Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-481
Regulation title	Radiation Protection Regulations
Action title	Amend regulation to update sections related to X-ray machines based on latest version of the Suggested State Regulations.
Date this document prepared	March 30, 2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The State Board of Health and the Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations to update those sections related to X-ray machines using the latest version of the *Suggested State Regulations* published by the Conference of Radiation Control Program Directors, Inc. The amended regulations will provide performance standards for bone densitometers, hand-held X-ray machines, computed radiography and air kerma rate meters on new fluoroscopic and CT machines. The proposed regulatory action is intended to supersede the Radiation Protection Regulations, which became effective September 12, 2006.

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., 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 32.1-227 et seq.

Section 32.1-229.1 The Board shall, in accordance with the Administrative Process Act (§ 2.2-4000 et seq.), promulgate such regulations as the Board deems necessary to protect the health and safety of health care workers, patients, and the general public, including but not limited to regulations to: ….. 2. Schedule for inspections of X-ray machines;… 4. Standards for certification of X-ray machines; and 5. Qualifications for private inspectors.

Refer to the following web site for viewing the statutory authority cited in Section 32.1-229.1 of the Code of Virginia:
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1
The authority to promulgate schedules for inspecting X-ray machines and standards for certification of X-ray machines are mandatory.

On April 23, 2010, the State Board of Health assented to the Department publishing a Notice of Intended Regulatory Action to begin the process of pursuing and accomplishing the goals set forth herein.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The Code of Virginia requires VDH to ensure all X-ray machines are registered, periodically inspected and all X-ray machines used in the healing arts must be certified for use. The current regulations do not have performance standards for new technologies such as bone densitometers, hand-held X-ray machines, computed radiography and air kerma rate meters on new fluoroscopic and CT machines. Performance standards must be adopted in order to provide a meaningful certification for these machines and devices. Of particular importance is adopting a performance standard for the air kerma rate meter on new fluoroscopic and CT machines. The meter provides the physician user information regarding the patient's radiation exposure during the medical procedure. Recent scientific literature has reported significant increase in the population's exposure to radiation from medial use of X-ray equipment, specifically fluoroscopic and CT machines.

VDH staff are aware of certain inconsistencies in the regulation. The most significant is the definition of misadministration which is a term that was used for the regulation of both X-ray machines and radioactive materials. However, the U.S. Nuclear Regulatory Commission (NRC), which regulates radioactive material, now uses the term medical event and the definition for misadministration in the regulation was deleted to be compatible with NRC. This deletion inadvertently impacted the sections pertaining to X-ray machines, which still uses this term.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Sections of the regulation relating to X-ray machines, including radiation therapy will be updated using the *Suggested State Regulations* published by the Conference of Radiation Control Program Directors, Inc. This publication has been reviewed by the appropriate federal agencies which have concurred with its contents. The specific documents that will be adopted are as follows: Part F Diagnostic X-rays and

Imaging Systems in the Healing Arts (2009) and Part X Medical Therapy (2009). These publications and the rationale are available on line at: http://www.crcpd.org/ssrcr.aspx

Performance standards for new technologies such as bone densitometers, hand-held X-ray machines, computed radiography and air kerma rate meters on new fluoroscopic and CT machines will be adopted. X-ray machines used in radiation therapy will include performance standards for Intensity Modulated Radiation Therapy, electronic brachytherapy and therapy related computer systems.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 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 comments may do so via the Regulatory Townhall website, **www.townhall.virginia.gov**, or by mail, email or fax to Les Foldesi, Director, Division of Radiological Health, VDH 109 Governor Street, Room 732, Richmond, VA 23219, Phone:(804) 864-8151, FAX (804) 864-8155, (e-mail: Les.Foldesi@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 day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The agency will review and follow its Public Participation Guidelines, 12 VAC 5-11, to ensure compliance with its prescribed participatory approach in the development of this proposal.

Family impact

Assess the potential 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, except to the general extent that effective oversight of X-ray machines and other devices will provide the benefit of effective diagnostic and therapeutic capability while maintaining the safety of Virginia's citizens.