VIRGISTER OF REGULATIONS

VOL. 32 ISS. 17

PUBLISHED EVERY OTHER WEEK BY THE VIRGINIA CODE COMMISSION

APRIL 18, 2016

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Virginia Code Commission

http://register.dls.virginia.gov

THE VIRGINIA REGISTER OF REGULATIONS (USPS 001-831) is published biweekly for \$246.00 per year by Matthew Bender & Company, Inc., 3 Lear Jet Lane, Suite 102, P.O. Box 1710, Latham, NY 12110. Periodical postage is paid at Albany, NY and at additional mailing offices. POSTMASTER: Send address changes to The Virginia Register of Regulations, 136 Carlin Road, Conklin, NY 13748-1531.

VIRGINIA REGISTER INFORMATION PAGE

THE VIRGINIA REGISTER OF REGULATIONS is an official state publication issued every other week throughout the year. Indexes are published quarterly, and are cumulative for the year. The *Virginia Register* has several functions. The new and amended sections of regulations, both as proposed and as finally adopted, are required by law to be published in the *Virginia Register*. In addition, the *Virginia Register* is a source of other information about state government, including petitions for rulemaking, emergency regulations, executive orders issued by the Governor, and notices of public hearings on regulations.

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

An agency wishing to adopt, amend, or repeal regulations must first publish in the *Virginia Register* a notice of intended regulatory action; a basis, purpose, substance and issues statement; an economic impact analysis prepared by the Department of Planning and Budget; the agency's response to the economic impact analysis; a summary; a notice giving the public an opportunity to comment on the proposal; and the text of the proposed regulation.

Following publication of the proposal in the Virginia Register, the promulgating agency receives public comments for a minimum of 60 days. The Governor reviews the proposed regulation to determine if it is necessary to protect the public health, safety and welfare, and if it is clearly written and easily understandable. If the Governor chooses to comment on the proposed regulation, his comments must be transmitted to the agency and the Registrar no later than 15 days following the completion of the 60-day public comment period. The Governor's comments, if any, will be published in the *Virginia Register*. Not less than 15 days following the completion of the agency may adopt the proposed regulation.

The Joint Commission on Administrative Rules (JCAR) or the appropriate standing committee of each house of the General Assembly may meet during the promulgation or final adoption process and file an objection with the Registrar and the promulgating agency. The objection will be published in the *Virginia Register*. Within 21 days after receipt by the agency of a legislative objection, the agency shall file a response with the Registrar, the objecting legislative body, and the Governor.

When final action is taken, the agency again publishes the text of the regulation as adopted, highlighting all changes made to the proposed regulation and explaining any substantial changes made since publication of the proposal. A 30-day final adoption period begins upon final publication in the *Virginia Register*.

The Governor may review the final regulation during this time and, if he objects, forward his objection to the Registrar and the agency. In addition to or in lieu of filing a formal objection, the Governor may suspend the effective date of a portion or all of a regulation until the end of the next regular General Assembly session by issuing a directive signed by a majority of the members of the appropriate legislative body and the Governor. The Governor's objection or suspension of the regulation, or both, will be published in the *Virginia Register*. If the Governor finds that changes made to the proposed regulation have substantial impact, he may require the agency to provide an additional 30-day public comment period on the changes. Notice of the additional public comment period required by the Governor will be published in the *Virginia Register*.

The agency shall suspend the regulatory process for 30 days when it receives requests from 25 or more individuals to solicit additional public comment, unless the agency determines that the changes have minor or inconsequential impact.

A regulation becomes effective at the conclusion of the 30-day final adoption period, or at any other later date specified by the promulgating agency, unless (i) a legislative objection has been filed, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 21-day objection period; (ii) the Governor exercises his authority to require the agency to provide for additional public comment, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the period for which the Governor has provided for additional public comment; (iii) the Governor and the General Assembly exercise their authority to suspend the effective date of a regulation until the end of the next regular legislative session; or (iv) the agency suspends the regulatory process, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 30-day public comment period and no earlier than 15 days from publication of the readopted action.

A regulatory action may be withdrawn by the promulgating agency at any time before the regulation becomes final.

FAST-TRACK RULEMAKING PROCESS

Section 2.2-4012.1 of the Code of Virginia provides an exemption from certain provisions of the Administrative Process Act for agency regulations deemed by the Governor to be noncontroversial. To use this process, Governor's concurrence is required and advance notice must be provided to certain legislative committees. Fast-track regulations will become effective on the date noted in the regulatory action if no objections to using the process are filed in accordance with § 2.2-4012.1.

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency, upon consultation with the Attorney General, and at the discretion of the Governor, may adopt emergency regulations that are necessitated by an emergency situation. An agency may also adopt an emergency regulation when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment. The emergency regulation becomes operative upon its adoption and filing with the Registrar of Regulations, unless a later date is specified. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under certain circumstances as provided for in § 2.2-4011 D. Emergency regulations are published as soon as possible in the Register. During the time the emergency status is in effect, the agency may proceed with the adoption of permanent regulations through the usual procedures. To begin promulgating the replacement regulation, the agency must (i) file the Notice of Intended Regulatory Action with the Registrar within 60 days of the effective date of the emergency regulation and (ii) file the proposed regulation with the Registrar within 180 days of the effective date of the emergency regulation. If the agency chooses not to adopt the regulations, the emergency status ends when the prescribed time limit expires.

STATEMENT

The foregoing constitutes a generalized statement of the procedures to be followed. For specific statutory language, it is suggested that Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2 of the Code of Virginia be examined carefully.

CITATION TO THE VIRGINIA REGISTER

The Virginia Register is cited by volume, issue, page number, and date. **29:5 VA.R. 1075-1192 November 5, 2012,** refers to Volume 29, Issue 5, pages 1075 through 1192 of the Virginia Register issued on November 5, 2012.

The Virginia Register of Regulations is published pursuant to Article 6 (§ 2.2-4031 et seq.) of Chapter 40 of Title 2.2 of the Code of Virginia.

Members of the Virginia Code Commission: John S. Edwards, Chair; James M. LeMunyon, Vice Chair; Gregory D. Habeeb; Ryan T. McDougle; Pamela S. Baskervill; Robert L. Calhoun; Carlos L. Hopkins; E.M. Miller, Jr.; Thomas M. Moncure, Jr.; Christopher R. Nolen; Timothy Oksman; Charles S. Sharp; Mark J. Vucci.

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PUBLICATION SCHEDULE AND DEADLINES

This schedule is available on the Register's Internet home page (http://register.dls.virginia.gov).

April 2016 through April 2017

Volume: Issue	Material Submitted By Noon*	Will Be Published On
32:17	March 30, 2016	April 18, 2016
32:18	April 13, 2016	May 2, 2016
32:19	April 27, 2016	May 16, 2016
32:20	May 11, 2016	May 30, 2016
32:21	May 25, 2016	June 13, 2016
32:22	June 8, 2016	June 27, 2016
32:23	June 22, 2016	July 11, 2016
32:24	July 6, 2016	July 25, 2016
32:25	July 20, 2016	August 8, 2016
32:26	August 3, 2016	August 22, 2016
33:1	August 17, 2016	September 5, 2016
33:2	August 31, 2016	September 19, 2016
33:3	September 14, 2016	October 3, 2016
33:4	September 28, 2016	October 17, 2016
33:5	October 12, 2016	October 31, 2016
33:6	October 26, 2016	November 14, 2016
33:7	November 9, 2016	November 28, 2016
33:8	November 22, 2016 (Tuesday)	December 12, 2016
33:9	December 7, 2016	December 26, 2016
33:10	December 19, 2016 (Monday)	January 9, 2017
33:11	January 4, 2017	January 23, 2017
33:12	January 18, 2017	February 6, 2017
33:13	February 1, 2017	February 20, 2017
33:14	February 15, 2017	March 6, 2017
33:15	March 1, 2017	March 20, 2017
33:16	March 15, 2017	April 3, 2017

*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Agency Decision

<u>Title of Regulation:</u> 12VAC5-550. Board of Health Regulations Governing Vital Records.

Statutory Authority: § 32.1-12 and 32.1-249 through 32.1-276 of the Code of Virginia.

<u>Name of Petitioner:</u> James Parrish, Equality Virginia; and Arli Christian, National Center for Transgender Equality.

<u>Nature of Petitioner's Request:</u> The petitioner requests that the vital records regulations be amended as follows: Virginia's birth certificate gender change regulation should not require surgery, based on a modern understanding of appropriate treatment for transgender people. Virginia's birth certificate gender change regulation should not require a court order, as courts are a costly and complicated barrier to many transgender people, and medical providers, rather than judges, have the professional expertise to request the appropriate gender marker on a birth certificate.

Agency Decision: Request denied.

<u>Statement of Reason for Decision:</u> The Board of Health does not have statutory authority to amend the Regulations Governing Vital Records (12VAC5-550) as requested by the petitioner. Section 32.1-269 E of the Code of Virginia states as follows: "Upon receipt of a certified copy of an order of a court of competent jurisdiction indicating that the sex of an individual has been changed by medical procedure and upon request of such person, the State Registrar shall amend such person's certificate of birth to show the change of sex and, if a certified copy of a court order changing the person's name is submitted, to show a new name." Given this current statutory requirement, legislation would need to be enacted authorizing the Board of Health to amend the regulations as requested.

<u>Agency Contact:</u> Janet Rainey, Director, Department of Health, Division of Vital Records, 2001 Maywill Street, Suite 268, Richmond, VA 23230, telephone (804) 662-5245, FAX (804) 662-6272, or email janet.rainey@vdh.virginia.gov.

VA.R. Doc. No. R16-07; Filed March 17, 2016, 3:41 p.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Agency Decision

<u>Title of Regulation:</u> 12VAC30-20. Administration of Medical Assistance Services.

Statutory Authority: § 32.1-325 of the Code of Virginia.

Name of Petitioner: Jeremiah J. Jewett, III.

<u>Nature of Petitioner's Request:</u> The petitioner requests that the formal appeals regulations be amended as follows: "The DMAS director shall issue the final agency case decision to the provider, with a copy to the hearing officer, within 60 days of receipt of the hearing officer's recommended decision."

Agency Decision: Request denied.

<u>Statement of Reason for Decision:</u> After considering the petition for rulemaking, the DMAS director, under the authority of § 32.1-324 of the Code of Virginia, determined that the requested change does not require regulatory action. DMAS will begin sending final agency decisions to the provider, with a copy to the hearing officer. The copy sent to the hearing officer will not be redacted.

Agency Contact: Emily McClellan, Regulatory Supervisor, Division of Policy and Research, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-4300, or email emily.mcclellan@dmas.virginia.gov.

VA.R. Doc. No. R16-14; Filed March 18, 2016, 1:27 p.m.

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NOTICES OF INTENDED REGULATORY ACTION

TITLE 13. HOUSING

BOARD OF HOUSING AND COMMUNITY DEVELOPMENT

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Housing and Community Development intends to consider amending **13VAC5-31, Virginia Amusement Device Regulations**. The purpose of the proposed action is to update the regulation to incorporate by reference the 2015 editions of the nationally recognized American Society for Testing and Materials (ASTM) standards. This action is exempt from the Administrative Process Act in accordance with subdivision A 2 of § 2.2-4006 of the Code of Virginia.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 36-98.3 of the Code of Virginia.

Public Comment Deadline: May 18, 2016.

<u>Agency Contact:</u> Elizabeth O. Rafferty, Policy and Legislative Director, Department of Housing and Community Development, Main Street Centre, 600 East Main Street, Suite 300, Richmond, VA 23219, telephone (804) 371-7011, FAX (804) 371-7090, TTY (804) 371-7089, or email elizabeth.rafferty@dhcd.virginia.gov.

VA.R. Doc. No. R16-4667; Filed March 25, 2016, 10:10 a.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Housing and Community Development intends to consider amending **13VAC5-51, Virginia Statewide Fire Prevention Code**. The purpose of the proposed action is to update the regulation to incorporate by reference the 2015 editions of the nationally recognized model building codes and standards produced by the International Code Council. This action is exempt from the Administrative Process Act in accordance with subdivision A 12 of § 2.2-4006 of the Code of Virginia.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 27-97 of the Code of Virginia.

Public Comment Deadline: May 18, 2016.

Agency Contact: Elizabeth O. Rafferty, Policy and Legislative Director, Department of Housing and Community Development, Main Street Centre, 600 East Main Street, Suite 300, Richmond, VA 23219, telephone (804) 371-7011, FAX (804) 371-7090, TTY (804) 371-7089, or email elizabeth.rafferty@dhcd.virginia.gov.

VA.R. Doc. No. R16-4665; Filed March 25, 2016, 9:54 a.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Housing and Community Development intends to consider amending **13VAC5-63, Virginia Uniform Statewide Building Code**. The purpose of the proposed action is to update the regulation to incorporate by reference the 2015 editions of the nationally recognized model building codes and standards produced by the International Code Council. This action is exempt from the Administrative Process Act in accordance with subdivision A 12 of § 2.2-4006 of the Code of Virginia.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 36-98 of the Code of Virginia.

Public Comment Deadline: May 18, 2016.

<u>Agency Contact:</u> Elizabeth O. Rafferty, Policy and Legislative Director, Department of Housing and Community Development, Main Street Centre, 600 East Main Street, Suite 300, Richmond, VA 23219, telephone (804) 371-7011, FAX (804) 371-7090, TTY (804) 371-7089, or email elizabeth.rafferty@dhcd.virginia.gov.

VA.R. Doc. No. R16-4664; Filed March 25, 2016, 9:49 a.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Housing and Community Development intends to consider amending **13VAC5-91, Virginia Industrialized Building Safety Regulations**. The purpose of the proposed action is to update the regulation to incorporate by reference the 2015 editions of the nationally recognized model building codes and standards produced by the International Code Council. This action is exempt from the Administrative Process Act in accordance with subdivision A 12 of § 2.2-4006 of the Code of Virginia.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 36-73 of the Code of Virginia.

Public Comment Deadline: May 18, 2016.

<u>Agency Contact:</u> Elizabeth O. Rafferty, Policy and Legislative Director, Department of Housing and Community Development, Main Street Centre, 600 East Main Street, Suite 300, Richmond, VA 23219, telephone (804) 371-7011, FAX (804) 371-7090, TTY (804) 371-7089, or email elizabeth.rafferty@dhcd.virginia.gov.

VA.R. Doc. No. R16-4666; Filed March 25, 2016, 10:01 a.m.

REGULATIONS

For information concerning the different types of regulations, see the Information Page.

Symbol Key

Roman type indicates existing text of regulations. Underscored language indicates proposed new text. Language that has been stricken indicates proposed text for deletion. Brackets are used in final regulations to indicate changes from the proposed regulation.

TITLE 2. AGRICULTURE

BOARD OF AGRICULTURE AND CONSUMER SERVICES

Fast-Track Regulation

<u>Title of Regulation:</u> 2VAC5-200. Rules and Regulations Pertaining to the Disposal of Entire Flocks of Dead Poultry (repealing 2VAC5-200-10 through 2VAC5-200-60).

Statutory Authority: § 3.2-6029 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: May 18, 2016.

Effective Date: June 2, 2016.

Agency Contact: Charles Broaddus, DVM, Program Manager, Veterinary Services, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-4560, FAX (804) 371-2380, TTY (800) 828-1120, or email charles.broaddus@vdacs.virginia.gov.

Basis: Section 3.2-109 of the Code of Virginia establishes the Board of Agriculture and Consumer Services as a policy board with the authority to adopt regulations in accordance with the provisions of Title 3.2 of the Code of Virginia. Section 3.2-6001 of the Code of Virginia authorizes the board and the State Veterinarian to protect livestock and poultry from contagious and infectious disease. Section 3.2-6002 of the Code of Virginia authorizes the board to adopt regulations to prevent the spread of and to eradicate contagious and infectious livestock and poultry diseases. Section 3.2-6029 of the Code of Virginia authorizes the board to adopt regulations concerning the specifications of disposal pits, incinerators, composting, and rendering and all other matters within the purview and scope of Article 2 (§ 3.2-6024 et seq.) of Chapter 60 of Title 3.2 of the Code of Virginia to carry out the provisions of that article.

<u>Purpose</u>: This regulation was adopted in the late 1980s and describes rules that pertain to a poultry producer with 500 or more poultry that needs to dispose of the entire flock of dead poultry. Recent discussion with the poultry industry indicate that the regulation has not been utilized or applied since it was adopted over 25 years ago and the agency cannot foresee a circumstance where the regulation would be needed in the future. The regulation includes outdated language, including references to Department of Environmental Quality regulations that are no longer valid or applicable. It is generally redundant with § 3.2-6026 of the Code of Virginia

titled "Disposal of dead poultry." This section of the Code of Virginia lists the same methods of disposal that are listed in this regulation.

Rationale for Using Fast-Track Rulemaking Process: The regulation has not been utilized or applied since it was adopted over 25 years ago, and the agency cannot foresee a circumstance where the regulation would be needed in the future. There is no longer a need for this regulation. The agency is not aware of any stakeholders who think that the regulation should be retained or that the regulation is of any benefit to them.

<u>Substance</u>: Due to an existing Code of Virginia section that makes the regulation redundant and the fact that the regulation has never been utilized or applied since its adoption, this regulation is no longer needed. Therefore, the agency proposes to repeal the regulation.

<u>Issues:</u> The primary advantage to the public in repealing the regulation is that there would no longer be an outdated regulation that specifies actions that are no longer taken. The agency and Commonwealth will no longer be in a position of having an outdated regulation that is not enforced. This action is part of good governance in that an outdated, unnecessary regulation will be eliminated. There are no disadvantages to the public or the Commonwealth associated with repealing the regulation.

<u>Small Business Impact Review Report of Findings:</u> This regulatory action serves as the report of the findings of the regulatory review pursuant to § 2.2-4007.1 of the Code of Virginia.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. As the result of a periodic review, the Board of Agriculture and Consumer Services (Board) proposes to repeal its Rules and Regulations Pertaining to the Disposal of Entire Flocks of Dead Poultry.

Result of Analysis. Benefits likely outweigh costs for all proposed regulatory changes.

Estimated Economic Impact. This regulation provides the framework for the transportation and disposal methods for entire flocks of dead poultry (i.e., pits, incinerators, landfills and rendering).¹ Board staff reports that the substance of this regulation is redundant with the Code of Virginia,² the regulation has not been utilized in the 25 years it has been in effect and that the Board does not foresee a circumstance where it would be utilized in the future.

Because of this, and because the regulation contains outdated references that would likely be confusing to readers, the Board now proposes its repeal. No entity is likely to incur costs on account of this action. To the extent that readers might have found the obsolete language contradictory to other regulations and confusing, this repeal will provide the benefit of clarification.

Businesses and Entities Affected. Poultry farmers who maintain flocks of poultry would in theory be affected by both this regulation and its repeal. Board staff does not have an estimate of how many such flocks are maintained in the Commonwealth.

Localities Particularly Affected. No locality will be particularly affected by this proposed regulatory repeal.

Projected Impact on Employment. This proposed regulatory repeal is unlikely to have any effect on employment in the Commonwealth.

Effects on the Use and Value of Private Property. This proposed regulatory repeal is unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs. This proposed regulatory repeal is unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects. Small businesses are unlikely to incur any costs on account of this proposed regulatory repeal.

Alternative Method that Minimizes Adverse Impact. Small businesses are unlikely to incur any costs on account of the proposed regulatory repeal.

Adverse Impacts:

Businesses. Businesses are unlikely to incur any costs on account of this proposed regulatory repeal.

Localities. Localities in the Commonwealth are unlikely to see any adverse impacts on account of this proposed regulatory repeal.

Other Entities. No other entities are likely to be adversely affected by this proposed repeal.

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Summary:
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The regulation has not been used or applied since it was adopted more than 25 years ago, and the agency cannot foresee a circumstance in which the regulation would be needed in the future. The regulation includes outdated language and is generally duplicative of § 3.2-6026 of the Code of Virginia, which lists the same methods of disposal as the regulation. Therefore, the regulation is repealed.

VA.R. Doc. No. R16-4573; Filed March 30, 2016, 10:19 a.m.



TITLE 4. CONSERVATION AND NATURAL RESOURCES

MARINE RESOURCES COMMISSION

Forms

<u>REGISTRAR'S NOTICE</u>: A form used in administering the following regulation has been filed by the Marine Resources Commission. The form is not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of the form to access it. The form is also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

<u>Title of Regulation:</u> 4VAC20-395. General Permit for Emergency Situations and Water Quality Improvement Projects.

<u>Agency Contact:</u> Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248, or email jennifer.farmer@mrc.virginia.gov.

FORMS (4VAC20-395)

Local, State, Federal Joint Permit Application, NAO FM 1065/VMRC 30 300 (rev. 4/93).

<u>Tidewater Joint Permit Application (JPA) for Projects</u> <u>Involving Tidal Waters, Tidal Wetlands, and/or Dunes and</u> <u>Beaches in Virginia (rev. 3/2014)</u>

VA.R. Doc. No. R16-4659; Filed March 22, 2016, 8:38 a.m.

¹This regulation does not have a definition for rendering but instead refers to the federal regulation (9 CFR 82.1) that does.

 $^{^2\$\$}$ 3.2-6024 through 3.2-6030 (titled as Article II – Disposal of Dead Poultry)

<u>Agency Response to Economic Impact Analysis:</u> The agency concurs with the economic impact analysis of the Department of Planning and Budget.

Final Regulation

REGISTRAR'S	NOTICE:	The	Marine	Resources
Commission is	claiming	an e	xemption	from the
Administrative Process Act in accordance with § 2.2-4006 A				
11 of the Code	of Virginia;	howev	er, the co	mmission is
required to publish the full text of final regulations.				

<u>Title of Regulation:</u> **4VAC20-490.** Pertaining to Sharks (amending 4VAC20-490-20; adding 4VAC20-490-48).

Statutory Authority: § 28.2-201 of the Code of Virginia.

Effective Date: April 1, 2016.

<u>Agency Contact:</u> Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248, or email jennifer.farmer@mrc.virginia.gov.

Summary:

The amendments add (i) smoothhound shark to the smooth dogfish definition and (ii) a smooth dogfish commercial quota and smooth dogfish catch limitations.

4VAC20-490-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

"Agent" means any person who possesses the Commercial Fisherman Registration License, fishing gear license, or fishing permit of a registered commercial fisherman in order to fish that commercial fisherman's gear or sell that commercial fisherman's harvest.

"Carcass length" means that length measured in a straight line from the anterior edge of the first dorsal fin to the posterior end of the shark carcass.

"COLREGS Line" means the COLREGS Demarcation Line, as defined in the Code of Federal Regulations (33 CFR 80.510 Chesapeake Bay Entrance, VA).

"Commercial shark fisherman" means any commercial fisherman permitted to land or possess sharks (excluding spiny dogfish) that has landed and sold one pound of shark or more (excludes spiny dogfish) in that calendar year (January 1 through December 31).

"Commercially permitted aggregated large coastal shark" means any of the following species:

Blacktip, Carcharhinus limbatus

Bull, Carcharhinus leucas

Lemon, Negaprion brevirostris

Nurse, Ginglymostoma cirratum

Silky, Carcharhinus falciformis

Spinner, Carcharhinus brevipinna

Tiger, Galeocerdo cuvier

"Commercially permitted hammerhead shark" means any of the following species: Great hammerhead, Sphyrna mokarran

Scalloped hammerhead, Sphyrna lewini

Smooth hammerhead, Sphyrna zygaena

"Commercially permitted nonblacknose small coastal shark" means any of the following species:

Atlantic sharpnose, Rhizoprionodon terraenovae

Bonnethead, Sphyrna tiburo

Finetooth, Carcharhinus isodon

"Commercially permitted pelagic shark" means any of the following species:

Blue, Prionace glauca

Oceanic whitetip, Carcharhinus longimanus

Porbeagle, Lamna nasus

Shortfin mako, Isurus oxyrinchus

Thresher, Alopias vulpinus

"Commercially prohibited shark" means any of the following species:

Atlantic angel, Squatina dumeril

Basking, Cetorhinus maximus

Bigeye sand tiger, Odontaspis noronhai

Bigeye sixgill, Hexanchus nakamurai

Bigeye thresher, Alopias superciliosus

Bignose, Carcharhinus altimus

Blacknose, Carcharhinus acronotus

Caribbean reef, Carcharhinus perezii

Caribbean sharpnose, Rhizoprionodon porosus

Dusky, Carcharhinus obscurus

Galapagos, Carcharhinus galapagensis

Longfin mako, Isurus paucus

Narrowtooth, Carcharhinus brachyurus

Night, Carcharhinus signatus

Sand tiger, Carcharias taurus

Sevengill, Heptranchias perlo

Sixgill, Hexanchus griseus

Smalltail, Carcharhinus porosus

Whale, Rhincodon typus

White, Carcharodon carcharias

"Control rule" means a time-certain date, past, present or future, used to establish participation in a limited entry fishery and may or may not include specific past harvest amounts.

"Dressed weight" means the result from processing a fish by removal of head, viscera, and fins, but does not include removal of the backbone, halving, quartering, or otherwise further reducing the carcass.

"Finning" means removing the fins and returning the remainder of the shark to the sea.

"Fork length" means the straight-line measurement of a fish from the tip of the snout to the fork of the tail. The measurement is not made along the curve of the body.

"Large mesh gill net" means any gill net with a stretched mesh of greater than five inches.

"Longline" means any fishing gear that is set horizontally, either anchored, floating or attached to a vessel, and that consists of a mainline or groundline, greater than 1,000 feet in length, with multiple leaders (gangions) and hooks, whether retrieved by hand or mechanical means.

"Movable gill net" means any gill net other than a staked gill net.

"Permitted commercial gear" means rod and reel, handlines, shark shortlines, small mesh gill nets, large mesh gill nets, pound nets, and weirs.

"Recreational shore angler" means a person neither fishing from a vessel nor transported to or from a fishing location by a vessel.

"Recreational vessel angler" means a person fishing from a vessel or transported to or from a fishing location by a vessel.

"Recreationally permitted shark" means any of the following species:

Atlantic sharpnose, Rhizoprionodon terraenovae

Blacknose, Carcharhinus acronotus

Blacktip, Carcharhinus limbatus

Blue, Prionace glauca

Bonnethead, Sphyrna tiburo

Bull, Carcharhinus leucas

Finetooth, Carcharhinus isodon

Great hammerhead, Sphyrna mokarran

Lemon, Negaprion brevirostris

Nurse, Ginglymostoma cirratum

Oceanic whitetip, Carcharhinus longimanus

Porbeagle, Lamna nasus

Scalloped hammerhead, Sphyrna lewini

Shortfin mako, Isurus oxyrinchus

Smooth dogfish, Mustelus canis

Smooth hammerhead, Sphyrna zygaena

Spinner, Carcharhinus brevipinna

Thresher, Alopias vulpinus

Tiger, Galeocerdo cuvier

"Recreationally prohibited shark" means any of the following species:

Atlantic angel, Squatina dumeril

Basking, Cetorhinus maximus

Bigeye sand tiger, Odontaspis noronhai

Bigeye sixgill, Hexanchus nakamurai

Bigeye thresher, Alopias superciliosus

Bignose, Carcharhinus altimus

Caribbean reef, Carcharhinus perezii

Caribbean sharpnose, Rhizoprionodon porosus

Dusky, Carcharhinus obscurus

Galapagos, Carcharhinus galapagensis

Longfin mako, Isurus paucus

Narrowtooth, Carcharhinus brachyurus

Night, Carcharhinus signatus

Sand tiger, Carcharias taurus

Sandbar, Carcharhinus plumbeus

Sevengill, Heptranchias perlo

Silky, Carcharhinus falciformis

Sixgill, Hexanchus griseus

Smalltail, Carcharhinus porosus

Whale, Rhincodon typus

White, Carcharodon carcharias

"Research only shark" means any of the following species:

Sandbar, Carcharhinus plumbeus

"Shark shortline" means a fish trotline that is set horizontally, either anchored, floating or attached to a vessel, and that consists of a mainline or groundline, 1,000 feet in length or less, with multiple leaders (gangions) and no more than 50 corrodible circle hooks, whether retrieved by hand or mechanical means.

"Small mesh gill net" means any gill net with a stretched mesh of equal to or less than five inches.

"Smooth dogfish" means any shark of the species Mustelus canis. <u>Smooth dogfish are also known as "smoothhound shark."</u>

"Spiny dogfish" means any shark of the species Squalus acanthias.

4VAC20-490-48. Smooth dogfish commercial quota and catch limitations.

A. The annual commercial quota for smooth dogfish shall be 922,030 pounds in dressed weight.

B. It shall be unlawful for any person to take, harvest, or possess aboard any vessel or to land in Virginia any smooth dogfish harvested from federal waters once the National Oceanic and Atmospheric Administration (NOAA) Fisheries has determined and announced that 80% of the smooth dogfish coastwide quota has been harvested.

C. It shall be unlawful for any person to harvest or to land in Virginia any smooth dogfish for commercial purposes after the quota specified in subsection A of this section has been landed and announced as such.

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D. Any smooth dogfish harvested from state waters or federal waters for commercial purposes shall only be sold to a federally permitted dealer.

<u>E.</u> It shall be unlawful for any buyer of seafood to receive any smooth dogfish harvested from federal waters once NOAA Fisheries has determined and announced that 80% of the smooth dogfish coastwide quota has been harvested.

<u>F. It shall be unlawful for any buyer of seafood to receive</u> any smooth dogfish after the commercial quota specified in subsection A of this section has been attained and announced as such.

VA.R. Doc. No. R16-4661; Filed March 24, 2016, 9:46 a.m.

Final Regulation

<u>REGISTRAR'S NOTICE:</u> The Marine Resources Commission is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4006 A 11 of the Code of Virginia; however, the commission is required to publish the full text of final regulations.

<u>Title of Regulation:</u> **4VAC20-720. Pertaining to Restrictions on Oyster Harvest (amending 4VAC20-720-80).**

Statutory Authority: § 28.2-201 of the Code of Virginia.

Effective Date: March 24, 2016.

<u>Agency Contact:</u> Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248, or email jennifer.farmer@mrc.virginia.gov.

Summary:

The amendment allows payment of the oyster resource user fee to use one or more gear types only by (i) those harvesters who previously paid an oyster resource user fee and (ii) beginning May 1, 2016, those persons who wish to obtain an oyster hand tong license for the purpose of harvesting seed oysters.

4VAC20-720-80. Quotas and harvest limits.

A. It shall be unlawful for any person who does not possess a valid commercial fisherman's registration license and a valid gear license required by harvest area, as described in 4VAC20-720-75, and has not paid the current year's oyster resource user fee to harvest or possess any oysters for commercial purposes. Any individual who possesses the valid licenses and has paid the oyster resource user fee as described in this subsection shall be limited to a maximum harvest of eight bushels per day. It shall be unlawful for any vessel to exceed a daily vessel limit of 24 bushels clean cull oysters harvested from the areas described in 4VAC20-720-40 B 8 through 16.

B. It shall be unlawful for any person who does not possess a valid commercial fisherman's registration license and a valid gear license required by harvest area, as described in 4VAC20-720-75, and has not paid the current year's oyster resource user fee to harvest or possess any oysters for commercial purposes.

Any individual who possesses the valid licenses and has paid the oyster resource user fee as described in this subsection shall be limited to a maximum harvest of eight bushels per day. It shall be unlawful for any vessel to exceed a daily vessel limit for clean cull oysters harvested from the areas described in 4VAC20-720-40 B 2 through 7 and 17, whereby that vessel limit shall equal the number of registered commercial fisherman licensees on board the vessel who hold a valid gear license and who have paid the oyster resource user fee multiplied by eight.

C. It shall be unlawful for any vessel to exceed a daily vessel limit for clean cull oysters harvested from the areas described in 4VAC20-720-40 B 1, whereby that vessel limit shall equal the number of registered commercial fisherman licensees on board the vessel who hold a valid gear license and who have paid the oyster resource user fee multiplied by 12. It shall be unlawful for any person who does not possess a valid commercial fisherman's registration license and hold a valid gear license required by harvest area, as described in 4VAC20-720-75, and has not paid the current year's oyster resource user fee to harvest or possess any oysters for commercial purposes. Any individual who possesses the valid licenses and has paid the oyster resource user fee as described in this subsection shall be limited to a maximum harvest of 12 bushels per day.

D. It shall be unlawful for any vessel to exceed a daily vessel limit for clean cull oysters harvested from the areas described in 4VAC20-720-40 B 18, whereby that vessel limit shall equal the number of registered commercial fisherman licensees on board the vessel who are licensed by a valid gear license and have paid the oyster resource user fee, multiplied by eight. It shall be unlawful for any person who does not possess a valid commercial fisherman's registration license and a valid gear license required by harvest area, as described in 4VAC20-720-75, and has not paid the current year's oyster resource user fee to harvest or possess any oysters for commercial purposes. Any individual who possesses the valid licenses and has paid the oyster resource user fee, as described in this subsection, shall be limited to a maximum harvest of eight bushels per day.

E. Beginning February 23, 2016, payment of the oyster resource user fee that allows any harvester to use one or more gear types to harvest oysters or possess any bushel limit, as described in this section, shall be limited to those individuals who previously paid an oyster resource user fee. Beginning on May 1, 2016, payment of the oyster resource user fee shall be limited to (i) those individuals who previously paid an oyster resource user fee and (ii) those persons who wish to obtain an oyster hand tong license for the purpose of harvesting seed oysters.

<u>E. F.</u> In the Pocomoke and Tangier Sounds Rotation Area 1, no blue crab bycatch is allowed. It shall be unlawful to possess on board any vessel more than 250 hard clams.

VA.R. Doc. No. R16-4641; Filed March 24, 2016, 9:28 a.m.

Forms

<u>REGISTRAR'S NOTICE</u>: A form used in administering the following regulation has been filed by the Marine Resources

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Commission. The form is not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of the form to access it. The form is also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

<u>Title of Regulation:</u> **4VAC20-900. Pertaining to Horseshoe Crab.**

<u>Agency Contact:</u> Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248, or email jennifer.farmer@mrc.virginia.gov.

FORMS (4VAC20-900)

Virginia Marine Mandatory Reports, rev. 1/99.

Virginia Marine Mandatory Reports, MR 560001 (rev. 1/2015)

VA.R. Doc. No. R16-4660; Filed March 28, 2016, 8:18 a.m.

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TITLE 8. EDUCATION

STATE BOARD OF EDUCATION

Reproposed Regulation

<u>Title of Regulation:</u> 8VAC20-740. Regulations Governing Nutritional Standards for Competitive Foods Available for Sale in the Public Schools (adding 8VAC20-740-10 through 8VAC20-740-40).

Statutory Authority: § 22.1-207.4 of the Code of Virginia.

Public Hearing Information:

April 28, 2016 - 11 a.m. - James Monroe Building, 101 North 14th Street, 22nd Floor Conference Room; Richmond, VA 23219. The public hearing will begin immediately following adjournment of the Board of Education business meeting.

Public Comment Deadline: May 18, 2016.

<u>Agency Contact:</u> Catherine Digilio-Grimes, Director of School Nutrition Programs, Department of Education, P.O. Box 2120, Richmond, VA 23218, telephone (804) 225-2074, or email catherine.digilio-grimes@doe.virginia.gov.

<u>Basis</u>: Section 22.1-207.4 of the Code of Virginia requires the Board of Education, in cooperation with the Department of Health, to promulgate and periodically update regulations setting nutritional guidelines for all competitive foods sold to students during regular school hours that are not part of the federal school lunch or school breakfast program.

<u>Purpose:</u> Section 22.1-207.4 requires the development and implementation of regulations regarding nutritional guidelines. In addition, the rising rate of obesity in children has become a major health concern, both because of its impact on childhood health and its potential effect on the

development of chronic disease in adulthood. In response to this growing concern, attention has focused on the need to establish nutrition standards for foods in schools. Federal regulations governing the national school lunch and breakfast programs and afterschool snack program establish nutrition standards for school meals. In addition, federal regulations require every school division to have wellness policies that address nutrition and physical activity; the content and implementation of these local wellness policies have been at the discretion of the local school divisions. The proposed regulations would require each local school board to adopt the state nutrition guidelines as part of their existing local wellness policies.

Statewide nutritional guidelines for competitive foods available for sale to students on the school campus during the school day of any public school, and other public school food authorities such as residential child care institutions, would strengthen the local wellness policies and help address some of the factors that impact childhood obesity as well as increase the nutritional quality of foods offered in the school setting.

<u>Substance</u>: The language in the reproposed regulation is aligned with new federal regulation governing competitive foods in schools to provide clarity and consistency and avoid having different sets of regulations that school divisions would be required to follow. All references to beverages are eliminated. The reproposed regulation contains changes in the following sections:

• 8VAC20-740-10 - Definitions: modified several, added new definitions, and deleted some.

• 8VAC20-740-20 - Applicability: added item clarifying nonapplicability of food available for sale to adults only.

• 8VAC20-740-30 - Nutrition standards: reworded and expanded language to align with the federal regulation; added section on general standards, general exemptions and accompaniments.

• 8VAC20-740-40 - Implementations and compliance: expanded to address recordkeeping, oversight and compliance and noncompliance.

<u>Issues:</u> Nutrition standards for competitive foods can complement the federal school meal nutrition standards for an overall healthier eating environment in schools and implementation of consistent nutrition messages throughout the school day. Additionally, the rising rate of childhood obesity has become a major health concern because of both its impact on childhood health and as a contributing factor to the development of chronic disease in adulthood. In response to this growing concern, attention has focused on the need to establish nutrition standards for foods in schools by offering healthier food options on school grounds during the school day. From a nutritional perspective, the goal is to increase the consumption of whole grains, fruits, vegetables, and nonfat or low-fat dairy, and reduce fat, sugars, and sodium. Federal regulations governing the national school lunch program,

school breakfast program, and afterschool snack program establish nutrition standards for school meals. Strengthened federal nutrition standards governing competitive foods became effective July 1, 2014, and these proposed state nutrition standards are aligned with the federal Smarts Snacks in School rules. Statewide nutrition standards for competitive foods available for sale to students during the school day on the school campus would help to strengthen local wellness policies and address some of the factors that impact childhood obesity. Potential disadvantages associated with this regulation to the public and regulated community include the following: (i) school divisions will be impacted administratively, as they will be required to adopt the new state nutrition standards as part of their required local wellness policies, and (ii) as schools change the food offerings on the school site during the school day to meet the adopted nutrition standards, they may experience financial impact. Disadvantages to the Commonwealth and agency include the following: (i) the Department of Education will be required to ensure compliance with these state and federal regulations throughout the local school agency and school food authority with existing resources, and (ii) the department may need to provide additional ongoing staff support and technical assistance to school divisions in the implementation of these regulations

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Chapter 718 (2010 Acts of Assembly) amended the Code of Virginia by adding § 22.1-207.4 on nutritional guidelines for competitive foods. The legislation requires the Board of Education (Board), in cooperation with the Department of Health, to promulgate and periodically update regulations setting nutritional guidelines for all competitive foods sold to students during regular school hours. The term competitive foods refers to food available for sale to students on the school campus during the school day other than meals reimbursed under programs authorized by the federal Richard B. Russell National School Lunch Act and the Child Nutrition Act of 1966. Pursuant to the legislation, the Board proposes for this regulation the maximum calorie, fat, sugar, and sodium content for competitive foods.

In addition, federal regulations require every school division to have wellness policies that address nutrition and physical activity. The content and implementation of these policies have been at the discretion of the local school divisions. The proposed regulations would require each local school board to adopt the state nutrition guidelines as part of their existing local wellness policies.

Result of Analysis. There is insufficient data to accurately compare the magnitude of the benefits versus the costs. Detailed analysis of the benefits and costs can be found in the next section. Estimated Economic Impact. The U.S. Department of Agriculture adopted the Institutes of Medicines nutrition standards for competitive foods. These standards became effective as part of federal regulation on July 1, 2014. All schools that participate in the National School Lunch Program (NSLP) and School Breakfast Program (SBP) are bound by the federal regulation and its nutrition standards for competitive foods. All Virginia school divisions participate in the NSLP and SBP for elementary school. Chesterfield, Falls Church and Hanover do not participate in NSLP and SBP for high school. Falls Church does not participate in NSLP and SBP for middle school. All other Virginia school divisions participate in the federal programs for high school and middle school as well as elementary school.¹

The Board proposes competitive food nutritional standards (maximum calorie, fat, sugar, and sodium content) that are consistent with the federal regulation.² Thus, this proposed state regulation (8 VAC 20-740) will essentially only affect high schools in Chesterfield, Falls Church and Hanover, and the middle school in Falls Church.

Historically it has been common practice for schools to sell a la carte food items in addition to planned meals under the federal school lunch and school breakfast programs. An a la carte item means an individually priced food item served by the local school nutrition department that may or may not be part of the reimbursable meal under the federal child nutrition programs. A la carte items as well as food sold in vending machines and other food sold to students during regular school hours, including fundraisers, are subject to the maximum calorie, fat, sugar, and sodium content values in the federal and state regulations.

The standards in the federal regulation and this proposed state regulation effectively prohibit the sale of much of the competitive foods historically sold in schools. Thus, students will likely consume fewer foods during the school day that are high in calories, fat, sugar, and sodium. This may result in improved health for Virginia's schoolchildren. On the other hand it may have some negative consequences on revenues for schools. For example, one Virginia school division that on its own decided to stop selling french fries noticed an associated decrease in food sale revenue. This anecdotal example is countered though by a study³ published in the Journal of School Health which found that "Thus far, few data exist to substantiate the concern that changes in nutrition standards in schools lead to a loss in total revenue." An interesting phenomenon of increased participation in the National School Lunch Program was noted in a number of reports and might play a role in buffering financial losses.

At least some firms and farms which produce foods that meet the proposed standards for competitive food will likely encounter greater demand for their products. For example, standard hamburgers currently provided to schools do not meet the proposed standards, but healthier hamburgers which do meet the proposed standards and cost 20 percent more are

commercially available.⁴ Of course at least some other firms and farms which produce foods that do not meet the proposed standards for competitive food will likely encounter lesser demand for their products. Since Virginia school divisions all together comprise a significant market, due to the combination of the new federal regulation along with this proposed state regulation there will likely be some adjustment in food production to meet the changed demand.

Businesses and Entities Affected. The proposed regulations affect the 132 public school divisions in the Commonwealth as well as food producers and distributors which supply schools with food.

Localities Particularly Affected. The proposed regulations particularly affect Chesterfield, Falls Church and Hanover.

Projected Impact on Employment. Due to the combination of the new federal regulation along with this proposed state regulation, at least some firms and farms which produce foods which meet the proposed standards for competitive food will likely encounter greater demand for their products. These firms may hire new workers. Other firms and farms which produce foods that do not meet the proposed standards for competitive food will likely encounter lesser demand for their products. These firms may layoff workers.

Effects on the Use and Value of Private Property. Due to the combination of the new federal regulation along with this proposed state regulation, the value of firms which produce foods which meet the proposed standards for competitive food may increase. The value of firms which produce foods that do not meet the proposed standards for competitive food may decrease.

Small Businesses: Costs and Other Effects. Small businesses which produce foods that are sold to schools and do not meet the proposed standards are likely to lose demand for their products. Depending on the product, it may be possible to adjust the product to meet the proposed standards. That would likely add to the costs, though.

Small Businesses: Alternative Method that Minimizes Adverse Impact. There are no clear alternative methods that would both reduce costs and still produce the desired policy.

Real Estate Development Costs. The proposed regulations are unlikely to affect real estate development costs.

Small Businesses: If the proposed regulatory action will have an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include:

• an identification and estimate of the number of small businesses subject to the proposed regulation,

• the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents,

• a statement of the probable effect of the proposed regulation on affected small businesses, and

• a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

Additionally, pursuant to § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules (JCAR) is notified at the time the proposed regulation is submitted to the Virginia Register of Regulations for publication. This analysis shall represent DPBs best estimate for the purposes of public review and comment on the proposed regulation.

¹Source: Virginia Department of Education

⁴Source: a Virginia-based food distributor which currently serves several school divisions

<u>Agency's Response to Economic Impact Analysis:</u> The agency concurs with the economic impact analysis completed by the Department of Planning and Budget. The agency will continue to examine the economic and administrative impact of the regulations as they progress through the regulatory process under the Administrative Process Act.

Summary:

The reproposed amendments (i) establish nutritional standards for competitive foods available for sale to students on the school campus of any public school and other public school food authorities, such as residential child care institutions, during the school day; (ii) require all local school boards to adopt the nutritional standards as part of existing wellness policies; (iii) establish recordkeeping requirement; and (iv) require the Department of Education to ensure compliance with the standards.

The reproposed amendments are based on the Institute of Medicine's Recommended Standards for Competitive Foods in Schools and align the regulation with the U.S. Department of Agriculture interim final rule governing competitive foods in schools issued in June 2013.

<u>CHAPTER 740</u> <u>REGULATIONS GOVERNING NUTRITIONAL</u> [<u>GUIDELINES STANDARDS</u>] <u>FOR COMPETITIVE</u> <u>FOODS</u> [<u>SOLD</u> AVAILABLE FOR SALE] <u>IN THE</u> <u>PUBLIC SCHOOLS</u>

8VAC20-740-10. Definitions.

<u>"A la carte item" means an individually priced food item</u> served by the local school nutrition department that may or may not be part of the reimbursable meal under the federal <u>Child Nutrition Programs.</u>

²Pursuant to Chapter 718 (2010 Acts of Assembly), the proposed state regulations governing nutritional standards for competitive foods sold in public schools do not apply to beverages. The federal regulation does apply to beverages.

³Wharton CM, Long M, Schwartz MB. Changing nutrition standards in schools: the emerging impact on school revenue. J Sch Health. 2008; 78: 245-251.

<u>"After school activities" means activities that occur on</u> [<u>the</u>] <u>school</u> [<u>grounds campus</u>] <u>after</u> [<u>regular school hours</u> <u>the school day</u>].

"Beverage" means a drinkable liquid.

"Calorie" means the amount of heat required to change the temperature of one gram of water from 14.5 degrees Celsius to 15.5 degrees Celsius. Calorie is used synonymously with kilocalorie as a unit of measure for energy obtained from food and beverages.

"Child Nutrition Programs" means school meal programs funded and regulated by the U.S. Department of Agriculture (USDA) and includes the National School Lunch Program (NSLP), School Breakfast Program (SBP), [Afterschool Snack Programs (ASP),] Child and Adult Care Food Program (CACFP), Summer Food Service Program (SFSP), and Special Milk Program (SMP).

["Combination foods" means products that contain two or more components representing two or more of the recommended food groups: fruit, vegetable, dairy, protein, or grains.]

"Competitive food" means [any all] food [. excluding beverages, sold available for sale] to students on [the] school [grounds campus] during [regular the] school [hours that is not part of the reimbursable meals served through the National School Lunch Program (NSLP), School Breakfast Program (SBP), or Afterschool Snack Program (ASP) day other than meals reimbursed under programs authorized by the Richard B. Russell National School Lunch Act (42 USC § 1751 et seq.) and the Child Nutrition Act of 1966 (42 USC § 1771 et seq.)].

<u>Competitive food includes all foods</u> [<u>sold</u> available for <u>sale</u>] <u>to students:</u>

1. In school cafeterias as a la carte items [not offered as a component of the planned reimbursable menu].

2. In vending machines located on [school grounds during regular school hours the school campus during the school day].

3. As fundraisers held on [school grounds during regular school hours the school campus during the school day].

4. In school snack bars on [school grounds during regular school hours the school campus during the school day].

5. In school stores operated on [school grounds during regular school hours the school campus during the school day] by the school, a student association, or other school-sponsored organization.

6. At school activities such as special fundraisers, achievement rewards, classroom parties, school celebrations, classroom snacks, or school meetings held on [school grounds during regular school hours the school campus during the school day].

[<u>7. In culinary education programs where food prepared as</u> part of the educational curriculum is sold to students; however, this provision does not apply if food is sold to adults only.]

This term does not apply to food a student brings from home for consumption at school [or items available for sale to adults only in areas not accessible to students (e.g., teachers lounges)].

"Dietary Guidelines for Americans" means guidelines jointly issued by the U.S. Department of Health and Human Services and U.S. Department of Agriculture and revised every five years and that provide authoritative advice based on current scientific evidence and medical knowledge for people two years of age and older about how good dietary habits can promote health and reduce risk for major chronic diseases.

[<u>"Food of minimal nutritional value" or "FMNV" means</u> foods and beverages that are restricted by the U.S. Department of Agriculture (7 CFR 210.11(a)(2) and subsection (a) of Appendix B to 7 CFR Part 210 Definition) unless specifically exempted by USDA. The federal FMNV definition is limited to the following four specific categories of foods and beverages:

1. Soda water (any carbonated or aerated beverages, i.e., beverages that are labeled as "aerated" or that bubble and fizz for several minutes after opening).

2. Water ices (any frozen, sweetened water such as "...sicles" and flavored ice with the exception of products that contain fruit, fruit juice, milk, milk ingredients, or egg ingredients other than egg whites).

3. Chewing gum (regular and sugarless).

4. Certain candies (regular and sugarless), including:

<u>a. Hard candy (e.g., sour balls, candy sticks, lollipops,</u> <u>starlight mints, after dinner mints, sugar wafers, rock</u> <u>candy, cinnamon candy).</u>

<u>b. Jellies and gums (e.g., gum drops, jelly beans, and jellied and fruit flavored slices and shapes).</u>

<u>e. Marshmallow candies, fondant, such as candy corn and</u> <u>soft mints, licorice, spun candy, and candy coated</u> <u>popcorn.</u>

"Entree item" means an item that is either (i) a combination food of meat or meat alternate and whole grain rich food; (ii) a combination food of vegetable or fruit and meat or meat alternate; or (iii) a meat or meat alternate alone with the exception of yogurt; low-fat or reduced fat cheese; nuts, seeds, and nut or seed butters; and meat snacks (e.g., dried beef jerky).]

[<u>"Kcal" means kilocalorie, commonly known as calorie,</u> which is a unit of measure in the United States for energy obtained from food and beverages. A kilocalorie is equal to <u>1,000 calories.</u>]

"Obesity" means obesity in children and adolescents referring to the age-specific and sex-specific body mass index (BMI) that is equal to or greater than the 95th percentile of

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the BMI charts of the Centers for Disease Control and Prevention (CDC).

["Regular school hours" means the same as the standard school day, as defined in 8VAC20 131-5, a calendar day that averages at least five and one half instructional hours for students in grades 1 through 12, excluding breaks for meals and recess, and a minimum of three instructional hours for students in kindergarten. Regular school hours does not include school related activities or events that occur either before or after the standard school day, such as clubs, yearbook, band and choir practice, student government, drama, childcare programs, interscholastic sporting events, school plays, band concerts, or other school related programs.

"School campus" means, for the purpose of competitive food standards implementation, all areas of the property under the jurisdiction of the school that are accessible to students during the school day.

<u>"School day" means, for the purpose of competitive food</u> standards implementation, the period from the midnight before to 30 minutes after the end of the official school day.]

"School food authority" or "SFA" means, under the federal child nutrition laws, the entity that is legally responsible for the operations and administration of the local school nutrition programs (i.e., school division).

[<u>"School Health Advisory Board" or "SHAB" means an</u> entity formed according to the provisions of § 22.1 275.1 of the Code of Virginia that assists in the development of wellness policies as required by § 204 of Public Law 108 265 (42 USC § 1751 et seq.) and develops an annual report of activities that is required to be submitted to the Department of Education as amended.]

<u>"Trans fat" means food items containing vegetable shortening, margarine, or any partially hydrogenated vegetable oil unless the label required on the food, pursuant to applicable federal and state law, lists the trans fat content as [less than 0.5 zero] grams per serving.</u>

"Wellness policy" means a policy required for public schools participating in a nutrition program authorized by the Richard B. Russell National School Lunch Act (42 USC § 1751 et seq.) or the Child Nutrition Act of 1966 (42 USC § 1771 et seq.) [that meets minimum standards designed to support school environments that promote student wellness].

[<u>"Whole grains" means grains that are made with enriched</u> and whole grain meal or flour in accordance with the most recent grains guidance from the U.S. Department of Agriculture Food and Nutrition Service.

"Whole-grain rich" means products that contain at least 50% whole grains and the remaining grains in the product must be enriched.]

8VAC20-740-20. Applicability.

<u>A. This</u> [<u>regulation chapter</u>] <u>shall apply to all public school</u> <u>divisions, public schools, and</u> [<u>public</u>] <u>school food</u> <u>authorities (SFAs) in the Commonwealth of Virginia.</u> B. This [regulation chapter] shall not apply to beverages.

<u>C. This</u> [regulation chapter] shall apply to the nutritional content of food items [receluding beverages, sold available for sale] to students on the school [grounds campus] of any public school [during regular school hours, and other public SFAs such as residential child care institutions, during the school day]. It shall [include apply to]:

<u>1. Foods</u> [<u>sold</u> available for sale] to students in vending machines.

2. Foods [sold available for sale] to students as a la carte items in the school cafeteria.

<u>3. Foods</u> [sold available for sale] to students at snack bars and stores operated by the school, a student association, or other school-sponsored organization.

<u>4. Foods</u> [sold available for sale] to students at school activities such as fundraisers.

[<u>5. Foods available for sale to students by culinary or other</u> educational programs.]

D. This [regulation chapter] shall not apply to the nutritional content of foods [and beverages]:

1. Provided [through the National School Lunch, School Breakfast, and Afterschool Snack programs, as regulated by 7 CFR Part 210 and 7 CFR Part 220 as meals reimbursed under programs authorized by the Richard B. Russell National School Lunch Act (42 USC § 1751 et seq.) and the Child Nutrition Act of 1966 (42 USC § 1771 et seq.)].

2. [Sold Available for sale] at snack bars, concession stands, or athletic events after [regular school hours the school day].

3. [Sold Available for sale] either during intermission or immediately before or after athletics events [scheduled after the school day].

<u>4.</u> [<u>Sold Available for sale</u>] for school-related fundraising activities that take place off [the] school [grounds campus].

5. [Sold Available for sale] during activities that take place after [regular school hours the school day], such as clubs, yearbook, band and choir practice, student government, drama, sports practices, interscholastic sporting events, school plays, and band concerts.

[<u>6. Available for sale to adults only in areas not accessible to students.</u>

E. The requirements of this chapter supplement 8VAC20-290 and 8VAC20-580, which remain in effect.]

8VAC20-740-30. Nutrition standards.

[<u>Competitive_foods_sold_to_students_shall_support_the</u> <u>Dietary_Guidelines_for_Americans_by_complying_with_the</u> <u>following nutritional standards:</u>

<u>A. The nutrition standards apply to all foods available for</u> sale to students (i) outside the school meal programs; (ii) on

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the school campus; and (iii) at any time during the school day. The nutrition standards shall be consistent with the most recent Dietary Guidelines for Americans.

<u>B.</u> To be allowable, a competitive food must (i) meet all of the competitive food nutrient standards and (ii) must either:

<u>1. Be a grain product that contains 50% or more whole</u> grains by weight or have as the first ingredient a whole grain (i.e., whole-grain rich);

2. Have as the first ingredient one of the nongrain major food groups: fruits, vegetables, dairy, or protein foods (e.g., meat, beans, poultry, seafood, eggs, nuts, seeds, etc.);

<u>3. Be a combination food that contains 1/4 cup of fruit or vegetable; or</u>

4. Contain 10% of the Daily Value of a nutrient of public health concern based on the most recent Dietary Guidelines for Americans (i.e., calcium, potassium, vitamin D, or dietary fiber) for the period through June 30, 2016. Effective July 1, 2016, this criterion is obsolete and may not be used to qualify as a competitive food.

If water is the first ingredient, the second ingredient must be one of the food items listed in this subsection.

C. General exemptions:

1. Fresh, canned, and frozen fruits or vegetables with no added ingredients except water or, in the case of fruit, packed in 100% juice, extra light, or light syrup are exempt from the nutrient standards.

<u>2. Canned vegetables that contain a small amount of sugar</u> for processing purposes are also exempt from the nutrient standards.

3. An entree item offered as part of the national school lunch program under 7 CFR Part 210 or the school breakfast program under 7 CFR Part 220 is exempt from all competitive food standards if it is offered as a competitive food on the day of, or the school day after, it is offered in the lunch or breakfast program. Exempt entree items offered as a competitive food must be offered in the same or smaller portion sizes as in the lunch or breakfast program.

Side dishes offered as part of the lunch or breakfast program and served a la carte must meet the nutrition standards in this section.

<u>D. The accompaniments to a competitive food item must be</u> included in the nutrient profile as a part of the food item served in determining if an item meets the nutrition standards for competitive food. The contribution of the accompaniments may be based on the average serving size of the accompaniment used per item.

E. Nutrient standards:]

1. Standard 1: Calories.

<u>a. Snack items [and side dishes sold a la carte] (i) shall</u> <u>be [no more than] 200 calories [or less] per [portion</u> <u>item as served] or as packaged [. including the calorie</u> content in any accompaniments, such as butter, cream cheese, and salad dressing, and (ii) must meet all other nutrient standards].

b. [<u>A la carte entree items shall not exceed calorie limits</u> on comparable National School Lunch Program (NSLP) entrees. A la carte entree items shall not provide more calories or larger portion sizes than the comparable NSLP entree items. In accordance with 8VAC20 290 10, a la carte entree items for sale to students shall be limited to those entree items recognized as being components of the school breakfast program or school lunch program meal patterns.

Entree items sold a la carte, unless the entree item meets the exemption for NSLP/SBP entree items in subdivision C 3 of this section, shall (i) contain no more than 350 calories, including the calorie content of any accompaniments, per item as served or as packaged, and (ii) meet all of the other nutrient standards in this section.

c. The calories contained in any accompaniments must be included in the nutrient profile as a part of the item served.]

2. Standard 2: Fat.

a. [Snacks and food items shall meet the following criteria for dietary fat per portion or as packaged:

(1) No more than 35% of total calories from fat.

(2) Less than 10% of total calories from saturated fats.

(3) Zero grams of trans fat.

<u>b. Exceptions: Nuts and seeds (allowed as combination products as long as other nutrient standards are met; the fat content will not count against the total fat content of the product).</u>

Total fat. Competitive foods shall contain no more than 35% of total calories from fat per item as packaged or served. Exemptions to the total fat standard are granted for:

(1) Reduced fat cheese and part-skim mozzarella cheese. This exemption does not apply to combination foods.

(2) Nuts, seeds, and nut or seed butters. This exemption does not apply to combination foods that contain nuts, seeds, or nut or seed butters, such as peanut butter and crackers and trail mix.

(3) Products consisting of only dried fruit with nuts or seeds with no added nutritive sweeteners or fat.

(4) Seafood with no added fat.

b. Saturated fat. Competitive foods shall have less than 10% of total calories from saturated fat per item as packaged or served. Exemptions to the saturated fat standard are granted for:

(1) Reduced fat cheese and part-skim mozzarella cheese. This exemption does not apply to combination foods.

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(2) Nuts, seeds, and nut or seed butters. This exemption does not apply to combination foods that contain nuts, seeds, or nut or seed butters, such as peanut butter and crackers and trail mix.

(3) Products consisting of only dried fruit with nuts or seeds with no added nutritive sweeteners or fat.

c. Trans fat. Competitive foods must have zero grams of trans fat per item as packaged or served.]

<u>3. Standard 3: Sugar.</u> [<u>a. Snacks and food items shall</u> provide no more than 35% of calories from total sugars per portion or as packaged b. Exceptions Total sugar shall be no more than 35% of weight per item as packaged or served. Exemptions to the sugar standard are provided for]:

[(1) 100% fruits and fruit juices in all forms without added sugars.

(2) 100% vegetables and vegetable juices without added sugars.

(3) Unflavored nonfat and low fat (1.0%) milk and yogurt.

(4) Flavored nonfat and low fat (1.0%) milk with no more than 22 grams of total sugars per 8-ounce serving.

(5) Flavored nonfat and low fat yogurt with no more than 30 grams of total sugars per 8 ounce serving.

a. Dried whole fruits or vegetables.

b. Dried whole fruit or vegetable pieces.

c. Dehydrated fruits or vegetables with no added nutritive sweeteners.

<u>d.</u> Dried fruits with nutritive sweeteners that are required for processing or palatability purposes.]

4. Standard 4: Sodium.

[<u>a. Snack items shall meet a sodium content limit of 200</u> <u>milligrams or less per portion or as packaged.</u>

b. A la carte entree items recognized as being components of the school breakfast program or school lunch program meal patterns that are not part of the planned reimbursable menu shall meet a sodium content of 480 milligrams or less per portion. Portion sizes for a la carte entree items shall not be larger than the comparable portion size for NSLP entree items

a. Sodium content in snacks (i) shall be no more than 230 mg per item as packaged or served, including the sodium content in any accompaniments, such as butter, cream cheese, and salad dressing; and (ii) must meet all other nutrient standards. Effective July 1, 2016, the sodium standard shall be no more than 200 mg per item as packaged or served, including the sodium content in any accompaniments.

b. Entree items sold a la carte, unless the entre item meets the exemption for NSLP/SBP entree items in subdivision C 3 of this section (i) shall have no more than 480 mg of sodium per item as packaged or served, including the sodium content in any accompaniments, such as butter, cream cheese, and salad dressing; and (ii) must meet all other nutrient standards in this section].

[<u>5. Standard 5: Foods of minimal nutritional value. In accordance with 8VAC20 290 10 and 7 CFR Part 210, all foods of minimal nutritional value (FMNV) as defined in 8VAC20 740 10 shall be prohibited from being sold to students on school grounds during regular school hours.</u>]

8VAC20-740-40. Implementation and compliance.

A. Each local school board shall [incorporate and] adopt [these the] nutrition [guidelines as part of its existing local wellness policy standards in this chapter as a compulsory component of the divisionwide local wellness policy mandated by federal regulation for all local education agencies that participate in the national school lunch program. In addition to incorporating the nutrition standards for competitive foods, the local wellness policy shall (i) establish and identify school division leadership with the authority to enforce the local wellness policy throughout the school campus; (ii) establish specific goals for nutrition promotion, nutrition education, physical activities, and other schoolbased activities that promote wellness; and (iii) establish policies that address marketing and advertising of only foods that meet the nutrition standards for competitive foods, serve to promote student health, prevent childhood obesity, and combat problems associated with poor nutrition and physical inactivity].

B. [Each local school board shall submit annually to the Department of Education the School Health Advisory Board (SHAB) Progress Report as required by § 22.1 275.1 of the Code of Virginia. This report shall include a status report on the development and implementation of the local wellness policy. This report shall be used by the Department of Education to monitor compliance with this chapter. Local educational agencies and school food authorities must retain the records used to document compliance with this chapter; that is, the documentation used to assess the nutritional profile of the food item and determine whether a food item is an allowable competitive food (e.g., the nutrition labels, recipes, or product specifications).

1. Local educational agencies:

a. Shall be responsible for maintaining records documenting compliance with the competitive food nutrition standards for food available for sale in areas that are outside of the control of the school nutrition programs operation.

b. Shall be responsible for ensuring any organization or school activity designated as responsible for food service at the various venues in the school (other than the school nutrition programs) maintains records documenting compliance with the competitive food nutrition standards.

c. Shall designate an individual at the division or school level to monitor and ensure compliance with this chapter in all areas that are outside the control of the school nutrition programs operation. This designee shall not be school nutrition personnel.

<u>2</u>. The school food authority shall be responsible for maintaining records for foods served under the auspices of the nonprofit school nutrition programs account.

3. The Department of Education shall ensure that the local education agencies and school food authorities comply with these nutrition standards. Noncompliance determined by the local education agency, school food authority, or Department of Education shall require corrective action.]

VA.R. Doc. No. R11-2611; Filed March 24, 2016, 9:20 a.m.

STATE COUNCIL OF HIGHER EDUCATION FOR VIRGINIA

Fast-Track Regulation

<u>Title of Regulation:</u> 8VAC40-31. Regulations Governing Certification of Certain Institutions to Confer Degrees, Diplomas and Certificates (amending 8VAC40-31-160, 8VAC40-31-170, 8VAC40-31-260).

Statutory Authority: §§ 23-9.6:1 and 23-276.3 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: May 18, 2016.

Effective Date: June 3, 2016.

<u>Agency Contact</u>: Sylvia Rosa-Casanova, Director, Private and Out-of-State Postsecondary Education, State Council of Higher Education for Virginia, 101 North 14th Street, James Monroe Building, Richmond, VA 23219, telephone (804) 225-3399, FAX (804) 225-2604, or email sylviarosacasanova@schev.edu.

<u>Basis:</u> Chapter 21.1 (§ 23-276.1 et seq.) of Title 23 of the Code of Virginia grants the State Council of Higher Education for Virginia the authority to regulate certain private and out-of-state institutions of higher education. Section 23-276.3 of the Code of Virginia authorizes the State Council of Higher Education for Virginia to adopt, pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), such regulations as may be necessary to implement the provisions of Chapter 21.1.

<u>Purpose:</u> The reason for this change is to provide clarity, which protects the welfare of the public. Educational institutions certified to operate in Virginia rely on these regulations to maintain compliance with the laws governing their operation in Virginia. These changes remove errors and ambiguities not detected until after the changes to the regulations became effective on February 3, 2014.

Rationale for Using Fast-Track Rulemaking Process: These changes are noncontroversial because they correct

ambiguities that were inadvertently made during the last revision of the regulations that became effective February 3, 2014. The changes remove fees that are no longer charged and correct wording so that it does not conflict with wording in other sections of the regulation or with the Code of Virginia.

<u>Substance:</u> There are no substantive changes. These changes are to remove fees no longer charged or to remove ambiguities.

<u>Issues:</u> The primary advantages to the public and the agency or the Commonwealth are that the changes correct errors that cause ambiguity in the current regulation and remove fees that are no longer charged. There are no disadvantages to the public or the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis.

Summary of the Proposed Amendments to Regulation. The State Council of Higher Education (Council) for Virginia proposes to fix what they have referred to as five errors in this regulation. Two of the errors involve fees included on the fee chart that are no longer applicable. Two errors in the regulation involve wording that reflects former fees charged as opposed to current fees. The last error mistakenly uses the word "following" instead of the correct "prior to," which causes the paragraph to conflict with the Code of Virginia.

Result of Analysis. The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact. The Council proposes to remove the listing of two fees that no longer apply. The two fees that are no longer applicable are for unaccredited out-ofstate career-technical schools and for additional branches. The existing unaccredited out-of-state career technical schools had to become accredited by 2009. The Council does not permit any additional out-of-state career technical schools unless they already have accreditation.

According to the Council the additional branch fee has never been charged. Elsewhere in the regulation it is stated that "Postsecondary schools operating branches in Virginia must certify each separately" A branch location is considered separate and distinct because its administrators, programs, instructors are all different. This means they must submit an entire application to be reviewed prior to opening a branch location. As such, the Council charges a new school fee for additional branches rather than an "additional branch" fee. Removing fees from the regulation that are not applicable in practice will be beneficial in that it may reduce confusion for the public, but will not otherwise have any impact.

When this regulation was last revised the Council amended the fee schedule, but did not amend language in two places elsewhere in the regulation that referred to handling charges/administrative fees. This resulted in contradictory language concerning the dollar amount of handling charges/administrative fees. The Council proposes to amend

the language in the two places outside of the fee chart to conform to the fee chart. These proposed amendments will not change the fees charged in practice, but will be beneficial in that it will likely reduce confusion for the public.

The current regulation states that institutions shall notify Council staff of additions or changes to programs or branches no later than 30 days "following" said occurrence. The Council proposes to change "following" to "prior to." According to the Council, this proposal is correcting an error made during the last revision of this regulation. The Code of Virginia requires institutions to receive approval from the Council prior to: 1) offering degrees, courses for degree credit, programs of study leading to a degree, or non-degree credit¹ and 2) initiating other programs for degree credit or awarding degrees, certificates, or diplomas at a new or additional level.² Thus even with the mistaken language from the last revision, postsecondary institutions must already notify and receive approval from the Council prior to additions or changes to programs or branches. Therefore amending "following" to "prior to" will also be beneficial in reducing potential confusion, but will not otherwise have a significant impact.

Businesses and Entities Affected. The Council regulates approximately 300 postsecondary institutions of which approximately 50% would be considered small businesses.³

Localities Particularly Affected. The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment. The proposed amendments do not affect employment.

Effects on the Use and Value of Private Property. The proposed amendments do not significantly affect the use and value of private property.

Real Estate Development Costs. The proposed amendments do not affect real estate development costs.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects. The proposed amendments do not significantly affect costs for small businesses.

Alternative Method that Minimizes Adverse Impact. The proposed amendments do not adversely affect small businesses.

Adverse Impacts:

Businesses. The proposed amendments do not adversely affect businesses.

Localities. The proposed amendments do not adversely affect localities.

Other Entities. The proposed amendments do not adversely affect other entities.

³Source: State Council of Higher Education for Virginia

<u>Agency's Response to Economic Impact Analysis:</u> The State Council of Higher Education for Virginia concurs with the economic impact analysis.

Summary:

To correct certain inadvertent errors made during the 2014 revisions to the Regulations Governing Certification of Certain Institutions to Confer Degrees, Diplomas and Certificates, the amendments (i) remove fees that are no longer applicable, (ii) clarify current fees, and (iii) change "following" to "prior to" to conform 8VAC40-31-160 Q to the Code of Virginia.

8VAC40-31-160. Certification criteria for all postsecondary schools.

A. The criteria in this section shall apply to all postsecondary schools for which certification is required. With regard to postsecondary schools that are accredited by an accrediting agency recognized by the U.S. Department of Education, the council may apply a presumption of compliance with criteria in this section if the school has complied with an accreditation standard directed to the same subject matter as the criteria. The council need not apply this presumption if the accreditation standard is deficient in satisfying an identifiable goal of the council. The council shall articulate reasons that the accreditation standard is deficient.

B. The postsecondary school shall have a clear, accurate, and comprehensive written statement, which shall be available to the public upon request. The statement minimally shall include the following items:

1. The history and development of the postsecondary school;

2. An identification of any persons, entities, or institutions that have a controlling ownership or interest in the postsecondary school;

3. The purpose of the postsecondary school, including a statement of the relative degree of emphasis on instruction, research, and public service as well as a statement demonstrating that the school's proposed offerings are consistent with its stated purpose;

4. A description of the postsecondary school's activities including telecommunications activities away from its principal location, and a list of all program areas in which courses are offered away from the principal location;

5. A list of all locations in Virginia at which the postsecondary school offers courses and a list of the degree and nondegree programs currently offered or planned to be offered in Virginia;

¹§ 23-276.4(A)(3)

²§ 23-276.4(A)(4)

6. For each Virginia location, and for the most recent academic year, the total number of students who were enrolled as well as the total number and percentage of students who were enrolled in each program offered;

7. For each Virginia location, the total number of students that completed/graduated who completed or graduated from the school as of the end of the last academic year and the total number and percentage of students who completed/graduated completed or graduated from each program offered by the school as of the end of the last academic year; and

8. For unaccredited institutions of higher education and career-technical schools only, the total number of students who report employment in their field of study within (i) six months of graduation/completion completion or graduation and (ii) one year of graduation/completion completion or graduation.

C. The postsecondary school or branch shall have a current, written document available to students and the general public upon request that accurately states the powers, duties, and responsibilities of:

1. The governing board or owners of the school;

2. The chief operating officer, president, or director at that branch in Virginia;

3. The principal administrators and their credentials at that branch in Virginia; and

4. The students, if students participate in school governance.

D. The postsecondary school shall have, maintain, and provide to all applicants a policy document accurately defining the minimum requirements for eligibility for admission to the school and for acceptance at the specific degree level or into all specific degree programs offered by the postsecondary school that are relevant to the school's admissions standards. In addition, the document shall explain:

1. The standards for academic credit or course completion given for experience;

2. The criteria for acceptance of transfer credit where applicable;

3. The criteria for refunds of tuition and fees;

4. Students' rights, privileges, and responsibilities; and

5. The established grievance process of the school, which shall indicate that students should follow this process and may contact council staff to file a complaint about the school as a last resort. The written policy shall include a provision that students will not be subjected to adverse actions by any school officials as a result of initiating a complaint.

E. The postsecondary school shall maintain records on all enrolled students. At a minimum, these records shall include:

1. Each student's application for admission and admissions records containing information regarding the educational

qualifications of each regular student admitted that are relevant to the postsecondary school's admissions standards. Each student record must reflect the requirements and justification for admission of the student to the postsecondary school. Admissions records must be maintained by the school, its successors, or its assigns for a minimum of three years after the student's last date of attendance.

2. A transcript of the student's academic or course work at the school, which shall be retained permanently in either hard copy forms or in an electronic database with backup by the school, its successors, or its assigns.

3. A record of student academic or course progress at the school including programs of study, dates of enrollment, courses taken and completed, grades, and indication of the student's current status (graduated, probation, etc.) must be retained permanently. Any changes or alterations to student records must be accurately documented and signed by an appropriate school official.

4. A record of all financial transactions between each individual student and the school including payments from the student, payments from other sources on the student's behalf, and refunds. Fiscal records must be maintained for a minimum of three years after the student's last date of attendance. When tuition and fees are paid by the student in installments, a clear disclosure of truth-in-lending statement must be provided to and signed by the student.

5. The school shall make the documents referenced in subdivisions 1 through 4 of this subsection available to the student upon request. Academic transcripts shall be provided upon request if the student is in good financial standing.

F. Each school shall provide or make available to students, prospective students, and other interested persons a catalog, bulletin, brochure, or electronic media containing, at a minimum, the following information:

1. The number of students enrolled in each program offered.

2. For each Virginia location, the total number of students that completed/graduated who completed or graduated from the school as of the end of the last academic year and the total number and percentage of students who completed/graduated completed or graduated from each program offered by the school as of the end of the last academic year.

3. A description of any financial aid offered by the school including repayment obligations, standards of academic progress required for continued participation in the program, sources of loans or scholarships, the percentage of students receiving federal financial aid (if applicable) and the average student indebtedness at graduation.

4. A broad description, including academic and/or or career-technical objectives of each program offered, the

number of hours of instruction in each subject and total number of hours required for course completion, course descriptions, and a statement of the type of credential awarded.

5. A statement of tuition and fees and other charges related to enrollment, such as deposits, fees, books and supplies, tools and equipment, and any other charges for which a student may be responsible.

6. The school's refund policy for tuition and fees pursuant to subsection N of this section.

7. The school's procedures for handling complaints, including procedures to ensure that a student will not be subject to unfair actions as a result of his initiation of a complaint proceeding.

8. The name and address of the school's accrediting body, if applicable.

9. The minimum requirements for satisfactory completion of each degree level and degree program, or nondegree certificates/diplomas certificates or diplomas.

10. A statement that accurately describes the transferability of any courses.

11. A statement that accurately represents the transferability of any diplomas, certificates, or degrees offered by the school.

12. If the institution offers programs leading to the Associate of Applied Science or Associate of Occupational Science degree, a statement that these programs are terminal occupational/technical occupational or technical programs and that credits generally earned in these programs are not applicable to other degrees.

13. The academic or course work schedule for the period covered by the publication.

14. A statement that accurately details the type and amount of career advising and placement services offered by the school.

15. The name, location, and address of the main campus, branch, or instructional site operating in Virginia.

G. The school must have a clearly defined process by which the curriculum is established, reviewed and evaluated. Evaluation of school effectiveness must be completed on a regular basis and must include, but not be limited to:

1. An explanation of how each program is consistent with the mission of the school.

2. An explanation of the written process for evaluating each degree level and program, or career-technical program, once initiated and an explanation of the procedures for assessing the extent to which the educational goals are being achieved.

3. Documented use of the results of these evaluations to improve the degree and career-technical programs offered by the school.

H. Pursuant to § 23-276.3 B of the Code of Virginia, the school must maintain records that demonstrate it is financially sound; exercises proper management, financial controls and business practices; and can fulfill its commitments for education or training. The school's financial resources should be characterized by stability, which indicates the school is capable of maintaining operational continuity for an extended period of time. The stability indicator that will be used is the USDOE Financial Ratio (composite score).

1. Institutions of higher education shall provide the results of an annual audited, reviewed or compiled financial statement. Career-technical schools shall provide the results of an annual audited, reviewed or compiled financial statement or the school may elect to provide financial information on forms provided by council staff. The financial report shall be prepared in accordance with generally accepted accounting principles (GAAP) currently in effect. The financial report shall cover the most recent annual accounting period completed.

2. The USDOE composite score range is -1.0 to 3.0. Schools with a score of 1.5 to 3.0 meet fully the stability requirement in subsection I of this section; scores between 1.0 and 1.4 meet the minimum expectations; and scores less than 1.0 do not meet the requirement and shall be immediately considered for audit.

I. Pursuant to § 23-276.3 B of the Code of Virginia, the school shall have and maintain a surety instrument issued by a surety company or banking institution authorized to transact business in Virginia that is adequate to provide refunds to students for the unearned non-Title IV portion of tuition and fees for any given semester, quarter or term and to cover the administrative cost associated with the instrument claim. The instrument shall be based on the non-Title IV funds that have been received from students or agencies for which the education has not yet been delivered. This figure shall be indicated in an audited financial statement as a Current (non-Title IV) Tuition Liability. A school certified under this regulation shall be exempt from the surety instrument requirement if it can demonstrate a USDOE composite financial responsibility score of 1.5 or greater on its current financial statement; or if it can demonstrate a composite score between 1.0 and 1.4 on its current financial statement and has scored at least 1.5 on a financial statement in either of the prior two years. The school's eligibility for the surety waiver shall be determined annually, at the time of recertification.

1. Public postsecondary schools originating in a state other than Virginia that are operating a branch campus or instructional site in the Commonwealth of Virginia are exempt from the surety bond requirement.

2. New schools and unaccredited existing schools must complete at least five calendar years of academic instruction and/or or certification to qualify for the surety waiver/exemption waiver or exemption.

3. Existing schools seeking a waiver of the surety instrument requirement must submit an audited financial statement for the most recent fiscal year end that reflects the appropriate composite score as indicated in this subsection.

J. The school shall have a current written policy on faculty accessibility that shall be distributed to all students. The school shall ensure that instructional faculty are accessible to students for academic or course advising at stated times outside a course's regularly scheduled class hours at each branch and throughout the period during which the course is offered.

K. All recruitment personnel must provide prospective students with current and accurate information on the school through the use of written and electronic materials and in oral admissions interviews:

1. The school shall be responsible and liable for the acts of its admissions personnel.

2. No school, agent, or admissions personnel shall knowingly make any statement or representation that is false, inaccurate or misleading regarding the school.

L. All programs offered via telecommunications or distance education must be comparable in content, faculty, and resources to those offered in residence, and must include regular student-faculty interaction by computer, telephone, mail, or face-to-face meetings. Telecommunication programs and courses shall adhere to the following minimum standards:

1. The educational objectives for each program or course shall be clearly defined, simply stated, and of such a nature that they can be achieved through telecommunications.

2. Instructional materials and technology methods must be appropriate to meet the stated objectives of the program or course. The school must consider and implement basic online navigation of any course or program, an information exchange privacy and safety policy, a notice of minimum technology specification for students and faculty, proper system monitoring, and technology infrastructure capabilities sufficient to meet the demands of the programs being offered.

3. The school shall provide faculty and student training and support services specifically related to telecommunication activities.

4. The school shall provide for methods for timely interaction between students and faculty.

5. The school shall develop standards that ensure that accepted students have sufficient background, knowledge, and technical skills to successfully undertake a telecommunications program.

M. The school shall maintain and ensure that students have access to a library with a collection, staff, services, equipment and facilities that are adequate and appropriate for the purpose and enrollment of the school. Library resources shall be current, well distributed among fields in which the institution offers instructions, cataloged, logically organized, and readily located. The school shall maintain a continuous plan for library resource development and support, including objectives and selections of materials. Current and formal written agreements with other libraries or with other entities may be used. Institutions offering graduate work shall provide access to library resources that include basic reference and bibliographic works and major journals in each discipline in which the graduate program is offered. Careertechnical schools shall provide adequate and appropriate resources for completion of course work.

N. In accordance with § 23-276.3 B of the Code of Virginia, the school shall establish a tuition refund policy and communicate it to students. Each school shall establish, disclose, and utilize a system of tuition and fee charges for each program of instruction. These charges shall be applied uniformly to all similarly circumstanced students. This requirement does not apply to group tuition rates to business firms, industry, or governmental agencies that are documented by written agreements between the school and the respective organization.

1. The school shall adopt a minimum refund policy relative to the refund of tuition, fees, and other charges. All fees and payments, with the exception of the nonrefundable fee described in subdivision 2 of this subsection, remitted to the school by a prospective student shall be refunded if the student is not admitted, does not enroll in the school, does not begin the program or course, withdraws prior to the start of the program, or is dismissed prior to the start of the program.

2. A school may require the payment of a reasonable nonrefundable initial fee, not to exceed \$100, to cover expenses in connection with processing a student's enrollment, provided it retains a signed statement in which the parties acknowledge their understanding that the fee is nonrefundable. No other nonrefundable fees shall be allowed prior to enrollment.

3. The school shall provide a period of at least three business days, excluding weekends and holidays, during which a student applicant may cancel his enrollment without financial obligation other than the nonrefundable fee described in subdivision 2 of this subsection.

4. Following the period described in subdivision 3 of this subsection, a student applicant (one who has applied for admission to a school) may cancel, by written notice, his enrollment at any time prior to the first class day of the session for which application was made. When cancellation is requested under these circumstances, the school is required to refund all tuition paid by the student, less a maximum tuition fee of 15% of the stated costs of the course or program or \$100, whichever is less. A student applicant will be considered a student as of the first day of classes.

5. The date of the institution's determination that the student withdrew should be no later than 14 calendar days after the student's last date of attendance as determined by the institution from its attendance records. The institution is not required to administratively withdraw a student who has been absent for 14 calendar days. However, after 14 calendar days, the institution is expected to have determined whether the student intends to return to classes or to withdraw. In addition, if the student is eventually determined to have withdrawn, the end of the 14-day period begins the timeframe for calculating the refunds. In the event that a written notice is submitted, the effective date of termination shall be the date of the written notice. The school may require that written notice be transmitted via registered or certified mail, or by electronic transmission provided that such a stipulation is contained in the written enrollment contract. The school is required to submit refunds to individuals who have terminated their status as students within 45 days after receipt of a written request or the date the student last attended classes whichever is sooner. An institution that provides the majority of its program offerings through distance learning shall have a plan for student termination, which shall be provided to council staff for review with its annual or recertification application.

6. In the case of a prolonged illness or accident, death in the family, or other special circumstances that make attendance impossible or impractical, a leave of absence may be granted to the student if requested in writing by the student or designee. No monetary charges or accumulated absences may be assessed to the student during a leave of absence. A school need not treat a leave of absence as a withdrawal if it is an approved leave of absence. A leave of absence is an approved leave of absence if:

a. The school has a formal, published policy regarding leaves of absence;

b. The student followed the institution's policy in requesting the leave of absence and submits a signed, dated request with the reasons for the leave of absence;

c. The school determines that there is a reasonable expectation that the student will return to the school;

d. The school approved the student's request in accordance with the published policy;

e. The school does not impose additional charges to the student as a result of the leave of absence;

f. The leave of absence does not exceed 180 days in any 12-month period; and

g. Upon the student's return from the leave of absence, the student is permitted to complete the coursework he began prior to the leave of absence.

7. If a student does not resume attendance at the institution on or before the end of an approved leave of absence, the institution must treat the student as a withdrawal, and the date that the leave of absence was approved should be considered the last date of attendance for refund purposes.

8. The minimum refund policy for a school that financially obligates the student for a quarter, semester, trimester or other period not exceeding 4-1/2 calendar months shall be as follows:

a. For schools that utilize an add/drop period, a student who withdraws during the add/drop period shall be entitled to 100% refund for the period.

b. For unaccredited schools and schools that do not utilize an add/drop period:

(1) A student who enters school but withdraws during the first 1/4 (25%) of the period is entitled to receive as a refund a minimum of 50% of the stated cost of the course or program for the period.

(2) A student who enters a school but withdraws after completing 1/4 (25%), but less than 1/2 (50%) of the period is entitled to receive as a refund a minimum of 25% of the stated cost of the course or program for the period.

(3) A student who withdraws after completing 1/2 (50%), or more than 1/2 (50%), of the period is not entitled to a refund.

9. The minimum refund policy for a school that financially obligates the student for the entire amount of tuition and fees for the entirety of a program or course shall be as follows:

a. A student who enters the school but withdraws or is terminated during the first quartile (25%) of the program shall be entitled to a minimum refund amounting to 75% of the cost of the program.

b. A student who withdraws or is terminated during the second quartile (more than 25% but less than 50%) of the program shall be entitled to a minimum refund amounting to 50% of the cost of the program.

c. A student who withdraws or is terminated during the third quartile (more than 50% but less than 75%) of the program shall be entitled to a minimum refund amounting to 25% of the cost of the program.

d. A student who withdraws after completing more than three quartiles (75%) of the program shall not be entitled to a refund.

10. The minimum refund policy for a school that offers its programs completely via telecommunications or distance education shall be as follows:

a. For a student canceling after the 5th calendar day following the date of enrollment but prior to receipt by the school of the first completed lesson assignment, all moneys paid to the school shall be refunded, except the nonrefundable fee described in subdivision 2 of this subsection.

b. If a student enrolls and withdraws or is discontinued after submission of the first completed lesson assignment, but prior to the completion of the program, minimum refunds shall be calculated as follows:

(1) A student who starts the program but withdraws up to and including completion of the first quartile (25%) of the program is entitled to receive as a refund a minimum of 75% of the stated cost of the course or program for the period.

(2) A student who starts the program but withdraws after completing up to the second quartile (more than 25%, but less than 50%) of the program is entitled to receive as a refund a minimum of 50% of the stated cost of the course or program for the period.

(3) A student who starts the program but withdraws after completing up to the third quartile (more than 50%, but less than 75%) of the program is entitled to receive as a refund a minimum of 25% of the stated cost of the course or program for the period.

(4) A student who withdraws after completing the third quartile (75%) or more of the program is not entitled to a refund.

c. The percentage of the program completed shall be determined by comparing the number of completed lesson assignments received by the school to the total number of lesson assignments required in the program.

d. If the school uses standard enrollment terms, such as semesters or quarters, to measure student progress, the school may use the appropriate refund policy as provided in subdivision 8 or 9 of this subsection.

11. Fractions of credit for courses completed shall be determined by dividing the total amount of time required to complete the period or the program by the amount of time the student actually spent in the program or the period, or by the number of correspondence course lessons completed, as described in the contract.

12. Expenses incurred by students for instructional supplies, tools, activities, library, rentals, service charges, deposits, and all other charges are not required to be considered in tuition refund computations when these expenses have been represented separately to the student in the enrollment contract and catalogue, or other documents, prior to enrollment in the course or program. The school shall adopt and adhere to reasonable policies regarding the handling of these expenses when calculating the refund.

13. For programs longer than one year, the policy outlined in subdivisions 9, 10, and 11 of this subsection shall apply separately for each academic year or portion thereof.

14. Schools shall comply with the cancellation and settlement policy outlined in this section, including promissory notes or contracts for tuition or fees sold to third parties.

15. When notes, contracts or enrollment agreements are sold to third parties, the school shall continue to have the responsibility to provide the training specified regardless of the source of any tuition, fees, or other charges that have been remitted to the school by the student or on behalf of the student.

O. The school shall keep relevant academic transcripts for all teaching faculty to document that each has the appropriate educational credentials in the area of teaching responsibility. In the event teaching qualification is based on professional competencies and/or or scholarly achievements, relevant documentation to support reported experience must be retained by the school.

P. If an internship, externship, or production work is necessary as a part of the school's education program, the school must adhere to the following:

1. When programs contain internships or externships, in any form, the professional training must:

a. Be identified as part of the approved curriculum of the school and be specified in terms of expected learning outcomes in a written training plan.

b. Be monitored by an instructor of record during the entire period of the internship.

c. Not be used to provide labor or as replacement for a permanent employee.

d. Be performed according to a specified schedule of time required for training including an expected completion date.

e. If the internship, externship, or production work is part of the course requirement, the student may not be considered as a graduate or issued a graduation credential until the internship, externship, or production work has been satisfactorily completed.

2. When receiving compensation for services provided by students as part of their education program, the school must clearly inform customers that services are performed by students by (i) posting a notice in plain view of the public or (ii) requiring students to wear nametags that identify them as students while performing services related to their training.

Q. An institution shall notify council staff of the following occurrences no later than 30 days following prior to said occurrence:

1. Addition of new programs or modifications to existing program. Program names must adhere to the CIP taxonomy maintained by the National Center for Education Statistics.

2. Addition of a new branch location or instructional site.

3. Address change of a branch or instructional site in Virginia.

Notification of the above-referenced occurrences shall be submitted in writing on forms provided by and in a manner prescribed by the council.

R. An institution shall notify the council of the following occurrences no later than 30 days following said occurrence.

1. Naming of new school president.

2. Naming of new campus or branch director.

3. Naming of person responsible for the regulatory oversight of the institution.

Part VI

Certification Requirements

8VAC40-31-170. Initial certification, recertification, and change of ownership.

A. An institution shall not use the term "college" or "university" or words of similar meaning until it has received acknowledgment from council staff that the name is not in violation of 8VAC40-31-20.

1. A school may not use the term "college" in its name unless the school has been approved or seeks to offer programs at the associate degree or above.

2. A school may not use the term "university" in its name unless the school has been approved or seeks to offer programs at the master's degree or above.

3. The council may refuse to approve a name change when, in the council's judgment, the proposed name is likely to mislead the public about the school's identity or the nature of its programs.

4. A school seeking certification must notify council staff of its proposed name prior to filing such name with the State Corporation Commission.

5. Prior to receiving certification to operate, a copy of the school's certificate from the Virginia State Corporation Commission authorizing it to transact business in the Commonwealth under the acknowledged name must be submitted to council staff.

B. A school shall not operate in the Commonwealth of Virginia without first receiving certification to operate from the council. Certified schools shall not enter into any agreement to deliver or develop courses or programs of study in Virginia with noncertified postsecondary schools.

C. An out-of-state postsecondary school seeking certification to operate in the Commonwealth of Virginia must secure written documentation from the higher education coordinating and/or or approving agency in the state or country in which the school is formed, chartered, established, or incorporated indicating that the school is operating in good standing. If the school formerly operated in another state or country but is not operating there at the time of its application to operate in Virginia, the school must secure from the higher education coordinating and/or or approving agency documentation that it closed in good standing and would be allowed to re-establish reestablish a postsecondary school in that state or country. These written documentations must be provided to council staff.

D. A school submitting its initial application for certification will have 180 days to complete the application process, after which time its application will be withdrawn by the council and it will receive a refund of the application fee minus the <u>a</u> nonrefundable handling charge of \$300 administrative fee as listed in 8VAC40-31-260 D.

E. All certifications shall expire on the certificate expiration date. Applications for recertification must be submitted to council staff at least 60 days prior to the expiration date of the current certification. If a school allows its certification to operate to expire, the school shall not be eligible for recertification and must submit an application for initial certification including the appropriate application fee.

F. Certification is not transferable. In the event of a change of ownership of a certified school, the new owner or governing body must secure certification. The school must apply for certification within 45 business days following a change of ownership. During the 45-day period and the time required for the council staff to process the new application, up to and not exceeding 90 days, the old certification shall remain in effect provided that no changes have been made in the academic programs, policies, or financial considerations such that the change would constitute or create a violation of council's policies.

1. The following constitutes a change of ownership:

a. Purchase of the entire school or assets of school.

b. Transfer, sale, or purchase of stock, membership, or other direct or beneficial ownership interest by a single entity or by multiple entities in a single transaction or a series of transactions that results in at least 51% change in control.

2. The acquisition of an interest in a certified school by bequest, descent, survivorship, or operation of law does not constitute a change of ownership. However, the person acquiring the ownership interest shall send written notice to the council of such acquisition within 30 days of its closing or validation. The council may determine on a case-by-case basis that other similar transfers may not constitute a change of ownership.

3. New school owners are responsible for maintaining and servicing all student records that were the responsibility of the prior owners of the school.

4. New school owners are responsible for resolving all student complaints that were the responsibility of the prior owners of the school or that were filed with the council prior to the final approval of the change of ownership.

5. New school owners are responsible for honoring the terms of current student enrollment agreements, institutional scholarships, or institutional grants for all students who were enrolled or taking classes at the time the change of ownership took place.

G. Council staff will process all applications, conduct the site visit, and provide notice to applicants within 45 business

days of receipt of a completed application package. Approval of the certificate to operate by the council is subject to scheduling of council meetings and other factors affecting the agendas of council meetings.

H. Valid-through dates of Certificates to Operate certificates to operate and due dates of recertification applications are as follows:

1. Out-of-state private degree-granting and career-technical school certificates are valid for one year beginning on September 1 of the calendar year and ending on August 31 of the following calendar year. Applications are due not later than July 2.

2. Out-of-state public institution certificates are valid for one year beginning on September 15 of the calendar year and ending on September 14 of the following calendar year. Applications are due not later than July 16.

3. In-state private nonprofit institution certificates are valid for one year beginning on October 1 of the calendar year and ending on September 30 of the following calendar year. Applications are due not later than August 2.

4. In-state proprietary degree-granting and career-technical school certificates are valid for one year beginning on October 15 of the calendar year and ending on October 14 of the following calendar year. Applications are due not later than August 16.

5. In-state proprietary career-technical school certificates (letters A-D) are valid for one year beginning on November 1 of the calendar year and ending on October 31 of the following calendar year. Applications are due not later than September 2.

6. In-state proprietary career-technical school certificates (letters E-P) are valid for one year beginning on November 15 of the calendar year and ending on November 14 of the following calendar year. Applications are due not later than September 16.

7. In-state proprietary career-technical school certificates (letters Q-Z and others) are valid for one year beginning on December 1 of the calendar year and ending on November 30 of the following calendar year. Applications are due not later than October 2.

8VAC40-31-260. Fees.

A. All fees collected by council staff will be deposited in the State Treasury.

B. All fees are nonrefundable with the exception of withdrawal of an application in which case all fees will be refunded minus a reasonable handling charge of \$300 nonrefundable administrative fee noted in subsection D of this section.

C. Fees must be paid with a company check and made payable to the Treasurer of Virginia.

D. The annual fee is based on the annual gross tuition received by each administrative branch of institutions

certified to operate in Virginia. For out-of-state institutions certified to operate in Virginia, annual gross tuition means income generated from students enrolled at Virginia locations. The flat fee schedule is as follows:

focutions. The flue fee schedule is us fond	
New school orientation session, per person	\$150
Initial fee for all new institutions of higher education	\$6,000
Initial fee for all new career-technical schools	\$2,500
Annual fee for all unaccredited institutions of higher education	\$6,000
Annual fee for all unaccredited out- of state career technical schools	\$2,500
Renewal fee for all postsecondary schools with an annual gross tuition collected less than \$50,000, as recorded on most recent financial statement	\$250
Renewal fee for all postsecondary schools with an annual gross tuition collected greater than or equal to \$50,000 but less than \$100,000, as recorded on most recent financial statement	\$1,000
Renewal fee for all postsecondary schools with an annual gross tuition collected greater than or equal to \$100,000 but less than \$500,000, as recorded on most recent financial statement	\$2,500
Renewal fee for all postsecondary schools with an annual gross tuition collected greater than or equal to \$500,000 but less than \$1,000,000, as recorded on most recent financial statement	\$4,000
Renewal fee for all postsecondary schools with an annual gross tuition collected greater than or equal to \$1,000,000, as recorded on most recent financial statement	\$5,000
Returned check fee	\$35
Initial or renewed exemption application/request for name acknowledgement/agent registration	\$300
Nonrefundable administrative fee (withdrawal of application)	\$500 career- technical, \$1000

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	institutions of higher education
Request duplicate certificate to operate due to school name or address change	\$100
Request duplicate agent permit, to replace lost/stolen/misplaced permit	\$100
Application fee for each additional branch	\$300
Application fee for each additional site	\$100
Application fee for each additional program or modification to an existing program	\$100

E. A school that submits a payment that is returned for any reason must resubmit the required payment, any applicable late fee, and the assessed returned check fee of \$35 via a money order or certified bank check only.

VA.R. Doc. No. R16-4393; Filed March 29, 2016, 12:00 p.m.

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Fast-Track Regulation

<u>Title of Regulation:</u> 12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-10, 12VAC5-481-3390 through 12VAC5-481-3450; adding 12VAC5-481-3451, 12VAC5-481-3452, 12VAC5-481-3453).

Statutory Authority: §§ 32.1-12 and 32.1-229 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: May 18, 2016.

Effective Date: June 5, 2016.

Agency Contact: Steve Harrison, Director, Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8151, FAX (804) 864-8155, or email steve.harrison@vdh.virginia.gov.

<u>Basis:</u> Section 32.1-229 of the Code of Virginia authorizes the State Board of Health to require the licensure and inspection of radioactive materials facilities and mandates inspections of mammography facilities. Section 32.1-229.1 of the Code of Virginia requires the State Board of Health to promulgate regulations for the registration, inspection, and certification of x-ray machines. <u>Purpose</u>: The Virginia Department of Health (VDH), Office of Radiological Health (ORH) proposes to amend 12VAC5-481, Virginia Radiation Protection Regulations, to reflect changes in and new x-ray modalities pertaining to the medical field, amend existing and add new definitions, and update the regulations to meet the current Virginia Register Form, Style, and Procedure Manual.

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

<u>Substance</u>: The Conference of Radiation Control Program Directors (CRCPD) develops Suggested State Regulations (SSRs) upon which an individual state may base its regulations. The x-ray regulations were based upon the SSRs when adopted in 2006; this amendment will ensure that Virginia's regulations are brought up to date by incorporating the most recent CRCPD SSRs in totality. This action adds or amends provisions concerning radiation therapy machines, including electronic brachytherapy, as follows:

1. Adds new terms and definitions in 12VAC5-481-10, including conventional simulator, electronic brachytherapy, electronic brachytherapy device. electronic brachytherapy source, intensity modulated radiation therapy (IMRT), mobile electronic brachytherapy service, qualified inspector, qualified medical physicist, radiation therapy system, target-skin distance (TSD), and virtual simulator.

2. Amends definitions in 12VAC5-481-10, including beam-limiting device, leakage radiation, light field, prescribed dose, and therapeutic radiation machine.

3. Amends the following sections in Part XV, Therapeutic Radiation Machines: 12VAC5-481-3390, General administrative requirements for facilities using therapeutic radiation machines; 12VAC5-481-3400, General technical requirements for facilities using therapeutic radiation machines; 12VAC5-481-3410, Quality management program; 12VAC5-481-3420, Therapeutic radiation machines of less than 500 kV; 12VAC5-481-3430, Therapeutic radiation machines photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above), and electron therapy systems (500 kV and above); and 12VAC5-481-3450, Shielding and safety design requirements.

4. Adds the following new sections to Part XV, Therapeutic Radiation Machines: 12VAC5-481-3451, Quality assurance for radiation therapy simulation systems; 12VAC5-481-3452, Electronic brachytherapy;

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and 12VAC5-481-3453, Other use of electronicallyproduced radiation to deliver therapeutic radiation dosage.

<u>Issues:</u> The advantage of this action is that health care providers regulated by VDH will operate under clear worker and machine performance standards. Another advantage for health care professionals and patients is that regulations governing the application of radiation will meet nationally recognized performance standards, which will promote quality of care. There are no disadvantages to the public in promulgating the proposed regulation.

The advantage of the proposed regulation to the agency is that the proper regulation of therapeutic radiation producing machines will now be addressed. There are no disadvantages to the agency in promulgating the proposed regulation. There are no disadvantages to the public or the Commonwealth as a result of this initiative.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation: The State Health Commissioner proposes to amend the Virginia Radiation Protection Regulations to 1) add new definitions, amend existing definitions and update other sections of this regulation so that it accurately reflects current practice for therapeutic radiation machines and 2) update the regulation so that it conforms to the current Virginia Register Form, Style and Procedure Manual.

Result of Analysis. Benefits likely outweigh costs for all proposed regulatory changes.

Estimated Economic Impact. The Commissioner proposes to add eleven new definitions and amend a further five to account for new therapeutic radiation machine techniques and procedures. For instance, the Commissioner proposes to add a definition for "radiation therapy systems" and amend the definition of "therapeutic radiation machine." The Commissioner also proposes to add language to the regulatory text to clarify current procedures and requirements for the regulated community. Some of these changes will, for instance, replace general language that requires facilities that own machines covered by this regulation to have a quality management program with specific language that lays out exactly what is currently required of such a program.

All of these amendments, as well as the amendments that bring regulatory language into conformity with the state's regulatory style manual, are clarifying rather than substantive. No affected entity is likely to incur costs on account of any of these changes. To the extent that this regulation was out of date and out of sync with current radiation machine practices and terminology, these changes will benefit readers who will likely find the regulation easier to understand and comply with.

Businesses and Entities Affected. Virginia Department of Health staff reports that this x-ray program currently registers

approximately 21,464 x-ray machines. Of these 21,464, approximately 90 are therapeutic radiation machines. Staff further reports that approximately 1,500 registrants meet the criteria for small business.

Localities Particularly Affected. No locality will be particularly affected by this regulatory change.

Projected Impact on Employment. These regulatory changes are unlikely to have any effect on employment in the Commonwealth.

Effects on the Use and Value of Private Property. These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs. These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects. Small businesses are unlikely to incur any costs on account of these proposed regulatory changes.

Alternative Method that Minimizes Adverse Impact. Small businesses are unlikely to incur any costs on account of these proposed regulatory changes.

Adverse Impacts:

Businesses. Businesses are unlikely to incur any costs on account of these proposed regulatory changes.

Localities. Localities in the Commonwealth are unlikely to see any adverse impacts on account of this proposed regulatory change.

Other Entities. No entities are likely to incur any costs on account of these regulatory changes.

<u>Agency's Response to Economic Impact Analysis:</u> The Virginia Department of Health concurs with the economic impact analysis submitted by the Department of Planning and Budget.

Summary:

To reflect changes in and new x-ray modalities for the medical field, including therapeutic and electonic brachytherapy equipment, this action (i) amends and adds defined terms and (ii) updates the regulatory text to clarify current procedures and requirements.

Part I

General Provisions

12VAC5-481-10. Definitions.

The following words and terms as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

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" A_1 " means the maximum activity of special form radioactive material permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770.

" A_2 " means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

"Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer. It also means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Act" means §§ 32.1-227 through 32.1-238 of the Code of Virginia.

"Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 12VAC5-481-2490 and 12VAC5-481-2500 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or onetime measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"Acute" means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less). "Address of use" means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

"Adult" means an individual 18 or more years of age.

"Agency" means the Radiological Health Program of the Virginia Department of Health.

"Aggregated" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material as listed in 12VAC5-481-451.

"Agreement state" means any state with which the NRC or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials composed wholly or partly of licensed material exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in 12VAC5-481-3690; or

2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC hours.

"Air kerma" or "K" means kerma in air (see definition of "kerma").

"Air kerma rate" or "AKR" means the air kerma per unit time.

"Air-purifying respirator" means a respirator with an airpurifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

"Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper.

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays or gamma-rays to determine the elemental composition or to examine the microstructure of materials. "Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Tables 1 and 2 in 12VAC5-481-3690.

"Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

"Annually" means at intervals not to exceed one year.

"ANSI" means the American National Standards Institute.

"Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 12VAC5-481-451 and has completed the training required in 12VAC5-481-451.

"Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

"Assigned protection factor" or "APF" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

"As low as is reasonably achievable" or "ALARA" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Articulated joint" means a joint between two separate sections of a tabletop that provides the capacity for one of the sections to pivot on the line segment along which the sections join.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drive, guide, or come in contact with the source.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation. The nominal chemical composition of type 100 aluminum is 99.00% minimum aluminum, 0.12% copper.

"Authorized medical physicist" means an individual who:

1. Meets the requirements in 12VAC5-481-1760 and 12VAC5-481-1790; or

2. Is identified as an authorized medical physicist or teletherapy physicist on:

a. A specific medical use license issued by the NRC or another agreement state;

b. A medical use permit issued by an NRC master material licensee;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee; or

d. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

1. Meets the requirements in 12VAC5-481-1770 and 12VAC5-481-1790;

2. Is identified as an authorized nuclear pharmacist on:

a. A specific license issued by the NRC or another agreement state that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-440 I 2.

"Authorized user" means a practitioner of the healing arts who:

- 1. Meets the requirements in 12VAC5-481-1790 and any of the following:
 - a. 12VAC5-481-1910;
 - b. 12VAC5-481-1940;
 - c. 12VAC5-481-1980;
 - d. 12VAC5-481-1990;
 - e. 12VAC5-481-2000;
 - f. 12VAC5-481-2010;
 - g. 12VAC5-481-2030;
 - h. 12VAC5-481-2040; or

2. Is identified as an authorized user on:

a. A specific license issued by the NRC or another agreement state that authorizes medical use;

b. A permit issued by an NRC master material licensee that authorizes medical use;

c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use; or

d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use.

"Automatic exposure control" or "AEC" means a device that automatically controls one or more technique factors in order to obtain, at a preselected <u>location(s)</u> <u>location</u>, a required quantity of radiation (includes devices such as phototimers and ion chambers).

"Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

"Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, that have not been technologically enhanced, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices, or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the agency.

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field <u>or useful</u> <u>beam</u>.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Becquerel" or "Bq" means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

"Beneficial attribute" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the radioactivity of the product necessary to the use of the product.

"Beneficial to the product" see "Beneficial attribute."

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in-vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Board" means the State Board of Health.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Byproduct material" means:

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

3. a. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

b. Any material that:

(1) Has been made radioactive by use of a particle accelerator; and

(2) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

a. The NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

b. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"C-arm fluoroscope" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in 12VAC5-481-720.

"Cabinet x-ray system" means an x-ray system with the xray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or xray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet xray system.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

"Calibration" means the determination of (i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument or (ii) the strength of a source of radiation relative to a standard.

"Camera" (See "Radiographic exposure device").

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Cassette holder" means a device, other than a spot-film device, that supports or fixes the position of an x-ray film (imaging) cassette during an x-ray exposure.

"Category 1 quantities of radioactive material" or "Category 1" means a quantity of radioactive material meeting or exceeding the Category 1 threshold in Table 1 of 12VAC5-481-451. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Category 2 quantities of radioactive material" or "Category 2" means a quantity of radioactive material meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of 12VAC5-481-451. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 2 quantity. Category 2 quantities of radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

"Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the NRC.

"Certificate of compliance" or "CoC" means the certificate issued by the NRC that approves the design of a package for the transportation of radioactive material.

"Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Certified components" means components of x-ray systems that are subject to regulations promulgated under Pub. L. 90-602, the Radiation Control for Health and Safety Act of 1968 of the Food and Drug Administration.

"Certifying entity" means an independent certifying organization meeting the agency's requirements for documenting applicant's training in topics set forth in 12VAC5-481-1320 or equivalent state or NRC regulations.

"CFR" means Code of Federal Regulations.

"Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

"Chemical description" means a description of the principal chemical characteristics of a low-level radioactive waste.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days; and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "seethrough" type.

"cm" means centimeters.

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{x}} = \frac{1}{\overline{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \overline{x})^2}{n - 1} \right]^{1/2}$$

where:

s = Standard deviation of the observed values;

 \overline{X} = Mean value of observations in sample;

 $x_i = i_{th}$ observation in sample;

n = Number of observations in sample.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Collimator" means a device used to limit the size, shape, and direction of the primary radiation beam. For industrial radiography it means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values. "Committed dose equivalent" or " $H_{T,50}$ " means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" or " $H_{E,50}$ " is the sum of the products of the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma (w_T H_{T,50})$).

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n T} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane;

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Computer-readable medium" means that the regulatory agency's computer can transfer the information from the medium into its memory.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.

"Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

"Constraint" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport. "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

"Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN_x} - \overline{CTN_w}}$$

where:

 μ_x = Linear attenuation coefficient of the material of interest;

$$\mu_{w}$$
 = Linear attenuation coefficient of water;

 \overline{CTN}_{x} = of the material of interest;

 $\overline{CTN}_{W} = \text{of water.}$

"Control cable" or "drive" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

<u>"Conventional simulator" means any x-ray system designed</u> to reproduce the geometric conditions of the radiation therapy equipment.

"Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;

2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

3. For transport by any aircraft.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"Cradle" means either:

1. A removable device that supports and may restrain a patient above an x-ray table; or

2. A device:

a. Whose patient support structure is interposed between the patient and the image receptor during normal use;

b. Which is equipped with means for patient restraint; and

c. Which is capable of rotation about its long (longitudinal) axis.

"Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"Criticality safety index" or "CSI" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in Part XIII (12VAC5-481-2950 et seq.).

"CS" (See "Contrast scale").

"CT" (See "Computed tomography").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in these regulations.

"CTDI" (See "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beamlimiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k \left(\mu_x - \mu_w\right)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used;

 μ_x = Linear attenuation coefficient of the material of interest;

 μ_w = Linear attenuation coefficient of water.

"Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contribution from fluoroscopic and radiographic irradiation.

"Curie" means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material that decays at the rate

of 3.7E+10 disintegrations or transformations per second (dps or tps).

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

"Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

"Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license or release of the property under restricted conditions and termination of the license.

"Decontamination facility" means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Deep dose equivalent" or " H_d ," which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm²).

"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Department of Energy" means the Department of Energy established by Pub. L. 95-91, August 4, 1977, 91 Stat. 565, 42 USC § 7101 et seq., to the extent that the Department exercises functions formerly vested in the Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the Energy Research and Development Administration and to the Administrator thereof pursuant to §§ 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 USC § 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to § 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 USC § 7151, effective October 1, 1977).

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percentage of the total uranium present. Depleted uranium does not include special nuclear material.

"Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed

by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in 12VAC5-481-3690.

"Derived air concentration-hour" or "DAC hour" means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Detector" (See "Radiation detector").

"Deuterium" means, for the purposes of Part XIII (12VAC5-481-2950 et seq.) deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures, where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

"Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator and a disposable escape-only self-contained breathing apparatus (SCBA).

"Disposal" means the isolation of wastes from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package. "Disposal site" means that portion of a land disposal facility that is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the unit is usually a trench.

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"Diversion" means the unauthorized movement of radioactive material subject to 12VAC5-481-451 to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

"Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

"Dose equivalent" or " H_T " means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.

"Dose monitor unit" or "DMU" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Dose profile" means the dose as a function of position along a line.

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

"Drive cable" (See "Control cable").

"Effective dose equivalent" or " H_E " means the sum of the products of the dose equivalent (H_T) to each organ or tissue

and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated $(H_E = \Sigma w_T H_T)$.

"Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

<u>"Electronic brachytherapy source" means the x-ray tube</u> component used in an electronic brachytherapy device.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Energy compensation source" or "ECS" means a small sealed source, with an activity not exceeding 3.7 MBq (100 μ Ci), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

"Engineered barrier" means a manmade structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in these regulations.

"Enriched uranium" (See "Uranium - natural, depleted, enriched").

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"EPA identification number" means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR Part 263.

"Equipment" (See "X-ray equipment").

"Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

"Exclusive use" means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

"Explosive material" means any chemical compound, mixture, or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located and/or <u>or</u> used.

"Fail-safe characteristics" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations. It also means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to Part XV (12VAC5-481-3380 et seq.) of this chapter.

"Filtering facepiece" or "dusk mask" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

"Fingerprint orders" means the requirements of 12VAC5-481-451 C or orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to Category 1 and Category 2 quantities of radioactive material or safeguards information-modified handling.

"Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. "Fissile material" means

the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

1. Fissile Class I: A package that may be transported in unlimited numbers and in any arrangement, and that requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

2. Fissile Class II: A package that may be transported together with other packages in any arrangement but, for criticality control, in numbers that do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

"Fissile material package" means a fissile material packaging together with its fissile material contents.

"Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

"Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptors, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Fluoroscopic irradiation time" means the cumulative duration during an examination or procedure of operatorapplied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

"Focal spot" or "actual" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Former Atomic Energy Commission or NRC licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where Atomic Energy Commission or NRC licenses have been terminated.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

"Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"General environment" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific license issued under Part XVI, is performed.

"General purpose radiographic x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

"Generator" means a licensee who (i) is a waste generator as defined in this chapter or (ii) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

"Gonad shield" means a protective barrier for the testes or ovaries.

"Gray (Gy)" means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad).

"Guide tube (protection sheath)" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Half-value layer" or "HVL" means the thickness of a specified material that attenuates the beam of radiation to an extent that the AKR is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Hand-held radiographic unit" means x-ray equipment that is designed to be hand-held during operation.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2,000 hours of hands-on experience required for a radiation safety officer in 12VAC5-481-1310 B 2 or the hands-on experience for a radiographer as required by 12VAC5-481-1320 A.

"Hazardous waste" means those wastes designated as hazardous by the Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means the art or science or group of arts or sciences dealing with the prevention and cure or alleviation of ailments, diseases or infirmities, and has the same meaning as "medicine" when the latter term is used in its comprehensive sense.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, such as (kVp) times (mA) times (seconds).

"Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"High integrity container" or "HIC" means a container commonly designed to meet the structural stability requirements of 12VAC5-481-2572 and to meet U.S. Department of Transportation requirements for a Type A package.

"High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

"Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

"Image intensifier" means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solidstate detector, or gaseous detector that transforms incident xray photons either into a visible image or into another form that can be made into a visible image by further

transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Image receptor support device" means, for mammographic systems, that part of the system designed to support the image receptor during mammographic examination and to provide a primary protective barrier.

"Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

"Independent certifying organization" means an independent organization that meets the agency's criteria for documenting applicant's training in topics set forth in 12VAC5-481-1320 or equivalent agreement state or NRC regulations.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

1. Dose equivalent (i) by the use of individual monitoring devices or (ii) by the use of survey data; or

2. Committed effective dose equivalent (i) by bioassay or (ii) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC hours. (See the definition of DAC)

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters and personal air sampling devices.

"Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

"Inhalation class" (See "Class").

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

"Institutional controls" means: (i) permanent markers placed at a disposal site, (ii) public records and archives, (iii) government ownership and regulations regarding land or resource use, and (iv) other methods of preserving knowledge about the location, design, and contents of a disposal system.

"Instrument traceability" (for ionizing radiation measurements) means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a

program that requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

"Intensity modulated radiation therapy" or "IMRT" means radiation therapy that uses nonuniform radiation beam intensities that have been determined by various computerbased optimization techniques.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in these regulations, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Irradiation" means the exposure of matter to ionizing radiation.

"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

"Irradiator operator" means an individual who has successfully completed the training and testing described in 12VAC5-481-2830 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

"Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in 12VAC5-481-2830.

"Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

"kBq" means kilabecquerels.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus K=dEtr/dm, in units of J/kg, where the

special name for the units of kerma is gray (Gy). When the materials is air, the quantity is referred to as "air kerma."

"Kilovolt" or "kV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000 volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second.

"Land disposal facility" means the land, buildings, structures and equipment that is intended to be used for the disposal of wastes into the subsurface of the land. For purposes of this chapter, a "geologic repository" as defined in 10 CFR Part 60 or 10 CFR Part 63 is not considered a land disposal facility.

"Last image hold radiograph" or "LIH" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

"Leakage radiation" means radiation emanating from the diagnostic source assembly <u>or the radiation therapy system</u> except for:

1. The useful beam; and

2. Radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly that are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, (10 mAs), or the minimum obtainable from the unit, whichever is larger;

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximumrated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; or

3. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Lens dose equivalent" or "LDE" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of $0.3 \text{ cm} (300 \text{ mg/cm}^2)$.

"License" means a license issued by the agency in accordance with the regulations adopted by the board.

"Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the agency.

"Licensee" means any person who is licensed by the agency in accordance with these regulations and the Act.

"Light field" means that the area of the intersection of the light beam from the beam limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one fourth of the maximum in the intersection illuminated by light, simulating the radiation field.

"Limits" (See "Dose limits").

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential as follows:

Percent line-voltage regulation = $100 (V_n - V_l)/V_l$

where:

 $V_n =$ No-load line potential; and

 V_1 = Load line potential.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Local components" means part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Local law-enforcement agency" or "LLEA" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed Category 1 or Category 2 quantity of radioactive material is used, stored, or transported.

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by Part XIV (12VAC5-481-3140 et seq.) of this chapter.

"Logging supervisor" means the individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of this chapter and the conditions of the license.

"Logging tool" means a device used subsurface to perform well-logging.

"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Lost or missing licensed material" means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Lot tolerance percent defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

"Low specific activity material" or "LSA material" means radioactive material with limited specific activity that is nonfissile or is excepted under 12VAC5-481-2970 C, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

1. LSA-I

a. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclide that are not intended to be processed for the use of these radionuclides;

b. Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

c. Radioactive material, for which the A_2 value is unlimited; or

d. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 12VAC5-481-3720.

2. LSA-II

a. Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or

b. Other material in which the activity is distributed throughout, and the average specific activity does not exceed 1.0 E-04 A_2/g for solids and gases, and 1.0 E-05 A_2/g for liquids.

3. LSA-III

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77) in which:

a. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (e.g., concrete, bitumen, or ceramic);

b. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A_2 ; and

c. The estimated average specific activity of the solid does not exceed 2.0 E-03 $A_2/g.$

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

"Lung class" (See "Class").

"mA" means milliampere.

"mAs" means milliampere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this section.

"Management" means the chief executive officer or that individual's designee.

"MBq" means megabecquerels.

"Medical event" means an event that meets the criteria in 12VAC5-481-2080.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Megavolt" or "MV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

"Member of the public" means an individual except when that individual is receiving an occupational dose.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Minor" means an individual less than 18 years of age.

"Misadministration" means either:

1. An x-ray teletherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong mode of treatment;

c. Involving the wrong treatment site;

d. Where the calculated total administered dose differs from the total prescribed dose by more than 10% when the treatment consists of three or fewer fractions;

e. Where the calculated weekly administered dose differs from the weekly prescribed dose by 30%; or

f. Where the calculated total administered dose differs from the total prescribed dose by more than 20%; or

2. An x-ray brachytherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong treatment site; or

c. Where the calculated administered dose differs from the prescribed dose by more than 20%.

"mm" means millimeters.

"Mobile device" means a piece of equipment containing licensed radioactive materials that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting, or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

<u>"Mobile electronic brachytherapy service" means</u> <u>transportation of an electronic brachytherapy device to</u> <u>provide electronic brachytherapy at an address that is not the</u> <u>address of record.</u>

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Mobile x-ray equipment" (See "X-ray equipment").

"Mode of operation" means, for fluoroscopy systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"Monitor unit" or "MU" (See "Dose monitor unit").

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms. For Part XI (12VAC5-481-2330 et seq.) of this chapter, it means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Movement control center" means an operation center that is remote from the transport activity and that maintains the position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

"Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

"Multiple tomogram system" means a computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"NARM" means any naturally occurring or acceleratorproduced radioactive material. It does not include byproduct, source, or special nuclear material.

"National Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 12VAC5-481-3780. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 threshold but less than the Category 1 threshold.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes, which is essentially 100 weight percent thorium-232.

"Natural uranium" (See "Uranium - natural, depleted, enriched").

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Negative pressure respirator" or "tight fitting" means a respirator in which the air pressure inside the facepiece is

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negative during inhalation with respect to the ambient air pressure outside the respirator.

"No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival times may not be more than six hours after the estimated arrival time for shipments of Category 2 quantities of radioactive material.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \oplus \overline{CS} \oplus s}{\mu_w}$$

where:

 \overline{CS} = Linear attenuation coefficient of the material of interest.

 μ_w = Linear attenuation coefficient of water.

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Non-image-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

"NORM" means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

"Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant (or licensee), and data recording procedures, which are related to radiation safety.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam. 2. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"NRC Forms 540, 540A, 541, 541A, 542, and 542A" means official NRC forms referenced in this chapter. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Nuclear Regulatory Commission" or "NRC" means the NRC or its duly authorized representatives.

"Nuclear waste" means a quantity of source, byproduct or special nuclear material (the definition of nuclear waste in this part is used in the same way as in 49 CFR 173.403) required to be in NRC-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, from voluntary participation in medical research programs, or as a member of the public.

"Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

"Offshore waters" means that area of land and water, beyond the Commonwealth of Virginia's jurisdiction, on or above the U.S. Outer Continental Shelf.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Package" means the packaging together with its radioactive contents as presented for transport.

1. Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package

means a fissile material packaging together with its fissile material contents.

2. Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

3. Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in²) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of these regulations. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

"Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

"Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

"Particle accelerator" (See "Accelerator").

"Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

"PBL" (See "Positive beam limitation").

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, department of the Commonwealth other than the Department of Health, political subdivision of the Commonwealth, any other state or political subdivision or department thereof, and any legal successor, representative, agent, or department of the foregoing, but not including federal government agencies.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required. In radiography it means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Personnel monitoring equipment" (See "Individual monitoring devices").

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Physical description" means the items called for on NRC Form 541 to describe a low-level radioactive waste.

"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wetsource-storage irradiators and underwater irradiators.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by this state to prescribe drugs in the practice of medicine.

"Picture element" means an elemental area of a tomogram.

"PID" (See "Position indicating device").

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Portable x-ray equipment" (See "X-ray equipment").

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish

a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

Positron emission tomography radionuclide production facility" or "PET" means a facility operating a cyclotron or other particle accelerator for the purpose of producing radionuclides that decay by positron emission.

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Powered air-purifying respirator" or "PAPR" means an airpurifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb. 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Commission on Radiation Units and Measurements, September 15, 1984.

"Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or

2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

2. For teletherapy, the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique; or

3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

"Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and that will terminate irradiation when a preselected number of dose monitor units have been delivered.

"Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection barriers.

"Principal activities," as used in this chapter, means activities authorized by the license that are essential to achieving the <u>purpose(s) purposes</u> for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Private inspector" means an individual who meets the requirements set forth in 12VAC5-481-340 and who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Product" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, something produced, made, manufactured, refined, or benefited.

"Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

"Projection sheath" (See "Guide tube").

"Projector" (See "Radiographic exposure device").

"Protective apron" means an apron made of radiationattenuating or absorbing materials used to reduce exposure to radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. "Public dose" does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, or from voluntary participation in medical research programs.

"Pulsed mode" means operation of the x-ray system such that the x-ray tube is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or that can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Qualified inspector" means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic and therapeutic medical physics.

"Qualified medical physicist" means an individual qualified in accordance with 12VAC5-481-3390 D.

"Qualitative fit test" or "QLFT" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quality factor" or "Q" means the modifying factor, that is referenced in 12VAC5-481-240, that is used to derive dose equivalent from absorbed dose.

"Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose" (See "Dose").

"Radiation field" (See "Useful beam").

"Radiation head" means the structure from which the useful beam emerges.

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Radiation safety officer" or "RSO" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

"Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of 12VAC5-481-1310.

"Radiation safety officer for medical" means an individual who meets the requirements of 12VAC5-481-1750 and 12VAC5-481-1790 or is identified as an RSO on a medical use license issued by the agency, NRC or another agreement state, or a medical use permit issued by an NRC masters material licensee.

"Radiation therapy physicist" means an individual qualified in accordance with 12VAC5-481-340.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

<u>"Radiation therapy system" means a device that delivers</u> radiation to a specific area of the body where cancer cells or tumors are located.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay" (See "Bioassay").

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the agency's regulations and the conditions of the license or registration.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 12VAC5-481-1320.

"Radiographer instructor" means any radiographer who has been authorized by the agency to provide on-the-job training to radiographer trainees in accordance with Part V (12VAC5-481-1170 et seq.) of this chapter.

"Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic operations" means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

"Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee.

"Radiography" means:

1. For radioactive materials: See "Industrial radiography."

2. For x-ray: A technique for generating and recording an x-ray pattern for the purpose of providing the user with an image after termination of the exposure.

"Rating" means the operating limits as specified by the component manufacturer.

"Reasonably maximally exposed individual" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined

by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Registrant" means any person who is registered with the agency and is legally obligated to register with the agency pursuant to these regulations and the Act.

"Registration" means registration with the agency in accordance with the regulations adopted by the agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100 - 189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

"Reportable event" means the administration of either:

1. A diagnostic x-ray exposure where an actual or suspected acute or long-term functional damage to an organ or a physiological system has occurred. Exempt from this reporting requirement is any event when any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed;

2. A procedure where the patient or operator is injured as a result of a mechanical injury;

3. A teletherapy x-ray or electron dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or

4. A brachytherapy x-ray dose where the calculated administered dose differs from the prescribed dose by 10% or more.

"Research and development" means (i) theoretical analysis, exploration, or experimentation; or (ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstrative purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Residual radioactive material" means (i) waste (that the U.S. Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the

extraction of uranium and other valuable constituents of the ores and (ii) other waste (that the U.S. Secretary of Energy determines to be radioactive) at a processing site that relates to such processing, including any residual stock of unprocessed ores or low-grade materials. This term is used only with respect to materials at sites subject to remediation under Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Respiratory protective device" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials that are possessed by the licensee.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 12VAC5-481-240).

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sabotage" means deliberate damage, with malevolent intent, to a Category 1 or Category 2 quantity of radioactive material, a device that contains a Category 1 or Category 2 quantity of radioactive material, or the components of the security system.

"Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law-enforcement authorities. "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

"Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of any radioactive material.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of Category 1 or Category 2 quantities of radioactive material.

"Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

"Self-contained breathing apparatus " or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shallow dose equivalent " or " H_s ," which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2).

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every

location on the exterior meet the limitations specified in 12VAC5-481-640.

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means NRC Form 540 and, if required, NRC Form 540A, which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means the abbreviation for the International System of Units.

"SID" (See "Source-image receptor distance").

"Sievert" or "Sv" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Simulator" or "radiation therapy simulation system" means any x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Single tomogram system" means a CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram.

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Source" means the focal spot of the x-ray tube.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources. "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or

2. Ores that contain by weight one-twentieth of 1.0% (0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Source-skin distance" or "SSD" means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient's skin surface.

"Source traceability" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology, or by a laboratory that participates in a continuing measurement quality assurance program with National Institute of Standards and Technology or other equivalent national or international program.

"Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. The piece or capsule has at least one dimension not less than five millimeters (0.2 in.); and

3. It satisfies the test requirements specified by the NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material the NRC, pursuant to the provisions of § 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ grams contained U235}}{350} + \frac{50 \text{ grams } U - 235}{200} + \frac{50 \text{ grams } Pu}{200} = 1$$

"Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stability" means structural stability.

"State inspector" means an employee of the Virginia Department of Health designated to perform those duties or functions assigned the Radiological Health Program.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Stationary x-ray equipment" (See "X-ray equipment").

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations this chapter, "probabilistic effect" is an equivalent term.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

"Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

"Storage container" means a device in which sealed sources or radiation machines are secured and stored. "Stray radiation" means the sum of leakage and scattered radiation.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the wellbore or adjacent formation.

"Supplied-air respirator," "airline respirator," or "SAR" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Surface contaminated object" or "SCO" means a solid object that is not itself classed as radioactive material, but that has radioactive material distributed on any of its surfaces. An SCO must be in one of two groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:

a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed four becquerel per cm² (1 E-04 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm² (1 E-05 μ Ci/cm²) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1.0 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm² (0.1 μ Ci/cm²) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm² (0.1 μ Ci/cm²) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 400 becquerel per cm² (1 E-02 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm² (1 E-03 μ Ci/cm²) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μ Ci/cm²) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 , or the area of the surface if less than 300 cm^2 , does not exceed 8 E+05 becquerel per cm² ($20 \mu \text{Ci/cm}^2$)

for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μ Ci/cm²) for all other alpha emitters.

"Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

"Tabletop, stationary" means a tabletop that, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

"Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

<u>"Target-skin distance" or "TSD" means the distance</u> measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source, or both, to the surface of the irradiated object or patient.

"Technologically Enhanced Naturally Occurring Radioactive Material" or "TENORM" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, naturally occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the AEA and NRC regulations.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

2. For field emission equipment rated for pulsed operation, peak tube potential in kilovolts (kV), and number of x-ray pulses;

3. For CT equipment designed for pulsed operation, peak tube potential in kilovolts (kV), scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in milliampere-seconds (mAs);

4. For CT equipment not designed for pulsed operation, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in

milliampere-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kilovolts (kV), and either tube current in milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in milliampere-seconds (mAs).

"Telemetric position monitoring system" means a data transfer system that captures information by either instrumentation, measuring devices about the location or both, and status of a transport vehicle or package between the departure and destination locations.

"Teletherapy physicist" means an individual identified as a qualified teletherapy physicist on an agency license.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Temporary job site" means any location where industrial radiography, wireline service, well-logging, portable gauge, or x-ray fluorescence use is performed and where licensed material may be stored other than those location(s) locations of use authorized on the license.

"Tenth-value layer" or "TVL" means the thickness of a specified material that attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Test" means the process of verifying compliance with an applicable regulation.

"Therapeutic radiation machine" means x-ray or electronproducing equipment designed and used for external beam radiation therapy. For the purpose of this chapter, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

"These regulations" mean all parts of this chapter.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Total effective dose equivalent" or "TEDE" means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" or "TODE" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 12VAC5-481-1040.

"Traceable to a National Standard" (See "Instrument traceability" or "Source traceability").

"Transfer" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the physical relocation of NORM containing materials not directly associated with commercial distribution within a business's operation or between general or specific licensees. This term does not include a change in legal title to NORM containing materials that does not involve physical movement of those materials.

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

"Transport index" or "TI" means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft) feet)).

"Treatment site" means the correct anatomical description of the area intended to receive a radiation dose, as described in a written directive.

"Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

"Trustworthiness and reliability" means characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to Category 1 or Category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of 12VAC5-481-3770 or may be determined by procedures described in Table A-1 of 12VAC5-481-3770.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do

not have access to the sealed sources or the space subject to irradiation without entering the pool.

"Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or <u>or</u> related equipment are beneath the surface of the water.

"Unescorted access" means solitary access to an aggregated Category 1 or Category 2 quantity of radioactive material or the devices that contain the material.

"Uniform Low-Level Radioactive Waste Manifest" or "uniform manifest" means the combination of NRC Forms 540 and 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Unirradiated uranium" means uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Uranium - natural, depleted, enriched"

1. "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.

2. "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Useful beam" means the radiation that passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

"User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

"Variable-aperture beam-limiting device" means a beamlimiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources

external to the body could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

"Virtual simulator" means a computed tomography (CT) unit used in conjunction with relevant software that recreates the treatment machine and that allows import, manipulation, display, and storage of images from CT or other imaging modalities, or both.

"Virtual source" means a point from which radiation appears to originate.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

"Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subdivisions 2, 3, and 4 of the definition of byproduct material.

"Waste collector" means an entity, operating under a specific license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

"Waste generator" means an entity, operating under a license, that (i) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (ii) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

"Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or or persons licensed to dispose of radioactive waste.

"Waste processor" means an entity, operating under a specific license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility. "Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Weighting factor " or " w_T " for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors

W _T
0.25
0.15
0.12
0.12
0.03
0.03
$0.30^{a/}$
1.00 ^{b/}

^a/0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

^{b/}For the purpose of weighting the external whole body dose for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

"Well-bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools that may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Wireline" means a cable containing one or more electrical conductors that is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service that is performed in the well-bore using devices on a wireline. "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant but does not include the licensee or registrant.

"Working level" or "WL" means any combination of shortlived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters of radon-222 are polonium-218, lead-214, bismuth-214, and polonium-214; and those of radon-220 are polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" or "WLM" means an exposure to one working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in subdivision 6 of this definition, containing the following information:

1. For any administration of quantities greater than 1.11 megabecquerels (30 mCi) of sodium iodide I-125 or I-131: the radionuclide, and dosage; or

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; or

3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or

4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or

5. For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or

6. For all other brachytherapy,

a. Prior to implantation: the radionuclide, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

"X-ray control" means a device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

1. "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

2. "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

3. "Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s) tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube that is designed for the conversion of electrical energy into x-ray energy.

"Year" means the period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year. If a licensee or registrant changes in a year, the licensee or registrant shall assure that no day is omitted or duplicated in consecutive years.

12VAC5-481-3390. General administrative requirements for facilities using therapeutic radiation machines.

A. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the agency and reporting misadministrations within 10 days. The registrant or the registrant's agent shall ensure that the requirements of Part XV (12VAC5-481-3380 et seq.) of this chapter are met in the operation of the therapeutic radiation machine(s) machines.

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B. A therapeutic radiation machine that does not meet the provisions of these regulations this chapter shall not be used for irradiation of patients.

C. Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall require the authorized user to be a physician who:

1. Is certified in:

a. <u>Radiology</u> <u>Radiation oncology</u> or therapeutic radiology by the American Board of Radiology <u>or radiology</u> (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976;

b. Radiation oncology by the American Osteopathic Board of Radiology;

c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

or

2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(1) Review of the full calibration measurements and periodic quality assurance checks;

(2) Evaluation of prepared treatment plans and calculation of treatment times <u>and</u> patient treatment settings;

(3) Using administrative controls to prevent missadministrations misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations <u>or</u> contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or <u>or</u> treatment plans as warranted by patients' reaction to radiation; and

(4) Post-administration follow-up and review of case histories.

3. Notwithstanding the requirements of subdivisions 1 and 2 of this subsection, the registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 may also submit the training of the prospective authorized user physician for agency review on a case-by-case basis.

4. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the agency.

D. Training for radiation therapy qualified medical physicist. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 and 12VAC5-481-3430 shall require the radiation therapy qualified medical physicist to: 1. Be be registered with the agency, under the provisions of Part II (12VAC5-481-260 et seq.) of this chapter, as a provider of radiation services in the area of calibration and surveys of external beam radiation therapy units; and 2. Shall meet the requirements of 12VAC5-481-340 B 2 to:

1. Be certified by the American Board of Radiology in:

a. Therapeutic radiological physics;

b. Roentgen-ray and gamma-ray physics;

c. X-ray and radium physics; or

d. Radiological physics;

2. Be certified by the American Board of Medical Physics in Radiation Oncology Physics:

3. Be certified by the Canadian College of Medical Physics; or

4. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university and have completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a qualified medical physicist at a medical institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in 12VAC5-481-3400 A, 12VAC5-481-3420 P, 12VAC5-481-3420 Q, 12VAC5-481-3430 T, and 12VAC5-481-3430 U under the supervision of a qualified medical physicist during the year of work experience.

E. Qualifications of operators.

1. Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.

2. The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

F. Written safety procedures and rules shall be developed by a radiation therapy <u>qualified medical</u> physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

G. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who is specifically identified on the Certificate of Registration therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other nonhealing arts non-healing-arts purposes.

H. Visiting authorized user. Notwithstanding the provisions of subsection G of this section, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee, where applicable; and 2. The visiting authorized user meets the requirements established for <u>an</u> authorized <u>user(s)</u> <u>user</u> in subdivisions $\frac{1}{2}$ and $\frac{2}{2}$ C 1 and C 2 of this subsection section; and

3. The registrant maintains copies of all records specified by this subsection for five years from the date of the last visit shall maintain copies of the written permission required in subdivision 1 of this subsection and documentation that the visiting authorized user met the requirements of subdivision 2 of this subsection for five years from the date of the last visit.

I. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of Part XV of this chapter, these individuals are also subject to the requirements of 12VAC5-481-640, 12VAC5-481-680, and 12VAC5-481-760.

J. Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the agency:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Part XV of this chapter, as well as the name(s) of person(s) who performed such activities;

3. Records of maintenance <u>and/or</u> <u>or</u> modifications performed on the therapeutic radiation machine after September 20, 2006, as well as the <u>name(s)</u> <u>names</u> of <u>person(s)</u> <u>persons</u> who performed such services;

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

K. Records retention. All records required by Part XV of this chapter shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in Part XV of this chapter. All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated prior to the last agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the agency authorizes final disposal.

12VAC5-481-3400. General technical requirements for facilities using therapeutic radiation machines.

A. Surveys Protection surveys.

1. The registrant shall ensure that radiation <u>protection</u> surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 12VAC5-481-3440. The radiation <u>protection</u> survey shall be performed by, or under the direction of, a radiation therapy <u>qualified medical</u> physicist

or a private inspector <u>qualified inspector</u> and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field, and with a scattering phantom in the useful beam of radiation:

a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 12VAC5-481-640; and

b. Radiation levels in unrestricted areas do not exceed the limits specified in 12VAC5-481-720.

2. In addition to the requirements of 12VAC5 481 3400 A 1 subdivision 1 of this subsection, a radiation protection survey shall also be performed prior to any subsequent medical use and:

a. After making any change in the treatment room shielding;

b. After making any change in the location of the therapeutic radiation machine within the treatment room;

c. After relocating the therapeutic radiation machine; or

d. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

3. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy qualified medical physicist or a private inspector qualified inspector, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; the model number and serial number of the therapeutic radiation machine; the instrument(s) instruments used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

4. If the results of the surveys required by subdivision 1 or 2 of this subsection indicate any radiation levels in excess of the respective limit specified in subdivision 1 of this subsection, the registrant shall lock the control in the "OFF" position and not use the unit:

a. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

b. Until the registrant has received a specific exemption from the agency.

B. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by subsection A of this section indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 12VAC5-481-720, before beginning the treatment program the registrant shall:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 12VAC5-481-720;

2. Perform the survey required by subsection A of this section again; and

3. Include in the report required by subsection D of this section the results of the initial survey, a description of the modification made to comply with subdivision 1 of this subsection, and the results of the second survey; or

4. Request and receive a registration amendment under 12VAC5-481-720 that authorizes radiation levels in unrestricted areas greater than those permitted by 12VAC5-481-720.

C. Dosimetry equipment.

1. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration. <u>An</u> independent survey shall be conducted by a qualified inspector or qualified medical physicist other than the person performing the original survey prior to the equipment being used except as described in subsection <u>A</u> of this section:

a. For beams with energies greater than one MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

b. For beams with energies equal to or less than one MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

2. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision \mathbb{C} 1 of this section subsection. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in subdivision \mathbb{C} 1 of this section;

3. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-

compared, or compared as required by subdivisions C 1 and 2 of this section subsection; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy qualified medical physicist.

D. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall furnish a copy of the records required in subsections A and B of this section to the agency within 30 days following completion of the action that initiated the record requirement.

12VAC5-481-3410. Quality management program.

The facility shall implement a quality management program. The facility shall include in the quality management program written notification to the agency within 72 hours of discovery of a reportable event or a misadministration Each registrant or applicant subject to 12VAC5-481-3420 and 12VAC5-481-3430 shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

<u>A. Scope and applicability. The quality management</u> program shall address, at a minimum, the following specific <u>objectives:</u>

1. Written directives.

a. A written directive shall be dated and signed by an authorized user prior to the administration of radiation. If because of the patient's condition a delay caused by providing a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

b. The written directive shall contain the patient's or human research subject's name, type and energy of the beam, total dose, dose per fraction, treatment site, and number of fractions.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose or the next fractional dose.

<u>d.</u> The registrant shall retain a copy of the written directive for three years.

2. Procedures for administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

a. Prior to the administration of each course of radiation treatment, the patient's or human research subject's

identity is verified by more than one method as the individual named in the written directive;

b. Each administration is in accordance with the written directive;

c. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

(1) Checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and

(2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

<u>d. Any unintended deviation from the written directive is</u> <u>identified and evaluated, and appropriate action is taken;</u> <u>and</u>

e. The registrant retains a copy of the procedures for administrations for the duration of the registration.

B. Reports and notifications of misadministrations.

1. A registrant shall report any event resulting from the treatment of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from the treatment of a patient or human research subject, a registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

a. Involves the wrong patient, wrong treatment modality, or wrong treatment site;

b. The calculated weekly administered dose differs from the weekly prescribed dose by more than 30%; or

c. The calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

<u>3. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.</u>

4. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

a. The registrant's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual who received the misadministration;

<u>f. Actions, if any, that have been taken or are planned to prevent recurrence; and</u>

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g. Certification that the registrant notified the individual, or the individual's responsible relative or guardian, and if not, why not.

5. The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

6. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this subdivision, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

7. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

8. The registrant shall retain a record of a misadministration in accordance with subsection C of this section. A copy of the required record shall be provided to the referring physician if other than the registrant within 15 days after discovery of the misadministration.

<u>C. Records of misadministrations. A registrant shall retain a record of misadministrations reported in accordance with subsection B of this section for three years. The record shall contain the following:</u>

1. The registrant's name and the names of the individuals involved;

2. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

<u>3. A brief description of the event; why it occurred; and the effect, if any, on the individual;</u>

4. The actions, if any, taken or planned to prevent recurrence; and

5. Whether the registrant notified the individual, or the individual's responsible relative or guardian and, if not, whether such failure to notify was based on guidance from the referring physician.

12VAC5-481-3420. Therapeutic radiation machines of less than 500 kV.

A. Leakage radiation. When the $\frac{X}{x}$ ray $\frac{x}{x-x}$ tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV Systems systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (100 mrad) in any one hour.

2. > <u>Greater than 50</u> and \leq <u>less than 500 kV Systems</u> <u>systems</u>. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one cGy (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions A 1 and 2 of this section subsection for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

B. Permanent beam limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

C. Adjustable or removable beam limiting devices.

1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5.0% of the useful beam for the most penetrating beam used;

2. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

D. Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after September 20, 2006, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed one cGy (1 rad) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

E. Tube immobilization.

1. The $\frac{X - ray}{x - ray}$ tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

F. Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

G. Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

H. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. <u>Timer The timer shall be accurate to within 1.0%</u> of the selected value or one second, whichever is greater.

I. Control panel functions. The control panel, in addition to the displays required by other provisions in this section, shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the $\frac{x}{x}$ ray tube is possible;

2. An indication of whether $\frac{x - rays}{x - rays}$ are being produced;

3. A means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after September 20, 2006, a positive display of specific filter(s) <u>filters</u> in the beam.

J. Multiple tubes. When a control panel may energize more than one $\frac{X - ray}{x - ray}$ tube:

1. It shall be possible to activate only one $\frac{x - xy}{x - xy}$ tube at any time;

2. There shall be an indication at the control panel identifying which $\frac{X}{X}$ ray $\frac{x}{x}$ tube is activated; and

3. There shall be an indication at the tube housing assembly when that tube is energized.

K. Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

L. Shutters. Unless it is possible to bring the $\frac{X - ray}{x - ray}$ output to the prescribed exposure parameters within five seconds after the $\frac{X - ray}{x - ray}$ "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

M. Low filtration $\frac{X}{x}$ ray $\frac{x}{x}$ ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

N. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to adequate shielding to meet requirements of 12VAC5-481-3450, the treatment room shall meet the following design requirements:

1. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

2. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

O. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in subdivision 3 of this subsection is opened while the $\frac{X \text{ ray } x \text{ -ray}}{X \text{ -ray}}$ tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour.

P. Full calibration measurements.

1. Full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a radiation therapy <u>qualified medical</u> physicist:

a. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

b. At intervals not exceeding one year; and

c. Before medical use under the following conditions:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5.0% from the value obtained at the last full calibration and the difference cannot be reconciled; and

(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

d. Notwithstanding the requirements of subdivision 1 c of this subsection:

(1) Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes and/or or energies that are not within their acceptable range; and

(2) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in subdivision 1 c (1) of this subsection.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration shall include all measurements recommended for annual calibration by NCRP the National Council on Radiation Protection and Measurements (NCRP) Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

3. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall

include: the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X ray x-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy qualified medical physicist responsible for performing the calibration.

Q. Periodic quality assurance checks.

1. Periodic quality assurance checks shall be performed on the rapeutic radiation machines subject to this section, which are capable of operation at greater than or equal to 50 kV_{\pm}

2. To satisfy the requirement of subdivision 1 of this subsection, quality assurance checks shall meet the following requirements:

a. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy <u>qualified medical</u> physicist-; and

b. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subdivision P 1 of this section. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subdivision P 1 of this section, shall be stated=:

3. The cause for a parameter exceeding a tolerance set by the radiation therapy <u>qualified medical</u> physicist shall be investigated and corrected before the system is used for patient irradiation;

4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy qualified medical physicist's quality assurance check procedures, the system shall be recalibrated as required in subdivision P 1 of this section;

5. The registrant shall use the dosimetry system described in 12VAC5-481-3400 C 2 to make the quality assurance check required in subdivision 2 of this subsection;

6. The registrant shall have the radiation therapy <u>qualified</u> <u>medical</u> physicist review and sign the results of each radiation output quality assurance check within <u>one month</u> <u>30 days</u> of the date that the check was performed;

7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this section are performed at intervals not to exceed one month 30 days;

8. Notwithstanding the requirements of subdivisions 4 and 7 of this subsection, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks

required by subdivisions $6 \frac{4}{2}$ and 7 of this subsection have been performed within the 30-day period immediately prior to said administration;

9. To satisfy the requirement of subdivision 7 of this subsection, safety quality assurance checks shall ensure proper operation of:

a. Electrical interlocks at each external beam radiation therapy room entrance;

b. The "BEAM-ON" and termination switches;

c. Beam condition indicator lights on the access door(s) <u>door</u>, control console, and in the radiation therapy room;

d. Viewing systems; and

e. If applicable, electrically operated treatment room doors from inside and outside the treatment room; and

10. The registrant shall maintain a record of each quality assurance check required by subdivisions 1 and 7 of this subsection for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, the model number, and serial number of the therapeutic radiation machine; the manufacturer's name; the model number, and serial number for the instrument(s) instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

R. Operating procedures.

1. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subsections P and Q of this section have been met;

2. Therapeutic radiation machines shall not be left unattended unless secured pursuant to subdivision I 5 of this section;

3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

4. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and <u>an</u> apron of not less than 0.5 millimeters lead equivalency at 100 kV;

5. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

6. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 12VAC5-481-640.

S. Possession of survey instrument(s) instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) instruments shall be operable and calibrated in accordance with 12VAC5-481-3440.

<u>T. Electronic brachytherapy devices are subject to the</u> requirements of 12VAC5-481-3452 and are exempt from the requirements of this section.

12VAC5-481-3430. Therapeutic radiation machines photon therapy systems (500 kV and above) and electron therapy systems (500 kV and above).

A. Possession of survey instrument(s) instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess have access to appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) instruments shall be operable and calibrated in accordance with 12VAC5-481-3440.

B. Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in subdivision 1 of this subsection, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after September 20, 2006, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions 1 through, 2, and 3 of this subsection for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

C. Leakage radiation through beam limiting devices.

1. Photon radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) devices shall not exceed 2.0% of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field, or for multileaf collimators, shall not exceed manufacturer's specifications 100 square centimeter radiation field, or maximum available field size if less than 100 square centimeters;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

a. A maximum of 2.0% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

b. A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

3. Measurement of leakage radiation.

a. Photon radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value two tenth-value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters;

b. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

D. Filters and wedges.

1. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by subsection I of this section relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

3. For equipment manufactured after September 20, 2006, that utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

a. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

c. A display shall be provided at the treatment control panel showing the wedge $\frac{\text{filter(s)}}{\text{filters}}$, interchangeable field flattening $\frac{\text{filter(s)}}{\text{filters}}$, $\frac{\text{and/or } \text{or}}{\text{or}}$ interchangeable beam scattering $\frac{\text{foil(s)}}{\text{foils}}$ in use; and

d. An interlock shall be provided to prevent irradiation if any filter and/or <u>or</u> beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or <u>or</u> beam scattering foil selection operation carried out at the treatment control panel.

E. Stray radiation in the useful beam. For equipment manufactured after September 20, 2006, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that $\frac{X}{xay} \frac{x-ray}{x-ray}$ stray radiation in the useful electron beam, absorbed dose at the surface during $\frac{X}{xay} \frac{x-ray}{x-ray}$ irradiation, and stray neutron radiation in the useful $\frac{X}{xay} \frac{x-ray}{x-ray}$ beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

F. Beam monitors. All therapeutic radiation machines subject to this section shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after September 20, 2006, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements

may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before September 20, 2006, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system; $\frac{1}{2}$

3. The detector and the system into which that detector is incorporated shall meet the following requirements:

a. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning<u>;</u>.

b. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;.

c. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and.

d. For equipment manufactured after September 20, 2006, the design of the beam monitoring systems shall ensure that the:

(1) Malfunctioning of one system shall not affect the correct functioning of the other system(s) systems; and

(2) Failure of either system shall terminate irradiation or prevent the initiation of radiation.

e. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after September 20, 2006, each display shall:

(1) Maintain a reading until intentionally reset;

(2) Have only one scale and no electrical or mechanical scale multiplying factors;

(3) Utilize a design such that increasing dose is displayed by increasing numbers; and

(4) In the event of power failure, the beam monitoring information required in subdivision 3 e (3) of this subsection displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20_{-} minute period of time.

G. Beam symmetry.

1. Bent beam linear accelerators <u>A bent-beam linear</u> accelerator with beam flattening filter subject to this section shall be provided with <u>an</u> auxiliary device(s) <u>device</u> to monitor beam symmetry;

2. The device(s) device referenced in subdivision 1 of this subsection shall be able to detect field asymmetry greater than 10%; and

3. The <u>device(s)</u> <u>device</u> referenced in subdivision 1 of this subsection shall be configured to terminate irradiation if the specifications in subdivision 2 of this subsection cannot be maintained.

H. Selection and display of dose monitor units.

1. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

2. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

3. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

4. For equipment manufactured after September 20, 2006, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

I. Air kerma rate <u>or</u> absorbed dose rate. For equipment manufactured after September 20, 2006, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in subsection F of this section may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault <u>condition(s)</u> <u>conditions</u> an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) values specified in subdivisions 2 and 3 of this subsection for the specified operating conditions. Records of these maximum value(s) values shall be maintained at the installation for inspection by the agency.

J. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the preselected number of

dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after September 20, 2006, an indicator on the control panel shall show which monitoring system has terminated irradiation.

K. Termination of irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

L. Interruption of irradiation. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

M. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

N. Selection of radiation type. Equipment capable of both $\frac{x - ray}{x - ray}$ therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays (x-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

4. An interlock system shall be provided to prevent irradiation with $\frac{x - rays}{x - rays}$, except to obtain an image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for $\frac{x}{x-ray}$ therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the

treatment room do not agree with the selected operations carried out at the treatment control panel.

O. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

4. For equipment manufactured after September 20, 2006, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1.

P. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after September 20, 2006:

a. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one em centimeter of linear motion differs by more than 20% from the selected value;

b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5.0% from the dose monitor unit value selected;

c. An interlock shall be provided to prevent motion of more than five degrees or one <u>em centimeter</u> beyond the selected limits during moving beam radiation therapy;

d. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counter-clockwise moving beam radiation therapy-:

e. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement-:

6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 12VAC5-481-3430 J subsection J of this section; and

7. For equipment manufactured after September 20, 2006, an interlock system shall be provided to terminate irradiation if movement:

a. Occurs during stationary beam radiation therapy; or

b. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

Q. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 12VAC5-481-3450, the following design requirements are made:

1. Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

2. Control panel. In addition to other requirements specified in Part XV (12VAC5-481-3380 et seq.) of this chapter, the control panel shall also:

a. Be located outside the treatment room;

b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

c. Provide an indication of whether radiation is being produced; and

d. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

3. Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

4. Aural communications. Provision shall be made for continuous <u>two-way</u> aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous <u>two-way</u> aural communication is possible;

5. Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

6. Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7. Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 12VAC5-481-720, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s) barrier;

8. Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subsection K of this section. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

9. Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

10. Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing from treatment room, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

R. Radiation therapy Qualified medical physicist support.

1. The services of a radiation therapy <u>qualified medical</u> physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy <u>qualified medical</u> physicist shall be responsible for:

a. Full <u>calibration(s)</u> <u>calibrations</u> required by subsection T of this section and <u>protection</u> surveys required by 12VAC5-481-3400 A;

b. Supervision and review of dosimetry;

c. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

d. Quality assurance, including quality assurance check review required by subdivision U 5 of this section-;

e. Consultation with the authorized user in treatment planning, as needed; and

f. Performance of calculations <u>or</u> assessments regarding misadministrations.

2. If the radiation therapy qualified medical physicist is not a full-time employee of the registrant, the operating procedures required by subsection S of this section shall also specifically address how the radiation therapy qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy qualified medical physicist can be contacted.

S. Operating procedures.

1. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

2. Therapeutic radiation machines shall not be made available for medical use unless the requirements of 12VAC5-481-3400 A, and subsections T and U of this section have been met;

3. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

4. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

6. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

T. Acceptance testing, commissioning, and full calibration measurements.

1. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a radiation therapy <u>qualified medical</u> physicist.

3. Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: <u>AAPM Report No. 46," prepared by</u> Committee Task

Group 40^{<u>u</u>} and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: <u>Report of AAPM AAPM Report No. 47" prepared by</u> Radiation Therapy Task Group 45<u><u>u</u>. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.</u>

4. The radiation therapy <u>qualified medical</u> physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

a. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5.0% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy and/or or multimode capabilities shall only require measurements for those modes and/or or energies that are not within their acceptable range; and

b. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or or energies, measurements shall be performed on the effected mode or energy that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in subdivision 4 a of this subsection.

5. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number, and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy qualified medical physicist responsible for performing the calibration.

U. Periodic quality assurance checks.

1. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to this section at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of <u>AAPM Report No.</u> <u>46," prepared by</u> AAPM Radiation Therapy Committee Task Group 40";

2. To satisfy the requirement of subdivision 1 of this subsection, quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Report No. 46" prepared by AAPM Radiation Therapy Committee Task Group 40⁻⁻. Representative sampling shall include all referenced

periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

3. The registrant shall use a dosimetry system that has been inter-compared within the previous 12 months with the dosimetry system described in 12VAC5-481-3400 C 1 to make the periodic quality assurance checks required in subdivision 2 of this subsection;

4. The registrant shall perform periodic quality assurance checks required by subdivision 1 of this subsection in accordance with procedures established by the radiation therapy qualified medical physicist;

5. The registrant shall review the results of each periodic radiation output check according to the following procedures:

a. The authorized user and radiation therapy <u>qualified</u> <u>medical</u> physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy <u>qualified medical</u> physicist has determined that all parameters are within their acceptable tolerances;

b. If all quality assurance check parameters appear to be within their acceptable ranges, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy <u>qualified medical</u> physicist within three treatment days; and

c. The radiation therapy <u>qualified medical</u> physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month <u>30 days</u>.

6. Therapeutic radiation machines subject to this section shall have <u>applicable</u> safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: Report of AAPM Report No. 46," prepared by AAPM Radiation Therapy Committee Task Group 40⁻⁻ performed at intervals not to exceed one week;

7. To satisfy the requirement of subdivision 6 of this subsection, safety quality assurance checks shall ensure proper operation of:

a. Electrical interlocks at each external beam radiation therapy room entrance;

b. Proper operation of the "BEAM-ON," interrupt, and termination switches;

c. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

d. Viewing systems;

e. Electrically operated treatment room door(s) doors from inside and outside the treatment room;

f. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

8. The registrant shall promptly repair any system identified in subdivision 7 of this subsection that is not operating properly; and

9. The registrant shall maintain a record of each quality assurance check required by subdivisions 1 and 7 of this subsection for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number for the instrument(s) instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

<u>V.</u> Quality assurance checks for intensity modulated radiation therapy (IMRT) shall:

1. Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;

2. Be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82"; and

<u>3. Be performed in accordance with the manufacturer's contractual specifications.</u>

12VAC5-481-3450. Shielding and safety design requirements.

A. Each therapeutic radiation machine subject to 12VAC5-481-3420 or 12VAC5-481-3430 shall be provided with such primary and/or or secondary barriers as are necessary to ensure compliance with 12VAC5-481-640 and 12VAC5-481-720.

B. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. At a minimum, facility design information shall include:

1. All therapeutic radiation machines.

a. Basic facility information including name, telephone number, and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address, including room number, of the therapeutic radiation machine facility. The plan shall also indicate whether this is a new structure or a modification to an existing structure.

b. The primary areas where all wall, floor, and ceiling areas are struck by the useful beam.

c. The secondary barriers where all wall, floor, and ceiling areas do not have primary barriers.

2. Therapeutic radiation machines less than or equal to 150 kV (photons only). In addition to the requirements listed in subdivision 1 of this subsection, therapeutic radiation machine facilities that produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans that contain, at a minimum, the following additional information:

<u>a. Equipment specifications, including the manufacturer</u> and model number of the therapeutic radiation machine, as well as the maximum technique factors;

b. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter; total beam-on time per day or per week; average treatment time per patient; and the anticipated number of patients to be treated per day or per week;

c. A facility blueprint or drawing indicating scale (0.25 inch equals 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port; the port's travel and traverse limits; general direction of the useful beam; locations of any windows and doors; and location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 12VAC5-481-640;

<u>d.</u> The structural composition and thickness or lead or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room concerned;

e. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest areas where it is likely that individuals may be present shall be included; and

f. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (e.g., primary, secondary, and leakage barriers; restricted and unrestricted areas; and entry doors) and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified.

(2) If the software used to generate shielding requirements is not in the open literature, quality control sample calculations to verify the result obtained with the software shall be submitted.

3. Therapeutic radiation machines over 150 kV. In addition to the requirements listed in subdivision 1 of this subsection, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV or electrons, or both, shall submit shielding plans that contain, at a minimum, the following additional information:

a. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, gray (rad) at the isocenter, and the energy and type of radiation produced (e.g., photon, electron). The target to isocenter distance shall be specified;

b. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) at one meter; total beam-on time per day or per week; the average treatment time per patient; and the anticipated number of patients to be treated per day or per week;

c. Facility blueprint or drawing, including both floor plan and elevation views, indicating relative orientation of the therapeutic radiation machine; scale (0.25 inch equals 1 foot is typical); type, thickness, and minimum density of shielding material; direction of north, locations and size of all penetrations through each shielding barrier (ceiling, walls, and floor); and details of the door and maze;

<u>d.</u> The structural composition and thickness or concrete equivalent of walls, doors, partitions, floor, and ceiling of the room concerned;

e. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest areas where it is likely that individuals may be present shall be included;

f. Description of all assumptions that were used in shielding calculations including, but not limited to, design energy (e.g., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor, and ceiling), and "allowed" radiation exposure in both restricted and unrestricted areas; and

g. At least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition (e.g., primary, secondary, and leakage barriers; restricted and unrestricted areas; small angle scatter; entry doors; and maze), and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified; and

(2) If the software used to generate shielding requirements is not in the open literature, quality control

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sample calculations to verify the result obtained with the software shall be submitted.

4. Neutron shielding. In addition to the requirements listed in subdivision 3 of this subsection, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans that contain, at a minimum, the following additional information:

<u>a. The structural composition, thickness, minimum</u> <u>density, and location of all neutron shielding material;</u>

b. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

c. At least one example calculation that shows the methodology used to determine the amount of neutron shielding required for each physical condition (e.g., restricted and unrestricted areas, entry doors, and maze), and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, the software used and the version and revision date shall be identified; and

(2) If the software used to generate shielding requirements is not in the open literature, control sample calculations to verify the result obtained with the software shall be submitted.

<u>d.</u> The methods and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

12VAC5-481-3451. Quality assurance for radiation therapy simulation systems.

Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance and shall be performed in accordance with (i) "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, Report of AAPM Radiation Therapy Committee Task Group No.40" for a conventional simulator or (ii) "Quality assurance for computed tomography simulators and the computed tomography-simulation process: AAPM Report No. 83, Report of the AAPM Radiation Therapy Committee Task Group No. 66" for a virtual simulator.

12VAC5-481-3452. Electronic brachytherapy.

<u>A. Applicability. Electronic brachytherapy devices shall be</u> subject to the requirements of this section and shall be exempt for the requirements of 12VAC5-481-3420.

1. An electronic brachytherapy device that does not meet the requirements of this section shall not be used for irradiation of patients; and

2. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's institutional review board (IRB).

B. Possession of survey instruments. Each facility location authorized to use an electronic brachytherapy device in accordance with this section shall have access to appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with 12VAC5-481-3440 for the applicable electronic brachytherapy source energy.

<u>C. Facility design requirements for electronic brachytherapy</u> <u>devices. In addition to shielding adequate to meet</u> <u>requirements of 12VAC5-481-3450, the treatment room shall</u> <u>meet the following design requirements:</u>

<u>1. If applicable, provision shall be made to prevent</u> simultaneous operation of more than one therapeutic radiation machine in a treatment room.

<u>2. Access to the treatment room shall be controlled by a door at each entrance.</u>

3. Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

4. For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

5. For electronic brachytherapy devices capable of operating at greater than 150 kV:

a. The control panel shall be located outside the treatment room; and

b. Electrical interlocks shall be provided for all doors to the treatment room that will:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source to be shielded when an entrance door is opened; and

(c) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

D. Electrical safety for electronic brachytherapy devices.

<u>1. The high voltage transformer shall be electrically</u> isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

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2. The high voltage transformer shall be isolated from personnel (e.g., an operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

<u>3. The high voltage transformer shall have appropriate</u> safety labels warning personnel of potential electrical shock or heat related injuries.

4. Equipment manufactured after March 2009 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

a. IEC 60601-1:1998+A1+A2:1995;

b. IEC 60601-1-2:2001;

c. IEC 60601-2-8:1999; and

<u>d. IEC 60601-2-17:2004.</u>

<u>E. Control panel functions. The control panel, in addition to</u> the displays required by other provisions in this section, shall:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

2. Provide an indication of whether x-rays are being produced;

3. Provide a means for indicating electronic brachytherapy source potential and current;

4. Provide the means for terminating an exposure at any time; and

5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

<u>F. Timer. A suitable irradiation control device (timer) shall</u> be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

1. A timer shall be provided at the treatment control panel. The timer shall indicate planned setting and the time elapsed or remaining;

2. The timer shall not permit an exposure if set at zero;

3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

4. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system has not previously terminated irradiation.

5. The timer shall permit setting of exposure times as short as 0.1 second; and

<u>6. The timer shall be accurate to within 1.0% of the selected value or 0.1 second, whichever is greater.</u>

G. Qualified medical physicist support.

<u>1. The services of a qualified medical physicist shall be</u> required in facilities having electronic brachytherapy devices. The qualified medical physicist shall be responsible for:

<u>a. Evaluation of the output from the electronic</u> <u>brachytherapy source;</u>

b. Generation of the necessary dosimetric information;

c. Supervision and review of treatment calculations prior to initial treatment of any treatment site;

d. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection K of this section;

e. Consultation with the authorized user in treatment planning, as needed; and

<u>f. Performing calculations or assessments regarding</u> <u>patient treatments that may constitute a</u> <u>misadministration.</u>

2. If the qualified medical physicist is not a full-time employee of the registrant, the operating procedures required by subsection H of this section shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.

H. Operating procedures.

<u>1. Only individuals approved by the authorized user,</u> radiation safety officer, or qualified medical physicist shall be present in the treatment room during treatment;

2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of 12VAC5-481-3400 A and subsections I and J of this section have been met:

3. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room and all persons entering the treatment room to prevent entering persons from unshielded exposure from the treatment beam;

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

<u>a. Instructions for responding to equipment failures and</u> <u>the names of the individuals responsible for</u> <u>implementing corrective actions; and</u>

b. The names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation

safety officer to be contacted if the device or console operates abnormally;

7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation;

8. Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation safety officer to be contacted if the device or console operates abnormally; and

9. The radiation safety officer, or his designee, and an authorized user shall be notified as soon as possible if the patient has a medical emergency, suffers injury, or dies. The radiation safety officer or the qualified medical physicist shall inform the manufacturer of the event.

I. Safety precautions for electronic brachytherapy devices.

<u>1. A qualified medical physicist shall determine which</u> persons in the treatment room require monitoring when the beam is energized;

2. An authorized user and a qualified medical physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

3. A qualified medical physicist and either an authorized user or a nonauthorized user (physician or electronic brachytherapy device operator) under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

4. When shielding is required by subdivision C 4 of this section, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a qualified medical physicist shall designate shield locations sufficient to meet the requirements of 12VAC5-481-640 for any individual, other than the patient, in the treatment room; and

5. All personnel in the treatment room shall remain behind shielding during treatment. A qualified medical physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

J. Electronic brachytherapy source calibration measurements.

<u>1. Calibration of the electronic brachytherapy source</u> output for an electronic brachytherapy device subject to this section shall be performed by or under the direct supervision of a qualified medical physicist;

2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks:

3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in 12VAC5-481-3400 C;

<u>4. Calibration of the electronic brachytherapy source</u> <u>output shall include, as applicable, determination of:</u>

a. The output within 2.0% of the expected value, if applicable, or determination of the output if there is no expected value;

b. Timer accuracy and linearity over the typical range of use;

c. Proper operation of back-up exposure control devices;

d. Evaluation that the relative dose distribution about the source is within 5.0% of that expected; and

e. Source positioning accuracy to within one millimeter within the applicator;

5. Calibration of the x-ray source output required by subdivisions 1 through 4 of this subsection shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed; and

6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the model numbers and serial numbers of the instrument used to calibrate the electronic brachytherapy device; and the name and signature of the qualified medical physicist responsible for performing the calibration.

K. Periodic and day-of-use quality assurance checks for electronic brachytherapy devices.

<u>1. Quality assurance checks shall be performed on each electronic brachytherapy device:</u>

a. At the beginning of each day of use;

b. Each time the device is moved to a new room or each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer; and

c. After each x-ray tube installation.

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2. The registrant shall perform periodic quality assurance checks required by subdivision 1 of this subsection in accordance with procedures established by the qualified medical physicist.

3. To satisfy the requirements of subdivision 1 of this subsection, radiation output quality assurance checks shall include at a minimum:

a. Verification that output of the electronic brachytherapy source falls within 3.0% of expected values, as appropriate for the device, as determined by:

(1) Output as a function of time, or

(2) Output as a function of setting on a monitor chamber.

b. Verification of the consistency of the dose distribution to within 3.0% of that found during calibration required by subsection J of this section; and

c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter.

4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in 12VAC5-481-3400 C 1 to make the quality assurance checks required in subdivision 3 of this subsection.

5. The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

a. An authorized user and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within the acceptable tolerances:

b. If all radiation output quality assurance check parameters appear to be within the acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or qualified medical physicist within two days; and

c. The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

<u>6. To satisfy the requirements of subdivision 1 of this</u> subsection, safety device quality assurance checks shall, at <u>a minimum, assure:</u>

<u>a. Proper operation of radiation exposure indicator lights</u> <u>on the electronic brachytherapy device and on the control</u> <u>console;</u>

b. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

c. Proper operation of radiation monitors, if applicable;

<u>d.</u> The integrity of all cables, catheters, or parts of the device that carry high voltages; and

e. Connecting guide tubes, transfer tubes, transfer-tubeapplicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

7. If the results of the safety device quality assurance checks required in subdivision 6 of this subsection indicate the malfunction of any system, a registrant shall secure the control console in the "OFF" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

8. The registrant shall maintain a record of each quality assurance check required by subdivisions 3 and 7 of this subsection in an auditable form for three years.

a. The record shall include the date of the quality assurance check; the manufacturer's name, model number, and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check; and the name and signature of the qualified medical physicist who reviewed the quality assurance check; and

b. For radiation output quality assurance checks required by subdivision 3 of this subsection, the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name, model number, and serial number for the instrument used to measure the radiation output of the electronic brachytherapy device.

L. Therapy-related computer systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by or under the direct supervision of a qualified medical physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

<u>d.</u> The accuracy of the software used to determine radiation source positions from radiographic images; and

e. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic

transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the authorized user and the qualified medical physicist for correctness through means independent of that used for the determination of the parameters.

M. Training.

1. A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in subsection H of this section. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

2. In addition to the requirements of 12VAC5-481-3390 C for therapeutic radiation machine authorized users and 12VAC5-481-3390 D for qualified medical physicists, the therapeutic radiation machine authorized users and qualified medical physicists shall also receive devicespecific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

a. Device-specific radiation safety requirements;

b. Device operation;

c. Clinical use for the types of use approved by the U.S. Food and Drug Administration;

d. Emergency procedures, including an emergency drill; and

e. The registrant's quality assurance program.

3. A registrant shall retain a record of individuals receiving instruction required by subdivisions 1 and 2 of this subsection for three years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.

<u>N. Mobile electronic brachytherapy service. A registrant</u> providing mobile electronic brachytherapy service shall, at a <u>minimum:</u> <u>1. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.</u>

<u>2</u>. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

<u>3. Perform at each location on each day of use all of the required quality assurance checks specified in subsection K of this section to assure proper operation of the device.</u>

12VAC5-481-3453. Other use of electronically produced radiation to deliver therapeutic radiation dosage.

A person shall not utilize any device that is designed to electronically generate a source of ionizing radiation to deliver therapeutic radiation dosage and that is not appropriately regulated under any existing category of therapeutic radiation machine until:

<u>1. The applicant or registrant has, at a minimum, provided the agency with:</u>

a. A detailed description of the device and its intended application;

b. Facility design requirements, including shielding and access control;

c. Documentation of appropriate training for authorized user physicians and qualified medical physicists;

<u>d.</u> Methodology for measurement of dosages to be administered to patients or human research subjects;

e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

f. Radiation safety precautions and instructions; and

g. Other information requested by the agency in its review of the application; and

2. The applicant or registrant has received written approval from the agency to utilize the device in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the device.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-481)

Dosimetry of X-ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV: NCRP Report 69, 1981, National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, DC 20014

Comprehensive QA for Radiation Oncology: AAPM Report No. 46, 1994, American Association of Physicists in Medicine, Committee Task Group 40, Radiation Therapy Committee, published by the American Institute of Physics, One Physics Ellipse, College Park, MD 20740-3846

AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report Number 47, 1994, American Association of Physicists in Medicine Radiation Therapy Task Group 45,

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published by the American Institute of Physics, One Physics Ellipse, College Park, MD 20740-3846

Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82, Medical Physics, Vol. 30, No. 8, August 2003, American Association of Physicists in Medicine

Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83, Medical Physics, Vol. 30, No. 10, October 2003, American Association of Physicists in Medicine

VA.R. Doc. No. R16-4305; Filed March 25, 2016, 1:12 p.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Withdrawal of Proposed Regulation

<u>Titles of Regulations:</u> 12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-160, 12VAC30-50-210).

12VAC30-80. Methods and Standards for Establishing Payment Rates; Other Types of Care (amending 12VAC30-80-40).

The Department of Medical Assistance Services has WITHDRAWN the proposed regulatory action for 12VAC30-50, Amount, Duration, and Scope of Medical and Remedial Care Services; and 12VAC30-80, Methods and Standards for Establishing Payment Rates; Other Types of Care, which was published in 16:26 VA.R. 3459-3465 September 11, 2000. The agency has determined that this action is no longer relevant or necessary.

<u>Agency Contact:</u> William Lessard, Director, Division of Program Reimbursement, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 225-4593, or email william.lessard@dmas.virginia.gov.

VA.R. Doc. No. R00-1; Filed March 18, 2016, 11:41 a.m.

TITLE 15. JUDICIAL

VIRGINIA STATE BAR

Final Regulation

<u>REGISTRAR'S NOTICE</u>: The Virginia State Bar is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts agencies of the Supreme Court.

<u>Title of Regulation:</u> 15VAC5-40. Bylaws of the Virginia State Bar and Council (repealing 15VAC5-40-10 through 15VAC5-40-430).

Statutory Authority: § 54.1-3910 of the Code of Virginia.

Effective Date: March 25, 2016.

<u>Agency Contact:</u> Stephanie Blanton, Executive Assistant, Virginia State Bar, 1111 East Main Street, Suite 700, Richmond, VA 23219, telephone (804) 775-0576, or email blanton@vsb.org.

Summary:

Due to a determination that the Bylaws of the Virginia State Bar and Council are not regulations as defined by § 2.2-4101 of the Code of Virginia, 15VAC5-40 is repealed.

VA.R. Doc. No. R16-4610; Filed March 18, 2016, 3:05 p.m.

Final Regulation

<u>REGISTRAR'S NOTICE:</u> The Virginia State Bar is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts agencies of the Supreme Court.

<u>Title of Regulation:</u> 15VAC5-80. Regulations under the Virginia Consumer Real Estate Settlement Protection Act (amending 15VAC5-80-10 through 15VAC5-80-50).

Statutory Authority: § 55-525.30 of the Code of Virginia.

Effective Date: March 25, 2016.

<u>Agency Contact:</u> Stephanie Blanton, Executive Assistant, Virginia State Bar, 1111 East Main Street, Suite 700, Richmond, VA 23219, telephone (804) 775-0576, or email blanton@vsb.org.

<u>Summary:</u>

The amendments conform the regulation to changes enacted by Chapter 794 of the 2010 Acts of Assembly, which repealed Title 6.1 of the Code of Virginia and transferred the provisions regarding real estate settlements and settlement agents to new Chapters 27.2 (§ 55-525.8 et seq.) and 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia as part of the recodification of Title 6.1. The amendments update citations to the Code of Virginia and terminology.

CHAPTER 80

REGULATIONS UNDER THE VIRGINIA CONSUMER ATTORNEY REAL ESTATE SETTLEMENT PROTECTION ACT AGENTS REGULATIONS

15VAC5-80-10. Authority; applicability; scope.

These regulations are <u>This chapter is</u> issued by the Virginia State Bar pursuant to and under the authority of the Virginia Consumer Real Estate Settlement Protection Act (§ 6.1 2.19 et seq. <u>Chapter 27.3 (§ 55-525.16 et seq.) of Title 55</u> of the Code of Virginia) as enacted by the 1997 session of the General Assembly of Virginia. The Act <u>Chapter 27.3</u> does not apply to licensed attorneys who provide escrow, closing, or

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settlement services solely for public bodies as defined in § $\frac{11-37}{2.2-4301}$ of the Code of Virginia; thus, such attorneys are exempt from the registration, certification, and separate fiduciary trust account requirements set forth in these regulations of this chapter.

CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia), and therefore these regulations this chapter, applies to transactions involving the purchase of or lending on the security of real estate located in Virginia containing not more than four residential units. In addition, a lay settlement agent may provide escrow, settlement, and closing services for transactions involving any real property located in Virginia, provided the agent is registered under and in compliance with CRESPA. See the Real Estate Settlement Agent Registration Act (§ 6.1 2.30 et seq. §§ 55-525.17 and 55-525.18 of the Code of Virginia) Virginia. Lawyer settlement agents are not required to register under CRESPA Chapter 27.3 unless the transaction involves the purchase of or lending on the security of real estate located in Virginia containing not more than four residential dwelling units.

15VAC5-80-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise. <u>Unless otherwise defined in this section</u>, all terms in this chapter shall have the meanings set forth in Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia.

"Attorney" means a person licensed as an attorney under Chapter 39 (§ 54.1-3900 et seq.) of Title 54.1 of the Code of Virginia and who is an active member of the Virginia State Bar in good standing under the Rules of the Virginia Supreme Court.

"Bar" means the Virginia State Bar.

"Board" means the Virginia Real Estate Board.

"CRESPA" means the Virginia Consumer Real Estate Settlement Protection Act (§ 6.1 2.19 et seq. of the Code of Virginia). Unless otherwise defined herein, all terms in these regulations shall have the meanings set forth in CRESPA.

"Disciplinary board" means the Virginia State Bar Disciplinary Board.

"First dollar coverage" means an insurance policy which that obligates the company issuing the policy to pay covered claims in their entirety, up to the policy limits, regardless of the presence of a deductible amount to which the company may be entitled as a reimbursement from the insured.

"SCC" means the Virginia State Corporation Commission.

"These regulations" "This chapter" means 15VAC5-80, Regulations under the Virginia Consumer <u>Attorney</u> Real Estate Settlement Protection Act <u>Agents Regulations</u>.

15VAC5-80-30. Registration; reregistration; required fee.

Every licensed attorney now providing or offering, or intending to provide or offer, escrow, closing. or settlement

services as a settlement agent with respect to real estate transactions in Virginia shall register with the Bar using the registration form available from the Bar for that purpose. Settlement agents beginning to provide or offer such services shall register with the Bar prior to doing so. The registration requirement in this paragraph shall not apply to attorney settlement agents unless they provide or offer to provide escrow, settlement, and closing services for real estate subject to CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia, (i.e., real estate containing not more than four residential dwelling units). Thus, for example, attorneys who handle only commercial real estate transactions are not subject to these regulations this chapter.

Every settlement agent shall thereafter reregister after notice on a schedule established by the Bar, providing updated registration information. Every settlement agent shall have a continuing duty to advise the Bar of any change in name, address, or other pertinent registration data that occurs between registrations.

The fee for each registration and reregistration shall be \$35 for an attorney settlement agent. The Bar reserves the right to adjust the fee as necessary within the statutory limit of \$100. The prescribed fee shall accompany each registration or reregistration in the form of a check made payable to the Treasurer of Virginia.

Registration is subject to revocation or suspension if the Bar or other appropriate licensing authority finds the settlement agent out of compliance with <u>CRESPA</u> <u>Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia</u> or regulations issued thereunder.

15VAC5-80-40. Unauthorized practice of law guidelines; investigation of complaints.

The Bar will issue guidelines under CRESPA and in consultation with the SCC and the board to assist settlement agents in avoiding and preventing the unauthorized practice of law in connection with the furnishing of escrow, closing, or settlement services. In conformity with CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia, the rules of the Virginia Supreme Court₄ and the Bar's UPL unauthorized practice of law opinions, these guidelines will delineate activities which that can and cannot be carried out by registered nonattorney settlement agents in conducting settlements. The guidelines will be revised from time to time as necessary.

The guidelines will be available on the Bar's website and provided by the appropriate licensing authority to each registered settlement agent at the time of initial registration and at each reregistration. The guidelines will also be furnished to the SCC, the board, and all other state and federal agencies that regulate financial institutions, as well as to members of the general public upon request. The guidelines may be photocopied as necessary.

The Bar will continue to receive and investigate unauthorized practice of law complaints in the real estate

settlement area, as well as in other fields, under its unauthorized practice of law rules and procedures.

If the Bar receives complaints against nonattorney settlement agents that do not allege the unauthorized practice of law, it will refer the complaints to the appropriate licensing authority that has jurisdiction over the subject of the complaint. If the complaint involves an attorney settlement agent's noncompliance with 15VAC5-80-30, the Bar will conduct an informal investigation. If the Bar believes a violation has occurred, it will notify the attorney settlement agent in writing. If the apparent violation is not rectified within 30 days, the Bar will investigate the alleged violations pursuant to 15VAC5-80-50 D.

15VAC5-80-50. Attorney settlement agent compliance.

A. Attorney settlement agent certification. Each attorney settlement agent shall, at the time of initial registration and \underline{of} each subsequent reregistration, certify on the form available from the Bar for that purpose, that the attorney settlement agent has in full force and effect the following insurance and bond coverages, and that such coverages will be maintained in full force and effect throughout the time the attorney settlement agent agent acts, offers, or intends to act in that capacity:

1. A lawyer's professional liability insurance policy issued by a company authorized to write such insurance in Virginia providing first dollar coverage and limits of at least \$250,000 per claim covering the licensed attorney acting, offering, or intending to act as a settlement agent. The policy may also cover other attorneys practicing in the same firm or legal entity.

2. A blanket fidelity bond or employee dishonesty insurance policy issued by a company authorized to write such bonds or insurance in Virginia providing limits of at least \$100,000 covering all other employees of the attorney settlement agent or the legal entity in which the attorney settlement agent practices.

3. A surety bond issued by a company authorized to write such bonds in Virginia, on a form approved by the Virginia State Bar, providing limits of at least \$200,000 covering the licensed attorney acting, offering or intending to act as a settlement agent. A copy of the approved bond form is available from the Bar. The bond may also cover other attorney settlement agents practicing in the same firm or legal entity. The original surety bond must be attached to the attorney settlement agent's certification form and furnished to the Bar; a surety bond on which a law firm is named as principal may be furnished by the firm or any one attorney settlement agent in the firm, with other such attorney settlement agents in the same firm attaching a copy to their forms.

The Bar reserves the right to require other evidence of the above insurance and bond coverages <u>listed in this subsection</u> beyond the attorney's certification and surety bond, at its discretion.

An attorney settlement agent who has no employees other than the attorney settlement agent or other <u>than a</u> licensed <u>owner(s)</u>, <u>partner(s)</u>, <u>shareholder(s)</u> <u>owner</u>, <u>partner</u>, <u>shareholder</u>, or <u>member(s)</u> <u>member</u> of the legal entity in which the attorney settlement agent practices may apply to the Bar for a waiver of the coverage required in subdivision A 2 of this <u>section</u> <u>subsection</u>, using the <u>waiver request</u> form available from the Bar. Such waiver requests will be acted on by the Executive Committee of the Bar, whose decision shall constitute final action by the agency.

B. Separate fiduciary trust account. Each attorney settlement agent shall maintain one or more separate and distinct fiduciary trust account(s) accounts used only for the purpose of handling funds received in connection with escrow, closing, or settlement services. Funds received in connection with real estate transactions not covered by CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia may also be deposited in and disbursed from such account(s) accounts. All funds received by an attorney settlement agent in connection with escrow, closing, or settlement services shall be deposited in and disbursed from the separate fiduciary account(s) accounts in conformity with both the Bar's disciplinary rules and CRESPA Chapter 27.3. These separate fiduciary trust accounts shall be maintained in the same manner and subject to the same rules as those promulgated by the Bar for other lawyer trust accounts, as well as in conformity with CRESPA Chapter 27.3. One separate fiduciary trust account may be maintained and used by all attorney settlement agents practicing in the same firm or legal entity.

C. Settlement statements. All settlement statements for escrow, closing, and settlement services governed by CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia and these regulations this chapter shall be in writing and identify, by name and business address, the settlement agent.

D. Complaints against attorney settlement agents. The Bar shall receive complaints and/or or investigate alleged violations of CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or these regulations this chapter by attorney settlement agents. If, after investigation, the Bar does not have reasonable cause to believe that one or more violations of CRESPA and/or these regulations Chapter 27.3 or this chapter have occurred, the Bar may dismiss the complaint as unfounded.

If, after investigation, the Bar has reasonable cause to believe that one or more violations have occurred, the following procedures shall apply:

1. The attorney settlement agent shall be notified in writing of the alleged violation(s) violations.

2. The attorney settlement agent shall have 30 days from the date of such notification to respond in writing to the alleged violations. If, after receipt of the response, the Bar no longer has reasonable cause to believe that one or more violations of <u>CRESPA and/or these regulations</u> <u>Chapter</u> 27.3 (§ 55-525.16 et seq.) of <u>Title 55</u> of the Code of <u>Virginia or this chapter</u> have occurred, the Bar may dismiss the complaint as unfounded.

3. If the Bar believes the alleged violation presents or presented a risk to consumers protected under CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia, the Bar may request a hearing and issue an order requiring the attorney settlement agent to appear at the hearing, whether or not the attorney settlement agent has responded in writing to the notice of alleged violation(s) violation or the 30-day response time period has lapsed.

4. In conducting investigations of alleged violations of CRESPA and/or these regulations Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter by attorney settlement agents, the Bar, by Bar Counsel, shall have the authority to issue summonses or subpoenas to compel the attendance of witnesses and the production of documents necessary and material to any inquiry.

5. The following shall be applicable to hearings on alleged violations of CRESPA and/or these regulations Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter:

a. Hearings shall be held before the disciplinary board within 60 days of the issuance of the Bar's order to appear.

b. The standard of proof of violations of CRESPA Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or these regulations this chapter shall be clear and convincing evidence.

c. Hearings shall be conducted in the same manner as attorney misconduct hearings as set out in Rules of Court, Part Six, Section IV, Paragraph 13.

d. Agreed dispositions may be entered into in the same manner as agreed dispositions at the disciplinary board in attorney misconduct cases.

e. The attorney settlement agent's prior disciplinary record and prior record of violations of CRESPA and/or these regulations Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter shall be made available to the disciplinary board during the sanction stage of a hearing. The prior record of violations of CRESPA and/or these regulations Chapter 27.3 or this chapter may be made available to Bar subcommittees, district committees, the disciplinary board or a three-judge circuit court prior to the imposition of any sanction for attorney misconduct.

f. If the attorney settlement agent is found to have violated CRESPA and/or these regulations Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter, the attorney settlement agent may be

subject to the following penalties, at the disciplinary board's discretion:

(1) A penalty not exceeding \$5,000 for each violation;

(2) Revocation or suspension of the attorney settlement agent's registration; and

(3) Any other sanction available to the disciplinary board in attorney disciplinary proceedings under the rules of the Virginia Supreme Court, including, but not limited to, revocation or suspension of the attorney settlement agent's license to practice law.

6. The disciplinary board shall assess costs in accordance with the same rules and procedures that apply to the imposition of costs in attorney misconduct cases.

7. All matters and proceedings pertaining to alleged violations of CRESPA and/or these regulations Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter are public. Related attorney misconduct cases shall be heard by the disciplinary board together with alleged violations of CRESPA and/or these regulations Chapter 27.3 or this chapter. Any related disability issues shall be heard by the disciplinary board separately.

8. The Clerk of the Disciplinary System of the Bar shall maintain files and records pertaining to ended cases involving alleged violations of <u>CRESPA</u> and/or these regulations <u>Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter</u>. The clerk shall follow the same file destruction policies that are utilized in attorney misconduct cases.

9. The Bar may proceed against an attorney settlement agent for alleged violations of CRESPA and/or these regulations Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter notwithstanding that the attorney settlement agent has resigned from the practice of law, surrendered his license to practice law in the Commonwealth of Virginia or had his license to practice law in the Commonwealth of Virginia revoked.

10. An appeal from an order of the disciplinary board imposing sanctions under <u>CRESPA</u> and/or these regulations <u>Chapter 27.3 (§ 55-525.16 et seq.) of Title 55 of the Code of Virginia or this chapter</u> shall be conducted in accordance with the provisions of Rules of Court, Part Six, Section IV, Paragraph 13 pertaining to an appeal of an order of the disciplinary board imposing sanctions upon findings of attorney misconduct.

<u>NOTICE</u>: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (15VAC5-80)

Settlement Agent Official Registration Form for an Individual Attorney (rev. 7/09)

Reregistration Form for an Individual Attorney (rev. 7/09)

Virginia Attorney Real Estate Settlement Agent Financial Responsibility Certification (rev. 5/08)

Bond for Attorney Settlement Agent Principal as Individual (rev. 7/09)

Bond for Attorney Settlement Agent Principal as Law Firm (rev. 7/09)

Settlement Agent Official Registration Form for an Individual Attorney (rev. 7/2014)

<u>Virginia Attorney Real Estate Settlement Agent Financial</u> Responsibility Certification (includes waiver request) (rev. 3/2012)

<u>Bond for Attorney Settlement Agent - Principal as</u> Individual (rev. 3/2012)

Bond for Attorney Settlement Agent - Principal as Law Firm (rev. 3/2012)

VA.R. Doc. No. R16-3141; Filed March 18, 2016, 9:53 a.m.

TITLE 17. LIBRARIES AND CULTURAL RESOURCES

BOARD OF HISTORIC RESOURCES

Proposed Regulation

<u>Title of Regulation:</u> 17VAC5-30. Evaluation Criteria and Procedures for Designations by the Board of Historic Resources (amending 17VAC5-30-100, 17VAC5-30-110, 17VAC5-30-120, 17VAC5-30-160).

Statutory Authority: § 10.1-2205 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: June 17, 2016.

<u>Agency Contact:</u> Jennifer Pullen, Executive Assistant, Department of Historic Resources, 2801 Kensington Avenue, Richmond, VA 23221, telephone (804) 482-6085, FAX (804) 367-2391, or email jennifer.pullen@dhr.virginia.gov.

<u>Basis</u>: The Board of Historic Resources has authority to promulgate regulations necessary to carry out its powers and duties, including at a minimum criteria and procedures for the designation of historic landmarks, including buildings, structures, districts, objects, and sites under § 10.1-2205 of the Code of Virginia.

<u>Purpose:</u> The subject matter addressed is the owner objection process to properties nominated for historic district designation by the Board of Historic Resources for inclusion in the Virginia Landmarks Register (VLR). The intent of the

proposed amendments is to clarify and detail the process and requirements necessary for formal objection. Amendment and clarification of the existing procedures are necessary to more clearly set out the objection letter requirements for both property owners and the Department of Historic Resources (DHR) staff and set out what is required for an owner objection to be considered formal and valid. By clarifying and detailing existing language, the proposed amendments will make the objection process and requirements easier to understand for property owners and DHR staff. Making specific the records to be consulted and the timeframe in which they should be consulted in addition to creating specific deadlines and attestation requirements as well as requiring proof of ownership on the part of objecting owners are intended to prevent confusion or assumptions about the formal objection process and will benefit both property owners and DHR staff. By protecting property interests, the proposed action will benefit the public welfare.

Substance: The amendments to the existing regulations clarify language that written notification of the nomination and written notification of the public hearing will be sent to property owners listed, within 90 days of notification, in official land recordation records or tax records. In addition, property owners who wish to object to a designation must submit their formal objection seven business days prior to the board meeting. The amendments also add that in addition to the letter being notarized, it must also be attested and reference the property by address or parcel number. Also, in order to be counted by the director as a property owner, if the objecting party was not listed on the official land recordation records or tax records within 90 days of notification, then a copy of the recorded deed evidencing transfer of ownership must be submitted along with the written, attested, and notarized statement. Lastly, formal designations may be reconsidered at a subsequent board meeting if the director receives, at least 30 days prior to the next scheduled board meeting, written, attested, and notarized statements stating that there is no longer an objection. In current regulations, it is unclear as to what "current real estate tax assessment books" really means so amending it to specifically state the official land recordation records or tax records makes certain what records are to be consulted to determine property ownership within nominated district boundaries. Also, currently there is no time restriction or deadline on the director receiving formal letters of objection to a property being considered for designation on the VLR. Also, property owners are not required to state the subject property address or parcel number in a formal objection letter, nor is it required that the letter be attested. Current regulations do not require that a copy of the recorded deed evidencing ownership transferred to the objecting party be submitted along with the objection letter. Lastly, in current regulations, there is no time restriction or deadline for the director to receive letters for reconsideration.

<u>Issues:</u> The primary advantage to the public that is offered by the proposed regulation is a clear timeframe within which private property owners may participate in the VLR nomination process and to submit comments or objections to the proposed listing, and the proposed regulation clearly defines what local government records will be used and when for the purpose of identifying property owners within a nominated historic boundary. The primary disadvantage to the public is that the proposed regulation introduces a new requirement to provide a copy of a recorded deed showing evidence of a transfer of property if the transfer occurred after the date that then-current local government records were used to gather property owner information.

Under the current regulation, such a situation does not require a property owner to provide a copy of a recorded deed with their written objection. Under the proposed regulation, to object to VLR listing, a property owner must provide written notice no less than seven business days prior to a meeting of the Board of Historic Resources, but the property owner will retain a minimum of 30 days from notice of a proposed nomination to the deadline to object. The primary advantage to DHR and the Commonwealth is that DHR staff will have a clear definition of the local government records to be consulted for a proposed nomination, the timeframe within which they may be consulted, the timeframe within which property owner objections to VLR listings will be received prior to a joint board meeting, and a minimum of seven business days within which to process and verify the property owner's objection. Under the current regulation, property owner objections to a VLR listing may be received up to the day of a joint board meeting, leaving no opportunity for DHR staff to process the objection and keep Board of Historic Resources members informed of property owner objections. The proposed regulation offers no disadvantage to DHR or the Commonwealth. The proposed regulation offers advantages to local governments and to nomination authors by clearly explaining the types of local government records that will be consulted to identify property owners within a nominated historic boundary, the timeframe within which the records are to be consulted, and a deadline of at least seven business days prior to a joint board meeting for DHR staff to notify them of any property owner objections. The proposed regulation offers no disadvantage to local governments or to nomination authors.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed changes will clarify the owner objection process when an owner's real property is nominated to be included in the Virginia Landmarks Register.

Result of Analysis. The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact. This regulation establishes the owner objection process when the owner's real property is

nominated to be included in the Virginia Landmarks Register, which is the state's official list of properties important to Virginia's history. The purpose of the registration is to recognize the historic value of a property and encourage present and future owners to continue to exercise good stewardship. Participation is voluntary and registration itself does not limit the owner's rights in any way. However, owners of registered properties may donate historic preservation easements, participate in state historic rehabilitation tax credit programs, or accept grants which may place certain restrictions on alterations or demolitions.

In most cases, owners nominate their own properties. However, in cases where there are multiple owners or a property is located in a district nominated to be listed in the register, an owner has a right to object according to the procedures set out in this regulation. The proposed changes primarily clarify the objection process. Specifically, the Board of Historic Resources (Board) proposes to 1) require that a copy of the recorded deed evidencing transferred ownership to the objecting party be submitted along with the objection letter when official land records or tax records do not reflect the accurate ownership information; 2) require owners to state the subject property address or parcel number in a formal objection letter and require that the letter be attested; 3) require that formal letters of objection be submitted at least seven days prior to the Board meeting and require that letters for reconsideration be submitted at least 30 days prior the Board meeting; and 4) clarify that the ownership information be obtained from official land records or tax records for public hearing notifications sent to owners.

While requiring a copy of a recorded deed may introduce a nominal cost on the owners whose ownership is not yet reflected in the official land records or tax records, this requirement will be relevant only when a transfer of ownership occurred between the time the Board obtained ownership information and sent notices to the owners. The number of such cases is expected to be very small.¹ On the other hand, this change will ensure that the new owner of the property is notified and afforded a chance to object. Remaining proposed changes are expected to improve the clarity of the formal objection process requirements to prevent any confusion by the property owners and the staff, and are not expected to create any significant economic effects.

Businesses and Entities Affected. The proposed regulation applies to property owners who may wish to object to the nomination of their property for listing in the Virginia Landmarks Register. Between September 2014 and December 2015, the Department of Historic Resources received 58 nominations to either the Virginia Landmarks Register or the National Register, sent out 1673 notifications to the property owners, and received 6 objection letters. Separate statistics for the Virginia Landmarks Register alone is not available at this time.

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Localities Particularly Affected. The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment. The proposed amendments are unlikely to affect employment.

Effects on the Use and Value of Private Property. No impact on the use and value of private property is expected.

Real Estate Development Costs. No impact on real estate development costs is expected.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects. The proposed regulation will not affect small businesses unless a property they own is nominated for listing in the Virginia Landmarks Register, in which case the effects would be the same as discussed above.

Alternative Method that Minimizes Adverse Impact. No adverse impact on small businesses is expected.

Adverse Impacts:

Businesses. The proposed regulation will not adversely affect non-small businesses.

Localities. The proposed regulation will not adversely affect localities.

Other Entities. The proposed regulation will not adversely affect other entities.

Summary:

The proposed amendments address the process of owner objection to designation of properties by the Board of Historic Resources for inclusion in the Virginia Landmarks Register. The proposed amendments (i) clarify that written notification of the proposed designation and written notification of the public hearing will be sent to property owners listed within 90 days prior to the notification in official land recordation records or tax records; (ii) require property owners to submit their formal objections seven business days prior to the board meeting; (iii) require that the objection letter, in addition to being notarized, must be attested and reference the property by address or parcel number, or both; (iv) require that an objecting party who was not listed on the official land recordation records or tax records submit a copy of the recorded deed evidencing transfer of ownership with the

attested and notarized statement to be counted by the director in determining whether a majority of the owners object; and (v) provide that formal designations may be reconsidered at a subsequent board meeting if the director receives, at least 30 days prior to the next scheduled board meeting, written, attested, and notarized statements stating that there is no longer an objection.

Part IV

Public Notice and Public Hearings

17VAC5-30-100. Written notice of proposed nominations.

In any county, city, or town where the board proposes to designate property for inclusion in the Virginia Landmarks Register, the department shall give written notice of the proposal to the governing body and to the owner, owners, or the owner's agent (i) of property proposed to be designated as a historic landmark building, structure, object, or site, or to be included in a historic district, and to the owners, or their agents, (ii) of all abutting property and property immediately across the street or road or across any railroad or waterway less than 300 feet wide. The list of such owners shall be obtained from either the official land recordation records or tax records, whichever is more appropriate, within 90 days prior to the notification of the proposal.

17VAC5-30-110. Public hearing for historic district; notice of hearing.

<u>A.</u> Prior to the designation by the board of a historic district, the department shall hold a public hearing at the seat of government of the county, city, or town in which the proposed historic district is located or within the proposed historic district. The public hearing shall be for the purpose of supplying additional information to the board. The time and place of such hearing shall be determined in consultation with a duly authorized representative of the local governing body; and shall be scheduled at a time and place that will reasonably allow for the attendance of the affected property owners.

<u>B.</u> The department shall publish notice of the public hearing once a week for two successive weeks in a newspaper published or having general circulation in the county, city, or town. Such notice shall specify the time and place of the public hearing at which persons affected may appear and present their views, not less than six days or more than 21 days after the second publication of the notice in such newspaper.

<u>C.</u> In addition to publishing the notice, the department shall give written notice of the public hearing at least five days before such hearing to the owner, owners, or the owner's agent of (i) each parcel of real property to be included in the proposed historic district, and to the owners, or their agents, of (ii) all abutting property and property immediately across the street or road or across any railroad or waterway less than 300 feet wide <u>pursuant to 17VAC5-30-100</u>. Notice required to be given to owners by this section may be given concurrently with the notice required to be given to the owners by 17VAC5-30-100. A complete copy of the

¹ There were only 6 objections between September 2014 and December 2015 to the nominations for either the Virginia Landmarks Register or the National Register. Thus, the chance of one of them being a new owner is relatively small.

<u>Agency's Response to Economic Impact Analysis:</u> The agency concurs with the economic impact analysis submitted by the Department of Planning and Budget.

nomination report and a map of the historic district showing the boundaries shall be sent to the local jurisdiction for public inspection at the time of notice. The notice shall include a synopsis of why the district is significant.

<u>D.</u> The department shall make and maintain an appropriate record of all public hearings held pursuant to this section.

17VAC5-30-120. Mailings and affidavits; concurrent state and federal notice.

The department shall send the required notices by first class mail to the last known address of each person entitled to notice, as shown on the current real estate tax assessment books pursuant to 17VAC5-30-100. A representative of the department shall make an affidavit that the required mailings have been made. In the case where property is also proposed for inclusion in the National Register of Historic Places pursuant to nomination by the director, the department may provide concurrent notice of and hold a single public hearing on the proposed state designation and the proposed nomination to the National Register.

17VAC5-30-160. Owner objections.

<u>A.</u> Upon receiving the notification required by 17VAC5-30-100, any owner or owners of property proposed for designation by the board shall have the opportunity to concur in or object to that designation.

<u>B.</u> Property owners who wish to object to designation shall submit to the director a written, attested, and notarized statement certifying of objection. The statement of objection shall (i) reference the subject property by address or parcel number, or both; (ii) certify that the objecting party is the sole or partial owner of the property, as appropriate_{\overline{x}} and (iii) certify that the objecting party objects to the designation. The statement of objection must be received by the director at least seven business days prior to the meeting of the board at which the property is considered for designation.

If an owner C. An objecting party whose name did not appear on the current real estate tax assessment list official land recordation records or tax records used by the director pursuant to 17VAC5-30-120 certifies in a must submit with the written, attested, and notarized statement that of objection an attested and notarized copy of the party is the sole or partial owner of a nominated property, such owner recorded deed evidencing transfer of ownership to such objecting party. Only upon such submission shall such objecting owner be counted by the director in determining whether a majority of the owners has objected. The statement of objection must be received by the director at least seven business days prior to the meeting of the board at which the property is considered for designation.

<u>D</u>. The board shall take no formal action to designate the property or district for inclusion in the Virginia Landmarks Register if (i) the owner of a property, Θ (ii) the majority of owners of a single property with multiple owners, or (iii) a majority of the owners in a district, have has objected to the

designation. These objections must be received prior to the meeting of the board at which the property is considered for designation.

<u>E.</u> Where formal designation <u>at a board meeting</u> has been prevented by owner objection, the board may reconsider the property for designation <u>at a subsequent board meeting</u> upon presentation <u>to the director, at least 30 days prior to the next</u> <u>scheduled meeting of the board, of written, attested, and</u> notarized statements sufficient to indicate that the owner or majority of owners no longer <u>object</u> <u>objects</u> to the designation. In the case of a <u>proposed</u> reconsideration, the notification procedures set out in Part IV (17VAC5-30-100 et seq.) <u>of this chapter</u> shall apply.

<u>F.</u> Each owner of property in a district has one vote regardless of how many properties or what part of one property that party owns and regardless of whether the property contributes to the significance of the district.

VA.R. Doc. No. R16-4259; Filed March 17, 2016, 2:54 p.m.

DEPARTMENT OF HISTORIC RESOURCES

Proposed Regulation

<u>Title of Regulation:</u> 17VAC10-20. Evaluation Criteria and Procedures for Nominations of Property to the National Register or for Designation as a National Historic Landmark (amending 17VAC10-20-130, 17VAC10-20-140, 17VAC10-20-150, 17VAC10-20-200).

Statutory Authority: § 10.1-2202 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: June 17, 2016.

<u>Agency Contact:</u> Jennifer Pullen, Executive Assistant, Department of Historic Resources, 2801 Kensington Avenue, Richmond, VA 23221, telephone (804) 482-6085, or email jennifer.pullen@dhr.virginia.gov.

<u>Basis</u>: The Department of Historic Resources (DHR) has specific statutory authority under § 58.1-339.2 of the Code of Virginia to promulgate regulations necessary to implement the program. The regulation is mandated in whole by the state statute. The statute provides that the Director of DHR shall establish by regulation the requirements needed for the program, including the process and procedures by which nominations and designations of properties are approved by the State Review Board for forwarding to the National Park Service, which manages both the National Register of Historic Places (NRHP) and the National Historic Landmark (NHL) programs.

<u>Purpose:</u> The subject matter addressed is the owner objection process to properties nominated for designation by the State Review Board for inclusion in the National Register of Historic Places or designation as a National Historic Landmark. The intent of the planned regulatory action is to clarify and detail the process and requirements necessary for formal objection to designation. Amendment and clarification

of the existing procedures are necessary to more clearly set out the objection letter requirements for both property owners and DHR staff and what is required for an owner objection to be considered formal and valid. By clarifying and detailing existing language, the amendments will make the objection process and requirements easier to understand for property owners and DHR staff. Making specific the records to be consulted and the timeframe in which the records should be consulted, in addition to creating specific deadlines and attestation requirements, are all intended to prevent confusion or assumptions about the formal objection process and will benefit both property owners and DHR staff. By protecting property interests, the proposed action will benefit the public welfare.

<u>Substance</u>: The proposed amendments to the existing regulations add clarifying language that written notification of the nomination and written notification of the public hearing will be sent to property owners listed, within 90 days prior to the notification, in official land recordation records or tax records. In addition, property owners who wish to object to a designation must submit their formal objection seven business days prior to the board meeting. The proposed amendments also add that in addition to the letter being notarized, the letter must also be attested and must reference the property by address or parcel number.

In current regulations, it is unclear as to what "current real estate tax assessment books" means, so amending it to specifically state the official land recordation records or tax records makes clear what records are to be consulted to determine property ownership within nominated district boundaries. Also, there is no time restriction or deadline for the director to receive the formal objections. Lastly, in current regulations, property owners are not required to state the subject property address or parcel number in a formal objection letter, nor is it required that the letter be attested.

<u>Issues:</u> The primary advantage to the public that is offered by the proposed amendments is a clear timeframe within which private property owners may participate in the NRHP nomination process and to submit comments or objections to the proposed listing, and the changed regulation clearly defines what local government records will be used and when the records will be used for the purpose of identifying property owners within a nominated historic boundary.

The opportunity to object to NRHP listing will not be affected by the proposed amendments.

DHR staff will continue to receive property owner objections to an NRHP listing as required under federal regulations and will continue to process and forward such objections to the National Park Service even if the objections are received after the State Review Board has recommended that the nomination be listed in the NRHP, as the National Park Service has the final authority to approve a nomination for listing in the NRHP. The proposed amendments offer no disadvantage to DHR or the Commonwealth. The proposed amendments offer advantages to local governments and to nomination authors by clearly explaining the types of local government records that will be consulted to identify property owners within a nominated historic boundary, the timeframe within which the records are to be consulted, and a deadline of at least seven business days prior to a joint board meeting for DHR staff to notify local governments and nomination authors of any property owner objections. The proposed amendments offer no disadvantage to local governments or to nomination authors.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed changes will clarify the owner objection process when an owner's real property is nominated to be included in the National Register of Historic Places.

Result of Analysis. The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact. This regulation establishes the owner objection process when an owner's real property is nominated to be included in the National Register of Historic Places, which is the official list of structures, sites, objects, and districts that has historical and cultural significance for the nation. The National Register is a part of a national program to coordinate and support public and private efforts to identify, evaluate, and protect America's historic and archeological resources. Participation is voluntary and registration itself does not limit the owner's rights in any way. However, owners of registered properties may donate historic preservation easements, participate in federal historic rehabilitation tax credit programs, or accept grants which may place certain restrictions on alterations or demolitions.

In most cases, owners nominate their own properties. However, in cases where there are multiple owners or a property is located in a district nominated to be listed in the register, an owner has a right to object according to the procedures set out in this regulation. The proposed changes merely clarify the objection process. Specifically, the Department of Historic Resources (DHR) proposes to 1) clarify that the ownership information be obtained from official land records or tax records for public hearing notifications sent to owners; 2) require that formal letters of objection be submitted at least seven days prior to the State Review Board meeting; and 3) require owners to state the subject property address or parcel number in a formal objection letter and require that the letter be attested.

The proposed changes are expected to improve the clarity of the formal objection process requirements to prevent any confusion by the property owners and the staff and are not expected to create any significant economic effects.

Businesses and Entities Affected. The proposed regulation applies to property owners who may wish to object to the nomination of their property for listing in the National Register. Between September 2014 and December 2015, DHR received 58 nominations to either the Virginia Landmarks Register or the National Register, sent out 1673 notifications to the property owners, and received 6 objection letters. Separate statistics for the National Register alone is not available at this time.

Localities Particularly Affected. The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment. The proposed amendments are unlikely to affect employment.

Effects on the Use and Value of Private Property. No impact on the use and value of private property is expected.

Real Estate Development Costs. No impact on real estate development costs is expected.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects. The proposed regulation will not affect small businesses unless a property a small business owns is nominated for listing in the National Register, in which case the effects would be the same as discussed above.

Alternative Method that Minimizes Adverse Impact. No adverse impact on small businesses is expected.

Adverse Impacts:

Businesses. The proposed regulation will not adversely affect non-small businesses.

Localities. The proposed regulation will not adversely affect localities.

Other Entities. The proposed regulation will not adversely affect other entities.

<u>Agency's Response to Economic Impact Analysis:</u> The agency concurs with the economic impact analysis submitted by the Department of Planning and Budget.

Summary:

The proposed amendments address the process of owner objection to designation of properties by the State Review Board for inclusion in the National Register of Historic Places or designation as a National Historic Landmark. The proposed amendments (i) clarify that written notification of the nomination and written notification of the public hearing will be sent to property owners listed within 90 days prior to the notification in official land recordation records or tax records; (ii) require property owners to submit their formal objections seven business days prior to the board meeting; (iii) require that the objection letter, in addition to being notarized, be attested and reference the property by address or parcel number. or both; and (iv) require that an objecting party who was not listed on the official land recordation records or tax records submit a copy of the recorded deed evidencing

transfer of ownership with the attested and notarized statement to be counted by the director as a property owner.

Part IV

Public Notice and Public Hearings

17VAC10-20-130. Written notice of proposed nominations.

In any county, city, or town where the director proposes to nominate property to the National Park Service for inclusion in the National Register of Historic Places or for designation as a National Historic Landmark, the department shall give written notice of the proposal to the governing body and to the owner, owners, or the owner's agent of (i) property proposed to be nominated as a historic landmark building, structure, object, or site, or to be included in a historic district, and to the owners, or their agents, of (ii) all abutting property and property immediately across the street or road or across any railroad or waterway less than 300 feet wide. The list of such owners shall be obtained from either the official land recordation records or tax records, whichever is more appropriate, within 90 days prior to the notification of the proposal. The department shall send this written notice at least 30 but not more than 75 days before the State Review Board meeting at which the nomination will be considered.

17VAC10-20-140. Public hearing for historic district; notice of hearing.

<u>A.</u> Prior to the nomination of a historic district, the department shall hold a public hearing at the seat of government of the county, city, or town in which the proposed historic district is located or within the proposed historic district. The public hearing shall be for the purpose of supplying additional information to the director. The time and place of such hearing shall be determined in consultation with a duly authorized representative of the local governing body, and shall be scheduled at a time and place that will reasonably allow for the attendance of the affected property owners.

<u>B.</u> The department shall publish notice of the public hearing once a week for two successive weeks in a newspaper published or having general circulation in the county, city, or town. Such notice shall specify the time and place of the public hearing at which persons affected may appear and present their views, not less than six days or more than 21 days after the second publication of the notice in such newspaper.

<u>C.</u> In addition to publishing the notice, the department shall give written notice of the public hearing at least five days before such hearing to the owner, owners, or the owner's agent of (i) each parcel of real property to be included in the proposed historic district, and to the owners, or their agents, of (ii) all abutting property, and property immediately across the street or road, or across any railroad or waterway less than 300 feet wide <u>pursuant to 17VAC10-20-130</u>. Notice required to be given to owners by this section may be given concurrently with the notice required to be given to the

owners by 17VAC10-20-130. A complete copy of the nomination report and a map of the historic district showing the boundaries shall be sent to the local jurisdiction for public inspection at the time of notice. The notice shall include a synopsis of why the district is significant.

<u>D.</u> The department shall make and maintain an appropriate record of all public hearings held pursuant to this section.

17VAC10-20-150. Mailings and affidavits; concurrent state and federal notice.

The department shall send the required notices by first class mail to the last known address of each person entitled to notice, as shown on the current real estate tax assessment books <u>pursuant to 17VAC10-20-130</u>. A representative of the department shall make an affidavit that the required mailings have been made. In the case where property is also proposed for inclusion in the Virginia Landmarks Register pursuant to designation by the Virginia Board of Historic Resources, the department may provide concurrent notice of the proposed state designation and the proposed nomination to the National Register.

17VAC10-20-200. Owner objections.

<u>A.</u> Upon receiving the notification required by 17VAC10-20-130, the owners of property proposed for nomination shall have the opportunity to concur in or object to the nomination.

<u>B.</u> Any owner or owners of a private property who wish to object shall submit to the director a written, attested, and notarized statement eertifying of objection. The statement of objection shall (i) reference the subject property by address or parcel number, or both; (ii) certify that the objecting party is the sole or partial owner of the private property, as appropriate₇; and (iii) certify that the objecting party objects to the listing. The statement of objection must be received by the director at least seven business days prior to the meeting of the State Review Board at which the property is considered for nomination

<u>C.</u> If an owner objecting party whose name did not appear on the eurrent real estate tax assessment list official land recordation records or tax records used by the director pursuant to 17VAC10-20-150 certifies in a written, attested, and notarized statement that the party is the sole or partial owner of a nominated private property, such owner shall be counted by the director in determining whether a majority of the owners has objected. The statement of objection must be received by the director at least seven business days prior to the meeting of the State Review Board at which the property is considered for nomination.

<u>D.</u> If (i) the owner of a private property, $\frac{\text{or }}{(\text{ii})}$ the majority of the owners of a single private property with multiple owners, or (iii) the majority of the owners in a district, have has objected to the nomination prior to the submittal of a nomination, the director shall submit the nomination to the keeper only for a determination of eligibility for the National Register. In accordance with the National Historic

Preservation Act, the keeper shall determine whether the property meets the National Register criteria for evaluation, but shall not add the property to the National Register.

<u>E.</u> Each owner of private property in a district has one vote regardless of how many properties or what part of one property that party owns and regardless of whether the property contributes to the significance of the district.

VA.R. Doc. No. R16-4260; Filed March 17, 2016, 2:53 p.m.



TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL REGULATION

Final Regulation

<u>Title of Regulation:</u> 18VAC120-50. Regulations Governing Natural Gas Automobile Mechanics and Technicians (adding 18VAC120-50-10 through 18VAC120-50-230).

Statutory Authority: §§ 54.1-201 and 54.1-2356 of the Code of Virginia.

Effective Date: July 1, 2016.

<u>Agency Contact</u>: Eric L. Olson, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-2785, FAX (866) 430-1033, or email cngmech@dpor.virginia.gov.

Summary:

This action establishes a regulatory program for the voluntary certification of natural gas automobile mechanics and technicians in accordance with Chapter 763 of the 2014 Acts of Assembly. The new chapter includes establishment of (i) certification, renewal, and reinstatement requirements; (ii) standards of practice and conduct; (iii) grounds for disciplinary actions; (iv) education provider requirements for training programs; (v) fees; and (vi) an advisory board.

<u>Summary of Public Comments and Agency's Response:</u> No public comments were received by the promulgating agency.

<u>CHAPTER 50</u> <u>REGULATIONS GOVERNING NATURAL GAS</u> <u>AUTOMOBILE MECHANICS AND TECHNICIANS</u> <u>Part I</u>

Definitions

18VAC120-50-10. Definitions.

<u>A. Section 54.1-2355 of the Code of Virginia provides</u> definitions of other terms and phrases as used in this chapter.

<u>B. The following words and terms when used in this chapter</u> shall have the following meanings unless the context clearly indicates otherwise: <u>"Address of record" means the mailing address designated</u> by the certificate holder to receive notices and correspondence from the board or the board's agent.

<u>"Advisory board" or "board" means the Natural Gas</u> <u>Automobile Mechanics and Technicians Advisory Board.</u>

<u>"Applicant" means an individual seeking certification who</u> has submitted a fully executed application.

"Application" means a board prescribed form submitted with the appropriate fee and other required documentation, including, but not limited to, verification of formal vocational training, verification of experience, and documentation of other certifications and examinations.

"Department" means the Virginia Department of Professional and Occupational Regulation.

"Director" means the Director of the Virginia Department of Professional and Occupational Regulation.

"Formal vocational training" means courses in the trade administered at an accredited educational facility or formal training, approved by the director or his designee, conducted by trade associations, businesses, the military, correspondence schools, or other similar training organizations.

"Reciprocity" means a mutual agreement between the director and any other regulating body that accepts one or more of the eligibility criteria from that regulating body as having met the requirements of this chapter.

<u>"Regulant" means a licensee, certificate holder, or registrant</u> of any other regulatory programs in the Commonwealth of Virginia or any other jurisdiction.

<u>"Reinstatement" means the process and requirements</u> through which an expired certificate can be restored to effectiveness after the expiration date has passed.

<u>"Renewal" means the process and requirement for</u> periodically approving a certification for another period of time.

18VAC120-50-20. Advisory board.

A. The Natural Gas Automobile Mechanics and Technicians Advisory Board shall exercise the authority delegated by the director consistent with subsection A of § 2.2-2100 of the Code of Virginia and shall advise the department on any matters relating to the certification of natural gas automobile mechanics and technicians in the Commonwealth of Virginia.

B. The advisory board shall consist of eight members appointed by the director as follows: two representatives of private businesses that utilize natural gas powered vehicles, one representative of a local government that utilizes natural gas vehicles, one representative of a municipal transit agency that uses natural gas vehicles, one certified natural gas automobile mechanic or technician, one representative of an approved natural gas automobile mechanic or technician training provider, and two citizen members. All memberss must be residents of the Commonwealth of Virginia. After the original appointments, all appointments shall be for terms of four years, except that appointments to fill vacancies shall be for the unexpired terms.

<u>C. Each member shall serve a four-year term. No member shall serve more than two consecutive four-year terms.</u>

D. The advisory board shall meet upon the call of the director, but at least once per year.

Part II

Application Procedures and Entry Requirements

18VAC120-50-30. Application procedures.

A. Every applicant seeking certification shall submit an application with the appropriate fee specified in 18VAC120-50-80. Application shall be made on forms provided by the department and shall contain the following information and documentation:

<u>1. The full legal name of the applicant, a copy of a government-issued photo identification and verification that the applicant is at least 18 years old.</u>

2. The applicant shall disclose his social security number or a control number issued by the Virginia Department of Motor Vehicles in accordance with § 54.1-116 of the Code of Virginia.

3. The physical address of the applicant and, if it is going to be used as the address of record, a mailing address. A post office box, private mail box, or other mail service may be used as a mailing address, but not as the address of record.

4. Documentation of formal vocational training as required in 18VAC120-50-50 in a format approved by the director.

5. Documentation of experience, as required in 18VAC120-50-50 in a format approved by the director.

6. Each applicant shall disclose the following convictions in any jurisdiction:

a. All misdemeanor convictions within three years of the date of the application; and

b. All felony convictions at any time.

Any plea of nolo contendere shall be considered a conviction for the purpose of this subdivision. Individuals convicted in the Commonwealth of Virginia shall include a copy of their Central Criminal Records Exchange report that is no more than 90 days old. Individuals convicted outside of the Commonwealth of Virginia shall include a copy of their Central Criminal Records Exchange report and documentation of their out-of-state convictions from a source approved by the department.

7. Each applicant shall provide certified copies of all other licenses, certifications, or registrations held in any jurisdiction as a natural gas or alternative fuel vehicle mechanic or technician. Additionally, the applicant must provide documentation of any disciplinary action taken against any other license, certification, or registration.

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<u>B. By signing the application or submitting it electronically</u> to the department, the applicant certifies that he has read and understands the statutes and regulations that govern the program.

<u>C. The receipt of an application and the deposit of fees by</u> the department [does do] not indicate approval of the application.

D. Applicants will be notified if their application is incomplete. Applicants who fail to complete the process within one year of the date the original application was received by the department must submit a new application and fee.

18VAC120-50-40. General qualifications for certification.

Every applicant for certification as a certified natural gas automobile mechanic or technician shall meet the requirements and have the qualifications provided in this section.

1. The applicant shall be at least 18 years old.

2. Unless otherwise exempted, the applicant shall meet the current educational requirements by passing all required courses prior to the time the applicant sits for the examination and applies for certification.

3. Unless otherwise exempted, the applicant shall have passed the examination provided by [the] department or by a testing organization acting on behalf of the department.

4. The applicant shall meet the experience requirements in 18VAC120-50-50.

5. In those instances where the applicant is required to take the certification examination, the applicant shall follow all rules established by the department or testing organization with regard to conduct at the examination. Such rules shall include all written instructions communicated prior to the examination date and all instructions communicated at the site, either written or oral, on the date of the examination. Failure to comply with all rules established by the department or the testing organization with regard to conduct at the examination shall be grounds for denial of the application and may result in the voiding of the examination or scores or both.

6. The applicant shall sign, as part of the application, a statement certifying that the applicant has read and understands Chapter 23.4 (§ 54.1-2355 et seq.) of Title 54.1 of the Code of Virginia and this chapter.

7. The department may make further inquiries or investigations or require a personal interview with the applicant with respect to the qualification of the applicant to verify information and documentation, or to clarify information supplied.

8. In accordance with § 54.1-204 of the Code of Virginia, each applicant shall disclose the following information: a. All misdemeanor convictions within three years of the date of the application; and

b. All felony convictions during his lifetime.

Any plea of nolo contendere shall be considered a conviction for the purpose of this subdivision. The record of conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt. The department, at its discretion, may deny certification to any applicant in accordance with § 54.1-204 of the Code of Virginia.

9. The applicant shall report all suspensions, revocations, or surrender of a certificate or license that is connected with a disciplinary action or that has been the subject of discipline in any jurisdiction prior to applying for certification in Virginia. The director, at his discretion, may deny certification to any applicant based on prior suspensions, revocations, or surrender of certifications or licenses connected with disciplinary action by any jurisdiction.

18VAC120-50-50. Evidence of ability and proficiency.

<u>A natural gas automobile mechanic or technician certificate</u> shall be issued to an applicant who fulfills the requirements of 18VAC120-50-40 and one of the following:

1. One year of practical experience in the performance of services relating to the repair, conversion, or maintenance of motor vehicles that use, in whole or in part, natural gas as a fuel and successful completion of a training program approved by the director;

2. A current license as a professional engineer and one year of practical experience in the performance of services relating to the repair, conversion, or maintenance of motor vehicles that use, in whole or in part, natural gas as a fuel;

3. Successful completion of an apprenticeship program approved by the Virginia Apprenticeship Council or the U.S. Department of Labor, with a Dictionary of Occupational Title or Standard Industrial Classification identifier approved by the director, which includes a minimum of one year of practical experience in the performance of services relating to the repair, conversion, or maintenance of motor vehicles that use, in whole or in part, natural gas as a fuel; or

4. Three years of practical experience in the repair, conversion, or maintenance of motor vehicles that use, in whole or in part, natural gas as a fuel.

18VAC120-50-60. Qualifications for licensure by reciprocity or substantial equivalency.

Individuals certified or licensed as natural gas automobile mechanics or technicians by governing bodies located outside the Commonwealth of Virginia shall be in compliance with this chapter if the director has determined the certifying or licensing requirements to be substantially equivalent to the requirements in Virginia. In addition to the requirements set

forth in 18VAC120-50-40, these individuals must meet the following requirements:

1. The applicant shall have received the natural gas automobile mechanic or technician certification by virtue of having passed in the jurisdiction of original certification or licensing a written or oral examination deemed to be substantially equivalent to the Virginia examination; and

2. The applicant shall be in good standing as a certified or licensed natural gas automobile mechanic or technician in every jurisdiction where certified or licensed, and the applicant shall not have had a certificate or license that has been suspended, revoked, or surrendered in connection with a disciplinary action or that has been the subject of discipline in any jurisdiction prior to applying for certification in Virginia.

18VAC120-50-70. Application denial.

The director may refuse initial certification due to an applicant's failure to comply with entry requirements or for any of the reasons the director may discipline a certified natural gas automobile mechanic or technician.

18VAC120-50-80. Application fees.

A. All fees are nonrefundable and shall not be prorated. The date on which the fee is received by the department or its agent will determine whether the fee has been submitted within the time requirements of this chapter. Checks or money orders shall be made payable to the Treasurer of Virginia.

B. Fees are as follows:

Fee Type	Fee Amount	When Due
Original certification application	<u>\$150</u>	<u>Upon</u> submission of the application
Expedited application - application will be reviewed within two business days	<u>\$250 plus</u> application fee	<u>Upon</u> submission of the application

<u>C.</u> The fee for examination or re-examination is subject to contracted charges by an outside vendor. These contracts are competitively negotiated and bargained for in compliance with the Virginia Public Procurement Act (§ 2.2-4300 et seq. of the Code of Virginia). The board may adjust the fee charged to candidates in accordance with these contracts.

18VAC120-50-90. Renewal and reinstatement fees.

A. All fees are nonrefundable and shall not be prorated. The date on which the fee is received by the department or its agent will determine whether the fee has been submitted within the time requirements of this chapter. Checks or money orders shall be made payable to the Treasurer of Virginia.

B. Fees are as follows:

Fee Type	<u>Fee</u> <u>Amount</u>	When Due
<u>Certification</u> renewal	<u>\$100</u>	Within 60 days of, but no later than, the expiration date of the certification
Certification reinstatement	<u>\$150 -</u> <u>includes</u> <u>renewal fee</u>	Within one year of the expiration date of the certification

18VAC120-50-100. Certificate fees.

A. All fees are nonrefundable and shall not be prorated. The date on which the fee is received by the department or its agent will determine whether the fee has been submitted within time requirements set forth in this chapter. Checks or money orders shall be made payable to the Treasurer of Virginia.

B. Fees are as follows:

Fee Type	Fee Amount	When Due
<u>Wall</u> <u>certificate</u>	<u>\$40</u>	<u>Upon</u> submission of the request for <u>a wall</u> certificate
Duplicate pocket certification card	First request within same licensing period - \$0 Second request within same licensing period - \$25 Third or subsequent request within five years - \$50	<u>Upon</u> <u>submission of</u> <u>the request for</u> <u>a duplicate</u> <u>pocket</u> <u>certification</u> <u>card</u>

<u>C. Third and subsequent requests for duplicate certification</u> pocket cards or wall certificates may result in the director initiating an investigation to determine if a violation has occurred.

Part III Renewal and Reinstatement

18VAC120-50-110. Renewal.

<u>A. Certifications issued under this chapter shall expire two</u> years from the last day of the month in which they were issued.

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<u>B. The department will mail a renewal notice to the regulant</u> <u>at the last known mailing address of record.</u> Failure to receive <u>this notice shall not relieve the regulant of the obligation to</u> <u>renew.</u>

<u>C.</u> Regulants may renew their certifications up to 60 days prior to the expiration date by submitting the fee specified in 18VAC120-50-90. If the regulant fails to receive the renewal notice, a copy of the certification pocket card or wall certification may be submitted with the required fee as an application for renewal.

<u>D. By renewing the certification the regulant is attesting</u> <u>continued compliance with Part IV (Standards of Conduct</u> <u>and Practice [, 18VAC120-50-140 et seq.]) of this chapter.</u>

E. The director may deny renewal of a certification card for the same reasons that he may refuse initial issuance or that he may discipline a regulant. The regulant has a right to appeal any such action by the director under the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

<u>F.</u> Failure to timely pay any monetary penalty, reimbursement of cost, or other fee assessed by consent order or final order shall result in delaying or withholding services provided by the department, such as, but not limited to, renewal, reinstatement, processing of a new application, or examination administration.

18VAC120-50-120. Reinstatement.

<u>A. Should the department fail to receive the renewal</u> <u>application or fees by the expiration date, the regulant will be</u> <u>required to apply for reinstatement of the certification.</u>

<u>B. The date on which the reinstatement fee is received by</u> the department or its agent will determine whether the certification is reinstated or a new application is required.

C. In order to ensure that certification holders are qualified to practice as certified natural gas automobile mechanics and technicians, no reinstatement will be permitted once one year from the expiration date has passed. After that date, the applicant must apply for a new certification and meet the then current entry requirements, including the successful completion of the examination.

D. Any person who holds himself out as a certified natural gas automobile mechanic or technician, without the appropriate certification, may be subject to prosecution under Title 54.1 of the Code of Virginia.

E. The director may deny reinstatement of a certification for the same reasons that he may refuse initial issuance or that he may discipline a regulant. The regulant has a right to appeal any such action by the director under the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

F. Failure to timely pay any monetary penalty, reimbursement of cost, or other fee assessed by consent order or final order shall result in delaying or withholding services provided by the department, such as, but not limited to, renewal, reinstatement, processing of a new application, or examination administration.

<u>18VAC120-50-130. Status of regulant during the period</u> prior to reinstatement.

<u>A. When a regulant is reinstated, the individual shall</u> continue to have the same certificate number and shall be assigned an expiration date two years from the previous expiration date.

B. A regulant who reinstates his certification shall be regarded as having been continuously certified without interruption. Therefore, the regulant shall remain under the disciplinary authority of the board during this entire period and may be held accountable for activities during this period. Nothing in this chapter shall divest the director of the authority to discipline a regulant for a violation of the law or regulations during the period of certification.

Part IV Standards of Conduct and Practice

18VAC120-50-140. Grounds for disciplinary action.

The director may place a regulant on probation; impose a monetary penalty; or revoke, suspend, or refuse to renew a certification when the regulant has been found to have violated or cooperated with others in violating any provisions of this chapter or Chapter 23.4 (§ 54.1-2355 et seq.) of Title 54.1 of the Code of Virginia.

18VAC120-50-150. Maintenance of certification.

A. Any change of address shall be reported within 30 days of the change on a form provided by the department. The department shall not be responsible for the regulant's failure to receive notices or correspondence due to the regulant's failure to report a change of address. A post office box, private mail box, or other mailing service address alone is not acceptable as an address of record.

B. Any name change of the regulant shall be reported within 30 days of the change on a form provided by the department. The department shall not be responsible for the regulant's failure to receive notices or correspondence due to the regulant's failure to report a name change.

18VAC120-50-160. Transfer of certification prohibited.

No certification issued by the director shall be assigned or otherwise transferred.

18VAC120-50-170. Prohibited acts.

<u>A. All complaints against certified natural gas automobile</u> mechanics and technicians may be filed with the department at any time during business hours, pursuant to subdivision A 8 of § 54.1-201 of the Code of Virginia.

B. The following acts are prohibited:

<u>1. Failing in any material way to comply with the provisions of Chapter 1 (§ 54.1-100 et seq.) or Chapter 23.4 (§ 54.1-2355 et seq.) of Title 54.1 of the Code of Virginia or the regulations of the department;</u>

2. Furnishing substantially inaccurate or incomplete information to the department in obtaining, renewing, reinstating, or maintaining a certification;

3. Negligence or incompetence in the practice of alternative fuel vehicle repair, conversion, or maintenance;

4. Misconduct in the practice of alternative fuel vehicle repair, conversion, or maintenance;

5. Failing to respond to an agent of the department or providing false, misleading, or incomplete information to an investigator seeking information in the investigation of a complaint filed with the department against the regulant or failing or refusing to claim certified mail sent to the regulant's address of record shall constitute a violation of this regulation;

6. Making any misrepresentation or making a false promise that might influence, persuade, or induce;

7. Assisting another to violate any provision of Chapter 1 (§ 54.1-100 et seq.) or Chapter 23.4 (§ 54.1-2355 et seq.) of Title 54.1 of the Code of Virginia or this chapter; or combining or conspiring with or acting as agent, partner, or associate for another to do so;

8. Allowing one's certification to be used by another;

9. After initial certification, being convicted or found guilty, regardless of adjudication in any jurisdiction, of any felony or of any misdemeanor, there being no appeal pending therefrom or the time of appeal having elapsed. Any plea of guilty or nolo contendere shall be considered a conviction for the purposes of this subdivision. The record of a conviction received from a court shall be accepted as prima facie evidence of a conviction or finding of guilt;

10. Failing to inform the department in writing within 30 days that the regulant has pleaded guilty or nolo contendere or was convicted and found guilty of any felony or of a misdemeanor; and

11. Failing to ensure that all work performed on natural gas fuel vehicles is consistent with the requirements set forth by the department, the U.S. Environmental Protection Agency, the California Air Resources Board, the National Fire Protection Agency 52: Vehicular Gaseous Fuel Systems Code, or other applicable authority as determined by the director.

Part V

Education Providers and Training Requirements

18VAC120-50-180. Requirements for formal vocational training providers, instructor qualifications, and course requirements.

<u>A. The director is responsible for reviewing applications</u> from education providers seeking board approval. Provider and course applications must be submitted by the department's established deadlines. <u>B.</u> The course provider shall submit an application for course approval in a format approved by the director. The application shall include, but is not limited to:

1. The name of the provider;

2. Provider contact person, address, and telephone number;

3. Contact hours for each course submitted for approval;

<u>4. Schedule of courses, if established, including dates, time, and locations;</u>

5. Instructor information, including name, certification number, if applicable, and a list of other appropriate trade designations;

6. Course and material fees for each course offered; and

7. A syllabus for each course submitted for approval.

<u>C. Each applicant for approval as an instructor for an approved formal vocational training provider shall have one of the following qualifications:</u>

1. A Natural Gas Automobile Mechanic or Technician Certification issued by the director, or a comparable certification as determined by the director, and two consecutive years of discipline-free experience immediately prior to application; or

2. A minimum of three years of active experience in the subject matter being taught. Such applicants shall teach only in the area of their expertise and will be required to furnish proof of their expertise that is satisfactory to the director.

D. Approval of formal vocation training courses shall expire three years from the year in which the approval was issued, as indicated on the approval document. At the end of the three years, the course provider shall submit a new application to be approved by the director.

E. The course provider must establish and maintain a record for each student. The record shall include the student's name and address; social security number or a control number issued by the Virginia Department of Motor Vehicles; the course name and clock hours attended; and the course syllabus or outline, the name [or names] of the instructor, the date of successful completion, and the board's course code. Records shall be available for inspection during normal business hours by authorized representatives of the board. Providers must maintain all student and class records for a minimum of five years.

F. The course provider must provide each student with a certificate of course completion or other documentation that the student may use as proof of course completion. Such documentation shall contain the hours of credit completed. Fifty contact minutes shall equal one credit hour. No credit shall be awarded for partial credit hours or partial completion of the course.

<u>G. The course provider certifies that the laws, regulations, and industry practices that will be taught or utilized in the course are up-to-date and that subsequent changes in the laws,</u>

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regulations, or industry practices will be incorporated into the course curriculum as they occur.

18VAC120-50-190. Educational provider and course approval fees.

A. All fees are nonrefundable and shall not be prorated. The date on which the fee is received by the department or its agent will determine whether the fee has been submitted within the time requirements of this chapter. Checks or money orders shall be made payable to the Treasurer of Virginia.

B. Fees are as follows:

<u>Fee Type</u>	<u>Fee</u> <u>Amount</u>	When Due
Formal education provider approval initial application fee	<u>\$190</u>	<u>Upon submission</u> of the school application
Course approval application fee	<u>\$190</u>	Upon submission of the course application

18VAC120-50-200. Posting formal education provider certificate of approval.

<u>Copies of formal education provider certificates of approval</u> <u>must be available at the location a course is taught.</u>

18VAC120-50-210. Termination of approval.

<u>The director may withdraw approval of any formal</u> vocational provider or course for any of the following reasons:

1. The provider, instructors, courses, or subjects no longer meet the standards established by the director.

2. The provider or instructor solicits information from any person for the purpose of discovering past examination questions or questions that may be used in future examinations.

3. The provider or instructor distributes to any person copies of examination questions or otherwise communicates to any person examination questions without receiving the prior written approval of the owner to distribute or communicate those questions.

4. The provider, through an agent or otherwise, advertises its services in a fraudulent, deceptive, or misrepresentative manner.

5. Officials, instructors, or designees of the provider sit for the natural gas automobile technician or mechanic certification examination for any purpose other than to obtain a certification.

6. The provider or instructor fails to allow any agent of the board access to facilities or records to conduct a review or

audit of the approved courses, student records, or course materials.

7. The provider fails to submit an electronic roster of students completing a course within seven business days in a method and in a format approved by the department.

18VAC120-50-220. Course content.

<u>A. The following shall be included in the course that shall</u> not have less than 24 classroom hours, of which four hours are hands on training:

1. Conversions, repairs, and maintenance.

2. Safety.

3. National Fire Protection Agency 52: Vehicular Gaseous Fuel System Code.

4. Principles of natural gas.

5. Natural gas fuel line safety and inspection.

6. Natural gas fuel container mounting.

7. Fundamentals of natural gas engines.

8. Practical lab.

<u>B.</u> Courses shall be taught in a classroom environment. No online courses or correspondence courses shall be approved.

18VAC120-50-230. Reporting changes.

Any change in the information provided in subsection B of 18VAC120-50-180 must be reported to the director within 30 days of the change with the exception of changes in the schedule of courses, which must be reported within 10 days of the change. Failure to report the changes as required may result in the withdrawal of approval of the course provider by the director.

<u>NOTICE</u>: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (18VAC120-50)

[<u>Natural Gas Automobile Mechanics or Technicians</u> <u>Certification Application A505 2310CERT v1 (rev. 2/2016)</u>

<u>Natural Gas Automobile Mechanics or Technicians</u> <u>Experience Verification Form A505 2310EXP v3 (rev.</u> <u>2/2015)</u>

Natural Gas Automobile Mechanics or Technicians Training Provider Approval Application A505 2330SCHL v1 (rev. 2/2015)

<u>Natural Gas Automobile Mechanics or Technicians</u> <u>Education Course Approval Application A505 2331CRS v1</u> (rev. 2/2016)

<u>Natural Gas Automobile Mechanics or Technicians</u> Certification Application, A505-2310CERT-v1 (rev. 5/2016)

Natural Gas Automobile Mechanics and Technicians Experience Verification Form, A505-2310CNG_EXP-v3 (rev. 5/2016)

Natural Gas Automobile Mechanics and Technicians Training Provider Approval Application A505-2330SCHL-v1 (rev. 5/2016)

Natural Gas Automobile Mechanics and Technicians Education Course Approval Application A505-2331CRS-v1 (rev. 5/2016)]

Address Change Form, A406-ACHG-v5 (rev. 6/2015) Name Change Form, A406-NAMECHG-v4 (rev. 6/2015) VA.R. Doc. No. R14-4029; Filed March 25, 2016, 1:02 p.m.

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TITLE 22. SOCIAL SERVICES

STATE BOARD OF SOCIAL SERVICES

Final Regulation

<u>Title of Regulation:</u> 22VAC40-201. Permanency Services -Prevention, Foster Care, Adoption and Independent Living (amending 22VAC40-201-10; adding 22VAC40-201-115).

<u>Statutory Authority:</u> §§ 63.2-217, 63.2-900, and 63.2-915 of the Code of Virginia.

Effective Date: June 1, 2016.

Agency Contact: Phyl Parrish, Department of Social Services, Division of Family Services, 801 East Main Street, Richmond, VA 23219-2901, telephone (804) 726-7926, FAX (804) 726-7895, TTY (800) 828-1849, or email phyl.parrish@dss.virginia.gov.

Summary:

Pursuant to Chapter 437 of the 2013 Acts of Assembly, this regulatory action establishes a hearing process for individuals eligible for benefits under the foster care program and provides that those individuals may appeal to the Commissioner of Social Services when they believe a benefit has been denied or unreasonably delayed. The key provisions of the regulation address (i) who has a right to appeal to the commissioner, (ii) what decisions or benefits may not be appealed, (iii) who is notified of the right to an appeal and what is included in the notice, (iv) the ability of the commissioner to delegate the duty and authority to duly qualified officers, (v) information about the decision, and (vi) the appellant's right to judicial review.

<u>Summary of Public Comments and Agency's Response:</u> No public comments were received by the promulgating agency.

22VAC40-201-10. Definitions.

The following words and terms when used in this regulation chapter shall have the following meanings unless the context clearly indicates otherwise:

"Administrative panel review" means a review of a child in foster care that the local board conducts on a planned basis, and that is open to the participation of the birth parents or prior custodians and other individuals significant to the child and family, to evaluate the current status and effectiveness of the objectives in the service plan and the services being provided for the immediate care of the child and the plan to achieve a permanent home for the child.

"Adoption" means a legal process that entitles the person being adopted to all of the rights and privileges, and subjects the person to all of the obligations of a birth child.

"Adoption assistance" means a money payment or services provided to adoptive parents on behalf of a child with special needs.

"Adoption assistance agreement" means a written agreement between the child-placing agency and the adoptive parents of a child with special needs to provide for the unmet financial and service needs of the child.

"Adoption Manual" means Volume VII, Section III, Chapter C - Adoption/Agency Placement of the Service Program Manual of the Virginia Department of Social Services dated October 2009/March 2010.

"Adoption Progress Report" means a report filed with the juvenile court on the progress being made to place the child in an adoptive home. Section 16.1-283 of the Code of Virginia requires that an Adoption Progress Report be submitted to the juvenile court every six months following termination of parental rights until the adoption is final.

"Adoption search" means interviews and written or telephone inquiries made by a local department to locate and advise the biological parents or siblings of an adult adoptee's request, by Application for Disclosure or petition to the court, for identifying information from a closed adoption record.

"Adoptive home" means any family home selected and approved by a parent, local board or a licensed child-placing agency for the placement of a child with the intent of adoption.

"Adoptive home study" means an assessment of a family completed by a child-placing agency to determine the family's suitability for adoption. The adoptive home study is included in the dual approval process.

"Adoptive parent" means any provider selected and approved by a parent or a child-placing agency for the placement of a child with the intent of adoption.

"Adoptive placement" means arranging for the care of a child who is in the custody of a child-placing agency in an approved home for the purpose of adoption.

"Adult adoption" means the adoption of any person 18 years of age or older, carried out in accordance with § 63.2-1243 of the Code of Virginia.

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"Agency placement adoption" means an adoption in which a child is placed in an adoptive home by a child-placing agency that has custody of the child.

"AREVA" means the Adoption Resource Exchange of Virginia that maintains a registry and photo-listing of children waiting for adoption and families seeking to adopt.

"Assessment" means an evaluation of the situation of the child and family to identify strengths and services needed.

"Birth family" means the child's biological family.

"Birth parent" means the child's biological parent and for purposes of adoptive placement means a parent by previous adoption.

"Birth sibling" means the child's biological sibling.

"Board" means the State Board of Social Services.

"Child" means any natural person under 18 years of age.

"Child-placing agency" means any person who places children in foster homes, adoptive homes, or independent living arrangements pursuant to § 63.2-1819 of the Code of Virginia or a local board that places children in foster homes or adoptive homes pursuant to §§ 63.2-900, 63.2-903, and 63.2-1221 of the Code of Virginia. Officers, employees, or agents of the Commonwealth, or any locality acting within the scope of their authority as such, who serve as or maintain a child-placing agency, shall not be required to be licensed.

"Child with special needs" as it relates to adoption assistance means a child who meets the definition of a child with special needs set forth in §§ 63.2-1300 and 63.2-1301 B of the Code of Virginia.

"Children's Services Act" or "CSA" means a collaborative system of services and funding that is child centered, family focused, and community based when addressing the strengths and needs of troubled and at-risk youth and their families in the Commonwealth.

"Claim for benefits," as used in § 63.2-915 of the Code of Virginia and 22VAC40-201-115, means (i) foster care maintenance, including enhanced maintenance; (ii) the services set forth in a court approved foster care service plan, the foster care services identified in an individual family service plan developed by a family assessment and planning team or other multi-disciplinary team pursuant to the Children's Services Act (§ 2.2-5200 et seq. of the Code of Virginia), or a transitional living plan for independent living services; (iii) the placement of a child through an agreement with the child's parents or guardians, where legal custody remains with the parents or guardians; (iv) foster care prevention services as set out in a prevention service plan; or (v) placement of a child for adoption when an approved family is outside the locality with the legal custody of the child, in accordance with 42 USC § 671(a)(23).

"Close relative" means a grandparent, great-grandparent, adult nephew or niece, adult brother or sister, adult uncle or aunt, or adult great uncle or great aunt.

"Commissioner" means the commissioner of the department, his designee, or his authorized representative.

"Community Policy and Management Team-(CPMT)" or "CPMT" means a team appointed by the local governing body to receive funds pursuant to Chapter 52 (§ 2.2-5200 et seq.) of Title 2.2 of the Code of Virginia. The powers and duties of the CPMT are set out in § 2.2-5206 of the Code of Virginia.

"Comprehensive Services Act for At Risk Youth and Families (CSA)" means a collaborative system of services and funding that is child centered, family focused, and community based when addressing the strengths and needs of troubled and at risk youth and their families in the Commonwealth.

"Concurrent permanency planning" means a sequential, structured approach to case management which requires working towards a permanency goal (usually reunification) while at the same time establishing and working towards an alternative permanency plan.

"Custody investigation" means a method to gather information related to the parents and a child whose custody, visitation, or support is in controversy or requires determination.

"Department" means the State Department of Social Services.

"Denied," as used in § 63.2-915 of the Code of Virginia and 22VAC40-201-115, means the refusal to provide a claim for benefits.

"Dual approval process" means a process that includes a home study, mutual selection, interviews, training, and background checks to be completed on all applicants being considered for approval as a resource, foster or adoptive family home provider.

"Family Assessment and Planning Team (FAPT)" "Family assessment and planning team" or "FAPT" means the local team created by the CPMT (i) to assess the strengths and needs of troubled youths and families who are approved for referral to the team and (ii) to identify and determine the complement of services required to meet their unique needs. The powers and duties of the FAPT are set out in § 2.2-5208 of the Code of Virginia.

"Foster care" means 24-hour substitute care for children placed away from their parents or guardians and for whom the local board has placement and care responsibility. Foster care also includes children under the placement and care of the local board who have not been removed from their home.

"Foster care maintenance payments" means payments to cover federally allowable expenses made on behalf of a child in foster care including the cost of food, clothing, shelter, daily supervision, reasonable travel for the child to visit relatives and to remain in his previous school placement, and other allowable expenses in accordance with guidance developed by the department. "Foster Care Manual" means Chapter E - Foster Care of the Child and Family Services Manual of the Virginia Department of Social Services dated July 2011.

"Foster care placement" means placement of a child through (i) an agreement between the parents or guardians and the local board or the public agency designated by the CPMT where legal custody remains with the parents or guardians, or (ii) an entrustment or commitment of the child to the local board or licensed child-placing agency.

"Foster care prevention" means the provision of services to a child and family to prevent the need for foster care placement.

"Foster care services" means the provision of a full range of prevention, placement, treatment, and community services, including but not limited to independent living services, for a planned period of time as set forth in § 63.2-905 of the Code of Virginia.

"Foster child" means a child for whom the local board has assumed placement and care responsibilities through a noncustodial foster care agreement, entrustment, or court commitment before 18 years of age.

"Foster home" means the place of residence of any natural person in which any child, other than a child by birth or adoption of such person, resides as a member of the household.

"Foster parent" means an approved provider who gives 24hour substitute family care, room and board, and services for children or youth committed or entrusted to a child-placing agency.

"Independent living arrangement" means placement of a child at least 16 years of age who is in the custody of a local board or licensed child-placing agency and has been placed by the local board or licensed child-placing agency in a living arrangement in which he does not have daily substitute parental supervision.

"Independent living services" means services and activities provided to a child in foster care 14 years of age or older who was committed or entrusted to a local board of social services, child welfare agency, or private child-placing agency. Independent living services may also mean services and activities provided to a person who was in foster care on his 18th birthday and has not yet reached the age of 21 years. Such services shall include counseling, education, housing, employment, and money management skills development, access to essential documents, and other appropriate services to help children or persons prepare for self-sufficiency.

"Individual Family Service Plan (IFSP)" "Individual family service plan" or "IFSP" means the plan for services developed by the FAPT in accordance with § 2.2-5208 of the Code of Virginia.

"Intercountry placement" means the arrangement for the care of a child in an adoptive home or foster care placement into or out of the Commonwealth by a licensed child-placing agency, court, or other entity authorized to make such placements in accordance with the laws of the foreign country under which it operates.

"Interstate Compact on the Placement of Children (ICPC)" or "ICPC" means a uniform law that has been enacted by all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands which establishes orderly procedures for the interstate placement of children and sets responsibility for those involved in placing those children.

"Interstate placement" means the arrangement for the care of a child in an adoptive home, foster care placement, or in the home of the child's parent or with a relative or nonagency guardian, into or out of the Commonwealth, by a childplacing agency or court when the full legal right of the child's parent or nonagency guardian to plan for the child has been voluntarily terminated or limited or severed by the action of any court.

"Investigation" means the process by which the local department obtains information required by § 63.2-1208 of the Code of Virginia about the placement and the suitability of the adoption. The findings of the investigation are compiled into a written report for the circuit court containing a recommendation on the action to be taken by the court.

"Local department" means the local department of social services of any county or city in the Commonwealth.

"Nonagency placement adoption" means an adoption in which the child is not in the custody of a child-placing agency and is placed in the adoptive home directly by the birth parent or legal guardian.

"Noncustodial foster care agreement" means an agreement that the local department enters into with the parent or guardian of a child to place the child in foster care when the parent or guardian retains custody of the child. The agreement specifies the conditions for placement and care of the child.

"Nonrecurring expenses" means expenses of adoptive parents directly related to the adoption of a child with special needs including, but not limited to, attorney or other fees directly related to the finalization of the adoption; transportation; court costs, and reasonable and necessary fees of licensed child-placing agencies.

"Parental placement" means locating or effecting the placement of a child or the placing of a child in a family home by the child's parent or legal guardian for the purpose of foster care or adoption.

"Permanency" means establishing family connections and placement options for a child to provide a lifetime of commitment, continuity of care, a sense of belonging, and a legal and social status that go beyond a child's temporary foster care placements.

"Permanency planning" means a social work practice philosophy that promotes establishing a permanent living situation for every child with an adult with whom the child has a continuous, reciprocal relationship within a minimum amount of time after the child enters the foster care system.

"Permanency planning indicator <u>(PPI)</u>" <u>or "PPI"</u> means a tool used in concurrent permanency planning to assess the likelihood of reunification. This tool assists the worker in determining if a child should be placed with a resource family and if a concurrent goal should be established.

"Prior custodian" means the person who had custody of the child and with whom the child resided, other than the birth parent, before custody was transferred to or placement made with the child-placing agency when that person had custody of the child.

"Putative Father Registry" means a confidential database designed to protect the rights of a putative father who wants to be notified in the event of a proceeding related to termination of parental rights or adoption for a child he may have fathered.

"Residential placement" means a placement in a licensed publicly or privately owned facility, other than a private family home, where 24-hour care is provided to children separated from their families. A residential placement includes children's residential facilities as defined in § 63.2-100 of the Code of Virginia.

"Resource parent" means a provider who has completed the dual approval process and has been approved as both a foster and adoptive family home provider.

"Reunification" means the return of the child to his home after removal for reasons of child abuse and neglect, abandonment, child in need of services, parental request for relief of custody, noncustodial agreement, entrustment, or any other court-ordered removal.

"Service plan" means a written document that describes the programs, care, services, and other support which will be offered to the child and his parents and other prior custodians pursuant to § 16.1-281 of the Code of Virginia,

"Service worker" means a worker responsible for case management or service coordination for prevention, foster care, or adoption cases.

"SSI" means Supplemental Security Income.

"State pool fund" means the pooled state and local funds administered by CSA and used to pay for services authorized by the CPMT.

"Step-parent adoption" means the adoption of a child by a spouse; or the adoption of a child by a former spouse of the birth or adoptive parent in accordance with § 63.2-1201.1 of the Code of Virginia.

"Title IV-E" means the title of the Social Security Act that authorizes federal funds for foster care and adoption assistance.

"Visitation and report" means the visitation conducted pursuant to § 63.2-1212 of the Code of Virginia subsequent to the entry of an interlocutory order of adoption and the written report compiling the findings of the visitation which is filed in the circuit court. "Wrap around services" means an individually designed set of services and supports provided to a child and his family that includes treatment services, personal support services or any other supports necessary to achieve the desired outcome. Wrap around services are developed through a team approach.

"Youth" means any child in foster care between 16 and 18 years of age or any person 18 to 21 years of age transitioning out of foster care and receiving independent living services pursuant to § 63.2-905.1 of the Code of Virginia.

22VAC40-201-115. Foster care appeal process.

<u>A. Any individual whose claim for benefits available</u> pursuant to 42 USC § 670 et seq. or whose claim for benefits pursuant to § 63.2-905 of the Code of Virginia is denied or is not acted upon by the local department with reasonable promptness shall have a right to appeal to the commissioner.

<u>B.</u> A hearing need not be granted when either state or federal law requires automatic maintenance payment adjustments for classes of recipients unless the reason for an individual appeal is incorrect maintenance amount computation.

C. Placement decisions of local boards are final when in accordance with the relevant provisions of Title 16.1 of the Code of Virginia. However, in accordance with 42 USC § 671(a)(23), a hearing shall be granted for the denial or delay in placement of a child for adoption when an approved family is outside the locality with the legal custody of the child.

D. The hearing shall be face-to-face or, at the option of the commissioner or his designee, a hearing by telephone may be held if the individual agrees. The individual shall be afforded all rights as specified in this section, whether the hearing is face-to-face or by telephone.

E. The local department [or, in those cases where the local department is not involved, the licensed child placing agency, the family assessment and planning team, or other multidisciplinary team] shall inform an individual in writing of the right to appeal the denial of a benefit or the delay of a decision regarding a benefit under this section at the time the applicable plan is written and at the time of any action affecting claim for benefit. This shall include a written notice to the birth parents or caretaker at the time a child comes into foster care, a written notice to the guardian ad litem, and written notice to foster parents at the time the foster care agreement is signed. The notice shall include:

1. The right to a hearing;

2. The method by which the individual may obtain a hearing; and

<u>3. That the individual may be represented by an authorized</u> representative, such as legal counsel, relative, friend, or other spokesman, or he may represent himself.

F. The local department [or, in those cases where the local department is not involved, the licensed child placing agency, the family assessment and planning team, or other multidisciplinary team] shall provide timely notice of a decision to discontinue, terminate, suspend, or change a benefit for the child. Timely notice means the notice is mailed at least 10 days before the date the action becomes effective. If the individual requests a hearing within the timely notice period, the benefit shall not be suspended, reduced, discontinued, or terminated, but is subject to recovery if the action is sustained, until a decision is rendered after a hearing unless:

1. A determination is made at the hearing that the sole issue is one of state or federal law or policy or a change in state or federal law and not one of incorrect benefit computation;

<u>2. A change affecting the individual's benefit occurs while</u> the hearing decision is pending and the individual fails to request a hearing after notice of the change; or

<u>3. The individual specifically requests that he not receive</u> <u>continued benefits pending a hearing decision.</u>

G. An individual shall be allowed to request a hearing for up to 30 days after the denial of a claim for benefit. Reasonable notice of the hearing shall be provided to the individual. Within 90 days of the request for a hearing, the hearing shall be conducted, a decision reached, and the individual notified of the decision.

H. The commissioner may provide that a hearing request made after the date of action, but during a period not in excess of 10 days following such date, shall result in reinstatement of the benefit to be continued until the hearing decision unless (i) the individual specifically requests that continued benefit not be paid pending the hearing decision or (ii) at the hearing it is determined that the sole issue is one of state or federal law or policy. In any case where action was taken without timely notice, if the individual requests a hearing within 10 days of the mailing of the notice of the action and the commissioner determines that the action resulted from other than the application of state or federal law or policy or a change in state or federal law, the benefit shall be reinstated and continued until a decision is rendered after the hearing unless the individual specifically requests that he not receive continued benefits pending the hearing decision.

<u>I. Pursuant to § 63.2-915 of the Code of Virginia, the commissioner may delegate the duty and authority to consider and make determinations on any appeal filed in accordance with this section to duly qualified officers.</u>

J. The commissioner or designated hearing officer may deny or dismiss a request for a hearing where it has been withdrawn by the individual in writing or where it is abandoned. Abandonment may be deemed to have occurred if the individual without good cause fails to appear by himself or by authorized representative at the hearing scheduled for such individual.

K. The hearing shall include consideration of the denial of a claim for benefits or the local department's failure to act with reasonable promptness on a request for a benefit for the individual.

<u>L.</u> The individual requesting the hearing or his representative shall have adequate opportunity to:

1. Examine information relied upon by the local department, licensed child-placing agency, family assessment and planning team, or other multi-disciplinary team in considering the request for a benefit to the extent that the information does not violate confidentiality requirements;

2. Bring witnesses;

3. Establish all pertinent facts and circumstances;

4. Advance arguments without undue interference;

5. Question or refute testimony or evidence; and

6. Confront and cross-examine witnesses.

M. Decisions of the commissioner or designated hearing officer shall be based exclusively on evidence and other material introduced at the hearing. The transcript or recording of testimony and exhibits, or an official report containing the substance of what transpired at the hearing, together with all the papers and requests filed in the proceeding and the decision of the commissioner or hearing officer shall constitute the exclusive record and shall be available to the individual at a place accessible to him or his representative at a reasonable time.

<u>N. Decisions by the commissioner or hearing officer shall</u> <u>consist of a memorandum decision summarizing the facts and</u> <u>identifying the regulations and policy supporting the decision.</u>

O. The individual shall be notified of the decision in writing.

P. When the hearing decision is favorable to the individual, the local department [, licensed child placing agency, family assessment and planning team, or other multi disciplinary team] shall promptly begin the process to provide the requested service or, in the case of foster care maintenance, make corrective payments retroactively to the date the incorrect action was taken, unless foster care maintenance payments were continued during the pendency of the hearing decision.

Q. The decision of the commissioner shall be binding and considered a final agency action for purposes of judicial review. The hearing decision shall be a memorandum decision summarizing the facts and identifying the statutes and regulations supporting the decision.

VA.R. Doc. No. R14-3687; Filed March 29, 2016, 11:40 a.m.

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BOARD FOR ARCHITECTS, PROFESSIONAL ENGINEERS, LAND SURVEYORS, CERTIFIED INTERIOR DESIGNERS, AND LANDSCAPE ARCHITECTS

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Architects, Professional Engineers, Land Surveyors, Certified Interior Designers, and Landscape Architects conducted a small business impact review of **18VAC10-11**, **Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Board for Architects, Professional Engineers, Land Surveyors, Certified Interior Designers, and Landscape Architects is publishing its report of findings dated March 24, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

1. The current regulations are necessary for the board to comply with § 2.2-4007.02 of the Code of Virginia and Chapter 321 of the 2008 Acts of Assembly.

2. No public comments were received during the public comment period January 11, 2016, through February 1, 2016.

3. The regulations are not complex in nature.

4. The regulations do not overlap, duplicate, or conflict with federal or state laws or regulations but instead work in concert with them.

5. The last periodic review concluded December 2011. The current regulations became effective November 2008.

6. No small business impact has been identified.

<u>Contact Information:</u> Kathleen R. Nosbisch, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, Virginia, 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email apelscidla@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Architects, Professional Engineers, Land Surveyors, Certified Interior Designers, and Landscape Architects conducted a small business impact review of **18VAC10-20**, **Board For Architects, Professional Engineers, Land Surveyors, Certified Interior Designers, And Landscape Architects Regulations**, and determined that this regulation should be retained in its current form. The Board for Architects, Professional Engineers, Land Surveyors, Certified Interior Designers, and Landscape Architects is publishing its report of findings dated March 24, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia. 1. The current regulations establish minimum licensing requirements for architects, professional engineers, land surveyors, and landscape architects. Minimum standards are necessary for these professions because these individuals design the very infrastructure of the country including buildings, bridges, and other important structures. Ensuring that these professionals meet minimum education, training, experience, and examination standards is crucial to the protection of the public health, safety, and welfare. The regulations also establish specific requirements for the certification of interior designers. However, as a certificate program, it does not affect the practice of interior design by noncertified individuals. These regulations also establish minimum requirements for business registrations.

2. Four public comments were received during the public comment period January 11 through February 1, 2016. The first comment recommends that the regulation regarding the licensing/certification of architects, professional engineers, land surveyors, certified interior designers, and landscape architects be retained in order to help protect the health, safety, and welfare. The other comments pertain to allowing experience to replace education requirements. The board determined to keep the requirements as currently written.

3. The regulations are not complex in nature.

4. The regulations do not overlap, duplicate, or conflict with federal or state laws or regulations but instead work in concert with them.

5. The last periodic review concluded December 2011. The current regulations became effective January 1, 2016.

6. No small business impact has been identified.

<u>Contact Information:</u> Kathleen R. Nosbisch, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, Virginia, 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email apelscidla@dpor.virginia.gov.

STATE CORPORATION COMMISSION

Bureau of Insurance

March 23, 2016

Administrative Letter 2016-02

To: All Carriers with in force Long-Term Care Insurance Policies in Virginia and All Interested Parties

Re: Rules Governing Long Term Care Insurance 14VAC5-200-125 Annual Rate Reports

This Administrative Letter serves to remind carriers with Long-Term Care Insurance (LTCI) coverage in force in Virginia of new reporting requirements beginning in 2016.

In accordance with the Rules Governing Long Term Care Insurance (Rules) at 14VAC5-200-125, insurers must report to the commission annually by June 30 premium rates for all LTCI policies. The first annual rate reports are due no later than June 30, 2016.

The rules identify different reporting requirements depending upon when the policies were issued and whether or not the policies are currently being marketed. Insurers are responsible for consulting the rules for more specific information concerning the information to be reported.

To facilitate and standardize the completion and submission of the annual rate reports, we strongly encourage insurers to use the annual rate reporting forms developed by the bureau and to submit the annual rate reports and any accompanying documentation via the System for Electronic Rate and Form Filings (SERFF). The annual rate reporting forms, which vary depending upon the dates of issue of the policies and by their marketing status, may be found on the bureau's website at http://www.scc.virginia.gov/boi/co/health/index.aspx.

Any policy forms that have or will be combined for purposes of rate increases must also be combined in the annual rate report.

An annual rate report is not required for non-cancellable LTCI policies. An insurer may also request an exemption from future annual rate reports for any form or forms for which it provides written certification that it will not increase premiums in the future.

Questions or requests for clarification should be directed to Toni Janoski, Supervisor, Rates Section, Life and Health Division, Bureau of Insurance, (804) 371-9945, or email Toni.Janoski@scc.virginia.gov.

/s/ Jacqueline K. Cunningham Commissioner of Insurance

CRIMINAL JUSTICE SERVICES BOARD

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Criminal Justice Services is conducting a periodic review and small business impact review of **6VAC20-90**, **Rules Relating to Regional Criminal Justice Training Academies**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014). The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economic performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins April 18, 2016, and ends May 18, 2016.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Barbara Peterson-Wilson, Law Enforcement Program Coordinator, 1100 Bank Street, Richmond, Virginia, 23219, telephone (804) 225-4503, FAX (804) 786-0410, or email barbara.petersonwilson@dcjs.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

Revisions to the Virginia Criminal Justice Services Training Manual and Compulsory Minimum Training Standards

On March 24, 2016, the Criminal Justice Services Board's Committee on Training voted to approve revisions to the training standards related to terrorism awareness level training. A detailed summary of the revisions will be emailed to all training academies listed in the Department of Criminal Justice Services Criminal Justice Directory. The revisions will become effective May 19, 2016.

In accordance with the requirements of 6VAC20-20-25 and 6VAC20-50-21 this general notice serves as notification to all affected entities that revisions will be made to the *Virginia Criminal Justice Services Training Manual and Compulsory Minimum Training Standards* in the following areas:

Law Enforcement (Patrol) – Chapter 5, Patrol, 4.2, Special Note.

Civil Process Officers (Field Training) – Chapter 5, Field Training. Revisions have been made to Performance Outcomes 9.7, 9.8, 9.9, and to the Special Note Section.

Courtroom Security Officers (Field Training) – Chapter 5, Field Training. Revisions have been made to Performance Outcomes 9.10, 9.11, 9.12, and to the Special Note Section.

Jail Officers (Field Training) – Chapter 5, Field Training. Revisions have been made to Performance Outcomes 9.67, 9.68, and 9.69.

Basic Corrections Officer (Emergency Response) – Chapter 5, Emergency Response. Revisions have been made to Performance Outcomes 4.5, 4.5.2, 4.5.3, 4.5.4, the Lesson Plan Guide under Performance Outcome 4.5. (Identify Public Safety Response to Terrorism Awareness level training

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General Notices/Errata

courses), the Training Objectives Related to 4.5, and to the Criteria on which trainees will be tested.

Juvenile Corrections Officer (Emergency Response) – Chapter 5, Emergency Response. Revisions have been made to Performance Outcomes 4.7, 4.7.2, 4.7.3, 4.7.4, the Lesson Plan Guide under Performance Outcome 4.7. (Identify Public Safety Response to Terrorism Awareness level training course), the Training Objectives Related to 4.5, and to the Criteria on which trainees will be tested.

<u>Contact Information:</u> Barbara Peterson-Wilson, Law Enforcement Program Coordination, 1100 Bank Street, 12th Floor, Richmond, VA 23219, telephone (804) 225-4503, FAX (804) 786-0410, or email barbara.petersonwilson@dcjs.virginia.gov.

DEPARTMENT OF ENVIRONMENTAL QUALITY

State Implementation Plan Revision - Amended Motor Vehicle Emissions Budgets

The Department of Environmental Quality (DEQ) is seeking comments and announcing a public hearing on a proposed revision to the Commonwealth of Virginia State Implementation Plan (SIP). The Commonwealth intends to submit amended motor vehicle emissions budgets (MVEBs) as a revision to the Virginia SIP in accordance with the federal Clean Air Act. The SIP is the plan developed by the Commonwealth in order to fulfill its responsibilities under the Act to attain and maintain the ambient air quality standards promulgated by the U.S. Environmental Protection Agency (EPA).

DEQ is seeking comments on the amended MVEBs for the Northern Virginia portion of the Metropolitan Washington, DC-MD-VA PM2.5 Maintenance Area, which consists of the counties of Arlington, Fairfax, Loudoun, and Prince William and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park.

Public comment period: April 18, 2016, to May 19, 2016.

A public hearing will be conducted at the Department of Environmental Quality, Northern Region Office, 13901 Crown Court, Woodbridge, Conference Room 1, Virginia, at 10 a.m. on May 10, 2016. A map and directions maybe found at http://www.deq.virginia.gov/Locations/NorthernRegional Office.aspx.

This revision consists of amendments to the 1997 annual primary fine particulate (PM2.5) maintenance plan for the Washington DC-MD-VA PM2.5 Maintenance Area. These revisions include changes to on-road MVEBs for very fine particulate matter (PM2.5) and nitrogen oxides (NO_X) based on the EPA-approved MOVES2014 model. The MVEBs are being revised in order to meet commitments in the area's PM2.5 maintenance plan.

This notice is being given to satisfy the public participation requirements of federal regulations (40 CFR 51.102). The proposed amendments and any supporting technical documents will be submitted as a revision to the SIP under § 110(a) of the federal Clean Air Act in accordance with 40 CFR 51.104.

DEQ accepts written comments by email, fax, and postal mail. In order to be considered, comments must include the full name, address, and telephone number of the person commenting and be received by DEQ no later than the last day of the comment period. Both oral and written comments are accepted at the public hearing. DEQ prefers that comments be provided in writing, along with any supporting documents or exhibits. Comments must be submitted to Doris A. McLeod, Air Quality Planner, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, Virginia 23218, telephone (804) 698-4197, FAX (804) 698-4510, or email doris.mcleod@deq.virginia.gov. All materials received are part of the public record.

The proposal and any supporting documents are available on the DEQ Air Public Notices for Plans web site at http://www.deq.state.va.us/Programs/Air/PublicNotices/airpla nsandprograms.aspx. The documents may also be obtained by contacting Doris McLeod. The public may review the documents between 8:30 a.m. and 4:30 p.m. of each business day until the close of the public comment period at the following DEQ locations: Main Street Office, 8th Floor, 629 East Main Street, Richmond, VA, telephone (804) 698-4070 and Northern Regional Office, 13901 Crown Court, Woodbridge, VA, telephone (703) 583-3800.

Small Renewable Energy (Solar) Project - Accomack County

SunTec Solar Solutions LLC, has provided notice to the Department of Environmental Quality of its intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Accomack County, Virginia, pursuant to § 10.1-1197.6 B 1 of the Code of Virginia and 9VAC15-60. The project is located between the towns of Onancock, Virginia, and Tasley, Virginia, in the vicinity of the Tasley electrical substation. The project is expected to have four subprojects, each subproject expected to have a maximum capacity of 20 megawatts alternating current (AC), for a total combined maximum capacity of 80 megawatts AC. The subprojects will utilize traditional photovoltaic solar modules and are expected to rotate throughout the day to track the sun. The combined 80 MW of subprojects will be sited across up to roughly 500 acres of existing cleared land and across multiple parcels. The four subprojects may ultimately be broken out, such that four separate permits may be requested from the department, pursuant to this notice.

<u>Contact Information:</u> Mary E. Major, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105,

Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Small Renewable Energy (Solar) Project - Isle of Wight

On March 29, 2016, Ecoplexus, Inc. provided notice to the Department of Environmental Quality of its intent to submit the necessary documentation for a permit by rule for a small renewable solar energy project in Isle of Wight County. The project will be located on a 122-acre parcel located at approximately 15562 Scotts Factory Road, Smithfield, Virginia. The parcel is bounded by Scotts Factory Road (SR 620) to the east and is located about 0.4 miles south of the intersection of Scotts Factory Road and US 58. The project will consist of solar modules; the exact number, inverters, service boards, and transformers will be contingent upon final electrical design specifications, with a nameplate generation capacity of 14 megawatts AC. The notice of intended regulatory action will be published in the Virginia Register of Regulations on May 2, 2016.

<u>Contact Information:</u> Mary E. Major, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL REGULATION

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Department of Professional and Occupational Regulation conducted a small business impact review of **18VAC120-40**, **Virginia Professional Boxing and Wrestling Events Regulations**, and determined that this regulation should be retained in its current form. The Department of Professional and Occupational Regulation is publishing its report of findings dated March 24, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

1. The current regulations are necessary for the department to comply with § 54.1-831 of the Code of Virginia.

2. Two hundred and nine individual comments were received during the public comment period.

3. The regulations are not complex in nature.

4. The regulations do not overlap, duplicate, or conflict with federal or state laws or regulations but instead work in concert with them.

5. The last periodic review concluded December 2011. The current regulations became effective October 1, 2015.

6. No small business impact has been identified.

<u>Contact Information:</u> Kathleen R. Nosbisch, Executive Director, Department of Professional and Occupational

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Virginia Register of Regulations

Regulation, 9960 Mayland Drive, Suite 400, Richmond, Virginia, 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email apelscidla@dpor.virginia.gov.

STATE WATER CONTROL BOARD

Public Meeting and Public Comment - TMDL for the Lower Chickahominy River Watershed in New Kent, Charles City, and James City Counties

The Department of Environmental Quality (DEQ) seeks written and oral comments from interested persons on the development of total maximum daily loads (TMDLs) for the Lower Chickahominy River Watershed in New Kent, Charles City, and James City Counties. These streams are listed on the § 303(d) TMDL priority list and report as impaired due to violations of the state's water quality standards for bacteria for the recreation use.

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the State Water Control Law require the Department of Environmental Quality to develop TMDLs for pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL priority list and report.

Waterbodies identified for TMDL development include the following:

Stream	Impairment	Location
Beaverdam Creek		New Kent County
XAH- Beaverdam Creek, UT	Recreation Use	
Diascund Creek	(bacteria)	New Kent and James City Counties
Mill Creek		James City County
Barrows Creek		Charles City County
Chickahominy River		Charles City, James City, New Kent Counties
Gordon Creek		James City County

The final public meeting on the development of the TMDL to address the recreation impairment for these segments will be held on Tuesday April 26, 2016, at 1 p.m. at the Charles City County Social Center, 8320 Ruthville Road, Providence Forge, VA 23140. In the case of inclement weather the meeting will be rescheduled for April 27, 2016, at 1 p.m.

A 30-day public comment period will be held to solicit comments on the draft TMDL report. The public comment period will begin April 27 and end May 27, 2016. The draft TMDL report can be found at

General Notices/Errata

http://www.deq.virginia.gov/programs/water/waterqualityinformationtmdls/tmdl/tmdldevelopment/drafttmdlreports.aspx.

An advisory committee to assist in development of this TMDL was convened October 7, 2015, and January 19, 2016.

A component of a TMDL is the wasteload allocation (WLA); therefore, this notice is provided pursuant to § 2.2-4006 A 14 of the Administrative Process Act for any future adoption of the TMDL WLAs.

Information on the development of the TMDLs for the impairments is available upon request. All written comments include the name, address, and telephone number of the person submitting the comments and should be sent to the Kelley West, 4949-A Cox Road, Glen Allen, VA 23060, telephone (804) 527-6029, or email kelley.west@deq.virginia.gov.

Proposed Enforcement Action for A & R Logistics, Inc.

An enforcement action has been proposed for A & R Logistics, Inc. for alleged violations of the State Water Control Law in Chesapeake, Virginia. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. John Brandt will accept comments by email at john.brandt@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at the Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from April 18, 2016, to May 18, 2016.

Proposed Enforcement Action for the County of Accomack at Wallops Research Park

An enforcement action has been proposed for the County of Accomack for alleged violations of the State Water Control Law at Wallops Research Park. A description of the proposed action is available at the DEQ office named below or online at www.deq.virginia.gov. John Brandt will accept comments by email at john.brandt@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at the Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from April 18, 2016, to May 18, 2016.

Proposed Enforcement Action for S.B. Ballard Construction Company

An enforcement action has been proposed for S.B. Ballard Construction Company for alleged violations of the State Water Control Law in Norfolk, Virginia. A description of the proposed action is available at the DEQ office named below or online at www.deq.virginia.gov. John Brandt will accept comments by email at john.brandt@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at the Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from April 18, 2016, to May 18, 2016.

Proposed Enforcement Action for Delmarva Power & Light Company

An enforcement action has been proposed for Delmarva Power & Light Company for alleged violations of the State Water Control Law in Accomack County, Virginia. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. John Brandt will accept comments by email at john.brandt@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at the Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from April 18, 2016, to May 18, 2016.

Proposed Enforcement Action for Enterprise Leasing Company of Norfolk/Richmond, LLC

An enforcement action has been proposed for Enterprise Leasing Company of Norfolk/Richmond, LLC for alleged violations of the State Water Control Law in Chesapeake, Virginia. A description of the proposed action is available at DEQ office named below the or online at www.deq.virginia.gov. John Brandt will accept comments by email at john.brandt@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at the Department of Environmental Ouality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from April 18, 2016, to May 18, 2016.

Notice of Intent to Reauthorize Use of Virginia Aquatic Resources Trust Fund as a Form of Compensatory Mitigation under 9VAC25-210

Pursuant to § 62.1-44.15:20-23 of the Code of Virginia and 9VAC25-210-116 D, the State Water Control Board (the Board) is giving notice of its intent to reauthorize the Virginia Aquatic Resources Trust Fund (VARTF), one of several acceptable forms of compensatory mitigation for permitted impacts to state waters including streams and wetlands, to continue use of its existing program instrument (instrument), after considering public comment for a 30-day period starting April 18, 2016.

The Nature Conservancy (TNC) remains the sponsor of VARTF, an existing in-lieu fee compensatory mitigation program, which has been in operation in the Commonwealth of Virginia since 1995, in accordance with a memorandum of understanding between TNC and the U.S. Army Corps of Engineers (Corps), as amended in 2003. In 2011, the Virginia Department of Environmental Quality (DEQ) participated on a work group with the Corps, TNC, the Environmental Protection Agency (EPA), the U.S. Fish and Wildlife Service (USFWS), and the National Oceanic and Atmospheric Administration (NOAA) to develop the instrument, bringing VARTF into compliance with the Federal Mitigation Rule (33

CFR 332), which governs compensatory mitigation for activities authorized by Corps permits, as well as Virginia State Water Control Law and DEQ's Virginia Water Protection Permit (VWPP) program.

The purpose of this reauthorization is to maintain guidelines, responsibilities, and standards set forth in 2011 for the establishment, use, operation, and maintenance of VARTF in compliance with State Water Control Law and the VWPP program. The instrument satisfies the requirements set forth by the VWPP program in 9VAC25-210-116 D, including dedication to the achievement of no net loss of wetland acreage and functions or stream functions and water quality benefits; consultation with DEQ on site selection; provision of annual reports detailing projects and contributions by watershed; and a mechanism to establish fee amounts. Additionally, VARTF demonstrates, through annual reports, that its efforts have enhanced wetland acreage and functions or stream functions and water quality benefits, through the preservation, creation, or restoration of wetlands or streams. Lastly, VARTF continues to work in collaboration with the interagency review team for in-lieu fee programs on efforts to advance the VARTF program over time.

The board proposes to reauthorize VARTF to use the instrument, continuing as a compensatory mitigation option for a five-year period ending July 14, 2021. DEQ's approval will remain in effect until July 14, 2021, provided that the conditions of the instrument are met. Approval of VARTF may be made by letter, after accepting and considering public comments on its approval of VARTF for at least a 30-day public comment period. A copy of this public notice and links to the VARTF program instrument, exhibits, and most recent VARTF annual report are available on the DEQ website wetlands and streams public notice page at http://www.deq.virginia.gov/Programs/Water/WetlandsStrea ms/PublicNotices.aspx, under the program and regulatory section. These documents may also be obtained by calling or emailing David L. Davis. Written comments, including those by email, must be received no later than 11:59 p.m. on May 18, 2016, and should be submitted to David L. Davis using the contact information given below. Only those comments received within the comment period will be considered by the board. Written comments shall include the name, address, and telephone number of the person submitting the comment, shall reference "VARTF Reauthorization" in the subject line, and shall contain a complete, concise statement of the factual basis for comments.

<u>Contact Information:</u> David L. Davis, Virginia Department of Environmental Quality, Office of Wetlands and Stream Protection, P.O. Box 1105, Richmond, Virginia 23218, telephone (804) 698-4105, or email dave.davis@deq.virginia.gov.

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, General Assembly Building, 201 North 9th Street, 2nd Floor, Richmond, VA 23219; *Telephone:* Voice (804) 786-3591; *Email:* varegs@dls.virginia.gov.

Meeting Notices: Section 2.2-3707 C of the Code of Virginia requires state agencies to post meeting notices on their websites and on the Commonwealth Calendar at http://www.virginia.gov/connect/commonwealth-calendar.

Cumulative Table of Virginia Administrative Code Sections Adopted, Amended, or Repealed: A table listing regulation sections that have been amended, added, or repealed in the *Virginia Register of Regulations* since the regulations were originally published or last supplemented in the print version of the Virginia Administrative Code is available at http://register.dls.virginia.gov/documents/ cumultab.pdf.

Filing Material for Publication in the Virginia Register of *Regulations*: Agencies use the Regulation Information System (RIS) to file regulations and related items for publication in the Virginia Register of Regulations. The Registrar's office works closely with the Department of Planning and Budget (DPB) to coordinate the system with the Virginia Regulatory Town Hall. RIS and Town Hall complement and enhance one another by sharing pertinent regulatory information.

General Notices/Errata