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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-481
VAC Chapter title(s)	Virginia Radiation Protection Regulations
Action title	Intent to Repeal and Replace Virginia's Radiation Protection Regulations
Date this document prepared	9/20/2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

The Virginia Department of Health (VDH), Office of Radiological Health (ORH) is tasked with regulating sources of radiation within the Commonwealth in order to protect the public from unnecessary exposure. Section 32.1-229 of the Code of Virginia (Code) authorizes the Board of Health (Board) to establish a program of effective regulation of sources of radiation for the protection of public health and safety. After a review of 12VAC5-481, ORH determined that significant changes are required to update the regulations as well as the order of parts within the chapter. In its current form, 12VAC5-481 does not fully comply with the Virginia Register of Regulations' Form, Style, and Procedure manual. ORH is considering repealing and replacing 12VAC5-481 to address needed revisions.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

Board – Board of Health
ORH – Office of Radiological Health
VDH – Virginia Department of Health

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation, (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

ORH conducted a periodic review of 12VAC5-481 and posted the review result to Townhall on August 11, 2022. The periodic review identified a need for several significant changes to the content and organization of the chapter. Due to the large amount of required changes to the content and the reorganization of parts within chapter 481, it was determined that repealing and replacing this chapter is necessary. Section 32.1-229 of the Code mandates the Board maintain a program to regulate sources of radiation caused by a wide spectrum of applications. It is in the best interests of the public and regulated community for 12VAC5-481 to contain regulations that are current and comply with requirements established by the Virginia Register of Regulations.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

1. The promulgating agency is the State Board of Health.

2. State legal authority for retaining, amending, or repealing radiation protection regulations comes from the following sections of the Code of Virginia:
    a. § 32.1-12 authorizes the Board to "make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of [Title 32.1.]"
    b. § 32.1-228.1, which states the following:
        "A. The Department of Health is hereby designated as the state radiation control agency. The Commissioner of Health may employ, compensate, and prescribe the duties of such individuals as may be necessary to discharge the responsibilities imposed by this article."
    c. § 32.1-229, which states the following:
        "The Board shall:

1. Establish a program of effective regulation of sources of radiation for the protection of the public health and safety, including a program of education and technical assistance relating to radon that is targeted to those areas of the Commonwealth known to have high radon levels. As a part of such program, a list of persons who are nationally certified to offer screening, testing, or mitigation for radon shall be made available to the public.
2. Establish a program to promote the orderly regulation of radiation within the Commonwealth, among the states and between the federal government and the Commonwealth and to facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized.
3. Establish a program to permit maximum utilization of sources of radiation consistent with the public health and safety.
4. Promulgate regulations providing for (i) general or specific licenses to use, manufacture, produce, transfer, receive, acquire, own or possess quantities of, or devices or equipment utilizing, by-product, source, special nuclear materials, or other radioactive material occurring naturally or produced artificially, (ii) registration of the possession of a source of radiation and of information with respect thereto, and (iii) regulation of by-product, source and special nuclear material."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

As the state radiation control agency designated by § 32.1-228.1, VDH has a mandate to regulate and inspect sources of radiation in order to protect public health. The regulations contained within 12VAC5-481 exist to support this mandate and are necessary to prevent unnecessary exposure to sources of radiation caused by a wide spectrum of applications. ORH does not anticipate significant issues as the regulation is developed. ORH welcomes comments during the public comment period regarding the regulations contained within the proposed chapter.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

ORH is considering the following substantive changes to 12VAC5-481:

1. Revision of text and reorganization of parts and sections to comply with the Virginia Register of Regulations' Form, Style and Procedure Manual.

2. Amend existing sections to ensure the Virginia Radiation Protection Regulations are up to date, comprehensive, and easily interpreted.

3. Specific changes to the Virginia Radiation Protection Regulations under consideration include the following:

    a. Part I.

        i. Update Section 10, Definitions, as appropriate following changes to regulatory text.

        ii. Add a section to reflect the inspection schedules currently in effect.

    b. Part II.

        i. Electronic equipment that produces radiation incidental to its operation must be registered with the agency, but is exempt from inspection requirements provided the existing requirements for dose equivalent rate are met according to 12VAC5-481-270 A.

        ii. Include shielding review exemptions for certain intra and extraoral, bone density, podiatry, and shielding enclosed analytic x-ray systems (excluding CBCT).

        iii. Clarify the circumstances in which an x-ray machine shall be inspected within 60 days.

        iv. Eliminate regulatory requirements that are based on outdated technology and science.

    c. Part VI.

        i. Eliminate regulatory requirements that are based on outdated technology and science.

        ii. Add a new section titled “Veterinary radiographic equipment” and place all relevant regulatory text in this section.

        iii. Prohibit the use of non-image intensified fluoroscopy.

        iv. Clarifying language stating that bone densitometry x-ray units shall be used for the exclusive purpose of determining bone density.

    d. Part VIII.

        i. Revise the sections within Part VIII to incorporate the Radiation Safety Requirements for Non-healing Arts Radiation Generating Devices (RGD) suggested state regulations that were developed by the Conference of Radiation Control Program Directors. This would include new regulations on RGDs used for security screenings.

        ii. Eliminate regulatory requirements that are based on outdated technology and science.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The Board of Health is required by the Code of Virginia to establish a program of regulatory oversight related to radiation protection. As such, there are no viable alternatives for complying with the legislative mandate. The Virginia Radiation Protection Regulations, 12VAC5-481, remains critical to protecting the public from unnecessary radiation exposure caused by a wide spectrum of applications used in the healing arts, research, educational institutions, and industry.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and the ORM procedures), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify it as necessary for your agency. Otherwise, delete the paragraph below and insert "This NOIRA is not being used to announce a periodic review or a small business impact review."

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia, describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Cameron Rose, 109 Governor St, RM 733, Richmond, VA 23219, Phone: 804-864-7090, Fax: 804-864-8175, Email: Cameron.Rose@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.