Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-481
Regulation title	Virginia Radiation Protection Regulations
Action title	Update to the Diagnostic X-ray Therapy, Analytical & Radiation Machine Regs.
Date this document prepared	February 3, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. 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), Office of Radiological Health (ORH) proposes to amend 12VAC5-481, Radiation Protection Regulations, to adopt the 2009 Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs) to reflect new X-ray modalities in the medical field, reinsert definitions that were deleted in 2006 and update the regulations to meet Virginia Register Form, Style, and Procedure Manual guidance.

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 or board taking the action, and (3) the title of the regulation.

On June 5, 2014 the Board of Health voted to adopt the proposed regulatory changes to 12VAC5-481.

Legal basis

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

These regulations are authorized by the Code of Virginia 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

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.

During the 2006 revision of the Virginia Radiation Protection Regulations, and in order for Virginia to become an Agreement State, some definitions were deleted in order to comply with the Nuclear Regulatory Commission's rules (10 CFR). Some of these definitions, however, were used by the X-ray program. This amendment will reinsert these definitions into 12VAC5-481 and update their verbiage such that they would apply specifically to X-ray registrants.

The Conference of Radiation Control Program Directors (CRCPD) publishes Suggested State Regulations (SSR) upon which individual Agreement States base their regulations. The X-ray regulations were based upon the SSRs in 2006. The sections in Part VI were repealed and new sections were inserted that now include the 2009 revised CRCPD SSRs.

This amendment is essential to protect the health, safety and welfare of our citizens by ensuring that Virginia's regulations conform to the most recent SSRs as endorsed by the Nuclear Regulatory Commission and the thirty-seven (37) Agreement State Radiation Control Programs.

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 CRCPD SSRs were updated in 2009 to reflect current practices and devices used in the X-ray field. Virginia's X-ray regulations were last updated to conform to the CRCPD SSRs in 2006. 12VAC5-481 needs to be amended to reflect and conform to the current practices and to include regulations that govern all devices used in the X-ray field.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1. 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 that regulations governing the application of radiation will meet nationally recognized performance standards, which will promote quality of care. This amendment will include definitions that were removed in 2006 that pertain to the X-ray program.

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

2. The advantage of the proposed regulation to the agency is that fewer interpretations of the regulation will be needed for 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 a federal agency.

   There are no disadvantages to the agency in promulgating the proposed regulation

3. None

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.

Several changes, all non-substantive, have been made since the publication of the proposed regulations. These changes are enumerated in the table below:

Section number	Requirement at proposed stage	What has changed	Rationale for change
12 VAC5-481-10 Definitions	"Positive emission tomography (PET) radionuclide production facility" or "PET" means a facility operating a cyclotron or accelerator for the purpose of	"Positron Emission Tomography radionuclide production facility" or "PET" means a facility operating a cyclotron or [other particle] accelerator for the purpose of producing radionuclides that decay by	Cleaner language

	producing PET radionuclides.	positron emission.	
12 VAC5-481-10 Definitions	"Reportable event" means the administration of either: 3. A teletherapy x-ray dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or	"Reportable event" means the administration of either: 3. A teletherapy x-ray or electron dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or	Cleaner language
12VAC5-481-340 – Private Inspector qualifications	B. 1.a.(1) Therapeutic radiological physics	B.1.a.(1) Therapeutic radiological physics or therapeutic medical physics;	Designation changed by the American Board of Radiology in 2012.
12VAC5-481-1591 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 .25 mm lead equivalent materials; and	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 .25 mm lead equivalent materials. However, when distances provide sufficient protection from scatter radiation, or for low dose rate devices such as bone densitometry equipment, no protective devices may be necessary; and	Protective aprons may not be necessary if dose rate is low or distance provides the necessary reduction in radiation exposure.
12VAC5-481-1591 A.8	c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 5 of this subsection.	c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 5 of this subsection. Caregivers who stay in the room to assist with imaging of patients shall be positioned and/or instructed to keep the protective apron between them and the patient;	Care givers do not require the same level of training as facility staff. It is highly unlikely that a caregiver that occasionally helps hold a patient would receive more than 100 mrem/ year.
12VAC5-481-1591.A.9.c.	c. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.	c. Portable or mobile radiographic (exclude fluoroscopic) x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.	Need to specify radiographic equipment and not fluoroscopic equipment used in pain management centers.
12VAC5-481-	14. Operator list. The registrant shall maintain a list of x-ray operators	14. Operator list. The registrant shall maintain a list of x-ray operators for each facility.	Need to allow individuals waiting to test for their registry

1591 A.14	for each facility. Operators must be licensed by the Department of Health Professions where x-ray are used within the scope of practice or be certified by the ARRT, or be an individual enrolled in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, and if a dental assistance, comply with the Board of dentistry/s radiation certification requirements in 18VAC60-20-195.	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, or be an individual enrolled, or was enrolled within the past three months, in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, or if a dental assistant, comply with the Board of Dentistry's radiation certification requirements in 18 VAC60-20-195.	exam.
12VAC5-481-1621 B Reproducibility	2. Measuring compliance. Determination of compliance shall be based on 10 consecutive measurements taken within a time period of one hour.	2. Measuring compliance. Determination of compliance shall be based on four consecutive measurements taken within a time period of one hour.	Four exposures are sufficient to determine reproducibility. With 10 exposures, one would overwork the unit.
12VAC5-481-1621 C Linearity	3. Measuring compliance. Determination of compliance shall be based on 10 exposures made within one hour, at each of the two settings.	3. Measuring compliance. Determination of compliance shall be based on four exposures made within one hour, at each of the two settings.	Four exposures are sufficient to determine linearity. With 10 exposures, one would overwork the unit.

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
James Nunn, Medical Physicist for Lewis gale Hospital - Pulaski	12VAC5-481-10 Definitions concerning "Reportable event" Item 1. For a diagnostic x-ray exposure. Wanted to consider adding a dose threshold consistent with The Joint Commission's Sentinel Event Policy for diagnostic radiation overexposure.	Keep clear, concise and consistent with CRCPD SSRs. Do not refer to another policy used by Joint Commission. Change not recommended.
	12VAC5-481-10 Definitions concerning "Reportable event" Item	Keep consistent with CRCPD SSRs. Other states adopted this format. Change not

	4. A brachytherapy dose. Believes the rule may be burdensome on some institutions.	recommended.
Lee Anthony, Jr., Medical Physicist for Physics Associates – Roanoke and Harold Prussia, Medical Physicist from Riverside Hospitals	12VAC5-481-1591E concerning "non-serious" violations becoming "serious" if not corrected with the next inspection cycle.	Repeated non-serious violations that remain uncorrected are a concern to the Office of Radiological Health. Unless the registrant is required to repair the "non-serious" violation within a set time period, they will not fix, repair, or replace it. Change not recommended.
Harold Prussia, Medical Physicist from Riverside Hospitals	12VAC5-481-1655 Bone densitometry. D.2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure. Wants this section deleted.	Keep consistent with CRCPD SSRs. Other states adopted this format. Change not recommended.
	12VAC5-481-1641. Computed tomography equipment. D.2.b. The calibration of a CT x-ray system shall be performed (i) after initial installation and before use on human patients, (ii) annually or at intervals specified by a qualified medical physicists, and , and (iii) after any change or replacement of components that in the opinion of the qualified medical physicist could cause a change in the radiation output. Believes inspection after a major change is burdensome before patient use.	Keep consistent with CRCPD SSRs. Other states adopted this format. Change not recommended. After discussing this with the Medical Physicist, does not believe this is an issue. Change not recommended.

All changes made in this regulatory action

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

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
10		Definitions	Adding 21 definitions to conform to the 2009 SSRs, deleting 14 definitions and amending 114 definitions to meet Virginia Registrar standards;

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
290		Registration of radiation machine facilities	Revising the regulation reference;
340		Private inspector qualifications	Revising the word “x-ray” and amending the language for disqualifying individuals;
350		Assembler or transfer obligations	Update regulation to include FDA standard;
1580		Purpose and scope	Repealed;
	1581		Create a new purpose and scope section;
1590		General and administrative requirements	Repealed;
	1591		Create a new general and administrative requirements section which includes the 2009 CRCPD SSR update;
1600		General requirements for all diagnostic X-ray systems	Repealed;
	1601		Create a new general requirements for all diagnostic X-ray systems section which includes the 2009 CRCPD SSR update;
1610		Fluoroscopic X-ray systems	Repealed;
	1611		Create a new fluoroscopic equipment section which includes the 2009 CRCPD SSR update;
1620		Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems	Repealed;
	1621		Create a new radiographic section which includes the 2009 CRCPD SSR update;
1630		Intraoral dental radiographic systems	Repealed;
	1631		Create a new intraoral dental radiographic section which includes the 2009 CRCPD SSR update;
1640		Computed tomography X-ray systems	Repealed;
	1641		Create a new computed tomography equipment section which includes the 2009 CRCPD SSR update;

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
1650		Mammography	Repealed;
	1651		Create a new mammography requirements section which includes the 2009 CRCPD SSR update;
	1653	Hand-held radiography unit	Create a new hand-held radiography unit section which includes the 2009 CRCPD SSR update;
	1655	Bone densitometry	Create a new bone densitometry section which includes the 2009 CRCPD SSR update;
	1657	Quality assurance program	Create a new quality assurance program section which includes the 2009 CRCPD SSR update;
2110		Area requirements	Change the survey requirement from 12 months to 5 years; and
3410		Quality management program	Include the reporting requirement for a reportable event.