Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12 VAC 5-480
Regulation Title:	Radiation Protection Regulations
Action Title:	Repealing and promulgating
Date:	September 21, 2004

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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 facility inspections and patient notification of poor quality mammograms exceeds federal requirements in order to comply with recent state legislation. The state requirements allow unannounced inspections, the federal regulations do not allow unannounced inspections. The Code of Virginia requires patients to be notified within two business days of a poor quality mammogram, the federal regulations allow up to 30 days for facilities 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 beneficial applications of radiation in industry and

healthcare. Adequate regulatory controls for the useful application of radiation are 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 unnecessary exposure to radiation; and to improve the diagnostic quality of clinical imaging, and accurate delivery of therapeutic 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 reproducibility delivery of radiation to film or other imaging devices for successful clinical diagnosis, or deliver of therapeutic 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 major changes that the proposed regulation includes those 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- Devolites) 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 respect 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 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 another federal agency.

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

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 not expected to have a significant fiscal impact. Fees referenced in the current regulation are in a separate regulation entitled Radiation Protection Regulations: Fee Schedule (12 VAC 5- 480). Activities associated with the existing regulation are supported by general funds (0100 fund) in the amount of $719,525 for SFY2004. 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 facilities are supported by a federal contract (1000 funds, 10010 detail) in the amount of $152,324.64 for FFY2004.
This activity appears in the State Budget as Item 312- Regulation of Products (55700): Radiological Materials Regulation (Subprogram 55705) Cost Code 631 General Funds $719,525 SFY 2004.

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

Individuals, businesses or other entities that are likely to be affected by the regulation include those possessing or using certain radioactive 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 radioactive 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 faculties (approximately 2,000 facilities). Those entities on a three-year inspection cycle (approximately 4,000 facilities) would continue to incur 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 record keeping and reporting requirements.
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.

The proposed regulations were derived from the current revision of Suggested State Regulations (SSRs) published by the Conference of Radiation Control Program Directors, Inc. The SSRs were reviewed by the major federal agencies with regulatory responsibilities for radiation control, such as the FDA, NRC, and DOT. However, the SSRs are not published in the Federal Register.

Certain sections dealing with radioactive materials are incorporated by reference comparable NRC regulations that have been published in the Federal Register. NRC regulates certain kinds of radioactive materials depending on how they are produced. The States regulate the others.

The NRC also allows States to regulate the federal materials if the state chooses to. These states are referred to as NRC Agreement States. The Commonwealth of Virginia is not an NRC Agreement State; however, the regulations were designed to be compatible with the Agreement as authorized in the Code of Virginia.

The FDA regulates the manufacture of X-ray machines. The States regulate how the machines are used. Unlike the regulation of radioactive materials, there are few federal regulations that are appropriate to the use of X-ray machines, except for the use of mammography machines. Mammography facilities are regulated by both federal and state government.

The cross-walk follows:

PROPOSED		CURRENT
PART I – GENERAL PROVISIONS		PART I - DEFINITIONS
12 VAC 5-481-10	Definitions	12 VAC 5-480-10

Remarks: All definitions included in the individual Parts of the current regulations were moved to a combined Part, designated as Part I- Definitions. Some of the definitions were removed and are incorporated by reference the federal definitions along with the appropriate federal regulation in the appropriate section in the proposed regulation.

		PART II–GENERAL PROVISIONS

Remarks: All current sections in this Part are identical in the proposed regulations, except where noted. The new sections address enforcement issues that other states have experienced including Virginia.

12 VAC 5-481-20	Scope	12 VAC 5-480-70
12 VAC 5-481-30	Authority for Regulations	12 VAC 5-480-20
12 VAC 5-481-40	Administration of Regulations	12 VAC 5-480-30
12 VAC 5-481-50	Application of Regulations	12 VAC 5-480-40
12 VAC 5-481-60	Application of Administrative Process Act	12 VAC 5-480-50

Remarks: Updated on advice of AG's Office

12 VAC 5-481-70	Severability	12 VAC 5-480-60
12 VAC 5-481-80	Reserved	12 VAC 5-480-70

Remarks: The scope was moved to the beginning of this part after the definitions.

12 VAC 5-481-90	Exemptions from regulatory Requirements	12 VAC 5-480-80
12 VAC 5-481-100	Records	12 VAC 5-480-90
12 VAC 5-481-110	Inspections and enforcement	12 VAC 5-480-100

Remarks: Updated on advice of AG's Office

12 VAC 5-481-120	Emergency regulations	12 VAC 5-480-110

Remarks: Updated on advice of AG's Office

12 VAC 5-481-130	Impounding	12 VAC 5-480-120
12 VAC 5-481-140	Prohibited uses	12 VAC 5-480-130

Remarks: This section expands the prohibition of X-ray machine operators in healing arts to other than those who are licensed by one of the boards in the Department of Health Professions and is within the scope of their license.

12 VAC 5-481-150	Communications	12 VAC 5-480-140
12 VAC 5-481-160	Effective date	12 VAC 5-480-150

Remarks: Updated on advice of AG's Office

12 VAC 5-481-170	Removal of notices posted by agency prohibited	12 VAC 5-480-160
12 VAC 5-481-180	Tests	New

Remarks: Defines the scope of regulatory inspections or tests of equipment

12 VAC 5-481-190	Additional regulatory requirements	New

Remarks :Informs regulated community that new regulations or if necessary orders issued to impose additional requirements to protect public health and safety.

12 VAC 5-481-200	Violations	12 VAC 5-480-100

Remarks: Inserted on advice of AG's Office

12 VAC 5-481-210	Types of Hearings	12 VAC 5-480-120

Remarks: Inserted on advice of AG's Office

12 VAC 5-481-220	Hearing as a matter of right.	New

Remarks: Inserted on advice of AG's Office

12 VAC 5-481-230	Interpretations	New

Remarks: Inserted on advice of AG's Office

12 VAC 5-481-240 Units of exposure & dose New
Remarks: This section recognizes international units used in radiation protection.

12 VAC 5-481-250 Units of activity New
Remarks: This section recognizes international units used in radiation protection.

PART II - REGISTRATION OF RADIATION PART III - MACHINE FACILITIES AND SERVICES

Remarks: Current sections are nearly identical. There was some substitution of "agency" for "State Health Commissioner" in the proposed regulations.

12 VAC 5-481-260 Purpose and scope 12 VAC 5-480-170

12 VAC 5-481-270 Exemptions 12 VAC 5-480-180

12 VAC 5-481-280 Shielding plan review New
Remarks: The contents in this section appear in the current regulation as an appendix instead of the text as originally intended.

12 VAC 5-481-290 Registration of radiation machine facilities 12 VAC 5-480-190

12 VAC 5-481-300 Issuance of registration certificate and approval not implied 12 VAC 5-480-210
Remarks: Approval not implied section was Reserved in current regulations 12 VAC 5-480-250
This section was inadvertently deleted from previous versions of the regulations. The source is the SSRs. Also combined this section with the Issuance of the registration certificate.

12 VAC 5-481-310 Renewal of registration 12 VAC 5-480-230

12 VAC 5-481-320 Expiration of registration certificate 12 VAC 5-480-220

12 VAC 5-481-330 Report of changes 12 VAC 5-480-240

Remarks: Current regulations- Reserved. 12 VAC 5-480-250

12 VAC 5-481-340 Private Inspector Qualifications New
Remarks: This section is an Appendix in current regulations, and has been expanded to include federal criteria for those providing services to mammography facilities to meet the federal Mammography Quality Standards Act.

12 VAC 5-481-350 Assembler and/or transfer obligation 12 VAC 5-480-260

12 VAC 5-481-360	Reciprocal recognition of out-of-state radiation machines	12 VAC 5-480-270
12 VAC 5-481-370	Certification of X-ray systems	12 VAC 5-480-280

PART III - LICENSING OF RADIOACTIVE MATERIAL PART IV

Remarks: Proposed regulation is identical to current regulations. Those sections relating to the use of radioactive materials in the healing arts were transferred to a separate Part in the proposed regulations- Part VII - USE OF RADIONUCLIDES IN THE HEALING ARTS

Most of the sections in the proposed regulations incorporate by reference the appropriate or comparable federal regulations promulgated by the U.S. Nuclear regulatory Commission (NRC). The NRC made several changes since the current regulations and have been brought up to date.

Purpose and Scope

12 VAC 5-481-380	Purpose and scope	12 VAC 5-480-290
Remarks: Current regulations this section was reserved		12 VAC 5-480-300

Exemptions from the Regulatory Requirements

12 VAC 5-481-390	Source material	12 VAC 5-480-310
12 VAC 5-481-400	Radioactive material other than source material	12 VAC 5-480-320
Remarks: Current regulations these sections were reserved		12 VAC 5-480-330 thru 470

Licenses

12 VAC 5-481-410	Types of licenses	12 VAC 5-480-480
12 VAC 5-481-420	General licenses - source material	12 VAC 5-480-490
12 VAC 5-481-430	General licenses – radioactive material other than source material	12 VAC 5-480-500

Specific Licenses

12 VAC 5-481-440	Filing application for specific licenses	12 VAC 5-480-520
12 VAC 5-481-450	General requirements for the issuance of specific licenses	12 VAC 5-480-530

12 VAC 5-481-460	Special requirements for issuance of certain specific licenses for radioactive material	12 VAC 5-480-540
12 VAC 5-481-470	Special requirements for specific licenses of broad scope	12 VAC 5-480-550
12 VAC 5-481-480	Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material	12 VAC 5-480-560
Remarks: Current Regulations this section was reserved		12 VAC 5-480-570
12 VAC 5-481-490	Issuance of specific licenses	12 VAC 5-480-580
12 VAC 5-481-500	Specific terms and conditions of licenses	12 VAC 5-480-590
12 VAC 5-481-510	Expiration and termination of licenses	12 VAC 5-480-600
12 VAC 5-481-520	Renewal of licenses	12 VAC 5-480-610
12 VAC 5-481-530	Amendment of licenses at request of licensee	12 VAC 5-480-620
12 VAC 5-481-540	Agency action on applications to renew or amend	12 VAC 5-480-630
Licenses Held at the Time of the Effective Date of These Regulations		
12 VAC 5-481-550	Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these regulations	12 VAC 5-480-640
12 VAC 5-481-560	Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of these regulations	New

Remarks: This section is similar to the previous section; however, it covers the State regulated materials.

Transfer of Material

12 VAC 5-481-570	Transfer of material	12 VAC 5-480-680

Modification and Revocation of Licenses

12 VAC 5-481-580	Modification and revocation of licenses	12 VAC 5-480-780

Reciprocity

12 VAC 5-481-590	Reciprocal recognition of licenses	12 VAC 5-480-1180

Remarks: Appendices in current regulations are incorporated by reference the federal regulation.

PART IV - STANDARDS FOR PROTECTION AGAINST RADIATION	PART V

Remarks: This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Radiation Protection Standards (Title 10 Code of Federal Regulations [CFR] Part 20). The NRC promulgated major changes to 10 CFR 20 in 1992, and again in 2001. The standards were greatly expanded and became more restrictive compared to the current state regulation.

General Provisions

12 VAC 5-481-600	Purpose	12 VAC 5-480-1190
12 VAC 5-481-610	Scope	12 VAC 5-480-1190
		12 VAC 5-480-1200 thru 2180

Remarks: Current regulations these sections are reserved.

12 VAC 5-481-620	Implementation	New

Radiation Protection Programs

12 VAC 5-481-630	Radiation protection programs	New

Occupational Dose Limits	12 VAC 5-480-2190 through 12 VAC 5-480-2250

12 VAC 5-481-640	Occupational dose limits for adults	New
12 VAC 5-481-650	Compliance with requirements	New

for summation of external and internal doses		
12 VAC 5-481-660	Determination of external dose from airborne radioactive material	New
12 VAC 5-481-670	Determination of internal exposure	New
12 VAC 5-481-680	Determination of prior occupational dose	New
12 VAC 5-481-690	Planned special exposures	New
12 VAC 5-481-700	Occupational dose limits for minors	New
12 VAC 5-481-710	Dose to an embryo/fetus	New
Radiation Dose Limits for Individual Members of the Public		
12 VAC 5-481-720	Dose limits for individual members of the public	New
12 VAC 5-481-730	Compliance with dose limits for individual members of the public	New
Testing for Leakage or Contamination of Sealed Sources		
12 VAC 5-481-740	Testing for leakage or contamination of sealed sources	New
		12 VAC 5-480-2260 thru 3180

Remarks: These sections are reserved in current regulations.

Surveys and Monitoring		
12 VAC 5-481-750	General	12 VAC 5-480-3190
12 VAC 5-481-760	Conditions requiring individual monitoring of external and internal occupational dose	12 VAC 5-480-3200
12 VAC 5-481-770	Location of individual monitoring devices	12 VAC 5-480-3200
Control of Exposure from External Sources in Restricted Areas		
12 VAC 5-481-780	Control of access to	New

high radiation areas

12 VAC 5-481-790 Control of access to very high radiation areas — New

12 VAC 5-481-800 Control of access to very high radiation areas – irradiators — New

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

12 VAC 5-481-810 Use of process or other engineering controls — New

12 VAC 5-481-820 Use of other controls — New

12 VAC 5-481-830 Use of individual respiratory protection equipment — New

Security and Control of Licensed or Registered Sources of Radiation

12 VAC 5-481-840 Security and control of licensed or registered sources of radiation — New

Precautionary Procedures

12 VAC 5-481-850 Caution signs — 12 VAC 5-480-3210

12 VAC 5-481-860 Posting requirements — 12 VAC 5-480-3210

12 VAC 5-481-870 Exemptions to posting requirements — 12 VAC 5-480-3220

12 VAC 5-481-880 Labeling containers and radiation machines — 12 VAC 5-480-3210

12 VAC 5-481-890 Exemptions to labeling requirements — 12 VAC 5-480-3220

12 VAC 5-480-3230 thru 3240

Remarks: The content of these sections are covered in several of the new sections of the proposed regulation.

12 VAC 5-481-900 Procedures for receiving and opening packages — 12 VAC 5-480-3250

12 VAC 5-480-3260 thru 4180

Remarks: These sections are reserved in current the regulations.

Waste Disposal

12 VAC 5-481-910	General requirements	12 VAC 5-480-4190
12 VAC 5-481-920	Method for obtaining approval of proposed disposal procedures	12 VAC 5-480-4200
12 VAC 5-481-930	Disposal by release into sanitary sewerage	12 VAC 5-480-4210
		12 VAC 5-480-4220

Remarks: The contents were moved and greatly expanded to proposed PART XI - LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

12 VAC 5-481-940	Treatment or disposal by incineration	12 VAC 5-480-4230
12 VAC 5-481-950	Disposal of specific wastes	12 VAC 5-480-4240
		12 VAC 5-480-4250 thru 5180

Remarks: These sections were reserved in the current regulations.

12 VAC 5-481-960	Transfer for disposal and manifests	New
12 VAC 5-481-970	Compliance with environmental and health protection regulations	New

Records		12 VAC 5-480-5290 through 12 VAC 5-480-5360

Remarks: the current sections were expanded into several more sections in the proposed regulation.

12 VAC 5-481-980	General provisions	New
12 VAC 5-481-990	Records of radiation protection programs	New
12 VAC 5-481-1000	Records of surveys	New
12 VAC 5-481-1010	Records of tests for leakage or contamination of sealed sources	New
12 VAC 5-481-1020	Records of prior occupational dose	New

12 VAC 5-481-1030 Records of planned special exposures New

12 VAC 5-481-1040 Records of individual monitoring results New

12 VAC 5-481-1050 Records of dose to individual members of the public New

12 VAC 5-481-1060 Records of waste disposal New

12 VAC 5-481-1070 Records of testing entry control devices for very high radiation areas New

12 VAC 5-481-1080 Form of records New

Reports

12 VAC 5-481-1090 Reports of stolen, lost, or missing licensed or registered sources of radiation New

12 VAC 5-481-1100 Notification of incidents New

12 VAC 5-481-1110 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits New

12 VAC 5-481-1120 Reports of planned special exposures New

12 VAC 5-481-1130 Reports of individual monitoring New

12 VAC 5-481-1140 Notifications and reports to individuals New

12 VAC 5-481-1150 Reports of leaking or contaminated sealed sources New

Additional Requirements

12 VAC 5-481-1160 Vacating premises New

Appendices A and B

Remarks: Appendices in current regulations are incorporated by reference the federal regulations in 10 CFR 20 Appendix B Tables 1 and 2.

PART V - RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS PART VI

12 VAC 5-480-5370 through
12 VAC 5-480-8420

Remarks: This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) PART 34--LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS (Title 10 Code of Federal Regulations [CFR] Part 34). The NRC revised 10 CFR 34 in 1997. The proposed regulation expands this Part to address new industrial applications of radiation and radioactive materials which have a great potential to expose workers that may result in injury and death. Examples of such applications are high specific activity devices used for non destructive testing, and room sized cabinet X-ray machines used for various purposes. Both NRC and the states have identified significant enforcement issues regarding industrial radiographers and have required additional training and certification requirements.

General Requirements

12 VAC 5-480-5370

Note: This section in current regulations are the definitions, which are moved to the first section in proposed regulations.

12 VAC 5-481-1170 Purpose	12 VAC 5-480-5380
12 VAC 5-481-1180 Scope	12 VAC 5-480-5390
	12 VAC 5-480-5400 through 12 VAC- 5-480-6350

Note: These sections in current regulation are reserved.

12 VAC 5-481-1190 Exemptions	New
12 VAC 5-481-1200 Licensing and registration requirements for industrial radiography operations	New
12 VAC 5-481-1210 Performance requirements for industrial radiography equipment	New
12 VAC 5-481-1220 Limits on external radiation levels from storage containers and source changers	New
12 VAC 5-481-1230 Locking of sources of radiation, storage containers and source changers	12 VAC 5-480-6390
12 VAC 5-481-1240 Radiation survey instruments	12 VAC 5-480-6400
12 VAC 5-481-1250 Leak testing and replacement of sealed sources	12 VAC 5-480-6410

12 VAC 5-481-1260	Quarterly inventory	12 VAC 5-480-6420
12 VAC 5-481-1270	Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments	12 VAC 5-480-6440 & 12 VAC 5-480-6450
12 VAC 5-481-1280	Permanent radiographic installations	New
12 VAC 5-481-1290	Labeling, storage, and transportation	New

Radiation Safety Requirements

12 VAC 5-481-1300	Conducting industrial radiographic operations	New
12 VAC 5-481-1310	Radiation safety officer	New
12 VAC 5-481-1320	Training	12 VAC 5-480-7370
12 VAC 5-481-1330	Operating and emergency procedures	12 VAC 5-480-7380
12 VAC 5-481-1340	Supervision of radiographer's assistants	New
12 VAC 5-481-1350	Personnel monitoring	12 VAC 5-480-7390
		12 VAC 5-480-7340 thru 8360

Note: These sections in the current regulations are reserved.

12 VAC 5-481-1360	Radiation surveys	12 VAC 5-480-8390
12 VAC 5-481-1370	Surveillance	12 VAC 5-480-8370
12 VAC 5-481-1380	Posting	12 VAC 5-480-8380

Recordkeeping Requirements

12 VAC 5-480-8390 through 12 VAC 5-480-8420

Note: These sections in the current regulation are expanded in the proposed regulations into many more sections under the article entitled Record Keeping Requirements.

12 VAC 5-481-1390	Records for industrial radiography	New
12 VAC 5-481-1400	Records of receipt and transfer of sources of radiation	New
12 VAC 5-481-1410	Records of radiation survey instruments	New

12 VAC 5-481-1420 Records of leak testing of sealed sources and devices containing DU — New

12 VAC 5-481-1430 Records of quarterly inventory — New

12 VAC 5-481-1440 Utilization logs — New

12 VAC 5-481-1450 Records of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments — New

12 VAC 5-481-1460 Records of alarm system and entrance control checks at permanent radiographic installations — New

12 VAC 5-481-1470 Records of training and certification — New

12 VAC 5-481-1480 Copies of operating and emergency procedures — New

12 VAC 5-481-1490 Records of personnel monitoring — New

12 VAC 5-481-1500 Records of radiation surveys — New

12 VAC 5-481-1510 Form of records — New

12 VAC 5-481-1520 Location of documents and records — New

Notifications

12 VAC 5-481-1530 Notifications — New

Radiographer Certification

12 VAC 5-481-1540 Application and examinations — New

Remarks: There is a fee of $145 to recover the cost of reviewing application and cost of the examination materials. The American Society for Nondestructive Testing, Inc fee for the test materials is $145. Staff does not expect demand for radiographer certification until Virginia becomes an NRC Agreement State.

12 VAC 5-481-1550 Certification identification (ID) card — New

12 VAC 5-481-1560 Reciprocity — New

12 VAC 5-481-1570 Specific requirements — New

for radiographic personnel performing industrial radiography

PART VI - USE OF DIAGNOSTIC X-RAYS IN THE HEALING ARTS — PART VII

Remarks: In general the sections relating to radiation therapy machines were moved to a new PART XV THERAPEUTIC RADIATION MACHINES. The proposed regulation adopts the U.S. Food and Drug Administration's (FDA) machine performance standards for fluoroscopy machines, in particular the limits on radiation output exposure rates. The proposed regulation adopts a new section for mammography machines, which is identical to the federal requirements under the Mammography Quality Standards Act of 1992.
The proposed regulation includes text that appears in the current regulations as an appendix. The material includes radiation exposure limits to patients. There are new requirements that address film processing to ensure a facility produces radiographic images of diagnostic quality without using excessive radiation exposures that exceed nationally recognized standards.
Since the promulgation of the current regulation, non invasive test equipment are commonly available that can test for other machine parameters, such as kVp, and light field luminance. These important machines parameters are now practicable to collect. Also standard phantoms to simulate human anatomy have become available and are in common use to evaluate image resolution. The proposed regulation now includes standards for these machine parameters and image quality.

The current regulation has a section dedicated to veterinary X-ray equipment that was eliminated. The veterinary use equipment is addressed in the proposed regulation in the section that addresses general requirements, with provisions for veterinary machines where appropriate.

12 VAC 5-480-8430

Note: This section in current regulations contains the definitions, which are moved to the first section in proposed regulations.

12 VAC 5-481-1580 Purpose and scope	12 VAC 5-480-8440
12 VAC 5-481-1590 General and administrative requirements	12 VAC 5-480-8450
12 VAC 5-481-1600 General requirements for all diagnostic X-ray systems	12 VAC 5-480-8460
12 VAC 5-481-1610 Fluoroscopic X-ray systems	12 VAC 5-480-8470
12 VAC 5-481-1620 Radiographic systems other than fluoroscopic, dental intra-oral, or Computed tomography X-ray systems	12 VAC 5-480-8480
12 VAC 5-481-1630 Intra-oral dental radiographic systems	12 VAC 5-480-8490

12 VAC 5-480-8500

Note: This section in the current regulation related to therapeutic systems with energy less than 1 MeV was moved to a new Part, PART XV THERAPEUTIC RADIATION MACHINES.

12 VAC 5-480-8510

Note: This section in the current regulations related to therapeutic systems with energy of 1 MeV or greater was moved to a new Part, PART XV THERAPEUTIC RADIATION MACHINES.

12 VAC 5-480-8520

Note: This section in the current regulations related to veterinary X-ray equipment that was eliminated, and requirements are specified in other sections of the proposed regulation.

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12 VAC 5-481-1640 Computed tomography X-ray systems 12 VAC 5-480-8530

12 VAC 5-481-1650 Mammography New

Note: The new section in the proposed regulation includes provisions identical to federal requirements for the implementation of the Mammography Quality Assurance Act of 1994 as amended.

Appendices

Note: In the current regulations, the Appendices in this part were included in several sections in the proposed regulations to make the requirements enforceable. The Appendices are related to shielding requirements for plan reviews, Operator's booth design, information the agency requires for health screenings, and criteria to be designated as a Private Inspector.

PART VII - USE OF RADIONUCLIDES IN THE HEALING ARTS

PART VIII

12 VAC 5-480-8540 through 12 VAC 5-480-8570

Remarks: The current regulation only addressed sealed sources in this Part. The proposed regulation expanded this Part to include all radioactive materials used in medicine. As previously noted the Part that addressed radioactive materials licensing in the current regulation included sections that were specific to the use in medicine and are now combined in this Part in the proposed regulation.

This Part is expanded to include new training requirements, defined radiation protection program by the licensees, also certain licensees are required to have a quality assurance program. All of these additional requirements are based on NRC's regulations (Title 10 Code of Federal Regulations [CFR] Parts 30, 31, 32, 33, and 35). These federal regulations have been revised several times since the promulgation of the current state regulation.

12 VAC 5-480-8540

Note: This section in current regulations contains the definitions, which are moved to the first section in proposed regulations.

Purpose and Scope

12 VAC 5-481-1660	Purpose and scope	12 VAC 5-480-8550

General Regulatory Requirements

12 VAC 5-481-1670	General requirements	New
12 VAC 5-481-1680	Licensing and Exemptions	New
12 VAC 5-481-1690	Notifications	New

General Administrative Requirements

12 VAC 5-481-1700	Authority and responsibilities for the radiation protection programs and changes	New
12 VAC 5-481-1710	Supervision	New
12 VAC 5-481-1720	Written Directives	New
12 VAC 5-481-1730	Procedures for administrations requiring a written directive	New
12 VAC 5-481-1740	Suppliers for sealed sources or devices for medical use	New
12 VAC 5-481-1750	Training for Radiation Safety Officer	New
12 VAC 5-481-1760	Training for an authorized medical physicist	New
12 VAC 5-481-1770	Training for an authorized nuclear pharmacist	New
12 VAC 5-481-1780	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and pharmacist	New
12 VAC 5-481-1790	Recentness of training	New

General Technical Requirements

12 VAC 5-481-1800	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material	New
12 VAC 5-481-1810	Calibration of survey instruments	New

12 VAC 5-481-1820 Determination of dosages of unsealed byproduct material for medical use	New
12 VAC 5-481-1830 Authorization for calibration, transmission, and reference sources	New
12 VAC 5-481-1840 Requirements for possession of sealed sources and brachytherapy sources	New
12 VAC 5-481-1850 Labeling of vials and syringes	New
12 VAC 5-481-1860 Surveys of ambient radiation exposure rate	New
12 VAC 5-481-1870 Release of individuals containing unsealed byproduct material or implants containing byproduct material	New
12 VAC 5-481-1880 Provision of mobile medical service	New
12 VAC 5-481-1890 Decay-in-storage	New
Unsealed Byproduct Materials- Written Directive Not Required	
12 VAC 5-481-1900 Use of unsealed byproduct material for uptake, dilution, and excretion studies	New
12 VAC 5-481-1910 Training for uptake, dilution, and, and excretion studies	New
12 VAC 5-481-1920 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required	New
12 VAC 5-481-1930 Permissible molybdenum-99 concentration	New
12 VAC 5-481-1940 Training for imaging and localization studies	New
Unsealed Byproduct Material- Written Directive Required	
12 VAC 5-481-1950 Use of unsealed by product material for which a written directive is required	New
12 VAC 5-481-1960 Safety instruction	New
12 VAC 5-481-1970 Safety precautions	New

12 VAC 5-481-1980 Training for use of unsealed byproduct material for which a written directive is required — New

12 VAC 5-481-1990 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) — New

12 VAC 5-481-2000 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) — New

Manual Brachytherapy

12 VAC 5-481-2010 Manual Brachytherapy — New

Sealed Sources for Diagnosis

12 VAC 5-481-2020 Use of sealed sources for diagnosis — New

12 VAC 5-481-2030 Training for use of sealed sources for diagnosis — New

Photon Emitting remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units

12 VAC 5-481-2040 Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units — New

Training and Experience requirements

12 VAC 5-481-2050 Training and Experience Requirements — New

Other Medical Uses of Byproduct Material or Radiation From Byproduct material

12 VAC 5-481-2060 Other medical uses of byproduct material or radiation from byproduct materials — New

Records

12 VAC 5-481-2070 Records — New

Reports

12 VAC 5-481-2080 Reports — New

PART VIII -Radiation Safety Requirements for analytical X-ray Equipment — PART IX

Remarks: The sections in this Part of the proposed regulation are identical to the current regulation.

12 VAC 5-480-8580

Note: This section in the current regulations are the definitions, which are moved to the first section in proposed regulations.

12 VAC 5-481-2090	Purpose and scope	12 VAC 5-480-8590
12 VAC 5-481-2100	Equipment requirements	12 VAC 5-480-8600
New		
12 VAC 5-481-2110	Area requirements	12 VAC 5-480-8610
12 VAC 5-481-2120	Operating requirements	12 VAC 5-480-8620
12 VAC 5-481-2130	Personnel requirements	12 VAC 5-480-8630

Part IX- Radiation Safety requirements for particle accelerators — Part X

Purpose and scope

12 VAC 5-481-2140	Purpose and scope	12 VAC 5-480-8640

Registration Procedures

12 VAC 5-481-2150	Registration procedures	12 VAC 5-480-8650
12 VAC 5-481-2160	General requirements for the issuance of a registration for particle accelerators	12 VAC 5-480-8660
12 VAC 5-481-2170	Human use of particle accelerators	12 VAC 5-480-8670

Radiation Safety Requirements for the Use of Particle Accelerators

12 VAC 5-480-8680

Note: In current regulation this section is reserved.

12 VAC 5-481-2180	Limitations	12 VAC 5-480-8690

12 VAC 5-481-2190	Shielding and safety design requirements	12 VAC 5-480-8700
12 VAC 5-481-2200	Particle accelerator controls and interlock systems	12 VAC 5-480-8710
12 VAC 5-481-2210	Warning devices	12 VAC 5-480-8720
12 VAC 5-481-2220	Operating procedures	12 VAC 5-480-8730
12 VAC 5-481-2230	Radiation monitoring requirements	12 VAC 5-480-8740
12 VAC 5-481-2240	Ventilation systems	12 VAC 5-480-8750

PART X - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS — PART XI

Remarks: The sections in this Part of the proposed regulation are identical to the current regulation. This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Title 10 Code of Federal Regulations (CFR) Part 19.

12 VAC 5-481-2250	Purpose and Scope	12 VAC 5-480-8760
12 VAC 5-481-2260	Posting of notices to workers	12 VAC 5-480-8860
12 VAC 5-481-2270	Instructions to workers	12 VAC 5-480-8870
12 VAC 5-481-2280	Notifications and reports to individuals	12 VAC 5-480-8880
12 VAC 5-481-2290	Presence of representatives of licensees or registrants and worker during inspection	12 VAC 5-480-8890
12 VAC 5-481-2300	Consultation with workers during inspections	12 VAC 5-480-8900
12 VAC 5-481-2310	Requests by workers for inspections	12 VAC 5-480-8910
12 VAC 5-481-2320	Inspections not warranted; informal review	12 VAC 5-480-8920

PART XI - LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE — NEW

12 VAC 5-480-4220

Remarks: Although the Code of Virginia § 32.1-230 authorizes the agency with the Governor's approval to license and operate a low level radioactive materials waste repository, it is unlikely

that this will occur any time soon. However, the Commonwealth is a member of the South East Low Level Radioactive Waste Compact and must be prepared to take its turn to host a site. If the Governor chooses to exercise this authority the regulations will be in place to implement the licensing process. The basis for these sections are SSRs and in turn are primarily excerpts from NRC's 10 CFR 61, PART 61--LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

Purpose and Scope

12 VAC 5-481-2330 Purpose and scope

General Regulatory Provisions

12 VAC 5-481-2340 License required
12 VAC 5-481-2350 Content of application
12 VAC 5-481-2360 General information
12 VAC 5-481-2370 Specific technical information
12 VAC 5-481-2380 Technical analyses
12 VAC 5-481-2390 Institutional information
12 VAC 5-481-2400 Financial information
12 VAC 5-481-2410 Requirements for issuance of a license
12 VAC 5-481-2420 Conditions of licenses
12 VAC 5-481-2430 Application for renewal or closure
12 VAC 5-481-2440 Contents of application for site closure and stabilization
12 VAC 5-481-2450 Post-closure observation and maintenance
12 VAC 5-481-2460 Transfer of license
12 VAC 5-481-2470 Termination of license

General Performance Objectives

12 VAC 5-481-2480 General requirement
12 VAC 5-481-2490 Protection of the general population from releases of radioactivity
12 VAC 5-481-2500 Protection of individuals from inadvertent intrusion
12 VAC 5-481-2510 Protection of individuals during operations
12 VAC 5-481-2520 Stability of the disposal site after closure

Technical Requirements for Land Disposal Facilities

12 VAC 5-481-2530 Disposal site suitability requirements for land disposal
12 VAC 5-481-2540 Disposal site design for land disposal
12 VAC 5-481-2550 Land disposal facility operation and disposal site closure
12 VAC 5-481-2560 Environmental monitoring
12 VAC 5-481-2570 Alternative requirements for design and operations
12 VAC 5-481-2580 Institutional requirements
12 VAC 5-481-2590 Alternative requirements for waste classification and characteristics

Financial Assurances

12 VAC 5-481-2600 Applicant qualifications and assurances
12 VAC 5-481-2610 Funding for disposal site closure and stabilization
12 VAC 5-481-2620 Financial assurances for institutional controls

Records, Reports, Tests, and Inspections

12 VAC 5-481-2630 Maintenance of records, reports, and transfers
12 VAC 5-481-2640 Tests on land disposal facilities
12 VAC 5-481-2650 Agency inspections of land disposal facilities

PART XII – LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS NEW

This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS (Title 10 Code of Federal Regulations [CFR] Part 36). Large irradiators were not commonly used when the current regulation was promulgated in 1988. The NRC promulgated a new Part 36 in Title 10 CFR in 1993. The quantities of radioactive material involved can cause serious injury and death if used improperly, and the security of these sources are of interest to home land security.

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Purpose and scope
12 VAC 5-481-2660 Purpose and scope

Specific Licensing Requirements
12 VAC 5-481-2670 Application for a specific license
12 VAC 5-481-2680 Specific licenses for irradiators
12 VAC 5-481-2690 Start of construction
12 VAC 5-481-2700 Applications for exemptions
12 VAC 5-481-2710 Request for written statements

Design and Performance Requirements for Irradiators
12 VAC 5-481-2720 Performance criteria for sealed sources
12 VAC 5-481-2730 Access control
12 VAC 5-481-2740 Shielding
12 VAC 5-481-2750 Fire protection
12 VAC 5-481-2760 Radiation monitors
12 VAC 5-481-2770 Control of source movement
12 VAC 5-481-2780 Irradiator pools
12 VAC 5-481-2790 Source rack protection
12 VAC 5-481-2800 Power failures
12 VAC 5-481-2810 Design requirements
12 VAC 5-481-2820 Construction monitoring and acceptance testing

Operation of Irradiators
12 VAC 5-481-2830 Training
12 VAC 5-481-2840 Operating and emergency procedures
12 VAC 5-481-2850 Personnel monitoring
12 VAC 5-481-2860 Radiation surveys
12 VAC 5-481-2870 Detection of leaking sources.
12 VAC 5-481-2880 Inspection and maintenance
12 VAC 5-481-2890 Pool water purity
12 VAC 5-481-2900 Attendance during operation
12 VAC 5-481-2910 Entering and leaving the radiation room
12 VAC 5-481-2920 Irradiation of explosive or flammable materials

Records
12 VAC 5-481-2930 Records and retention periods
12 VAC 5-481-2940 Reports

PART XIII - TRANSPORTATION OF RADIOACTIVE MATERIAL NEW

Remarks: This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Packaging and Transportation of Radioactive Materials Regulation (Title 10 Code of Federal Regulations [CFR] Part 71). The NRC revised this regulation in 1995. The proposed regulation also requires compliance with U.S. Department of Transportation's regulations for the transportation of radioactive materials Title 49 CFR 172. The intent of these requirements are to hold the agency's licensees accountable for presenting radioactive materials in the proper package and appropriate shipping papers to commercial carriers.

Purpose and Scope

12 VAC 5-481-2950 Purpose and scope

General Regulatory Provisions

12 VAC 5-481-2960 Requirement for license
12 VAC 5-481-2970 Exemptions
12 VAC 5-481-2980 Transportation of licensed material

General Licenses

12 VAC 5-481-2990 General licenses for carriers
12 VAC 5-481-3000 General license: Nuclear Regulatory Commission - approved packages
12 VAC 5-481-3010 General license: previously approved packages
12 VAC 5-481-3020 General license: U. S. Dept of Transportation specification container
12 VAC 5-481-3030 General license: use of foreign approved package
12 VAC 5-481-3040 General license: fissile material, limited quantity per package
12 VAC 5-481-3050 General license: fissile material, limited moderator per package

Operating Controls and Procedures

12 VAC 5-481-3060 Assumptions as to unknown properties of fissile material
12 VAC 5-481-3070 Preliminary determinations
12 VAC 5-481-3080 Routine determinations
12 VAC 5-481-3090 Air transport of plutonium
12 VAC 5-481-3100 Shipment records
12 VAC 5-481-3110 Reports
12 VAC 5-481-3120 Advance notification of transport of nuclear waste

Quality Assurance

12 VAC 5-481-3130 Quality assurance requirements

PART XIV - RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES NEW

This Part is essentially the U.S. Nuclear Regulatory Commission's (NRC) Title 10 Code of Federal Regulations [CFR] Part 39. The NRC promulgated a new Part 39 in Title 10 CFR in 1987 when the current state regulation was in Administrative Act Process. Agency staff did not become aware of this federal regulation and the extensive well logging activities used in the mining and oil/gas exploration industry in Southwest Virginia until after the public comment period.

Purpose and Scope

12 VAC 5-481-3140 Purpose
12 VAC 5-481-3150 Scope

Prohibition

12 VAC 5-481-3160 Prohibition

Equipment Control

12 VAC 5-481-3170 Limits on levels of radiation
12 VAC 5-481-3180 Storage precautions
12 VAC 5-481-3190 Transport precautions
12 VAC 5-481-3200 Radiation survey instruments
12 VAC 5-481-3210 Leak testing of sealed sources
12 VAC 5-481-3220 Quarterly inventory
12 VAC 5-481-3230 Utilization records
12 VAC 5-481-3240 Design, performance, and certification criteria for sealed sources used in downhole operations

12 VAC 5-481-3250 Labeling
12 VAC 5-481-3260 Inspection and maintenance

Requirements for Personal Safety

12 VAC 5-481-3270 Training requirements
12 VAC 5-481-3280 Operating and emergency procedures
12 VAC 5-481-3290 Personnel monitoring

Precautionary Procedures in Logging and Subsurface Tracer Studies

12 VAC 5-481-3300 Security
12 VAC 5-481-3310 Handling tools
12 VAC 5-481-3320 Subsurface tracer studies
12 VAC 5-481-3330 Particle accelerators

Radiation Surveys and Records

12 VAC 5-481-3340 Radiation surveys
12 VAC 5-481-3350 Documents and records required at field stations
12 VAC 5-481-3360 Documents and records required at temporary jobsites

Notification

12 VAC 5-481-3370 Notification of incidents, abandonment, and lost sources

Part XV NEW

THERAPEUTIC RADIATION MACHINES

Remarks: Sections 3420 and 3430 of the proposed regulation are identical to the current regulation; however, these two sections were in PART VII-. USE OF DIAGNOSTIC X-RAYS IN THE HEALING ARTS. The use of therapeutic radiation machines have expanded considerably during the past decade and several safety and enforcement issues have been identified by the states, and the U.S, Food and Drug Administration. The new requirements include evaluation of physician credentials, medical physicists training and qualifications, calibration of test equipment, and a quality management program.

12 VAC 5-481-3380 Purpose and scope

12 VAC 5-481-3390 General administrative requirements for facilities using therapeutic radiation machines

12 VAC 5-481-3400 General technical requirements for facilities using therapeutic radiation machines

12 VAC 5-481-3410 Quality management program

12 VAC 5-481-3420 Therapeutic radiation machines of less than 500 kV 12 VAC 5-480-8500

12 VAC 5-481-3430 Therapeutic radiation machines – photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above) 12 VAC 5-480-8510

12 VAC 5-481-3440 Calibration of survey instruments

12 VAC 5-481-3450 Shielding and safety design requirements

Part XVI NEW
REGULATION AND LICENSING OF TECHNOLOGICALLY ENHANCED NATURALLY OCCURRING RADIOACTIVE MATERIALS (TENORM)

Remarks: This is a new part that addresses the issue of handling of diffuse natural-occurring radioactive material that has become concentrated in certain commodities, such as scrap metal, and municipal waste shipments. The states have attempted to develop nationally recognized standards to prevent economic loss, as well as protect the public health and safety. The basis for these sections are from the SSRs.

12 VAC 5-481-3460 Purpose
12 VAC 5-481-3470 Scope
12 VAC 5-481-3480 Exemptions
12 VAC 5-481-3490 Standards for Radiation Protection for TENORM
12 VAC 5-481-3500 Protection of Workers During Operations
12 VAC 5-481-3510 Release for Unrestricted Use
12 VAC 5-481-3520 Disposal and Transfer of Waste for Disposal
12 VAC 5-481-3530 General License
12 VAC 5-481-3540 Specific Licenses
12 VAC 5-481-3550 Filing Application for Specific Licenses
Note: This section includes an application fee of $50.00 to recover the adminstrative cost of issuig a licnese. Staff does not expect a significant number of business or individuals to apply for a specific license. Disposal of diffuse radioactive materials above a certain level require disposal to a low level radioactive waste repository and requires the waste facility may require the shipper to obtain a state license be fore the material is accepted at the facility.
12 VAC 5-481-3560 Requirements for the Issuance of Specific Licenses
12 VAC 5-481-3570 Safety Criteria for Products
12 VAC 5-481-3580 Table of Organ Doses
12 VAC 5-481-3590 Issuance of Specific Licenses
12 VAC 5-481-3600 Conditions of Specific Licenses Issued Under 12 VAC 5-481-3560

12 VAC 5-481-3610 Expiration and Termination of Specific Licenses
12 VAC 5-481-3620 Renewal of Specific Licenses
12 VAC 5-481-3630 Amendment of Specific Licenses at Request of Licensee
12 VAC 5-481-3640 Agency Action on Applications to Renew and Amend Specific Licenses
12 VAC 5-481-3650 Modification and Revocation of Specific Licenses
12 VAC 5-481-3660 Reciprocal Recognition of Specific Licenses
12 VAC 5-481-3670 Financial Surety Arrangements
12 VAC 5-481-3680 Effective Date

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 regulation 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.