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Fast-Track Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-481
Regulation title(s)	Virginia Radiation Protection Regulations
Action title	Revise Part I - General Provisions; Amend and add sections to Part XV – Therapeutic Radiation Machines
Date this document prepared	March 16, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

The Virginia Department of Health (VDH), Office of Radiological Health (ORH) proposes to amend 12VAC5-481, Radiation Protection Regulations to reflect changes in as well as new x-ray modalities pertaining to the medical field, amend and add new definitions, and update the regulations to meet the current *Virginia Register Form, Style, and Procedure Manual*.

Acronyms and Definitions

COV - Code of Virginia
CRCPD - Conference of Radiation Control Program Directors
e-brachytherapy - Electronic Brachytherapy
IMRT - Intensity Modulated Radiation Therapy
kV - Kilovolt
keV - Kilo-electronvolt

ORH - Office of Radiological Health
SSRs - Suggested State Regulations
TSD - Target-Skin Distance (TSD)
VDH - Virginia Department of Health

Statement of final agency action

The State Board of Health approved this regulatory action on September 17, 2015.

Legal basis

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.

Purpose

The Virginia Department of Health (VDH), Office of Radiological Health (ORH) proposes to amend 12VAC5-481, Radiation Protection Regulations to reflect changes in as well as new X-ray modalities pertaining to the medical field, amend and add new definitions, and update the regulations to meet the *current Virginia Register Form, Style, and Procedure Manual*.

Rationale for using fast-track process

Practitioners have requested that regulations providing for the use of therapeutic radiation machines be instituted in the Commonwealth in order to remain up-to-date with regard to current practices. The regulated community has requested that regulations be put into place for the proper operation of therapeutic and e-brachytherapy equipment. This initiative was discussed and endorsed at the November 2014 Radiation Advisory Board meeting. Accordingly, ORH does not view this initiative as being controversial in nature.

Substance

The Conference of Radiation Control Program Directors (CRCPD) develops Suggested State Regulations (SSR) upon which individual states may base their regulations. The X-ray regulations were based upon the SSRs when adopted in 2006; this amendment will ensure that Virginia's regulations are brought up to date by incorporating the most recent CRCPD SSRs in totality. This amendment adds new provisions concerning radiation therapy machines, including electronic brachytherapy, as described below:

- Adds eleven (11) new definitions in Part I, General Provisions, Section 10 that include:
    - Conventional simulator; electronic brachytherapy; electronic brachytherapy device; electronic brachytherapy source; intensity modulated radiation therapy (IMRT); mobile electronic

brachytherapy service; qualified inspector; qualified medical physicist; radiation therapy system; target-skin distance (TSD); virtual simulator.

- Amends five (5) definitions in Part I, General Provisions, Section 10: beam-limiting device; leakage radiation; light field; prescribed dose; therapeutic radiation machine.
- Amends the following sections in Part XV, Therapeutic Radiation Machines:
  - 3390, General Administrative Requirements;
  - 3400, General Technical Requirements for facilities using therapeutic radiation machines;
  - 3410, Quality management program;
  - 3420, Therapeutic Radiation Machines of less than 500 kV;
  - 3430, Therapeutic Radiation Machines – Photon Therapy Systems (500kV and Above) and Electron Therapy Systems (500keV and Above);
  - 3450, Shielding and Safety Design Requirements
- Adds the following new sections to Part XV, Therapeutic Radiation Machines:
  - 3451, Quality Assurance for Radiation Therapy Simulation Systems;
  - 3452, Electronic Brachytherapy;
  - 3453, Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage

Issues

1. The advantage of the proposed regulation is that healthcare providers regulated by VDH will operate under clear worker and 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. There are no disadvantages to the public in promulgating the proposed regulation.

2. The advantage of the proposed regulation to the agency is that the proper regulation of therapeutic radiation producing machines will now be addressed. There are no disadvantages to the agency in promulgating the proposed regulation

3. None.

There are no disadvantages to the public or the Commonwealth as a result of this initiative.

Requirements more restrictive than federal

There are no requirements that being instituted as a result of this action that exceed applicable federal requirements.

Localities particularly affected

There are no localities particularly affected by this proposed action.

Regulatory flexibility analysis

Virginia radiation protection regulations already exist and need to be amended to address radiation therapy machines, to include e-brachytherapy operation and use. There is not an alternative non-regulatory approach that will be sufficient to protect the health and safety of the public.

Economic impact

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	$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 a therapeutic radiation machine, including e-brachytherapy units, 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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The X-ray program currently registers approximately 21,464 x-ray machines, of which 90 of these are therapeutic radiation machines. Approximately 1,500 registrants 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 including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	$0
Beneficial impact the regulation is designed to produce.	Ensure Virginia's X-ray regulations meet current standards and practices.

Alternatives

Abolishing the regulation or failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide an adequate regulatory program that protects public health and safety. VDH will consider recommendations from the Radiation Advisory Board and the regulated community for alternative means of meeting the intent of the model regulations or additional requirements to address concerns that may be unique within the Commonwealth.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to **[Stan Orchel, Jr., Virginia Department of Health, Office of Radiological Health, 109 Governor Street, Room 733, Richmond, VA 23219, (804)864-8170 (Office Phone), (804)864-8175 (fax), stan.orchel@vdh.virginia.gov**]. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

Periodic review and small business impact review report of findings

This fast-track is not the result of a periodic review/small business impact review.

Family impact

There are no family impacts associated with this action.

Detail of changes

Changes to existing regulation(s):

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10		Definitions	Adds eleven (11) new definitions and changes five (5) definitions to conform to the SSRs on brachytherapy, providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.

New regulations being promulgated:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
3390	General Administrative Requirements for Facilities Using Therapeutic Radiation	12VAC5-481-260 et seq, 12VAC5-481-640, 12VAC5-481-680,	Establish administrative controls and training requirements for the use of

	Machines	12VAC5-481-760	therapeutic radiation machines, providing a positive impact that incorporates updated guidance on operation and use.
3400	General Technical Requirements for Facilities Using Therapeutic Radiation Machines	12VAC5-481-640 12VAC5-481-720	Provide for protection surveys, room modifications, dosimetry requirements and records of surveys and measurements, providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.
3410	Quality Management Program		Directs the development, implementation, and maintenance of a quality management program, providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.
3420	Therapeutic Radiation Machines of Less Than 500 kV	12VAC5-481-640	Establishes leakage, beam limiting devices, filters, timers, control panel functions, quality assurance checks, operating procedures, etc., providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.
3430	Therapeutic Radiation Machines Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)		Establishes leakage, beam limiting devices, filters, timers, control panel functions, quality assurance checks, operating procedures, etc., providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.
3450	Shielding and Safety Design Requirements	12VAC5-481-640 and 12VAC5-481-720	Requires primary and/or secondary barriers as are necessary to ensure compliance, providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.
3451	Quality Assurance For Radiation Therapy Simulation Systems		Establishes quality assurance for a conventional or virtual simulator, providing a positive impact that incorporates updated guidance on therapeutic machine operation and use.
3452	Electronic Brachytherapy	12VAC5-481-640	Establishes requirements for the use of electronic

			brachytherapy devices, providing a positive impact that incorporates updated guidance on operation and use.
3453	Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage		Establishes requirements for using other electronically-produced radiation devices, e.g., proton therapy, to deliver therapeutic radiation dosage and providing a positive impact that incorporates updated guidance on operation and use.