Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health (State Board of)
VAC Chapter Number:	12 VAC 5-480
Regulation Title:	Radiation Protection Regulations
Action Title:	Repealing and promulgating
Date:	10/21/2002

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Virginia Department of Health (VDH) intends to abolish the existing Radiation Protection Regulations (12 VAC 5- 480) and promulgate new regulations (12 VAC 5-481) containing current radiological health standards, including federal standards, and state legislation. These proposed regulations are intended to supercede the Radiation Protection Regulations, which became effective July 6, 1988.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

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
Where applicable the radiation protections standards, the standards for X-ray machine performance, and radioactive material licensing is identical to the existing federal minimum requirements. The proposed regulation for mammography faclity inspections and patient notification of poor quality mammograms exceeds federal requirements in order to comply with recent state legislation. The state requirements allow unannounced inpsections, the federal requlations do not allow unannounced insepctions. The Code of Virginia requires patients to be notified within two business days of a poor quality mammogram, the fedral regulations allow up to 30 days for faclities to notify their patients.
The Office of the Attorney General issued a statement that the proposed Radiation Protection Regulations were reviewed and that the Department possesses the authority to promulgate these regulations pursuant to Chapter 6, Article 8 of Title 32.1 of the Code of Virginia.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The existing regulation is being replaced in its entirety due to the numerous changes in radiation protection practices since publication of its effective date on July 6, 1988. The harmful effects of radiation are well known, as well as, the many benefical applications of radiation in industry and

healthcare. Adequate regulatory controls for the useful application of radiation is necessary to protect the health, safety and welfare of citizens.
The goals of promulgating the proposed regulation are: to provide the Commonwealth's citizens the same level of protection from radiation exposure as other citizens in the nation or those employed at federal facilities in the Commonwealth; to reduce unnecesary exposure to radiation; and to improve the diagnostic quality of clinical imaging, and accurate delievery of therapuetic doses of radiation to patients. One of the biggest problems with the use of radiation in the healing arts is the need for accurate and reproduablity delievery of radiation to film or other imaging devices for sucessful clinical diagnosis, or deliever of therapuetic radiation doses to patients for successful treatment. The proposed regulation incorporates current performance standards to address this problem.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The magor changes that the proposed regulation includes thoses regarding:
1. US. Nuclear Regulatory Commission's (NRC) implemented major changes to the Radiation Protection Standards (Title 10 Code of Federal Regulations Part 21) in 1992, and again in 2001.
2. Congress passed the Mammography Quality Standards Act of 1992 (MQSA) which provided dual regulatory authority to state and federal governments for the regulation of mammography facilities. The MQSA regulations were implemented in 1994 and revised in 2001. The existing regulation does not have standards specific to mammography machines, nor qualifications for Private Inspectors consistent with the federal regulations.
3. The Suggested State Regulations (SSRs) published by the Conference of Radiation Control Program Directors form the basis for VDH's Radiation Protection Regulations have been revised several times since 1988 to include standards for new X-ray equipment, exposure limits and improve image quality. The SSRs also include revisions for radioactive materials licensing comparable to revised federal standards.
4. Mammography Legislation- The General Assembly passed legislation (House Bills 1487 and 1488- Devolities) in the 2000 session that requires VDH to conduct inspections of mammography machines, and requires facilities to inform patients before leaving the facility whether the image quality is adequate before leaving the facility, respectively. The existing regulations do not have performance standards specific to mammography machines.
5. Radioactive Materials Legislation- The General Assembly passed legislation (House Bill 2655- Katzen) in the 1999 session that authorizes VDH to impose civil penalties on licensees who violate the conditions of their license or the regulation.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

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 repsect to occupational worker standards, and X-ray machine performance standards. Another advantage for healthcare professionals and patients is the expectation that the application of radiation will meet nationally recognized performance standards and improve the quality of healthcare.

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 exisitng regulation and not addressed. Another advantage is that agency staff will no longer need take additional time to explain regulatory differences to facilities that are dually regulated by another federal agency.

There are no disadvantages to the public or the Commonwealth in promulgating the proposed reagulation.

The agency may expect public comments regarding the credentials of X-ray machine operators, which may go beyond licensure by any of the boards in the Department of Health Professions. There may be requests to adopt quality control programs in other areas of diagnostic and therapeutic radiology similar to the federal mammography program, or certification requirements under the agency's Certificate of Public Need Program. There is interest in the medical community and the Food and Drug Administration regarding operator training and credentials for interventional fluoroscopy.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The proposed regulation is expected to not have a significant fiscal impact. Activities associated with the existing regulation are supported by general funds (0100 fund) in the amount of $702,000 for SFY2002. The X-ray registration activity collects $90,000 to $120,000 annually, which is returned to the general fund (0100 fund, 02198 detail). The inspections of

mammography faclities are supported by a federal contract (1000 funds, 10010 detail) in the amount of $168,568.12 for FFY2002.
This activity appears in the State Budget as Item 312- Regulation of Products (55700): Radiological Materials Regulation (Subprogram 55705) Cost Code 631 General Funds $701,059 SFY 2002.

The projected cost to localities would remain the same. Those faclities that have an X-ray machine are required to pay a $15 registration fee annually, or every three years if a dental, podiactric, or veterinary machine.

Individuals, businesses or other entities that are likely to be affected by the regulation include those possessing or using certain radiaoctive materials (220 licenses), and X-ray producing machines (17,000 machines). In most cases, healthcare professionals use X-ray machines. The applications of radioactive materials are diverse and covers a broad spectrum of businesses, academia, healthcare and research institutions
.
The agency estimates that there are 220 facilities that have radioctive materials licenses, and approximately 6,000 X-ray machine registrants.

Projected cost of the regulation for affected entities are for X-ray registrants $15 registration fee, $65-$380 for an X-ray machine inspection for those entities on an annual inspection cycle, such as chiropractic and medical facilties (approximately 2,000 faclitiies). Those entities on a three year insepction cycle (approximatley 4,000 facilities) would continue to incurr a $15 registration fee every three years and $65 - $190 for an X-ray machine inspection. VDH collects the registration fees; however, most entities use a private inspector to perform the X-ray machine inspection. There may be a minimum indirect cost to these entities for recordkeeping and reporting requriements.
There are no direct costs to those entities issued radioactive materials licenses.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

Due to the numerous changes in radiation protection standards, the agency elected to abolish the existing regulation and promulgate a new regulation.

Alternatives

Please describe the specific 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.

Abolishing the regulation, or failure to update the existing regulation would be inconsistent with the agency's mission and the need to protect public health and safety.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

The NOIRA Comment period was published on 4/22/2002 for the period 4/22/2002 - 5/24/2002. No public comments were received during the NOIRA comment period.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The regulation has undergone review by agency staff and the Radiation Advisory Board to ensure that the terminology is understandable. The regulaton is written using terminology that is customary to users of radiation producing machines, and radioactive materials.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The agency will initiate a review of the regulation within three years from the effective date.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.