Virginia Regulatory Town Hall

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Proposed 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
Date this document prepared	January 3, 2012

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

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The Virginia Department of Health (VDH), Division of Radiological Health (DRH) proposes to amend 12VAC5-481, Radiation Protection Regulations, to reflect changes to Federal regulations and new X-ray modalities in the medical field, reinsert definitions that were deleted in 2006 and update the regulations to meet current *Virginia Register Form, Style, and Procedure Manual*.

This amendment specifically:

- Adds 21 new definitions in section 10 that include:
    - Air Kerma Rate; Articulated Joint; Cassette Holder; Cradle; cm; Cumulative Air Kerma; Fluoroscopic Irradiation Time, Fluoroscopy; Hand Held Radiographic Unit; Kerma; Last Image Hold Radiograph; Misadministration; mm; Mode of Operation; Non-image-intensified Fluoroscopy; Primary Protective Barrier; Pulsed Mode; Radiography; Reportable Event; Tabletop, Stationary; and X-ray Control;
- Deletes 14 definitions in section 10 that include:
    - Added Filtration; Cephalometric Device; Certified System; Changeable Filters; Dead-man Switch; Diagnostic X-ray Imaging System; Entrance Exposure Rate; HVL; Inherent Filtration; Maximum Line Current; Protective Barrier; Radiographic Imaging System; Secondary Protective Barrier; and Termination of Irradiation;
- Amends 115 definitions in section 10;

- Amends the following sections in Part II:
    - 290, Registration of Radiation Machine Facilities;
    - 340, Private Inspector Qualifications;
    - 350, Assembler or Transfer Obligation; and

- Repeals each section in Part VI and adds the corresponding new section:
    - 1581, Purpose and Scope;
    - 1591, General and Administrative Requirements;
    - 1601, General Requirements for all Diagnostic X-ray Systems;
    - 1611, Fluoroscopic Equipment;
    - 1621, Radiographic Equipment;
    - 1631, Intraoral Dental Radiographic Equipment;
    - 1641, Computed Tomography Equipment;
    - 1651, Mammography Requirements;
    - 1653, Hand Held Radiographic Unit;
    - 1655, Bone Densitometry;
    - 1657, Quality Assurance Program; and

- Amends section 2110, Area Requirements, and 3410, Quality Management Program.

Acronyms and Definitions

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

CFR: Code of Federal Regulations
CRCPD: Conference of Radiation Control Program Directors
DRH: Division of Radiological Health
NRC: Nuclear Regulatory Commission
SSR: Suggested State Regulations
VDH: Virginia Department of Health

Legal basis

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

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

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 only to X-ray registrants.

The Conference of Radiation Control Program Directors (CRCPD) has Suggested State Regulations (SSR) upon which individual states may 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 include the 2009 revised CRCPD SSRs. This amendment will ensure that Virginia's regulations conform to the most recent SSRs.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" 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 the regulatory action poses 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

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

Where applicable the radiation protections standards and the standards for X-ray machine performance are identical to the existing federal minimum requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There will be no localities particularly affected unless they use an X-ray device/machine subject to these regulations.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to: Steve Harrison, Acting Director, Division of Radiological Health, 109 Governor Street, Room 730, Richmond, VA 23219; phone: 804-864-8151; fax: 804-864-8165 and e-mail: steve.harrison@vdh.virginia.gov**.** Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last date of the public comment period.

Economic impact

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

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	$0
Projected cost of the *new regulations or changes to existing regulations* on localities.	$0
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	This amendment affects anyone who uses an X-ray device in the Commonwealth.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Currently, the X-ray program registers approximately 7,500 entities of which approximately 7,000 entities may meet the small business criteria.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	$0
Beneficial impact the regulation is designed to produce.	Ensure Virginia's X-ray regulations meet current standards and practices.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives available. In order to ensure that public health is protected, the Virginia Radiation Regulations 12VAC5-481 must be amended to conform to the current CRCPD SSRs.

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.

There is no alternative regulatory method as the CRCPD SSRs are the nation's standards for the regulation of radiation. The Virginia Radiation Regulations 12VAC5-481 must be amended to conform to the 2009 CRCPD SSR amendments.

Public comment

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

No public comments were received during the comment period which ended 9/15/10.

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.

There are no family impacts.

Detail of changes

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

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

For changes to existing regulations, use this chart:

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;
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;

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
	1641		Create a new computed tomography equipment section which includes the 2009 CRCPD SSR update;
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.