radiation detector" Technical change requested by private inspector to provide clarity. "teletherapy physicist" grammatical correction.
150	Communications	Changed agency address to reflect current address.	Technical change.
210	Types of hearings	Replaced 9-6.14:11 with § 2.2-4019. Informal fact finding proceedings. Replace 9-6.14:12 with § 2.2-4020. Formal hearings; litigated issues.	Corrects incorrect Code citation.
340	Private Inspector Qualifications	A-2-a changed continuing education requirements from 5 CEUs every year to 15 CEUs every three years. A-2-b removed a set number of facilities and decreased number of machines required to be inspected from 20 to 10. B. Clarifies section by inserting after teletherapy machine "… performing radiation protection surveys,…" B-1-d corrected the following citations: ~~12 VAC 5-481-3730 A~~ 12 VAC 5-481-3400 A ; ~~12 VAC 5-481-3750 P~~ 12 VAC 5-481-3420 P; ~~12 VAC 5-481-3760 T~~ 12 VAC 5-481-3430 T ; ~~12 VAC 5-481-3750 Q~~ 12 VAC 5-481- 3420 Q; and ~~12 VAC 5-481-3760 U~~ 12 VAC 5-481-3430 U B-1-e corrected the following citation: Notwithstanding the provisions of ~~12 VAC 5-481-3720 D 5~~ 12 VAC 5-481-3390 D; certification pursuant to ~~12 VAC 5-481-3720 D 2~~ 12 VAC 5-481-340 B 1 (a); ~~12 VAC 5-481-3720 D 3~~ 12 VAC 5-481-340 B 1 (b) ; and/or ~~12 VAC 5-481-3720 D 4~~ 12 VAC 5-481-340 B 1 (c) shall be required on or before ~~December 31, 1999~~, [July 1,	A-2-a Technical change made as compromise from public comment. A-2-b Technical change made as compromise from public comment. B. Private inspector requested technical change to provide clarity. B-1-d Corrects incorrect citation. B-1-d Corrects incorrect citation, and changes implementation date.

		2007]for all persons currently qualifying as a radiation therapy Physicist pursuant to 12 VAC 5-481 3720 D5 12 VAC 5-481-340 B 1 (d). B-2-a change Continuing Medical Education Credits (CME) to Continuing Education Units (CEU), and changed continuing education requirements from 5 CEUs every year to 15 CEUs every three years. C-2-a changed continuing education requirements from 5 CEUs every year to 15 CEUs every three years, and removed removed last sentence that referred to training for different modalities. C-2-b replaced 3 facilities in 12 months with 2 facilities and 6 machines in 24 months.	B-2-a Technical change made as compromise from public comment. C-2-a Technical change made as compromise from public comment. C-2-b Technical change made to be consistent with federal regulations.
430	General licenses-radioactive material other than source material	B. deleted "and" and inserted " , shall comply with the provisions of 12 VAC 5-481-1090 and 12 VAC 5-481-1100 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts IV (12VAC 5-481-600 et seq.) and X (12 VAC 5-481-2250 et seq.) of these regulations". Also replaced federal reference with more recent citation.	B. technical change-incomplete sentence.
480	Special requirements for specific license to manufacture, assemble, repair, or distribute commodities, products or devices which contain radioactive materials.	A-1 deleted the "1" referenced to in 12 VAC 5-481-400 A1. D-1- b- (2) reference to 12 VAC 5-481-630 A should reference 12 VAC 5-481-640. D-3 reference to 12 VAC 5-481-630 A should reference 12 VAC 5-481-640. D-4-d-(1) replaced federal reference with more recent citation. H-3-b replaced 12 VAC 5-481-660 A 1 with 12 VAC 5-481-850 H-5 replaced 12 VAC 5-481-720 with 12 VAC 5-481-910 I replaced 12 VAC 5-481-430 J with 12 VAC 5-481-430 H M-1 replaced 12 VAC 5-481-420 D with 12 VAC 5-481-420 B M-1-b replaced 12 VAC 5-481-630 A with 12 VAC 5-481-640	A-1 Corrects typographical error. D-1- b- (2) Corrects typographical error. D-3 Corrects typographical error. D-4-d-(1) technical change H-3-b corrects incorrect citation. H-5. corrects incorrect citation. I. corrects incorrect citation. M-1. corrects incorrect citation. M-1-b corrects incorrect citation.

		M-4 (d through f) replace D with 12 VAC 5-481-420 B	M-4 (d through f) corrects typographical error.
590	Reciprocal recognition of licenses	A-2 replaced 12 VAC 5-481-430 D 1 with 12 VAC 5-481-430 B B-2 replaced 12 VAC 5-481-430 D 1 with 12 VAC 5-481-430 B	A-2 corrects incorrect citation. B-2 corrects incorrect citation.
640	Occupational dose limits for adults	Replaced federal reference with more recent citation.	Technical change.
680	Determination of prior occupational dose	E-1 replaced reference to 12 VAC 5-481-640 F with VAC 5-481-640	E-1 corrects incorrect citation.
720	Dose limits for individual members of the public	Replaced federal reference with more recent citation.	Technical change.
740	Testing for leakage or contamination of sealed sources	B-6 deleted text and incorporate by reference 10 CFR 39.35	B-6 Technical change to provide clarity.
770	Location of individual monitoring devices	B. replaced reference to 12 VAC 5-481-710 A with 12 VAC 5-481-710. C. replaced reference to 12 VAC 5-481-640 A 2 a with 12 VAC 5-481-640. D. replaced reference to 12 VAC 5-481-640 A 2 b with 12 VAC 5-481-640. Also correct typo by replacing "C" with "D"	B. corrects incorrect citation. C. corrects incorrect citation. D. corrects incorrect citation. And corrects typographical error.
830	Use of individual respiratory protection equipment.	Replaced federal references with more recent citation.	Technical change.
1060	Records of waste disposal	Replaced reference to 12 VAC 5-481-1020 with 12 VAC 5-481-920	Corrects incorrect citation. And corrects typographical error.
1190	Exemptions	A-1-c replaced references to 12 VAC 5-481-720 A through C with VAC 5-481-720	A-1-c corrects incorrect citation. And corrects typographical error.
1590	General and Administrative Requirements	A-2-c replaced "film processor" to "image processor". A-3 removed 3-b and 3-c and inserted "Reserved". A-5-c added after " whole body barriers" "…, or protective aprons…" A-14 added to the end "… or an individual enrolled in an accredited program for radiologic technology and is under the supervision of a	A-2-c Technical change to provide clarity. A-3 Private inspector requested technical change to provide clarity. A-5-c Private inspector requested technical change to provide clarity. A-14 Technical change to provide clarity.

		licensed or certified radiologic technologist." A-14-a inserted at the end ", and if a dental assistant, they comply with the Board of Dentistry's radiation certification requirements in 18 VAC 60-20-95".	 A-14-a Technical change requested from public comment.
1610	Fluoroscopic X-ray systems	C-2 replace 1.32 mC/kg min and 5 R/min with 5.2 mC/kg min and 20 R/min. F adding item F-5 "9 centimeters for all portable fluoroscopes when used for special applications." H-3 add at the end of the last sentence " interventional cardiac catheterization, and interventional special procedures."	C-2 Technical change to stay consistent with federal regulations. F Technical change to stay consistent with federal regulations. H-3 Private inspector requested technical change to provide clarity.
1620	Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems.	B-4 in the formula, replace "#" with "<". B-6-3 added after ",except veterinary systems" the following: ", bone densitometers, and other self-contained machines whose design was approved by the FDA."	B-4 typographical error corrected. B-6 3 Private inspector requested technical change to provide clarity.
1630	Dental intraoral dental radiographic systems	1630 C 5 b (1) replaced reference to 12 VAC 5-481-1630 C 5 1 with 12 VAC 5-481-1630 C 5 a	1630 C 5 b (1) corrects incorrect citation.
1650	Mammography	A-5 , replaced 12 line pairs with 11 line pairs when a high-contrast resolution bar test pattern is orientated with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line pairs/mm when the bars are parallel to that axis. The bar pattern must be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor. When more than one target material is provided, the measurement must be made using the appropriate focal spot for each target material. A-6-a removed last sentence that refers to a maximum force for compression. A-10-a replaced with "All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.	A-5 Technical change to stay consistent with federal regulations. A-6-a Technical change to stay consistent with federal regulations. A-10-a Technical change to stay consistent with federal regulations.

		B-1-(c) change reference to 1650 B III to 1650-B-3. B-3 deleted last sentence replaced with "The Private Inspector shall determine the corrective action interval." C-6 replaced Appendix A with 12 VAC 5-481-340 C.	B-1-(c) typographical error corrected. B-3 Private inspector requested technical change to provide clarity. C-6 technical change.
1670	General requirements	Replaced federal references to definitions, implementation with more recent citations.	Technical change.
1680	Licensing and exemption	Replaced federal reference to license amendments with more recent citation.	Technical change.
1690	Notifications	Replaced federal reference to notifications with a more recent citation.	Technical change
1750	Training for Radiation safety Officer	Replaced federal reference with a more recent citation.	Technical change.
1760	Training for an authorized medical physicist	Replaced federal reference with a more recent citation.	Technical change.
1770	Training for an authorized nuclear pharmacist.	Replaced federal reference with a more recent citation.	Technical change.
1780	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, and pharmacist.	Replaced federal reference with a more recent citation.	Technical change.
1870	Release of individuals containing unsealed byproduct material or implants containing byproduct material	Replaced federal reference with a more recent citation.	Technical change.
1900	Use of unsealed byproduct material for uptake, dilution, and excretion	Replaced federal reference with a more recent citation.	Technical change.
1910	Training for uptake, dilution, and excretion	Replaced federal reference with a more recent citation.	Technical change.
1920	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	Replaced federal reference with a more recent citation.	Technical change.
1940	Training for imaging and localization studies.	Replaced federal reference with a more recent citation.	Technical change.
1950	Use of unsealed byproduct material for	Replaced federal reference with a more recent citation.	Technical change.

	which a written directive is required		
1960	Safety instruction	Replaced correct reference to federal regulation 10CFR35.310, not 10CFR35.300	Corrects typographical error.
1970	Safety precautions	Replaced federal reference with a more recent citation.	Technical change.
1980	Training for use of unsealed byproduct material for which a written directive is required	Replaced federal reference with a more recent citation.	Technical change.
1990	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).	Replaced federal reference with a more recent citation.	Technical change.
2000	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	Replaced federal reference with a more recent citation, and included reference to missing federal regulations for training requirements for parenteral administration of unsealed by product material..	Technical change.
2010	Manual brachytherapy	Replaced federal references to training for manual brachytherapy sources and the ophthalmic use of strontium-90.	Technical change.
2030	Training for use of sealed sources for diagnosis.	Replaced federal reference with a more recent citation.	Technical change.
2040	Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units	Inserted federal reference for dosimetry equipment that was missing and replaced federal reference with a more recent citation.	Technical change.
2050	Training and Experience Requirements	Replaced federal references Training for an authorized nuclear pharmacist with a more recent citation.	Technical change.
2070	Records	Replaced federal reference to Records of calibration measurements of brachytherapy sources with a more recent citation.	Technical change.
2240	Ventilation systems	A. replaced reference to Part IV 12 VAC 5-481-600 et seq.) Appendix F with Table 1 of Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure;	A technical change to stay consistent with federal regulations.

		Effluent Concentrations; Concentrations for Release to Sewerage (10 CFR 20 Appendix B, 58 FR 67659, Dec. 22, 1993) B. replaced reference to Part IV 12 VAC 5-481-600 et seq.) Appendix F with Table 2 of Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (10 CFR 20 Appendix B, 58 FR 67659, Dec. 22, 1993)	B technical change to stay consistent with federal regulations.
2410	Requirements for issuance of a license.	H replaced reference to 12 VAC 5-481-10328 with 12 VAC 5-481-2580	H corrects incorrect citation.
2980	Transportation of licensed material	A-3 replaced reference to 12 VAC 5-481-900 E with 12 VAC 5-481-900	A-3 corrects incorrect citation.
3000	General license: Nuclear regulatory Commission approved packages	C. replaced reference to 12 VAC 5-481-3000 7 A with 12 VAC 5-481-3000 A	C. corrects incorrect citation.
3080	Routine determinations	J. Replaced 12 VAC 5-481-3080 1 with 12 VAC 5-481-3080 I	J. corrects typographical error.
3120	Advanced notification of transport of nuclear waste	B-3-a, replaced "Appendix L, Table 1" with Table A-1 of Appendix A to Part 71--Determination of A_1 and A_2 (10 CFR 71, 69 FR 3800, Jan. 26, 2004) B-3- b, replaced "Appendix L, Table 1" with Table A-1 of Appendix A to Part 71--Determination of A_1 and A_2 (10 CFR 71, 69 FR 3800, Jan. 26, 2004)	B-3-a technical change to stay consistent with federal regulations. B-3-b technical change to stay consistent with federal regulations.
3270	Requirements for personal safety	A-1 replaced Appendix M with section 39.61(e)(1)(vi) of Part 39—Licenses and Radiation Safety Requirements for Well Logging (10 CFR 39, 52 FR 8234, Mar. 17, 1987)	A-1 technical change to stay consistent with federal regulations.
3390	General administrative requirements for facilities using therapeutic radiation machines.	A inserted after agency in first sentence ".. and reporting misadministrations within 10 days." D-1 deleted "compliance" prior to survey. D-2 Replace reference to Appendix M with Section 340-B-2	A Technical change to provide clarity. D-1 Technical change provides clarity. D-2 corrects a technical error.
3400	General technical requirements for facilities using therapeutic radiation machines.	C-1 deleted last sentence.	C-1 Technical change requested by private inspector to provide clarity.
3410	Quality management program	Deleted "The facility may use quality management programs found in either Appendix P or Q" and replaced with "The facility shall include in the quality management program notification of a misadministration, a recordable event, and recording written directives."	Technical change requested by private inspector to provide clarity.
3430	Therapeutic radiation machines- photon therapy	C-1 added to end of sentence "... or for multi-leaf collimators, shall not exceed manufacture's	C-1 Technical change requested by private

<table>
<tr><td></td><td>systems (500 kV and above) and electron therapy systems (500 kV and above)</td><td>specifications”.

C-2 added to end of sentence “... or for multi-leaf collimators, shall not exceed manufacture’s specifications”.

Q-4 deleted “two-way “ in both sentences.

Q-10 added words after removing “… from treatment room, or…”</td><td>inspector to provide clarity.

C-2 Technical change requested by private inspector to provide clarity.

Q-4 Technical change requested by private inspector to provide clarity.

Q-10 Technical change requested by private inspector to provide clarity.</td></tr>
<tr><td>3450</td><td>Shielding and safety design requirements</td><td>B deleted last sentence, there is no Appendix O</td><td>B Technical change requested by private inspector to provide clarity.</td></tr>
<tr><td>3510</td><td>Release for unrestricted use</td><td>A. replaced “Appendix R” with “Table 1 in this Part”.
And insert Table 1

Table 1
Acceptable Surface Contamination Levels[1] for TENORM
<table><tr><td></td><td>AVERAGE[2,3,6]</td><td>MAXIMUM[2,4,6]</td><td>REMOV</td></tr><tr><td>Alpha</td><td>5,000 dpm/100 cm^2</td><td>15,000 dpm/100 cm^2</td><td>1,000 dp</td></tr><tr><td>Beta-gamma</td><td>5,000 dpm/100 cm^2</td><td>15,000 dpm/100 cm^2</td><td>1,000 dp</td></tr></table>[1] Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[2] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
[3] Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.
[4] The maximum contamination level applies to an area of not more than 100 cm^2.
[5] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area A (where A is less than 100 sq. cm) is determined, the entire surface should be wiped and the contamination level multiplied by 100/A to convert a “per 100 sq. cm” basis.
[6] The average and minimum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2μGy/hr) at 1 cm, respectively, measured through not more than 7 milligrams per square</td><td>A. technical change to stay consistent with federal regulations.</td></tr>
</table>

		centimeter of total absorber.	
3520	Disposal and transfer of waste for disposal	B. replaced "Appendix R" with "Table 1 in 12 VAC 5-481-3510 A".	B. technical change to stay consistent with federal regulations.
3560	Requirements for issuance of a specific license	B. replaced "Appendix R" with "Table 1 in 12 VAC 5-481-3510 A".	B. technical change to stay consistent with federal regulations.

Public comment

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

Commenter	Comment	Agency Response
Howard Amols, Ph.D. AAPM President & Lynne A. Ferobent AAPM Legislative and Regulatory Affairs Manager	The American Association of Physicists in Medicine (AAPM) applauds the Commonwealth of Virginia on proposing a comprehensive revision to its Radiation Protection Regulations (12 VAC 5-480), however AAPM requests an extension of the comment date until January 15, 2006. Due to the wholesale revision of the regulations and incorporation by reference of a number of the Suggested State Regulations that are currently under revision, AAPM feels that it would benefit the Commonwealth and the users of radioactive materials in Virginia to extend the comment date.	Delaying the promulgation of the proposed regulation would not serve the public interest. The agency has received several comments from members of the AAPM as well as others affected by the regulations. Given that the proposed regulation incorporates by reference federal regulations with respect to radioactive materials, the agency has little flexibility to modify these requirements, and certainly cannot be less restrictive. No change.
	Additionally, some of the proposed changes incorporate by reference Task Group reports developed by the AAPM for use by its members as guidance and were not intended to be adopted as regulation.	Disagree. The Suggested State Regulations have incorporated by reference protocols of several nationally recognized organizations, such as the AAPM. No change.
Pam Cline , Director, Radiology School Riverside School of Health Careers	Section 1590 General and administrative Requirements Item A-14: Page 307 of 12 VAC5-481 states that x-ray machine operators must be licensed by the state or ARRT certified. This would make it unlawful for	Although Section 1590 A-5 allows persons to be in a room during X-ray procedures for training, the regulation is not clear that one in training can operate the controls. Suggest clarifying item A-14 by adding to the end "… or an individual enrolled in an accredited program for radiologic technology and

Pam Cline , Director, Radiology School Riverside School of Health Careers	students to perform radiographs. Students must perform radiographs to become radiologic technologists. The guidelines under which they are allowed to do this are clearly delineated by the Joint Review Committee on Education in Radiologic Technology (JRCERT). Ideally the statement should read "those who are licensed by the state, ARRT certified or are enrolled in a school of radiologic technology that is accredited by an agency acceptable by the ARRT." As the Director of an x-ray school I must emphasize how important this matter is. Facilities will not allow our students to perform radiographs if this clause is not added for fear of breaking the law. Where will the next generation of technologists come from?	is under the supervision of a licensed or certified radiologic technologist."
	In addition there should be a gratis time from the date of graduation until the technologist becomes ARRT certified. Such technologists are registry eligible but may not have received their test date and thus may not be ARRT certified for a period of time to be agreed upon.	Disagree, students may need an incentive to complete their program by taking and passing the registry exam. Students may also apply for licensure with the Department of Health Professions. No change.
Betty Schwab , Radiation Safety Supervisor Virginia Commonwealth University	Section 340 Private Inspector qualifications Item A-2-b Continuing Experience Requirements for Private Inspectors The continuing experience requirement on page 113 states that private inspectors "must have surveyed at least 10 diagnostic X-ray facilities and at least 20 diagnostic X-ray machines within the preceding 12 months". Private inspectors who work full time at one large facility such as a university/hospital or one large hospital will not be able to meet the requirement for 10 facilities in a 12 month period. I don't think there should be a requirement for the number of facilities surveyed.	Agree. Staff recognizes that some employers restrict employees work to only the employer's facility and would therefore not be able to meet the continuing experience requirements. The continuing experience qualification requirement is important, since over 75% of the individuals on the Private Inspector's list have not submitted a single inspection report for a facility in Virginia. These individuals serve no purpose to our registrants seeking physicists support. Staff recommends modifying Section 340 Item A-2 b to remove a set number of facilities and decrease the number of machines from 20 to 10.
Dean W. Broga PhD, Director/Radiation Safety Officer Virginia Commonwealth University	Section 340 Private Inspector qualifications Item A-2-b Continuing Experience Requirements for Private Inspectors The present proposed regulation would limit both mammographic and diagnostic physicist working at one	The requirement for a greater number of diagnostic machines inspected to maintain proficiency compared to mammography machines is due to the

	facility from surveying their own facility's equipment. This is not the case in therapy. Therapy private inspectors are required to complete only one facility and one unit per year. This makes no sense. The mammographic requirements are three times that of the present Federal MQSA standard which only require 2 facilities in a 24 month period. Why the State would choose to supercede the federal requirements, is not clear. The requirements for diagnostic inspections seem unusually high, 10 facilities and 20 tubes. Why they need to exceed the requirements for mammography is unclear.	diversity of make and models of diagnostic machines. Staff recommends modifying Section 340 Item A-2-b to remove a set number of facilities and decrease the number of machines from 20 to 10.
Dean W. Broga PhD, Director/Radiation Safety Officer Virginia Commonwealth University	I would propose that the mammography requirements be aligned with those of the MQSA and that the diagnostic be similar to therapy in that they require 1 facility and 3 tubes in a 12 month period. If passed in their present format, the regulations would severely impact on the ability of facilities to get required surveys done by placing unnecessary restriction on the physicist performing diagnostic surveys and undoubtedly increase the cost to those facilities.	With respect to mammography equipment, the intent is to be identical to federal requirements which are 2 facilities and 6 machines in a 24 month period, instead of 3 facilities in 12 months. Staff recommends modifying Section 340 Item C-2-b to replace 3 facilities in 12 months with 2 facilities and 6 machines in 24 months.
	Nothing in these regulations defines either the educational, continuing education or continuing experience requirements for State Inspectors. I think it is in the public healths interest to ensure that State Inspectors meet the same minimum requirements for the inspection of facilities and equipment that are required for Private Inspectors. It has been implied in the past that they do so by job definition but that is not clearly delineated in these regulations and thus allows the State to employee State Inspectors who are not qualified to meet the same level set forth in these regulations. This is not only misleading to the registrant who might choose to use them but an unfair competitive edge since the State is in essence competing with the private sector in this market. At a minimum, State Inspectors should have to meet all of	State inspectors performing diagnostic inspections for a fee do meet the same regulatory requirements as the other Private Inspectors. With respect to mammography inspections, State Inspectors meet the federal educational and continuing education/experience requirements for State Inspectors and their performance is audited by a federal auditor annually. State Inspectors do not provide physics services to mammography facilities for a fee. The inspection fees are paid to the State and not the individual, therefore there is no motivation to perform inspections other than by request of the registrants where Private Inspectors are unavailable at a reasonable cost. No change.

	the educational, continuing educational and experience requirements set forth for Private Inspectors if they are going to provide inspection services for a fee.	
George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc.	12 VAC 5-481-10: The definition of "misadministration" for teletherapy (teletherapy seems to be defined to include therapeutic x-ray machines) based on a percentage of prescribed dose is very difficult to interpret in the context of modulated beam delivery, now common practice. The prescription for IMRT necessarily consists of a set of upper and lower dose-volume constraints for a number of target and sensitive anatomic structures, not a single dose value to a single point.	Disagree. We would apply the 20% limit to exceeding either the upper or lower bound of the prescribed dose. No change.
George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc	12 VAC 5-481-10 and 12 VAC 5-481-3430 R 1: The proposed regulations provide a definition of "misadministration" for teletherapy (teletherapy seems to be defined to include therapeutic x-ray machines), and 12 VAC 5-481-3430 R 1 f requires that the facility employ the services of a radiation therapy physicist who shall be responsible for "performance of calculations/assessments regarding misadministrations," but there is nothing in the proposed regulations regarding reporting requirements for misadministrations. What are the radiation therapy physicist's role, authority and responsibility in the event of a suspected teletherapy misadministration?	In general Section 3390 A describes the responsibility of the registrant or its agent. Staff recommend clarifying Section 3390 A by inserting after agency in first sentence "…, and reporting misadministrations within 10 days."
	12 VAC 5-481-340 B 2 b: The requirement that the therapy private inspector survey a minimum of one facility and one machine each year is difficult to interpret since the terms "survey [a] facility" and "survey [a] machine" are not defined elsewhere in the proposed regulations. If the intent is that each inspector perform both at least one machine calibration and at least one radiation protection survey per year, then the wording should be modified accordingly. If that is in fact	Disagree. See definition of "Survey", which applies to both machine and facility's procedures.

	the intent, then I would raise the further objection that many private inspectors in radiation therapy who perform regular machine calibrations do not perform radiation protection surveys at all and so will chronically fail to remain qualified.	
George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc	12 VAC 5-481-340 B 2 a: The requirement of this paragraph cannot be met since only physicians are awarded Continuing Medical Education (CME) credits. Medical Physicists can earn Medical Physics Continuing Education Credit (MPCEC) credits from educational programs that are accredited by CAMPEP. There may also be other sources of continuing education credit for physicists but they are not called CMEs.	Agree. Change CME to Continuing Education Units (CEUs). Affects Section 340 items A2a, and B2a.
	12 VAC 5-481-340 B 2 b: The requirement to perform at least one annual machine calibration (if that is what the language of this paragraph means) per 12 months to remain qualified is too stringent. The timing of the annual calibration of an accelerator is fixed in a particular month at the time of its installation. A physicist who works only at one facility and calibrates only one accelerator at that facility will be unduly punished if he/she changes jobs in mid-cycle and moves to a clinic whose machine has an annual calibration date later in the annual cycle than the one from which he/she came. 18 to 24 months is a more reasonable frequency requirement.	Disagree. No change.
	12 VAC 5-481-3390 D 1: The term "compliance survey" is not defined.	Agree. Clarify Section 3390-D-1 by deleting “compliance”.
	12 VAC 5-481-3390 D 2: There is no Appendix M.	Agree. Technical change. Appendix M in existing regulations was moved to Section 340-B-2
	12 VAC 5-481-3390 F: What is the scope of the "written safety procedures and rules?" This paragraph seems	Disagree. Staff recognizes the diversity of therapeutic equipment, and individual operator experience. It is the registrant’s responsibility to

	unworkably vague.	develop safety procedures for its employees and the use of its equipment. No change.
	12 VAC 5-481-3390 J 4: This paragraph seems to require that even routine maintenance or simple repair of a minor component requires a signature from someone in authority acting on behalf of the licensee before returning the machine to use. That is far too stringent a requirement given the frequency of minor repairs and preventive maintenance. Perhaps addition of the qualifier "[service] that could affect beam quality, steering or output" would be a useful clarification	Disagree. The registrant can establish a procedure for who can return a machine to service depending on the nature of the repairs or service. No change.
George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc	12 VAC 5-481-3400 A 1, 12 VAC 5-481-3400 A 3 and 12 VAC 5-481-3400 C 1: The language "a radiation therapy physicist or a private inspector" is confusing. It is not at all clear what distinction the word "or" is calling out. The DEFINITIONS say that "Radiation therapy physicist" means an individual qualified in accordance with 12 VAC 5-481-340 (note that the definition does not say "registered"). The DEFINITIONS also say "Private inspector" means an individual who meets the requirements set forth in 12 VAC 5-481-340 and who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. So the qualifications for a "private inspector" are more stringent than those for a "radiation therapy physicist."	Disagree. By definition, radiation physicist is the same as a Private Inspector qualified in the category for radiation therapy.
	12 VAC 5-481-340 describes three categories of inspector, namely "diagnostic X-ray (except mammography)" in section A, "therapeutic X-ray and teletherapy machines" in section B, and "mammography" in section C. I note that section B does not include any language regarding radiation protection surveys, only language regarding	Agree. Clarify Section 340-B by inserting after teletherapy machine "… performing radiation protection surveys,…".

George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc	calibration and spot-checks of machines. Given all that, the paragraph seems to me very unclear as to who is qualified to perform the work specified in 12 VAC 5-481-3400 A 1, 12 VAC 5-481-3400 A 3 or 12 VAC 5-481-3400 C 1.	
	12 VAC 5-481-3400 C: The placement of this section in amongst several other sections concerned with radiation protection surveys is confusing, especially since the term "dosimetry equipment" is never defined but does not seem to be related to protection surveys. One presumes the section refers to the equipment necessary to perform an absolute measurement of the output of the therapeutic radiation machine, but that is not made clear.	Disagree. Section 3400 Item C-2 specifically states that the dosimetry system is for quality assurance check measurements. No change.
	12 VAC 5-481-3400 C 1: The last sentence of the first paragraph, "An independent survey shall be conducted by a private inspector or radiation therapy physicist other than the person performing the original survey prior to the equipment being used except as described in 12 VAC 5-481-3400 A 4," makes no sense as applied to dosimetry equipment. It appears to have been misplaced from another section. It is a mystery how one goes about surveying dosimetry equipment. The reference to 12 VAC 5-481-3400 A 4, which is related to remediation of problems detected during a radiation protection survey, just deepens the mystery. Surely this sentence is a mistake.	Agree. Delete last sentence in Section 3400 C-1
	12 VAC 5-481-3410: There is no Appendix P or Appendix Q. There is nothing else in the proposed regulations regarding the form and content of the required quality management program.	Agree. Delete references to Appendix P and Appendix Q in Section 3410.
	12 VAC 5-481-3430 C: I believe that most modern therapeutic X-ray machines, equipped as they routinely are with multi-leaf collimators (MLC), cannot satisfy the requirements of this section as written. The requirements,	Agree. Clarify Section 3430 C-1, and C-3-a by inserting at end of sentence "… or for multi-leaf collimators, shall not exceed manufacturer's specifications."

	particularly 12 VAC 5-481-3430 C 1 as qualified by 12 VAC 5-481-3430 C 3 a, are apparently more stringent than the current IEC requirements (standard 60601-2-1).	
George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc	12 VAC 5-481-3430 Q 4: The requirement for "continuous" two-way aural communication is unworkable as worded. It is clearly important that there be two-way aural communication between the operator and the patient, and the monitoring of the patient should be continuous. However, it is neither desirable nor workable for aural communication in the other direction, from the operator to the patient, to be continuous. A great deal of conversation takes place at the console before, during and after patient treatment that should not be overheard by the patient for a variety of reasons, including but by no means limited to consideration of HIPAA requirements regarding the privacy of other patients. The preferred, and typical, mode is that the operator can push a button on the intercom to communicate on demand with the patient when necessary.	Agree. Clarify Section 3430-Q-4 by deleting "two-way" in both sentences.
	12 VAC 5-481-3430 Q 10: This requirement seems to be too stringent. As written and strictly interpreted, this paragraph would require a survey each time a wedge filter is used and removed. It is well known that wedges and other treatment aids are activated on each use, and the wedges are quite clearly components of the machine. One presumes the intent of the paragraph is to reduce exposure to service personnel who may handle components of the accelerator head which are normally inaccessible and can become highly activated, but the wording of the paragraph does not make that distinction and would pose an undue hardship if interpreted strictly as written.	Agree. Clarify Section 3430-Q-10 by inserting after removing "…from treatment room, or…".
	12 VAC 5-481-3430 R 1 a: This paragraph seems to require that the same radiation therapy physicist perform both calibration and protection	Disagree. Different persons may conduct calibrations, spot checks than those who conduct the radiation survey; however, they both must be qualified as described in Section 340. No change.

	surveys. These are two different subspecialties of medical physics and not all radiation therapy physicists do both. The wording should be modified to explicitly accommodate the fact that protection surveys may be performed by a different qualified expert than the calibration and other tasks of 12 VAC 5-481-3430 R 1.	
George W. Sherouse PhD, Consulting Radiation Oncology Physicist Sherouse Systems, Inc	12 VAC 5-481-3430 T 2, 12 VAC 5-481-3430 T 3, 12 VAC 5-481-3430 U 1, 12 VAC 5-481-3430 U2 and 12 VAC 5-481-3430 U 6: The AAPM task group reports cited were meant to be advisory documents to be used by qualified medical physicists in the development of acceptance and quality management programs that are appropriate to the local circumstances. Furthermore, much of their content has been rendered somewhat obsolete by recent rapid developments in technology, and the AAPM is in the process of dramatically revising their recommendations. It is inappropriate for these specific task group reports or their specific recommendations to be included in their entirety as regulatory requirements.	Disagree. The Suggested State Regulations have referenced protocols of several organizations including the AAPM for several decades. Staff has interpreted regulation liberally whenever a particular protocol has been superceded. No change.
	12 VAC 5-481-3430 U 7 f: Weekly checking of all emergency power cutoff switches is excessive and burdensome. Many therapeutic x-ray machines have They are typically tested monthly at most (as is recommended by the AAPM's TG-40 report). The language of this paragraph is unclear as to whether one switch per week must be tested or whether all switches must be tested weekly or whether the facility retains discretion to determine the appropriate testing schedule.	Disagree. Proposed regulation specifically states that for multiple emergency switches, at least one is tested each week, and the rest are tested on a rotating basis. No change.
	12 VAC 5-481-3450 B: There is no Appendix O.	Agree. Clarify by deleting last sentence in Section 3450-B.
	Missing: The proposed regulations do not specify the protocol by which a teletherapy unit is to be calibrated. It	Disagree. AAPM's TG-45 is referenced in Section 340-T-3. No change.

	would be preferable to require that a teletherapy machine be calibrated using a protocol currently recommended by the AAPM.	
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	The "Proposed Virginia Radiation Protection Regulations" contains many new requirements however very few stakeholders were made aware of the comment period. Also the Appendixes are referenced as part of the regulation but are not available for review. I suggest a more through notification process for the stakeholders, and that the comment period should be extended three months after the appendixes are published. **Comments on 12 VAC 5-481-10. Definitions.**	Disagree. The agency followed the Administrative Process with respect to public participation and notification. Several of the appendices from the existing regulations were incorporated into the text of the proposed regulations, others were deleted. See previous comments to determine which ones were identified during public comment period.
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	p. 42 "mAa" means milliampere. Should this read "mA" means milliampere?	Agree. Change to "mA"
	p. 43 "Misadministration" means the administration of: .... Consider using NRC's term Medical Event instead of Misadministration.	Disagree. Suggested State regulations uses the term Misadministration. No change.
	p. 48 Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (Sn) is calculated using the following expression: Consider broadening definition to include other imaging modalities.	Disagree. Noise is specifically defined for CT. In the rest of the regulations it has its general meaning. No change.
	p. 58 "Radiation detector" Consider combining the two different "radiation detector" definitions that are on the same page but with different definitions.	Agree. Clarify by deleting second definition for "radiation detector".
	It seems that there are two similar but different definitions for therapy simulators. p 59 "Radiation therapy simulation system" p. 68 "Simulator (radiation therapy simulation system)"	Agree. Differences not significant. No change.
	P. 85 "Written directive" means an order in writing for a specific patient,	Electronic signatures are recognized. No change.

	dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (6), containing the following information Will it be acceptable to order procedures through electronic charting?	
	p. 77 "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an agency license. Some faculties have more than one qualified teletherapy physicist; therefore, consider replacing the word "the" with "a".	Agree. Change “the” to “a’ in definition.
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	p. 84 "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee. Will Effective Dose Equivalent (EDE) correction factors be allowed for calculating occupational workers whole body doses that wear protective aprons? For example ((EDE = 1.5 x H1 + 0.04 x H2) where H1 is the deep dose component from the under-apron badge and H2 is the component from the collar badge.	Staff will continue to allow use of the Webster formula, where appropriate in calculating radiation dose from exposure records. No change.
	12 VAC 5-481-150. Communications. All communications and reports concerning this chapter, and applications filed thereunder, should be addressed to the agency at the following address: Virginia Department of Health , Radiological Health Program, 1500 E. Main Street, Room 240, Richmond, Va. 23119-2448. Is the address correct?	Agree. The agency moved after the proposed regulations were drafted. Change address to: 109 Governor Street, Room 730; Richmond, VA 23219
	P. 103 **12 VAC 5-481-280. Shielding plan review.** A. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be available to the agency for review. The required information is found in 12 VAC 5-481- 280 E. Will the current method of maintaining the	Plans are submitted to the agency only upon request. No change.

	records on site for inspection be sufficient or will the plans need approved by the agency prior to construction?	
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	**06 12 VAC 5-481-280. Shielding p n review.** **F 1 a**. The operator shall be allotted not less than 0.70 square meter (7.5 square feet) of unobstructed floor space in the booth; **b.** The operator's booth may be any geometric configuration with no dimension of less than 0.6 m (2 feet); Will there be a grandfather clause for existing control booths that are less than 7.5 square feet and/or with a dimension that is less than 2 feet? If allowed will the grandfathered dimension be allowed with installation of a new console?	Agree. Staff intends to apply these requirements for new facilities and installation of new machines in existing facilities. No change.
	115 **12 VAC 5-481-340. Private Inspector Qualifications.** **12 VAC 5-481-340 A 2** a. Continuing education. Private inspectors must participate in continuing education programs relating to diagnostic X-ray, either by teaching or completing at least five continuing education units (CMEs) per year. The total required credit is 15 CME per 3 years and since MQSA requires 15 CME per 3 years and since many CME programs are designed to provide the needed credits in one trip to a 15 hour course, consider changing the State requirement to match MQSA's time cycle of the same total but over three years.	Agree. It was the intent to make state requirements identical to the federal requirements. Clarify Section 340 to make the continuing education requirements identical to mammography and the federal requirements by changing item A-2-a, B-2-a, and C-2-a to require 15 CEU every three years instead of 5 CEUs every year.
	12 VAC 5-481-340 C 2 a. Continuing education. At all times after the third anniversary of completion of the initial requirements of this section, the private inspector shall have taught or completed at least 15 continuing education units in mammography during the preceding three years. This continuing education shall include training appropriate to each mammographic modality evaluated by the private inspector during his or her surveys or oversight of quality	Agree. The federal regulations no longer have training requirements for each type of modality. Modify Section 340-C-2-a by removing last sentence that refers to training for different modalities.

	assurance programs. Note: MQSA no longer requires that the training be specific to the modalities evaluated.	
	P 122 **12 VAC 5-481-370. Certification of X-ray systems.** A 4. Certification may be denied if any non-compliances are not corrected within 45 days from the date of inspection. Will both serious and non-serious non-compliances have the same time limit for correction?	Non-serious items of non compliance are expected to be corrected by the next inspection. Repeat non serious items can become serious items of non compliance. No change.
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	P. 207 **12 VAC 5-481-740 B 6.** Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. Stored not in use Brachytherapy sources should also be exempt from leak testing to help keep workers hand dose ALARA.	Agree. Clarify by deleting text of Section 740-B-6 by incorporating by reference 10 CFR 39.35 Leak testing of sealed sources.
	ART VI USE OF DIAGNOSTIC X-AYS IN THE HEALING ARTS 12 AC 5-481-1580 Throughout the Diagnostic sections consider using the word image in place of film, as many facilities are now "filmless" This will avoid a potential loophole for imaging that doesn't use film	Agree. Clarify section 1580 by replacing “film” with “image” where appropriate.
	p. 295 12 VAC 5-481-1590. General and administrative requirements. A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the X-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the X-ray system(s). 1. An X-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes. Comment: Does this mean that the any system will have to be immediately removed from service for any minor separation form the	No. No change.

	requirements?	
	12 VAC 5-481-1590 B 2 b The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film. How often will darkroom fog have to be determined for non-mammography darkrooms?	The Private Inspector will need to determine which tests to conduct and depend on image quality for that facility. No change.
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	**P 295-297 12 VAC 5-481-1590.a General and administrative requirements** 2. Individuals who will be operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The agency may use interview, observation and/or testing to determine compliance. The following are areas in which the agency considers it important that an individual have expertise for the competent operation of X-ray equipment: c. Film processing Comment: At the facilities that Film processing has become obsolete the workers should not be required to know about film processing	Agree. Clarify Section 1590-A-2-c by replacing "film processor" with "image processor".
	p. 297 12 VAC 5-481-1590 A. 5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined: Comment: Consider modifying the rule so that caregivers can continue to provide care to other patients in multipatient areas. For example it is not practical to have all of the staff members leave emergency departments, Intensive care or Operating Department recover areas	Disagree. Proposed regulations has flexibility for physician to determine whose presence is necessary during the exposure. No change.

	during an x-ray exposure.	
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	**p. 298 12 VAC 5-481-1590 A.** 5.b. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; Comment: Consider allowing 3-meter (10 feet) separation from patient and x-ray tube to be substituted for 0.25 mm lead apron requirement. Will operators be required to wear lead aprons during bone density procedures? Scatter radiation from many units is less than 100 mrem per year at the operator's position.	The term lead equivalent is used, so one may use a suitable thickness of air, usually in terms of distance from the radiation source. Certain machines are designed with adequate shielding so that lead aprons are not necessary such as bone densitometers, and baggage security machines. No change.
	p 298 **12 VAC 5-481-1590 A** 5.c. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor. Comment: In the areas where the distance between patients is less than 2 meters, there is often not enough room to place a mobile whole body shield. Therefore, consider allowing the use of protective aprons instead of whole body protective barrier for protection of the adjacent patient.	Agree. Insert into Section 1590-A-5-c after “whole body protective barriers” “…, or protective aprons…”.
	P. 299 **12 VAC 5-481-1590 A 8.c**. The human holder shall be instructed in personal radiation safety and protected as required by 12 VAC 5-481-1590 A 5; Diagnostic facilities use adult non-pregnant family members to hold patients in an effort to reduce the times that radiographers hold patients. What amount of training will have to be given to the family members that hold patients during exams?	The registrant will need to advise family members when holding the patient the depth of training will depend on the amount of exposure and the number of exposures that are expected, and also taking into consideration the ability of the family member to understand the risks . No change.
	p. 304 **12 VAC 5-481-1590 A 11**. Healing arts screening. Any person proposing to conduct a healing arts	Healing arts screening refers to those diagnostic exposures where patients are “self referred”. This is different from mammography screening, which

	screening program shall not initiate such a program without prior approval of the agency. ... Most mammography facilities perform" screening mammography" Do those mammography facilities need to provide the information required by 12 VAC 5-481-1590 A 11?	refers to a medical test that is usually followed up with another test(s) when there is a positive result. In the case of mammography, the follow up tests are additional projections, and needle biopsy to make a definitive diagnosis. Most patients for mammography screening exams are now referred by a physician. No change.
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	p.307 **12 VAC 5-481-1590 A 14** a. The name of the X-ray machine operator. Operators must be licensed by the Department of Health Professions where X-rays are used within the scope of practice or be certified by the ARRT. Does this mean that anyone that is licensed by the Department of Health Professions may take x-rays at a facility performing x-rays within the scope of practice. E.g. Would a Licensed Acupuncturists working at a chiropractic clinic would be allowed to take spinal x-rays since the scope of practice at the chiropractic clinic allows one to perform spine x-rays? Radiation Safety training and competency requirement should be added to the regulations. Doctors currently can buy and operate x-ray and fluoroscopic devices without demonstrating knowledge in use of the equipment, interruption of images or in radiation safety Does this rule mean that dental assistants that have passed radiation safety courses but that are not licensed are not allowed to operate intraoral x-ray units?	Each Board in the Department of Health Profession regulates the scope of practice for each profession it regulates. Scope of practice for a chiropractor includes use of X-rays, the licensed Acupuncturists does not, and should not operate the X-ray machine. In the case of dental assistants, you are correct, the Board of dentistry does not license this group. Technical change to Section 1590-A-14-a by inserting at end of sentence ", and if a dental assistant, they must comply with the Board of Dentistry's radiation certification requirements in 18 VAC 60-20-195."
	p. 321 **12 VAC 5-481-1600**. Maintaining compliance. Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard. Question: Will current units be exempt from future changes in standards of 21 CFR Part 1020?	Yes, unless the machine is later modified. No change.
	P 321 **12 VAC 5-481-1600 K** Mechanical timers. The use of a mechanical timer is prohibited.	Mechanical timer does not apply to panoramic machines. Its exposure duration is controlled by the rotation speed of the electric motor and trips limit

	Will an exemption be given to dental panoramic systems units that effectively have mechanical timers? On many panoramic systems the arm reaching the end of travel terminates the exposure.	switches. No change.
	P. 327 **12 VAC 5-481-1610 C2.** The maximum entrance exposure should be specified for high-level control operations. The current 21CFR1020.32 e2,ii limit is 20 R/min 5.16x10-3 C/kg per minute	Agree. Technical change in Section 1610-C-1-a-2 replace 1.32 mC/kg min and 5 R/min with 5.2 mC/kg min and 20 R/min.
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	**p. 9 12 VAC 5-481-10. Definitions** . "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper and D. Barrier transmitted radiation rate limits. AND p. 330 **12 VAC 5-481-1610 D 1**. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 □C/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate. 2. Measuring compliance of barrier transmission. Comment: Many current image intensifiers have field of views much larger than the projected size of the attenuation block defined in the definitions. If the field is set larger than the blocks the image intensifier may be damaged. Therefore is it acceptable to test the barrier transmission with the field limited to the size of the attenuation blocks?	Yes, one may reduce the filed size to accommodate the attenuation block size. No change.

Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	P331 and P 332 4. **12 VAC 5-481-1610 F**. Source-to-skin distance. 4. 20 centimeters for all mobile fluoroscopes when used for specific surgical applications. What surgical applications will qualify for 20 cm Source-to-skin distance? Will use the use of mini C-arms be allowed. Mini c-arms have a minimum SID of 9 cm.	Agree. Technical change to Section 1610-F by adding item F-5 "9 centimeters for all portable fluoroscopes when used for special applications."
	P. 332 **12 VAC 5-481-1610 G. Fluoroscopic X-ray systems.** G. Fluoroscopic timer. 1. Means shall be provided to preset the cumulative on time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting. Does this mean that the Fluoro output must stop at 5 minutes, Or that the timer activates an alarms and stops incrementing after 5 minutes Note: Many units have a preset alarm for 5 minutes or less but continue to allow fluoro and continue to document elapsed time.	The timers are designed to alarm after five minutes after which they must be reset to stop the alarm. No change.
	p.333 **12 VAC 5-481-1610 F** H. 3. The agency may grant exemptions to 12 VAC 5-481-1610 H 2 where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption. The following is a suggested list of fluoroscopic procedures where such exemptions will be automatically granted: angiograms, arthrograms, biliary drainage procedures, fluoroscopic biopsy procedures, myelograms, percutaneous cholangiograms, percutaneous nephrostomies, sinograms or istulograms, t-tube cholangiograms. Will Interventional Cardiac cath, and Interventional Special Procedures be included on the list of exemptions (eg. stent placement, and Pic lines).	Agree. Technical change to include in Section 1620-H-3 at the end of the last sentence " interventional cardiac catheterization, and interventional special procedures."
	P 335 12 VAC 5-481-1620 A. Beam	Disagree. No change.

Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 12 VAC 5-481-1620 H 2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge). This rule apparently requires that images obtained with mobile x-ray units to show three-sided collimation (since mobile units do not have pbl). Visible collimation on three corners or sides of an image is a good goal but may be impossible to obtain with some mobile x-ray situations. Instead consider a performance standard of 80% of the images will have viable collimation on three sides or three corners	
	P. 341 **VAC 5-481-1620.B 4**. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (Xi) of exposure to the indicated timer setting, in units of C kg^{-1} s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as: (X_1-X_2) # $0.1(X_1+X_2)$  Does the symbol # stand for less than? See same formula on page 349. **12 VAC 5-481-1630 C 4.**	Agree. Technical change in Section 1620-B-4 in the formula, replace “#” with “less than and equals to” symbol.
	P. 341 12**VAC 5-481-1620.** B.6. Operator protection, except veterinary systems. a. Stationary systems. Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted behind a protected barrier so that the operator can remain behind that	Agree. Technical change in Section 1620-B-6 add after “,except veterinary systems” the following: “, bone densitometers, and other self-contained machines whose design was approved by the FDA.”

	protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, dental panographic and podiatry X-ray systems may, as an alternative, be provided with means to allow the operator to be at least nine feet from the tube housing assembly during exposures. Comment: The design and installation of many bone density units require that the operator be less than 9 feet from the patient. Hand bone density units have the exposure switch permanently mounted to the unit less than 1 foot from the patient.	
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	P. 343 **VAC 5-481-1620. G** and P. 351 **VAC 5-481-1630 E**. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40% to 100% of the maximum rated: Comments: Will units that do not have power supply as specified by the manufacturer be allowed to have coefficient of variation of exceeding 0.10? How will the inspector know if the machine or power supply is defective?	Machines must meet the mA/mAs linearity test, irrespective if the power supply is specified by the manufacturer. If the machine fails this test, it is up to the registrant to find a service representative to determine how it will be brought into compliance. No change.
	P. 360 **VAC 5-481-1640** D.2.f.(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; Consider removing the requirement for measuring dose profiles since the more important measurements of CTDI and noise measurement will indicate problems with slice thickness. Does the dose profile need to be annually measured or does it just need to be "measurable"	Dose profile must be measurable. No change.
	P.360 D.2.f.(2) The CTDI along the two axes specified in 12 VAC 5-481-	Disagree. A facility may perform additional test if needed for comparison with other data. No change.

	1640 D 2 d (2) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; Since many units are now multi slice consider allowing the use of $CTDI_{vol}$ and or $CTDI_{w}$ in place of CTDI.	
Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	**VAC 5-481-1650.** **Mammography.** Note the PROPOSED VIRGINIA RADIATION PROTECTION REGULATIONS do not reflect the current MQSA regulations. Some of the proposed regulations are more lenient than the MQSA. The following noted items are where the VA regulations are stricter than MQSA. P. 365 **12 VAC 5-481-1650 A 5**. Resolution. The combination of focal spot size, source-to-image receptor distance and magnification shall result in a resolution of at least 12 line pairs per millimeter (cycles/mm) measured when a resolution pattern is positioned 4.2 cm above all breast supports and when the resolution pattern is either perpendicular to or parallel with the chest wall edge of the image receptor support. Consider using the MQSA standard of 11 and 13 line pairs per millimeter (cycles/mm) Some units in MQSA/ACR compliance will not be able to visualize 12 lp/mm in both orientations.	Agree. Technical change to Section 1650-A-5, replace 12 line pairs with 11 line pairs when a high-contrast resolution bar test pattern is orientated with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line pairs/mm when the bars are parallel to that axis. The bar pattern must be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor. When more than one target material is provided, the measurement must be made using the appropriate focal spot for each target material.
	P. 365 **12 VAC 5-481-1650 A 6 a** The X-ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least three minutes. The maximum force shall be no greater than 40 pounds. MQSA now allows a maximum force of 45 pounds	Disagree. There is now no upper limit for breast compression. Technical change to Section 1650-A-6-a remove last sentence.

Harold Prussia , Radiation Safety Officer Riverside Regional Medical Center	P. 365 **12 VAC 5-481-1650 A 6 b**. The chest wall edge of the compression paddle shall extend beyond the chest wall edge of the image receptor by no more than 2% of the Source-to-Image Receptor Distance with the compression paddle placed 4.2 cm above the breast support device. With the compression paddle in this position, the chest wall edge of the compression paddle shall not be visible in the acquired image. Does this rule refer only to contact mode or does it include magnification mode? Many magnification paddles will not comply with this rule.	This applies only to contact mode. No change.
	P. 366 **12 VAC 5-481-1650 A 6** The mammographic system shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than 2% of the SID. MQSA rules now allow the field to be larger than the image at all edges.	Agree. Technical change for Section 1650-A-10-a, replace with "All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that thee x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.
	P. 368 **12 VAC 5-481-1650 A 16** Dose. The mean glandular dose for one craniocaudal view, measured with the phantom referenced in 12 VAC 5-481-1650 A 15, based on exposure measured at the breast entrance location, and using dose conversion factors specified by the Health Care Financing Administration in their Medicare Mammography Survey Protocols, shall not exceed the following values: Is the above-specified phantom equivalent to the ACR suggested phantom?	Yes it is. No change.
	P. 370 **12 VAC 5-481-1650 B 3**. Equipment quality control tests. The registrant shall ensure that the following quality control tests are performed when applicable equipment	Agree. Staff noted typo in Section 1650-B-3, change reference to 1650 B III to 1650-B-3. Also delete last sentence in Section 1650-B-3 and replace with "The Private Inspector shall determine

	or components are initially..... patient mammography may not be performed until correction is accomplished. Some needed corrective repairs will not prevent the unit/facility from making diagnostic quality images. Instead of requiring immediate repair consider assigning time limits for repair similar to MQSA regulations. This will avoid unnecessary "down days" and will avoid turning back rescheduling patients.	the corrective action interval."
	General comments: The fees charged for surveys requested by the registrant and performed by a Department of Health inspector should be increased to reflect the additional tests that the new regulations will require. The fees should also be increased as the current low fees place a de facto price cap on prices that private inspectors can charge.	The proposed regulation does not include the fee schedule. The fee schedule is in 12 VAC 5-490. No change.
Stephen C. Coon Standards Engineer TomoTherapy Inc	The section "P 5 a " on page 573 dealing with selected relationships between incremental dose monitor units and incremental movement appears inappropriate for technologies utilizing helical moving beam therapy. In the case of helical moving beam therapy, which typically requires several full rotations of the treatment head, 10 degrees of rotation represents a very small fraction of the total treatment. As such, other mechanisms may be more appropriate for monitoring dose parameters, and the decision to trip an interlock needs to consider a percentage of total prescribed dose.	Disagree. No change.
	Also: The definition of "Redundant beam monitoring system" should be modified to: "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system MAY BE designed to terminate irradiation in accordance with a pre-selected number of dose monitor units."	Disagree. No change.
	Modern moving beam IMRT systems	This is covered in Section 3450-P-4. No change.

	such as those employing full rotational/helical beam delivery, depend on correct plan parameters (including delivery time, rotational position, MLC leaf control, couch position, and controlling timer) to be in place for proper delivery. The use of a preselected number of dose monitor units alone is not always sufficient as a termination criterion; monitoring all of the above plan parameters may be required.	
Roy Heltzel, M.S., DABR Health Physics Consultation Roy Heltzel, M.S., DABR Health Physics Consultation	1) 12 VAC 5-481-340 A.2.b Page 113 The requirement that a private inspector survey 10 facilities and 20 diagnostic machines within the preceding 12 months will eliminate a number of otherwise well-qualified private inspectors who do not perform diagnostic x-ray machine inspection on a full time basis. This requirement should be reduced to 3 facilities and 5 diagnostic machines (or less) to prevent the reduction of the private inspector ranks.	Agree. See previous comment.
	2) 12 VAC 5-481-1640 D.2.f (2) Page 360 The use of CTDI as defined in 12 VAC 5-481-10 and used in this section should be changed to use either CTDI100 or preferably CTDIw as defined by the International Electrotechnical Commission and used in ACR accreditation surveys for CT units and in the Reference Value Limits specified by the AAPM and ICRP.	Agree. The State Suggested Regulations still refer to CTDI. A facility may chose to perform other doss profiles for comparison with other data. No change.
	3) 12 VAC 5-481-1590 C. and D. Page 315 The requirement that private inspectors provide the inspection report to the registrant within 14 days of the inspection and that the registrant submit this copy within 30 days of the inspection is unrealistic and unreasonable. Due to the nature of the profession, private inspectors are sometimes traveling to registrant locations and on the road for several weeks without returning to an office. Given the fact that these forms must still be submitted in hardcopy format	Disagree. Staff believes the time requirements are reasonable. No change.

	and that the regulations allow for the filing of survey reports for CT systems within 60 days of the date of survey (12 VAC 5-481-1640 D.1.b Page 358) these requirements should be changed to allow the private inspector to provide the inspection report within 60 days of the inspection and the registrant 90 days from the inspection to submit the copy to the agency. Two conditions should be applied to these changes: 1) If a serious deficiency is identified during an inspection, this must be reported to the registrant within 14 days of the inspection, and 2) The registrant should file a copy of the inspection report with the agency prior to the expiration of the existing registration certificate.	
Roy Heltzel, M.S., DABR Health Physics Consultation	4) 12 VAC 5-481-1590 A.13 Page 307 The name of the human holder need not be recorded on the x-ray utilization log if all additional requirements for patient holding, human holder shielding and radiation monitoring are followed. The human holder's radiation exposure is being kept as low as reasonably achievable and is being reviewed by the registrant's "person responsible for radiation safety" thus the additional recording is unnecessary and burdensome.	Disagree. No change.
	5) Form TH-02 The Town Hall Agency Background Document (Form TH-02) does not address the financial impact of the state inspection of x-ray machines on the private inspector. Since it has been and should be the intention of the State Radiological Health Program to not compete with the private inspectors in the provision of x-ray machine inspection services, the prices listed in the Fiscal Impact Statement and in 12 VAC 5-490-20 should be set well above current and future private inspector average rates. The prices currently listed are set such that they allow the state to unfairly compete with private inspectors. This must be changed and prevented in the future.	Inspection fees are in another set of regulations, 12 VAC 5-490. No change.

	6) Website Comments I would like to express my agreement with some comments currently posted on the Virginia Regulatory Town Hall website. These comments include the inequity of private inspector qualification requirements which do not appear to apply to state inspectors, the difference between CME and MPCEC credits for private inspector continuing education, the grandfathering of existing control booths that do not meet the new dimension requirements, the use of effective dose equivalent for shielded occupational workers, and allowing 15 MPCEC credits in 3 years instead of the currently proposed 5 credits per year.	See responses to previous commenters.
Lee Anthony, Ph.D. Physics Associates	As a part of the public comment process, I would highly recommend that Virginia's new "Rules & Regulations for Ionizing Radiation " be brought into conformance with current NRC regulations. This will be necessary for our becoming an agreement state. Thank you for receiving this recommendation.	Staff identified the following sections where the NRC adopted changes after the proposed regulations were submitted to the Board of Health for approval: 12 VAC5-481-640 20.1201 Occupational dose limits for adults 12 VAC5-481-720 20.1301 Dose limits for individual members of the public. 12 VAC5-481-430B, 12 VAC5-481-480 D. 4. d. 1) 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere. 12 VAC5-481-830 20.1703 Use of individual respiratory protection equipment. 12 VAC5-481-1670 35.2 Definitions 12 VAC5-481-1670 35.10 Implementation 12 VAC5-481-1680 35.13 License amendments 12 VAC5-481-1690 35.14 Notifications 12 VAC5-481-1760 35.51 Training for an authorized medical physicist 12 VAC5-481-1770 35.55 Training for an authorized nuclear pharmacist. 12 VAC5-481-1780 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized

Lee Anthony, Ph.D. Physics Associates		user, nuclear pharmacist, and authorized nuclear pharmacist. 12 VAC5-481-1870 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material 12 VAC5-481-1900 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required. 12 VAC5-481-1910 35.190 Training for uptake, dilution, and excretion 12 VAC5-481-1920 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required. 12 VAC5-481-1940 35.290 Training for imaging and localization studies. 12 VAC5-481-1950 35.300 Use of unsealed byproduct material for which a written directive is required ERROR: 12VAC5-481-1960 35.300 Safety instruction, should be 10CFR35.310 12 VAC5-481-1980 35.390 Training for use of unsealed byproduct material for which a written directive is required 12 VAC5-481-1990 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). 12 VAC5-481-2000 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). 12 VAC5-481-2010 35.490 Training for use of manual brachytherapy sources. 12 VAC5-481-2010 35.491 Training for ophthalmic use of strontium-90. 12 VAC5-481-2030 35.590 Training for use of sealed sources for diagnosis. 12 VAC5-481-2040 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. 12 VAC5-481-2050 35.980 Training for an authorized nuclear pharmacist

Terry R. Eastman, R.T. FASRT, Technical Director Radiographic Techniques	As public commentary to 12 VAC 5-481-1590 has been requested, please find enclosed supportive material for this regulation. Also specific recommendations made on 11/22/99. 3. A X-ray Technique Chart shall be … Most facilities have a protocol list of positioning routines and film sizes to be used. It is not practical to lace the film size on the chart. The grid ratio should be noted, but again, it is not practical to list the focus for each view. Although there are ways to display charts, I suggest a Kardex file presentation.	Agree. Technical correction in Section 1590-A-3, remove 3-b and 3-c and insert "Reserved".
Terry R. Eastman, R.T. FASRT, Technical Director Radiographic Techniques	An exposure limit guideline for a lateral skull should also be included. 12 VAC-5-481-1600: Should there be information here on calibration? Extensive work has shown that failure to use charts ca often be traced to calibration problems. Suggest that the regulations also state where automated exposure controls (AEC) are used that a chart be posted. This will list the KVp and ion cell to be used . without a chart, operators may use various kVp values for the same anatomical part. It is important that the same ion cell be used for specific views to ensure uniform results.	Disagree. There is no NEXT data available for this projection. No change. The Private Inspector may include additional charting, tests, etc in either the operating procedures or in a quality assurance program tailored to the facility's needs. No change.
	Technical advances invite that the use of Computed radiography (CR) be addressed. Ongoing work finds that the database of the program being used to optimize image quality rather than an appropriate exposure technique.	Staff will consider this in future revisions to the regulations. No change.

Enter any other statement here

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-480- 10	12VAC5-481-10	Part I- General Provisions	Remarks: All definitions included in the individual Parts of the current regulations were moved to a combined Part, designated as Part I- Definitions. The following sections are re-designated as Part II- General Provisions. Some of the definitions were removed and are incorporated by reference the federal definitions along with the appropriate federal regulation in the appropriate section in the proposed regulation. *Result of comment period*: Technical and grammatical changes "mAa" changed to "mA" "radiation detector" deleted second definition. "teletherapy physicist" changed "the" to "a".
12VAC5-480- 20	12VAC5-481-30	Authority for Regulations	
12VAC5-480- 30	12VAC5-481-40	Administration of Regulations	
12VAC5-480- 40	12VAC5-481-50	Application of Regulations	
12VAC5-480- 50	12VAC5-481-60	Application of Administrative Process Act	Updated on advice of AG's Office
12VAC5-480- 60	12VAC5-481-70	Severability	
12VAC5-480- 70	12VAC5-481-80	Scope	The scope was moved to the beginning of this part after the definitions.
12VAC5-480- 80	12VAC5-481-90	Exemptions from regulatory requirements	
12VAC5-480- 90	12VAC5-481-100	Records	
12VAC5-480- 100	12VAC5-481-110	Inspections and enforcement	Updated on advice of AG's Office
12VAC5-480- 110	12VAC5-481-120	Emergency regulations	Updated on advice of AG's Office
12VAC5-480- 120	12VAC5-481-130	Impounding	
12VAC5-480- 130	12VAC5-481-140	Prohibited uses	This section expands the prohibition of X-ray machine operators in healing arts to other than those who are licensed by one of the boards in the Department of Health Professions and is within the scope of their license.
12VAC5-480- 140	12VAC5-481-150	Communications	*Result of comment period*: Changed agency address to reflect current address.

12VAC5-480- 150	12VAC5-481-160	Effective date	Updated on advice of AG's Office
12VAC5-480- 160	12VAC5-481-170	Removal of notices posted by agency prohibited	
	12VAC5-481-180	N/A	New section- Tests Defines the scope of regulatory inspections or tests of equipment
	12VAC5-481-190	N/A	New section-Additional regulatory requirements Informs regulated community that new regulations or if necessary orders issued to impose additional requirements to protect public health and safety.
	12VAC5-481-200	N/A	New section-Violations Inserted on advice of AG's Office
	12VAC5-481-210	N/A	New section-Types of Hearings Inserted on advice of AG's Office *Result of comment period*: Corrects incorrect citations. Replaced 9-6.14:11 with § 2.2-4019. Informal fact finding proceedings. Replace 9-6.14:12 with § 2.2-4020. Formal hearings; litigated issues.
	12VAC5-481-220	N/A	New section-Hearing as a matter of right. Inserted on advice of AG's Office
	12VAC5-481-230	N/A	New section-Interpretations Inserted on advice of AG's Office
	12VAC5-481-240	N/A	New section-Units of exposure & dose This section recognizes international units used in radiation protection.
	12VAC5-481-250	N/A	New section-Units of activity This section recognizes international units used in radiation protection.
12VAC5-480- 170	12VAC5-481-260	Part II- Registration of Radiation Machine Facilities and Services Purpose and scope	The following sections are re-designated Part III. Proposed sections are nearly identical. There was some substitution of "agency" for "State Health Commissioner"..
12VAC5-480- 180	12VAC5-481-270	Exemptions	
	12VAC5-481-280	N/A	New section- Shielding plan review The contents in this section appear in the current regulation as an appendix instead of the text as originally intended.
12VAC5-480- 190	12VAC5-481-290	Registration of radiation machine facilities	
12VAC5-480- 200	12VAC5-481-300	Reserved	New section- Approval not implied section was Reserved in current regulations. This section was inadvertently deleted from previous versions of the regulations. The source is the *Suggested State Regulations*. Also combined this section with the Issuance of the registration certificate.
12VAC5-480- 210	12VAC5-481-300	Issuance of the registration certificate.	

12VAC5-480- 220	12VAC5-481-320	Expiration of registration certificate	
12VAC5-480- 230	12VAC5-481-310	Renewal of registration	
12VAC5-480- 240	12VAC5-481-330	Report of changes	
12VAC5-480- 250		Reserved	
	12VAC5-481-340	N/A	Private Inspector Qualifications This section is an Appendix in current regulations, and has been expanded to include federal criteria for those providing services to mammography facilities to meet the federal Mammography Quality Standards Act. *Result of comment period*: Technical changes requested by several Private Inspectors. A-2-a changed continuing education requirements from 5 CEUs every year to 15 CEUs every three years. A-2-b removed a set number of facilities and decreased number of machines required to be inspected from 20 to 10. B. Clarifies section by inserting after teletherapy machine "… performing radiation protection surveys,…" B-1-d corrected the following citations: 12 VAC 5-481-3730 A 12 VAC 5-481-3400 A ; 12 VAC 5-481-3750 P 12 VAC 5-481-3420 P; 12 VAC 5-481-3760 T 12 VAC 5-481-3430 T ; 12 VAC 5-481-3750 Q 12 VAC 5-481- 3420 Q; and 12 VAC 5-481-3760 U 12 VAC 5-481-3430 U B-1-e corrected the following citation: Notwithstanding the provisions of 12 VAC 5-481-3720 D 5 12 VAC 5-481-3390 D; certification pursuant to 12 VAC 5-481-3720 D 2 12 VAC 5-481-340 B 1 (a); 12 VAC 5-481-3720 D 3 12 VAC 5-481-340 B 1 (b) ; and/or 12 VAC 5-481-3720 D 4 12 VAC 5-481-340 B 1 (c) shall be required on or before December 31, 1999, [July 1, 2007]for all persons currently qualifying as a radiation therapy Physicist pursuant to 12 VAC 5- 481 3720 D5 12 VAC 5-481-340 B 1 (d). B-2-a change Continuing Medical Education Credits (CME) to Continuing Education Units (CEU), and changed continuing education requirements from 5 CEUs every year to 15

			CEUs every three years. C-2-a changed continuing education requirements from 5 CEUs every year to 15 CEUs every three years, and removed removed last sentence that referred to training for different modalities. C-2-b replaced 3 facilities in 12 months with 2 facilities and 6 machines in 24 months.
12VAC5-480- 260	12VAC5-481-350	Assembler and/or transfer obligation	
12VAC5-480- 270	12VAC5-481-360	Reciprocal recognition of out-of-state radiation machines	
12VAC5-480- 280	12VAC5-481-370	Certification of X-ray systems	
12VAC5-480- 290	12VAC5-481-380	Part III- Licensing of Radioactive Materials Purpose and Scope	The following sections are re-designated Part IV. Theses sections are identical to current regulations. Those sections relating to the use of radioactive materials in the healing arts were transferred to a separate Part in the proposed regulations- Part VII - USE OF RADIONUCLIDES IN THE HEALING ARTS Most of the sections in the proposed regulations incorporate by reference the appropriate or comparable federal regulations promulgated by the U.S. Nuclear regulatory Commission (NRC). The NRC made several changes since the current regulations and have been brought up to date.
12VAC5-480- 300		Reserved	Eliminated
12VAC5-480- 310	12VAC5-481-390	Source material	
12VAC5-480- 320	12VAC5-481-400	Radioactive material other than source material	
12VAC5-480- 330 through 470		Reserved	Eliminated
12VAC5-480- 480	12VAC5-481-410	Types of licenses	
12VAC5-480- 490	12VAC5-481-420	General licenses - source material	
12VAC5-480- 500	12VAC5-481-430	General licenses – radioactive material other than source material	*Result of comment period*: Technical change. B. deleted “and” and inserted “ , shall comply with the provisions of 12 VAC 5-481-1090 and 12 VAC 5-481-1100 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts IV (12VAC 5-

			481-600 et seq.) and X (12 VAC 5-481-2250 et seq.) of these regulations". Also replaced federal reference with more recent citation.
12VAC5-480- 510		Reserved	Eliminated
12VAC5-480- 520	12VAC5-481-440	Filing application for specific licenses	
12VAC5-480- 530	12VAC5-481-450	General requirements for the issuance of specific licenses	
12VAC5-480- 540	12VAC5-481-460	Special requirements for of certain specific licenses for radioactive material	
12VAC5-480- 550	12VAC5-481-470	Special requirements for specific licenses of broad scope	
12VAC5-480- 560	12VAC5-481-480	Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material	*Result of comment period*: Corrects several grammatical errors and incorrect citations. A-1 deleted the "1" referenced to in 12 VAC 5-481-400 A1. D-1- b- (2) reference to 12 VAC 5-481-630 A should reference 12 VAC 5-481-640. D-3 reference to 12 VAC 5-481-630 A should reference 12 VAC 5-481-640. D-4-d-(1) replaced federal reference with more recent citation. H-3-b replaced 12 VAC 5-481-660 A 1 with 12 VAC 5-481-850 H-5 replaced 12 VAC 5-481-720 with 12 VAC 5-481-910 I replaced 12 VAC 5-481-430 J with 12 VAC 5-481-430 H M-1 replaced 12 VAC 5-481-420 D with 12 VAC 5-481-420 B M-1-b replaced 12 VAC 5-481-630 A with 12 VAC 5-481-640 M-4 (d through f) replace D with 12 VAC 5-481-420 B
12VAC5-480- 570		Reserved	Eliminated
12VAC5-480- 580	12VAC5-481-490	Issuance of specific licenses	
12VAC5-	12VAC5-	Specific terms and conditions	

480- 590	481-500	of licenses	
12VAC5-480- 600	12VAC5-481-510	Expiration and termination of licenses	
12VAC5-480- 610	12VAC5-481-520	Renewal of licenses	
12VAC5-480- 620	12VAC5-481-530	Amendment of licenses at request of licensee	
12VAC5-480- 630	12VAC5-481-540	Agency action on applications to renew or amend	
12VAC5-480- 640	12VAC5-481-550	Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these regulations	
	12VAC5-481-560	N/A	New section--Persons possessing naturally New occurring and accelerator-produced radioactive material on effective date of these regulations. This section is similar to the previous section; however, it covers the State regulated materials.
12VAC5-480- 650 thru 670		Reserved	Eliminated
12VAC5-480-680	12VAC5-481-570	Transfer of material	
12VAC5-480-690 thru 770		Reserved	Eliminated
12VAC5-480-780	12VAC5-481-580	Modification and revocation of licenses	
12VAC5-480-790 thru 1170		Reserved	Eliminated
12VAC5-480-1180	12VAC5-481-590	Reciprocal recognition of licenses	Appendices in the proposed regulations are incorporated by reference the federal regulation in other sections. *Result of comment period*: Corrects several incorrect citations. A-2 replaced 12 VAC 5-481-430 D 1 with 12 VAC 5-481-430 B B-2 replaced 12 VAC 5-481-430 D 1 with 12 VAC 5-481-430 B
12VAC5-480-1190	12VAC5-481-600	Part IV- Standards for Protection Against Radiation Purpose	The following sections are re-designated Part V This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Radiation

			Protection Standards (Title 10 Code of Federal Regulations [CFR] Part 20). The NRC promulgated major changes to 10 CFR 20 in 1992, and again in 2001. The standards were greatly expanded and became more restrictive compared to the current state regulation.
12VAC5-480- 1200 thru 2180		Reserved	Eliminated
12VAC5-480- 2190 thru 2250		Occupational Dose Limits	These sections were eliminated and replaced with expanded and reorganized sections based on federal changes to 10 CFR 20.
	12VAC5-481-610	N/A	New section- Scope
	12VAC5-481-620	N/A	New section-Implementation
	12VAC5-481-630	N/A	New section-Radiation protection programs
	12VAC5-481-640	N/A	New section- Occupational dose limits for adults *Result of comment period*: Technical change. Replaced federal reference with more recent citation.
	12VAC5-481-650	N/A	New section- Compliance with requirements for summation of external and internal doses
	12VAC5-481-660	N/A	New section- Determination of external dose from airborne radioactive material
	12VAC5-481-670	N/A	New section- Determination of internal exposure
	12VAC5-481-680	N/A	New section- Determination of prior occupational dose *Result of comment period*: Corrects incorrect citation. E-1 replaced reference to 12 VAC 5-481-640 F with VAC 5-481-640
	12VAC5-481-690	N/A	New section- Planned special exposures
	12VAC5-481-700	N/A	New section- Occupational dose limits for minors
	12VAC5-481-710	N/A	New section- Dose to an embryo/fetus
	12VAC5-481-720	N/A	New section- Dose limits for individual members *Result of comment period*: Technical change. Replaced federal reference with more recent citation.
	12VAC5-481-730	N/A	New section- Compliance with dose limits for individual members of the public
	12VAC5-	N/A	New section- Testing for leakage or

	481-740		contamination of sealed sources *Result of comment period*: Technical change. B-6 deleted text and incorporate by reference 10 CFR 39.35
12VAC5-480-2260 thru 3180		Reserved	Eliminated
12VAC5-480-3190	12VAC5-481-750	General	
12VAC5-480-3200	12VAC5-481-760	Personnel monitoring	This is a new section-Conditions requiring individual monitoring of external and internal occupational dose. The section in existing regulations was divided into two sections.
	12VAC5-481-770	N/A	This is a new section- Location of individual monitoring devices *Result of comment period*: Corrects several incorrect citations. B. replaced reference to 12 VAC 5-481-710 A with 12 VAC 5-481-710. C. replaced reference to 12 VAC 5-481-640 A 2 a with 12 VAC 5-481-640. D. replaced reference to 12 VAC 5-481-640 A 2 b with 12 VAC 5-481-640. Also correct typo by replacing “C” with “D”
	12VAC5-481-780	N/A	New section- Control of access to high radiation areas
	12VAC5-481-790	N/A	New section- Control of access to very high radiation areas
	12VAC5-481-800	N/A	New section- Control of access to very high radiation areas – irradiators
	12VAC5-481-810	N/A	New section- Use of process or other engineering controls
	12VAC5-481-820	N/A	New section- Use of other controls
	12VAC5-481-830	N/A	New section- Use of individual respiratory protection equipment *Result of comment period*: Technical change. Replaced federal references with more recent citation.
	12VAC5-481-840	N/A	New section- Security and control of licensed or registered sources of radiation
12VAC5-480-3210	12VAC5-481-850	Caution signs, labels, and signals	New section- Caution signs
	12VAC5-481-860	N/A	New section- Posting requirements
12VAC5-	12VAC5-	Exemptions to posting	New section- Exemptions to posting

480-3220	481-870	requirements and labeling requirements	requirements
	12VAC5-481-880	N/A	New section- Labeling containers and radiation machines
	12VAC5-481-890	N/A	New section- Exemptions to labeling requirements
12VAC5-480-3230		Instruction of personnel	Eliminated
12VAC5-480-3240		Storage and control of sources of radiation	Eliminated
12VAC5-480-3250	12VAC5-481-900	Procedures for picking up, receiving, and opening packages	New section- Procedures for receiving and opening packages
12VAC5-480-3260 thru 4180		Reserved	Eliminated
12VAC5-480-4190	12VAC5-481-910	General requirements	
12VAC5-480-4200	12VAC5-481-920	Method for obtaining approval of proposed disposal procedures	
12VAC5-480-4210	12VAC5-481-930	Disposal by release into 12 VAC 5-480-4210 sanitary sewerage	
12VAC5-480-4220		Disposal by burial in soil	Eliminated. Expanded into a new Part XI- Licensing Requirements For Land Disposal of Radioactive Waste
12VAC5-480-4230	12VAC5-481-940	Disposal by incineration	Re-named-Treatment or disposal by incineration
12VAC5-480-4240	12VAC5-481-950	Disposal of specific wastes	
12VAC5-480-4250 thru 5280		Reserved	Eliminated
	12VAC5-481-960	N/A	New section- Transfer for disposal and manifests
	12VAC5-481-970	N/A	New section- Compliance with environmental and health protection regulations
12VAC5-480-5290 thru 5310		Records, Notifications	Eliminated
12VAC5-480-5320		Reserved	Eliminated
12VAC5-480- 5330		Reports of overexposures and excessive levels and concentrations	Eliminated
12VAC5-480- 5340		Reserved	Eliminated
12VAC5-480- 5350		Vacating premises	Eliminated

12VAC5-480- 5360		Notifications and reports to individuals, Appendices	Deleted and expanded into several sections Appendices in existing regulations are incorporated by reference the federal regulations in 10 CFR 20 Appendix B Tables 1 and 2.
	12VAC5-481-980	N/A	New section- General provisions
	12VAC5-481-990	N/A	New section- Records of radiation protection programs
	12VAC5-481-1000	N/A	New section- Records of surveys
	12VAC5-481-1010	N/A	New section- Records of tests for leakage or contamination of sealed sources
	12VAC5-481-1020	N/A	New section- Records of prior occupational dose
	12VAC5-481-1030	N/A	New section- Records of planned special exposures
	12VAC5-481-1040	N/A	New section- Records of individual monitoring results
	12VAC5-481-1050	N/A	New section- Records of dose to individual members of the public
	12VAC5-481-1060	N/A	New section- Records of waste disposal *Result of comment period*: Corrects incorrect citation. Replaced reference to 12 VAC 5-481-1020 with 12 VAC 5-481-920
	12VAC5-481-1070	N/A	New section- Records of testing entry control devices for very high radiation areas
	12VAC5-481-1080	N/A	New section- Form of records
	12VAC5-481-1090	N/A	New section- Reports of stolen, lost, or missing licensed or registered sources of radiation
	12VAC5-481-1100	N/A	New section- Notification of incidents
	12VAC5-481-1110	N/A	New section- Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits
	12VAC5-481-1120	N/A	New section- Reports of planned special exposures
	12VAC5-481-1130	N/A	New section- Reports of individual monitoring
	12VAC5-481-1140	N/A	New section- Notifications and reports to individuals
	12VAC5-481-1150	N/A	New section- Reports of leaking or contaminated sealed sources
	12VAC5-481-1160	N/A	New section- Vacating premises
12VAC5-		Definitions	Deleted and incorporated into section 10

480- 5370			
12VAC5-480- 5380	12VAC5-481-1170	Part V – Radiation Safety Requirements For Industrial Radiographic Operations Purpose	**The following sections are re-designated Part VI. This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) PART 34--LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS (Title 10 Code of Federal Regulations [CFR] Part 34). The NRC revised 10 CFR 34 in 1997. The proposed regulation expands this Part to address new industrial applications of radiation and radioactive materials which have a great potential to expose workers that may result in injury and death. Examples of such applications are high specific activity devices used for non destructive testing, and room sized cabinet X-ray machines used for various purposes. Both NRC and the states have identified significant enforcement issues regarding industrial radiographers and have required additional training and certification requirements.**
12VAC5-480- 5390	12VAC5-481-1180	Scope	
12 VAC 5-480-5400 thru 6350		Reserved	
12VAC5-480- 6360		Issuance of specific license for use of sealed sources in radiography	Deleted
12VAC5-480- 6370		Limits on levels of radiation for radiographic exposure devices and storage containers	
12VAC5-480- 6380		Locking of radiographic exposure devices, storage containers, and source changers	
	12VAC5-481-1190	N/A	New section- Exemptions *Result of comment period*: Corrects incorrect citation. A-1-c replaced references to 12 VAC 5-481-720 A through C with VAC 5-481-720
	12VAC5-481-1200	N/A	New section- Licensing and registration requirements for industrial radiography operations
	12VAC5-481-1210	N/A	New section- Performance requirements for industrial radiography equipment
	12VAC5-481-1220	N/A	New section- Limits on external radiation levels from storage containers and source

			changers
12VAC5-480- 6390	12VAC5-481-1230	Storage precautions	Locking of sources of radiation, storage containers and source changers
12VAC5-480- 6400	12VAC5-481-1240	Radiation survey Instruments	
12VAC5-480- 6410	12VAC5-481-1250	Leak testing, repair, tagging, opening, modification, and replacement of sealed sources	Leak testing and replacement of sealed sources
12VAC5-480- 6420	12VAC5-481-1260	Quarterly inventory	
12VAC5-480- 6430		Utilization logs	Deleted
12VAC5-480- 6440		Inspection and maintenance of radiographic exposure devices, storage containers, and source changers	Deleted and combined in the next section of proposed regulation.
12VAC5-480- 6450	12VAC5-481-1270	Inspection and maintenance of high radiation area control devices or alarm systems	Inspection and maintenance of radiation & machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments
12VAC5-480- 6460	12VAC5-481-1280	Permanent radiographic installations	
12VAC5-480- 6470 thru 7360		Reserved	
	12VAC5-481-1290		New section- Labeling, storage, and transportation
	12VAC5-481-1300		New section- Conducting industrial radiographic operations
	12VAC5-481-1310		New section- Radiation safety officer
12VAC5-480- 7370	12VAC5-481-1320	Training and testing	
12VAC5-480- 7380	12VAC5-481-1330	Operating and emergency procedures	
	12VAC5-481-1340	N/A	New section- Supervision of radiographer's assistants
12VAC5-480- 7390	12VAC5-481-1350	Personnel monitoring control	
12VAC5-480- 7400 thru 8360		Reserved	
	12VAC5-481-1360		Note: out of sequence, see 12VAC5-480-8390
12VAC5-480- 8370	12VAC5-481-1370	Security	Surveillance
12VAC5-480- 8380	12VAC5-481-1380	Posting	
12VAC5-480- 8390	12VAC5-481-1360	Radiation surveys and survey records	Radiation surveys
12VAC5-480- 8400			These sections in the current regulation are expanded in the proposed regulations into

thru 8420			many more sections under the article entitled Record Keeping Requirements.
	12VAC5-481-1390		New section- Records for industrial radiography
	12VAC5-481-1400		New section- Records of receipt and transfer of sources of radiation
	12VAC5-481-1410		New section- Records of radiation survey instruments
	12VAC5-481-1420		New section- Records of leak testing of sealed sources and devices containing DU
	12VAC5-481-1430		New section- Records of quarterly inventory
	12VAC5-481-1440		New section- Utilization logs
	12VAC5-481-1450		New section- Records of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments
	12VAC5-481-1460		New section- Records of alarm system and entrance control checks at permanent radiographic installations
	12VAC5-481-1470		New section- Records of training and certification
	12VAC5-481-1480		New section- Copies of operating and emergency procedures
	12VAC5-481-1490		New section- Records of personnel monitoring
	12VAC5-481-1500		New section- Records of radiation surveys
	12VAC5-481-1510		New section- Form of records
	12VAC5-481-1520		New section- Location of documents and records
	12VAC5-481-1530		New section- Notifications
	12VAC5-481-1540		New section- Application and examinations Remarks: There is a fee to recover the cost of reviewing application and cost of the examination materials.
	12VAC5-481-1550		New section- Certification identification (ID) card
	12VAC5-481-1560		New section- Reciprocity
	12VAC5-481-1570		New section- Specific requirements for radiographic personnel performing industrial radiography
12VAC5-480- 8430		Part VI- Use of Diagnostic X-rays in the Healing Arts Definitions	Deleted. The following sections are re-designated Part VII. Definitions are moved to 12VAC5-481-10. In general the sections relating to radiation

			therapy machines were moved to a new PART XV THERAPEUTIC RADIATION MACHINES. The proposed regulation adopts the U.S. Food and Drug Administration's (FDA) machine performance standards for fluoroscopy machines, in particular the limits on radiation output exposure rates. The proposed regulation adopts a new section for mammography machines, which is identical to the federal requirements under the Mammography Quality Standards Act of 1992.
12VAC5-480- 8440	12VAC5-481-1580	Scope	
12VAC5-480- 8450	12VAC5-481-1590	General requirements	General and administrative requirements *Result of comment period*: Technical changes to provided clarity. A-2-c replaced "film processor" to "image processor". A-3 removed 3-b and 3-c and inserted "Reserved". A-5-c added after " whole body barriers" "…, or protective aprons…" A-14 added to the end "… or an individual enrolled in an accredited program for radiologic technology and is under the supervision of a licensed or certified radiologic technologist." A-14-a inserted at the end ", and if a dental assistant, they comply with the Board of Dentistry's radiation certification requirements in 18 VAC 60-20-95".
12VAC5-480- 8460	12VAC5-481-1600	General requirements for all diagnostic x-ray systems	
12VAC5-480- 8470	12VAC5-481-1610	Fluoroscopic x-ray systems except for computed tomography x-ray systems	Fluoroscopic X-ray systems *Result of comment period*: Technical changes to provided clarity and be consistent with FDA. C-2 replace 1.32 mC/kg min and 5 R/min with 5.2 mC/kg min and 20 R/min. F adding item F-5 "9 centimeters for all portable fluoroscopes when used for special applications." H-3 add at the end of the last sentence " interventional cardiac catheterization, and

			interventional special procedures."
12VAC5-480- 8480	12VAC5-481-1620	Radiographic systems other than fluoroscopic, dental intraoral, veterinarian, or computed tomography	Radiographic systems other than fluoroscopic, dental intra-oral, or Computed tomography X-ray systems The current regulation has a section dedicated to veterinary X-ray equipment that was eliminated. The veterinary use equipment is addressed in the proposed regulation in the section that addresses general requirements, with provisions for veterinary machines where appropriate. *Result of comment period*: Technical changes to provided clarity. B-4 in the formula, replace "#" with "<". B-6 add after ",except veterinary systems" the following: ", bone densitometers, and other self-contained machines whose design was approved by the FDA."
12VAC5-480- 8490	12VAC5-481-1630	Intraoral dental radiographic systems	*Result of comment period*: Corrects incorrect citation. 1630 C 5 b (1) replaced reference to 12 VAC 5-481-1630 C 5 1 with 12 VAC 5-481-1630 C 5 a
12VAC5-480- 8500		Therapeutic x-ray systems of less than one MeV	Deleted. This section in the current regulations related to therapeutic systems with energy less than 1 MeV was moved to a new Part, PART XV THERAPEUTIC RADIATION MACHINES.
12VAC5-480- 8510		X-ray and electron therapy systems with energies of one MeV and above	Deleted. This section in the current regulations related to therapeutic systems with energy of 1 MeV or greater was moved to a new Part, PART XV THERAPEUTIC RADIATION MACHINES.
12VAC5-480- 8520		Veterinary medicine radiographic installations	Deleted. This section in the current regulations related to veterinary X-ray equipment that was eliminated, and requirements are specified in other sections of the proposed regulation
12VAC5-480- 8530	12VAC5-481-1640	Computed tomography systems, Appendices	Appendices were incorporated into the text of the sections within this Part.
	12VAC5-481-1650		Mammography *Result of comment period*: Technical changes to provide clarity and to stay consistent with the FDA. A-5 , replaced 12 line pairs with 11 line pairs when a high-contrast resolution bar test pattern is orientated with the bars perpendicular to the anode-cathode axis, and

			a minimum resolution of 13 line pairs/mm when the bars are parallel to that axis. The bar pattern must be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor. When more than one target material is provided, the measurement must be made using the appropriate focal spot for each target material. A-6-a removed last sentence that refers to a maximum force for compression. A-10-a replaced with "All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID. B-1-(c) change reference to 1650 B III to 1650-B-3. B-3 deleted last sentence replaced with "The Private Inspector shall determine the corrective action interval." C-6 replaced Appendix A with 12 VAC 5-481-340 C.
12VAC5-480- 8540		Part VII- Use of Radionuclides in the Healing Arts Definitions	The following sections are re-designated Part VIII. Definitions are moved to 12VAC5-481-10.
12VAC5-480- 8550	12VAC5-481-1660	Scope	Purpose and scope The current regulation only addressed seal sources in this Part. The proposed regulation expanded this Part to include all radioactive materials used in medicine. This Part is expanded to include new training requirements, defined radiation protection program by the licensees, also certain licensees are required to have a quality assurance program. All of these additional requirements are based on NRC's regulations (Title 10 Code of Federal Regulations [CFR] Parts 30, 31, 32, 33, and 35). These federal regulations have been revised several times since the promulgation of the current state regulation
12VAC5-480- 8560		Interstitial, intracavitary and superficial applications	Deleted

12VAC5-480- 8570		Teletherapy	Deleted
	12VAC5-481-1670	N/A	New section- General requirements *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1680	N/A	New section- Licensing and Exemptions *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1690	N/A	New section- Notifications *Result of comment period*: Replaced federal references to with more recent citations.
	12VAC5-481-1700	N/A	New section- Authority and responsibilities for the radiation protection programs and changes
	12VAC5-481-1710	N/A	New section- Supervision
	12VAC5-481-1720	N/A	New section- Written Directives
	12VAC5-481-1730	N/A	New section- Procedures for administrations requiring a written directive
	12VAC5-481-1740	N/A	New section- Suppliers for sealed sources or devices for medical use
	12VAC5-481-1750	N/A	New section- Training for Radiation Safety Officer *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1760	N/A	New section- Training for an authorized medical physicist *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1770	N/A	New section- Training for an authorized nuclear pharmacist *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1780	N/A	New section- Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and pharmacist *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1790	N/A	New section- Recentness of training
	12VAC5-481-1800	N/A	New section- Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material
	12VAC5-	N/A	New section- Calibration of survey

	481-1810		instruments
	12VAC5-481-1820	N/A	New section- Determination of dosages of unsealed byproduct material for medical use
	12VAC5-481-1830	N/A	New section- Authorization for calibration, transmission, and reference sources
	12VAC5-481-1840	N/A	New section- Requirements for possession of sealed sources and brachytherapy sources
	12VAC5-481-1850	N/A	New section- Labeling of vials and syringes
	12VAC5-481-1860	N/A	New section- Surveys of ambient radiation exposure rate
	12VAC5-481-1870	N/A	New section- Release of individuals containing unsealed byproduct material or implants containing byproduct material *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1880	N/A	New section- Provision of mobile medical service
	12VAC5-481-1890	N/A	New section- Decay-in-storage
	12VAC5-481-1900	N/A	New section- Use of unsealed byproduct material for uptake, dilution, and excretion studies *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1910	N/A	New section- Training for uptake, dilution, and excretion studies *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1920	N/A	New section- Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1930	N/A	New section- Permissible molybdenum-99 concentration
	12VAC5-481-1940	N/A	Training for imaging and localization studies *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1950	N/A	New section- Use of unsealed by product material for which a written directive is required *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1960	N/A	New section- Safety instruction *Result of comment period*: Replaced federal

			references with more recent citations.
	12VAC5-481-1970	N/A	New section- Safety precautions *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1980	N/A	New section- Training for use of unsealed byproduct material for which a written directive is required *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-1990	N/A	New section- Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-2000	N/A	New section- Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-2010	N/A	New section- Manual Brachytherapy *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-2020	N/A	New section- Use of sealed sources for diagnosis
	12VAC5-481-2030	N/A	New section- Training for use of sealed sources for diagnosis *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-2040	N/A	New section- Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-2050	N/A	New section- Training and Experience Requirements *Result of comment period*: Replaced federal references with more recent citations.
	12VAC5-481-2060	N/A	New section- Other medical uses of byproduct material or radiation from byproduct materials
	12VAC5-481-2070	N/A	New section- Records *Result of comment period*: Replaced federal

			references with more recent citations.
	12VAC5-481-2080	N/A	New section- Reports
12VAC5-480- 8580		Part VIII- Radiation Safety Requirements for Analytical Equipment Definitions	The following sections are re-designated Part IX. Definitions are moved to 12VAC5-481-10. The sections in this Part of the proposed regulation are identical to the current regulation.
12VAC5-480- 8590	12VAC5-481-2090	Purpose and scope	
12VAC5-480- 8600	12VAC5-481-2100	Equipment requirements	
12VAC5-480- 8610	12VAC5-481-2110	Area requirements	
12VAC5-480- 8620	12VAC5-481-2120	Operating requirements	
12VAC5-480- 8630	12VAC5-481-2130	Personnel requirements	
12VAC5-480- 8640	12 AC5-81-2140	Part IX- Radiation Safety requirements for particle accelerators Definitions	The following sections are re-designated Part X. Definitions are moved to 12VAC5-481-10. This section is re-designated as Purpose and scope
12VAC5-480- 8650	12VAC5-481-2150	Registration requirements	Registration procedures
12VAC5-480- 8660	12VAC5-481-2160	General requirements for the issuance of a registration for particle accelerators	
12VAC5-480- 8670	12VAC5-481-2170	Human use of particle accelerators	
12VAC5-480- 8680		Reserved	Deleted
12VAC5-480- 8690	12VAC5-481-2180	Limitations	
12VAC5-480- 8700	12VAC5-481-2190	Shielding and safety design requirements	
12VAC5-480- 8710	12VAC5-481-2200	Particle accelerator controls and interlock systems	
12VAC5-480- 8720	12VAC5-481-2210	Warning devices	
12VAC5-480- 8730	12VAC5-481-2220	Operating procedures	
12VAC5-480- 8740	12VAC5-481-2230	Radiation monitoring requirements	
12VAC5-480- 8750	12VAC5-481-2240	Ventilation systems	*Result of comment period*: Technical change to stay consistent with federal regulations. A. replaced reference to Part IV 12 VAC 5-481-600 et seq.) Appendix F with Table 1 of Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (10

			CFR 20 Appendix B, 58 FR 67659, Dec. 22, 1993) B. replaced reference to Part IV 12 VAC 5-481-600 et seq.) Appendix F with Table 2 of Appendix B to Part 20--Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (10 CFR 20 Appendix B, 58 FR 67659, Dec. 22, 1993)
12VAC5-480- 8760	12VAC5-481-2250	Part X – Notices, Instructions, and Reports to Workers; Inspections Purpose and Scope	The following sections are re-designated Part XI. Definitions are moved to 12VAC5-481-10.
12VAC5-480- 8770 thru 8850		Reserved	Deleted
12VAC5-480- 8860	12VAC5-481-2260	Posting of notices to workers	
12VAC5-480- 8870	12VAC5-481-2270	Instructions to workers	
12VAC5-480- 8880	12VAC5-481-2280	Notifications and reports to individuals	
12VAC5-480- 8890	12VAC5-481-2290	Presence of representatives of licensees or registrants and worker during inspection	
12VAC5-480- 8900	12VAC5-481-2300	Consultation with workers during inspections	
12VAC5-480- 8910	12VAC5-481-2310	Requests by workers for inspections	
12VAC5-480- 8920	12VAC5-481-2320	Inspections not warranted; informal review	
	12VAC5-481-2330	N/A	The following sections are re-designated Part XI – Licensing Requirements for Land Disposal of Radioactive New section- Purpose and scope Although the Code of Virginia § 32.1-230 authorizes the agency with the Governor's approval to license and operate a low level radioactive materials waste repository, it is unlikely that this will occur any time soon. However, the Commonwealth is a member of the South East Low Level Radioactive Waste Compact and must be prepared to take its turn to host a site. If the Governor chooses to exercise this authority the regulations will be in place to implement the licensing process. The basis for these sections are Suggested State Regulations and in turn are primarily excerpts from NRC's 10 CFR 61, PART 61--

			LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE
	12VAC5-481-2340	N/A	New section- License required
	12VAC5-481-2350	N/A	New section- Content of application
	12VAC5-481-2360	N/A	New section- General information
	12VAC5-481-2370	N/A	New section- Specific technical information
	12VAC5-481-2380	N/A	New section- Technical analyses
	12VAC5-481-2390	N/A	New section- Institutional information
	12VAC5-481-2400	N/A	New section- Financial information
	12VAC5-481-2410	N/A	New section- Requirements for issuance of a license *Result of comment period*: Corrects incorrect citation. H replaced reference to 12 VAC 5-481-10328 with 12 VAC 5-481-2580
	12VAC5-481-2420	N/A	New section- Conditions of licenses
	12VAC5-481-2430	N/A	New section- Application for renewal or closure
	12VAC5-481-2440	N/A	New section- Contents of application for site closure and stabilization
	12VAC5-481-2450	N/A	New section- Post-closure observation and maintenance
	12VAC5-481-2460	N/A	New section- Transfer of license
	12VAC5-481-2470	N/A	New section- Termination of license
	12VAC5-481-2480	N/A	New section- General requirement
	12VAC5-481-2490	N/A	New section- Protection of the general population from releases of radioactivity
	12VAC5-481-2500	N/A	New section- Protection of individuals from inadvertent intrusion
	12VAC5-481-2510	N/A	New section- Protection of individuals during operations
	12VAC5-481-2520	N/A	New section- Stability of the disposal site after closure
	12VAC5-481-2530	N/A	New section- Disposal site suitability requirements for land disposal
	12VAC5-481-2540	N/A	New section- Disposal site design for land disposal
	12VAC5-481-2550	N/A	New section- Land disposal facility operation and disposal site closure
	12VAC5-481-2560	N/A	New section- Environmental monitoring
	12VAC5-	N/A	New section- Alternative requirements for

	481-2570		design and operations
	12VAC5-481-2580	N/A	New section- Institutional requirements
	12VAC5-481-2590	N/A	New section- Alternative requirements for waste classification and characteristics
	12VAC5-481-2600	N/A	New section- Applicant qualifications and assurances
	12VAC5-481-2610	N/A	New section- Funding for disposal site closure and stabilization
	12VAC5-481-2620	N/A	New section- Financial assurances for institutional controls
	12VAC5-481-2630	N/A	New section- Maintenance of records, reports, and transfers
	12VAC5-481-2640	N/A	New section- Tests on land disposal facilities
	12VAC5-481-2650	N/A	New section- Agency inspections of land disposal facilities
	12VAC5-481-2660	N/A	The following sections are re-designated Part XII – Licensing and Radiation Safety Requirements for Irradiators New section- Purpose and scope This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS (Title 10 Code of Federal Regulations [CFR] Part 36). Large irradiators were not commonly used when the current regulation was promulgated in 1988. The NRC promulgated a new Part 36 in Title 10 CFR in 1993. The quantities of radioactive material involved can cause serious injury and death if used improperly, and the security of these sources are of interest to home land security.
	12VAC5-481-2670	N/A	New section- Application for a specific license
	12VAC5-481-2680	N/A	New section- Specific licenses for irradiators
	12VAC5-481-2690	N/A	New section- Start of construction
	12VAC5-481-2700	N/A	New section- Applications for exemptions
	12VAC5-481-2710	N/A	New section- Request for written statements
	12VAC5-481-2720	N/A	New section- Performance criteria for sealed sources
	12VAC5-481-2730	N/A	New section- Access control
	12VAC5-481-2740	N/A	New section- Shielding
	12VAC5-481-2750	N/A	New section- Fire protection

	12VAC5-481-2760	N/A	New section- Radiation monitors
	12VAC5-481-2770	N/A	New section- Control of source movement
	12VAC5-481-2780	N/A	New section- Irradiator pools
	12VAC5-481-2790	N/A	New section- Source rack protection
	12VAC5-481-2800	N/A	New section- Power failures
	12VAC5-481-2810	N/A	New section- Design requirements
	12VAC5-481-2820	N/A	New section- Construction monitoring and acceptance testing
	12VAC5-481-2830	N/A	New section- Training
	12VAC5-481-2840	N/A	New section- Operating and emergency procedures
	12VAC5-481-2850	N/A	New section- Personnel monitoring
	12VAC5-481-2860	N/A	New section- Radiation surveys
	12VAC5-481-2870	N/A	New section- Detection of leaking sources
	12VAC5-481-2880	N/A	New section- Inspection and maintenance
	12VAC5-481-2890	N/A	New section- Pool water purity
	12VAC5-481-2900	N/A	New section- Attendance during operation
	12VAC5-481-2910	N/A	New section- Entering and leaving the radiation room
	12VAC5-481-2920	N/A	New section- Irradiation of explosive or flammable materials
	12VAC5-481-2930	N/A	New section- Records and retention periods
	12VAC5-481-2940	N/A	New section- Reports
	12VAC5-481-2950	N/A	The following sections are re-designated Part XIII Transportation of Radioactive Material New section- Purpose and scope Remarks: This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Packaging and Transportation of Radioactive Materials Regulation (Title 10 Code of Federal Regulations [CFR] Part 71). The NRC revised this regulation in 1995. The proposed regulation also requires compliance with U.S. Department of Transportation's regulations for the transportation of radioactive materials

			Title 49 CFR 172. The intent of these requirements are to hold the agency's licensees accountable for presenting radioactive materials in the proper package and appropriate shipping papers to commercial carriers.
	12VAC5-481-2960	N/A	New section- Requirement for license
	12VAC5-481-2970	N/A	New section- Exemptions
	12VAC5-481-2980	N/A	New section- Transportation of licensed material *Result of comment period*: Corrects incorrect citation. A-3 replaced reference to 12 VAC 5-481-900 E with 12 VAC 5-481-900
	12VAC5-481-2990	N/A	New section- General licenses for carriers
	12VAC5-481-3000	N/A	New section- General license: Nuclear Regulatory Commission - approved packages *Result of comment period*: Corrects incorrect citation. C. replaced reference to 12 VAC 5-481-3000 7 A with 12 VAC 5-481-3000 A
	12VAC5-481-3010	N/A	New section- General license: previously approved packages
	12VAC5-481-3020	N/A	New section- General license: U. S. Dept of Transportation specification container
	12VAC5-481-3030	N/A	New section- General license: use of foreign approved package
	12VAC5-481-3040	N/A	New section- General license: fissile material, limited quantity per package
	12VAC5-481-3050	N/A	New section- General license: fissile material, limited moderator per package
	12VAC5-481-3060	N/A	New section- Assumptions as to unknown properties of fissile material
	12VAC5-481-3070	N/A	New section- Preliminary determinations
	12VAC5-481-3080	N/A	New section- Routine determinations *Result of comment period*: Corrects typographical error. J. Replaced 12 VAC 5-481-3080 1 with 12 VAC 5-481-3080 I
	12VAC5-481-3090	N/A	New section- Air transport of plutonium
	12VAC5-481-3100	N/A	New section- Shipment records

	12VAC5-481-3120	N/A	New section- Advance notification of transport of nuclear waste *Result of comment period*: Technical changes to stay consistent with federal regulations. B-3-a, replaced "Appendix L, Table 1" with Table A-1 of Appendix A to Part 71-- Determination of A1 and A2 (10 CFR 71, 69 FR 3800, Jan. 26, 2004) B-3- b, replaced "Appendix L, Table 1" with Table A-1 of Appendix A to Part 71-- Determination of A1 and A2 (10 CFR 71, 69 FR 3800, Jan. 26, 2004)
	12VAC5-481-3130	N/A	New section- Quality assurance requirements
	12VAC5-481-3140	N/A	The following sections are re-designated Part XIV – Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies New section- Purpose This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Title 10 Code of Federal Regulations [CFR] Part 39. The NRC promulgated a new Part 39 in Title 10 CFR in 1987 when the current state regulation was in Administrative Act Process. Agency staff did not become aware of this federal regulation and the extensive well logging activities used in the mining and oil/gas exploration industry in Southwest Virginia until after the public comment period.
	12VAC5-481-3150	N/A	New section- Scope
	12VAC5-481-3160	N/A	New section- Prohibition
	12VAC5-481-3170	N/A	New section- Limits on levels of radiation
	12VAC5-481-3180	N/A	New section- Storage precautions
	12VAC5-481-3190	N/A	New section- Transport precautions
	12VAC5-481-3200	N/A	New section- Radiation survey instruments
	12VAC5-481-3210	N/A	New section- Leak testing of sealed sources
	12VAC5-481-3220	N/A	New section- Quarterly inventory
	12VAC5-481-3230	N/A	New section- Utilization records

	12VAC5-481-3240	N/A	New section- Design, performance, and certification criteria for sealed sources used in downhole operations
	12VAC5-481-3250	N/A	New section- Labeling
	12VAC5-481-3260	N/A	New section- Inspection and maintenance
	12VAC5-481-3270	N/A	New section- Training requirements *Result of comment period*: Technical changes to stay consistent with federal regulations. A-1 replaced Appendix M with section 39.61(e)(1)(vi) of Part 39—Licenses and Radiation Safety Requirements for Well Logging (10 CFR 39, 52 FR 8234, Mar. 17, 1987)
	12VAC5-481-3280	N/A	New section- Operating and emergency procedures
	12VAC5-481-3290	N/A	New section- Personnel monitoring
	12VAC5-481-3300	N/A	New section- Security
	12VAC5-481-3310	N/A	New section- Handling tools
	12VAC5-481-3320	N/A	New section- Subsurface tracer studies
	12VAC5-481-3330	N/A	New section- Particle accelerators
	12VAC5-481-3340	N/A	New section- Radiation surveys
	12VAC5-481-3350	N/A	New section- Documents and records required at field stations
	12VAC5-481-3360	N/A	New section- Documents and records required at temporary jobsites
	12VAC5-481-3370	N/A	New section- Notification of incidents, abandonment, and lost sources
	12VAC5-481-3380	N/A	The following sections are re-designated Part XV – Therapeutic Radiation Machines New section- Purpose and scope The use of therapeutic radiation machines have expanded considerably during the past decade and several safety and enforcement issues have been identified by the states, and the U.S, Food and Drug Administration. The new requirements include evaluation of physician credentials, medical physicists training and qualifications, calibration of test equipment, and a quality management program.
	12VAC5-	N/A	New section- General administrative

	481-3390		requirements for facilities using therapeutic radiation machines *Result of comment period*: Technical changes to provide clarity. A inserted after agency in first sentence ".. and reporting misadministrations within 10 days." D-1 deleted "compliance" prior to survey. D-2 Replace reference to Appendix M with Section 340-B-2
	12VAC5-481-3400	N/A	New section- General technical requirements for facilities using therapeutic radiation machines *Result of comment period*: Technical change requested by a Private Inspector to provide clarity. C-1 deleted last sentence.
	12VAC5-481-3410	N/A	New section- Quality management program *Result of comment period*: Technical change requested by a Private Inspector to provide clarity. Deleted "The facility may use quality management programs found in either Appendix P or Q" and replaced with "The facility shall include in the quality management program notification of a misadministration, a recordable event, and recording written directives."
	12VAC5-481-3420	N/A	New section- Therapeutic radiation machines of less than 500 kV
	12VAC5-481-3430	N/A	New section- Therapeutic radiation machines- photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above) *Result of comment period*: Technical change requested by a Private Inspector to provide clarity. C-1 added to end of sentence "... or for multi-leaf collimators, shall not exceed manufacture's specifications". C-2 added to end of sentence "... or for multi-leaf collimators, shall not exceed manufacture's specifications".

			Q-4 deleted “two-way “ in both sentences. Q-10 added words after removing “… from treatment room, or…”
	12VAC5-481-3440	N/A	New section- Calibration of survey instruments
	12VAC5-481-3450	N/A	New section- Shielding and safety design requirements *Result of comment period*: Technical change requested by a Private Inspector to provide clarity. B deleted last sentence, there is no Appendix O
	12VAC5-481-3460	N/A	The following sections are re-designated Part XVI -Regulation and Licensing of Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) New section- Purpose Remarks: This is a new part that addresses the issue of handling of diffuse natural-occurring radioactive material that has become concentrated in certain commodities, such as scrap metal, and municipal waste shipments. The states have attempted to develop nationally recognized standards to prevent economic loss, as well as protect the public health and safety. The basis for these sections are from the State Suggested Regulations.
	12VAC5-481-3470	N/A	New section- Scope
	12VAC5-481-3480	N/A	New section- Exemptions
	12VAC5-481-3490	N/A	New section- Standards for Radiation Protection for TENORM
	12VAC5-481-3500	N/A	New section- Protection of Workers During Operations
	12VAC5-481-3510	N/A	New section- Release for Unrestricted Use *Result of comment period:* technical change to stay consistent with federal regulations. A. replaced “Appendix R” with “Table 1 in this Part”. And insert Table 1
	12VAC5-481-3520	N/A	New section- Disposal and Transfer of Waste for Disposal *Result of comment period:* technical change to stay consistent with federal regulations.

			B. replaced “Appendix R” with “Table 1 in 12 VAC 5-481-3510 A”.
	12VAC5-481-3530	N/A	New section- General License
	12VAC5-481-3540	N/A	New section- Specific Licenses
	12VAC5-481-3550	N/A	New section- Filing Application for Specific Licenses
	12VAC5-481-3560	N/A	New section- Requirements for the Issuance of Specific Licenses *Result of comment period:* technical change to stay consistent with federal regulations. B. replaced “Appendix R” with “Table 1 in 12 VAC 5-481-3510 A”.
	12VAC5-481-3570	N/A	New section- Safety Criteria for Products
	12VAC5-481-3580	N/A	New section- Table of Organ Doses
	12VAC5-481-3590	N/A	New section- Issuance of Specific Licenses
	12VAC5-481-3600	N/A	New section- Conditions of Specific Licenses Issued Under 12 VAC 5-481-3560
	12VAC5-481-3610	N/A	New section- Expiration and Termination of Specific Licenses
	12VAC5-481-3620	N/A	New section- Renewal of Specific Licenses
	12VAC5-481-3630	N/A	New section- Amendment of Specific Licenses at Request of Licensee
	12VAC5-481-3640	N/A	New section- Agency Action on Applications to Renew and Amend Specific Licenses
	12VAC5-481-3650	N/A	New section- Modification and Revocation of Specific Licenses
	12VAC5-481-3660	N/A	New section- Reciprocal Recognition of Specific Licenses
	12VAC5-481-3670	N/A	New section- Financial Surety Arrangements
	12VAC5-481-3680	N/A	New section- Effective Date

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.

Abolishing the regulation, or failure to update the existing regulations would be inconsistent with the agency's mission and the need to protect pubic health and safety. The agency has adopted regulations that are identical in most cases as the federal regulations to be consistent with the other states. These regulations provide for less stringent regulation of entities that possess or use radioactive materials in either small quantities or have radiation producing machines with low energies. These are typically small businesses or small dental offices and veterinary facilities.

The agency has provided less stringent X-ray machines inspection schedules for certain types of practices in the healing arts, such as dental, podiatric, and veterinary facilities, which are on a three year inspection cycle. The other types of practices, such as, medical and hospitals, are on an annual inspection frequency.

With respect to the reporting requirements, the agency has allowed the use of federal forms in place of state forms to reduce duplication of paperwork for reporting the installation of X-ray machines. Reporting requirements for radioactive materials are identical to the federal government to eliminate confusion among our licensees who are also regulated by the Nuclear Regulatory Commission for certain types of materials that the state does not regulate.

Both agency and federal regulation of radioactive materials and X-ray machines are becoming more performance based rather than enforcement of compliance with prescriptive requirements, particularly in mammography services and the use of radioactive materials.

With respect to the exemption of small businesses from all or any part of the regulation, the proposed regulations are designed to protect public health and safety. The agency has balanced the risk of harm versus the benefit derived from the use of radioactive materials and radiation producing machines. Towards that end, it is economical for small businesses in Virginia to use radioactive materials for those materials that the state regulates.

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.