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Virginia Code Commission

<http://register.dls.virginia.gov>

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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 60-day public comment period, 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**, Chairman; **Gregory D. Habeeb**; **James M. LeMunyon**; **Ryan T. McDougle**; **Robert L. Calhoun**; **E.M. Miller, Jr.**; **Thomas M. Moncure, Jr.**; **Wesley G. Russell, Jr.**; **Charles S. Sharp**; **Robert L. Tavenner**; **Christopher R. Nolen**; **J. Jasen Eige**.

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PUBLICATION SCHEDULE AND DEADLINES

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

December 2013 through December 2014

<u>Volume: Issue</u>	<u>Material Submitted By Noon*</u>	<u>Will Be Published On</u>
30:7	November 13, 2013	December 2, 2013
30:8	November 26, 2013 (Tuesday)	December 16, 2013
30:9	December 11, 2013	December 30, 2013
30:10	December 23, 2013 (Monday)	January 13, 2014
30:11	January 8, 2014	January 27, 2014
30:12	January 22, 2014	February 10, 2014
30:13	February 5, 2014	February 24, 2014
30:14	February 19, 2014	March 10, 2014
30:15	March 5, 2014	March 24, 2014
30:16	March 19, 2014	April 7, 2014
30:17	April 2, 2014	April 21, 2014
30:18	April 16, 2014	May 5, 2014
30:19	April 30, 2014	May 19, 2014
30:20	May 14, 2014	June 2, 2014
30:21	May 28, 2014	June 16, 2014
30:22	June 11, 2014	June 30, 2014
30:23	June 25, 2014	July 14, 2014
30:24	July 9, 2014	July 28, 2014
30:25	July 23, 2014	August 11, 2014
30:26	August 6, 2014	August 25, 2014
31:1	August 20, 2014	September 8, 2014
31:2	September 3, 2014	September 22, 2014
31:3	September 17, 2014	October 6, 2014
31:4	October 1, 2014	October 20, 2014
31:5	October 15, 2014	November 3, 2014
31:6	October 29, 2014	November 17, 2014
31:7	November 12, 2014	December 1, 2014

*Filing deadlines are Wednesdays unless otherwise specified.

NOTICES OF INTENDED REGULATORY ACTION

TITLE 12. HEALTH

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

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 Medical Assistance Services intends to consider amending **12VAC30-20, Administration of Medical Assistance Services**. The purpose of the proposed action is to comply with Item 307 III of Chapter 3 of the 2012 Acts of Assembly, Special Session I, which authorizes the Department of Medical Assistance Services (DMAS) to promulgate regulations to implement changes related to appeals administered by and for the department. The amendments will address DMAS timelines and specifications for filing required documentation, including the sufficiency of the contents of case summaries, and will clarify DMAS' authority to administratively invalidate untimely filed appeals.

The agency does not intend to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq.

Public Comment Deadline: January 1, 2014.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

VA.R. Doc. No. R14-3105; Filed November 1, 2013, 2:51 p.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 Medical Assistance Services intends to consider amending **12VAC30-80, Methods and Standards for Establishing Payment Rates; Other Types of Care**. The purpose of the proposed action is to implement a prospective payment methodology for outpatient hospital services and to maintain reimbursement of drug rebates for outpatient hospital services. The current cost-based methodology is out of date, inefficient, and costly. The Department of Medical Assistance Services (DMAS) is proposing to implement the Enhanced Ambulatory Patient Group (EAPG) reimbursement methodology as authorized by Item 307 XX of Chapter 806 of the 2013 Acts of Assembly. The EAPG reimbursement methodology is deemed to be a more efficient and predictable reimbursement methodology for DMAS to pay hospitals that furnish services to Medicaid recipients in an outpatient hospital setting.

The agency does not intend to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396.

Public Comment Deadline: January 1, 2014.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

VA.R. Doc. No. R14-3799; Filed November 6, 2013, 3:23 p.m.

Withdrawal of 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 Medical Assistance Services has WITHDRAWN the Notice of Intended Regulatory Action for **12VAC30-120, Waivered Services**, which was published in **24:20 VA.R. 2836 June 9, 2008**. This action is being withdrawn as the agency has determined that this action is no longer relevant or necessary.

Agency Contact: Brian McCormick, Regulatory Coordinator, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

VA.R. Doc. No. R08-1142; Filed November 12, 2013, 2:46 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF MEDICINE

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 Medicine intends to consider amending **18VAC85-50, Regulations Governing the Practice of Physician Assistants**. The purpose of the proposed action is to establish the education, experience, and examination requirements for physician assistants to perform fluoroscopy, in accordance with Chapter 81 of the 2012 Acts of Assembly.

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

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Public Comment Deadline: January 1, 2014.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4558, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

VA.R. Doc. No. R14-3348; Filed November 12, 2013, 3:45 p.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

Title of Regulation: 2VAC5-410. Rules and Regulations for the Enforcement of the Virginia Agricultural Liming Materials Law (amending 2VAC5-410-40, 2VAC5-410-50).

Statutory Authority: § 3.2-3701 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 1, 2014.

Effective Date: January 16, 2014.

Agency Contact: Erin Williams, Policy and Planning Coordinator, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-1308, FAX (804) 371-7479, TTY (800) 828-1120, or email erin.williams@vdacs.virginia.gov.

Basis: Section 3.2-109 of the Code of Virginia authorizes the Board of Agriculture and Consumer Services to adopt regulations in accordance with Title 3.2 of the Code of Virginia regarding agriculture, animal care, and food. The Virginia Department of Agriculture and Consumer Services (VDACS) administers the provisions of the Agriculture Liming Materials Act (Chapter 37 (§ 3.2-3700 et seq.) of Title 3.2 of the Code of Virginia). Section 3.2-3701 of the Act authorizes the board to adopt regulations necessary to carry out the provisions of the Act.

Purpose: AOAC International is a provider and facilitator of the development, use, and harmonization of validated analytical methods and laboratory quality assurance programs and services. This regulation references AOAC International's official methods of analysis for the components of agricultural liming materials. AOAC International has not amended the substance of the official methods of analysis that are currently cited in 2VAC5-410-40; however, AOAC International has revised the numbering system it uses for its official methods of analysis. As such, the current regulation cites obsolete method numbers. The proposed amendments will update the method numbers to cite the 18th edition of the "Official Methods of Analysis of AOAC International."

This regulation assists in ensuring that agricultural liming material sold in Virginia will effectively neutralize soil acidity within the growing season of the crop being grown,

thereby assisting in the protection of the welfare of Virginia's agriculture industry.

Rationale for Using Fast-Track Process: The proposed amendments update obsolete references and are not substantive amendments. As such, this rulemaking is expected to be noncontroversial.

Substance: The proposed amendments update obsolete references to (i) AOAC International, formerly the Association of Official Analytical Chemists; (ii) AOAC International's publication, "Official Methods of Analysis of AOAC International"; and (iii) the relevant methods of analysis included in AOAC International's publication. AOAC International has not amended the substance of official methods of analysis that are cited in 2VAC5-410-40; however, AOAC International has revised the numbering system it uses for its official methods of analysis, which makes it necessary to amend the relevant references in this regulation. The proposed amendments do not substantively alter the existing regulation.

Issues: The proposed amendments clarify for manufacturers of agricultural liming materials which methods of analysis VDACS uses in testing agricultural liming material. This regulation assists in ensuring that agricultural liming material sold in Virginia will effectively neutralize soil acidity within the growing season of the crop being grown, thereby assisting in the protection of the welfare of Virginia's agriculture industry. This regulatory action poses no disadvantage to the public or the Commonwealth.

Small Business Impact Review Report of Findings: This fast-track rulemaking 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 Regulation. The Board of Agriculture and Consumer Services (Board) proposes to update obsolete references in its regulations for enforcement of the Virginia agriculture liming materials laws.

Result of Analysis. Benefits likely outweigh costs for this regulatory action.

Estimated Economic Impact. Current regulations contain references to an outdated test method manual and outdated test method numbers. Current regulations also contain old contact information for the Association of Official Analytical Chemists (AOAC). The Board now proposes to update all of this language so that all references are correct and current. No entity is likely to incur costs on account of these regulatory

changes. Interested parties will benefit from having regulations that guide them to the correct manual and test method numbers and that contain the correct address for the AOAC.

Businesses and Entities Affected. The Virginia Department of Agriculture and Consumer Services (VDACS) reports that distributors of liming materials are governed by these regulations and will be affected by these regulatory changes. There are 71 such distributors currently registered with VDACS.

Localities Particularly Affected. No locality is likely to be particularly affected by these proposed regulations.

Projected Impact on Employment. Employment in the Commonwealth is unlikely to be affected by these proposed regulations.

Effects on the Use and Value of Private Property. These propose regulations are unlikely to affect the value or use of property in the Commonwealth.

Small Businesses: Costs and Other Effects. No small businesses will incur costs on account of these proposed regulations.

Small Businesses: Alternative Method that Minimizes Adverse Impact. No small businesses will incur costs on account of these proposed regulations.

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

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis

presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The agency concurs with the analysis of the Department of Planning and Budget.

Summary:

The amendments update references to (i) AOAC International, formerly the Association of Official Analytical Chemists; (ii) AOAC International's publication, "Official Methods of Analysis of AOAC International"; and (iii) the relevant methods of analysis included in AOAC International's publication.

2VAC5-410-40. Methods of analysis and sampling.

~~Test methods~~ Methods of analysis shall be those published ~~in the latest edition of the Association of Official Analytical Chemist "Book of Methods" by AOAC International (formerly the Association of Official Analytical Chemists) in "Official Methods of Analysis of AOAC International," 18th Edition, 2005.~~

	<u>AOAC Test Official Method</u>
Sampling Procedures	§ 1. Method No. 1.001 <u>924.01</u>
Screen Analysis	§ 1. Method No. 1.002 <u>924.02</u>
Magnesium Analysis	§ 2. Method No. 2.109 Thru 2.113 <u>965.09</u>
Calcium Analysis	§ 1. Method No. 1.019 <u>965.09</u>
Calcium Carbonate Equivalent	§ 1. Method No. 1.004 and No. 1.005 <u>955.01</u>

Procedures used in sample preparation and analysis for enforcement of this chapter are available from:

AOAC International
481 North Frederick Avenue
Suite 500
Gaithersburg, MD 20877-2417

2VAC5-410-50. Results of official agricultural liming materials analysis.

~~A.~~ The Commissioner of the Department of Agriculture and Consumer Services shall report the results of official samples to all registrants of agricultural liming materials annually.

~~NOTE: Procedures used in sample preparation and analysis for enforcement of this chapter are available from:~~

~~Association of Official Analytical Chemists~~
~~1111 North 29th Street~~
~~Suite 210~~
~~Arlington, Virginia 22209~~

DOCUMENTS INCORPORATED BY REFERENCE (2VAC5-410)

Official Methods of Analysis of the Association of AOAC International, 18th Edition, 2005, AOAC International

Regulations

(formerly the Association of Official Analytical Chemists),
481 North Frederick Avenue, Suite 500, Gaithersburg, MD
20877-2417

V.A.R. Doc. No. R14-3625; Filed November 12, 2013, 9:54 a.m.



TITLE 4. CONSERVATION AND NATURAL RESOURCES

DEPARTMENT OF FORESTRY

Fast-Track Regulation

Title of Regulation: **4VAC10-40. Reforestation of Timberlands Regulations (amending 4VAC10-40-10, 4VAC10-40-50, 4VAC10-40-70, 4VAC10-40-80, 4VAC10-40-170).**

Statutory Authority: § 10.1-1101 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 1, 2014.

Effective Date: January 31, 2014.

Agency Contact: Ronald S. Jenkins, Administrative Officer, Department of Forestry, 900 Natural Resources Drive, Suite 800, Charlottesville, VA 22903, telephone (434) 977-6555, FAX (434) 293-2768, or email ron.jenkins@dof.virginia.gov.

Basis: Section 10.1-1101 of the Code of Virginia provides the Department of Forestry with the authority to promulgate regulations necessary or incidental to the performance of duties or execution of powers conferred under Chapter 11 (§ 10.1-1100 et seq.) of Title 10.1 of the Code of Virginia. In addition, § 10.1-1103 of the Code of Virginia provides the Board of Forestry with authority to formulate recommendations to the State Forester concerning regulations and other matters applicable to Article 10 (§ 10.1-1170 et seq.) of Chapter 11 of Title 10.1 of the Code of Virginia, including types of equipment to be purchased, rental rates for equipment, and reforestation practices.

Purpose: The Department of Forestry conducted a periodic review of the Reforestation of Timberlands Regulations, which included a 30-day public comment period ending November 10, 2011. During this periodic review, the agency received no comments. However, the Department of Forestry requested review and received comments from its Board of Forestry and Reforestation of Timberlands Board. Comments from the members of these boards were incorporated into the regulations as proposed amendments. The proposed amendments will update the definitions and current forestry practices in Virginia from language that was originally designed in 1971 and updated in 1980. The amendments have no impact on public health, safety, or welfare.

Rationale for Using Fast-Track Process: During the periodic review and other review of the Reforestation of Timberlands

Regulations, the agency did not receive a single concern or proposal to amend the regulation except to bring the regulations current with definitions and current forestry practices. The reviewers included members of the industry and agency staff who are very familiar with all aspects of forestry and especially forestry incentives available through the Reforestation of Timberlands Regulations and Reforestation of Timberlands Act. During these reviews, there was no indication of controversy about the proposed amendments and the board members reached a unanimous agreement on them.

Substance: The amendments to the regulations:

1. In 4VAC10-40-10, delete the definition of "owner."
2. In 4VAC10-40-50, delete pond pine, Virginia pine, and tulip poplar tree species from nonqualifying type of land cover, which will allow land cover with these species to be eligible for reforestation incentive payments under the Reforestation of Timberlands Act.
3. In subdivision 1 of 4VAC10-40-70, delete "including release, by means of chemical, mechanical or hand methods, of seedlings from overtopping shade of trees, brush, or shrubs" and add subdivision 3 to provide that post-reforestation cultural treatments shall also be eligible for reforestation of timberlands incentives along with site preparation and reforestation.
4. In 4VAC10-40-170, delete current language in subsection B where incentive payments to landowners for approved projects are set at 60% of actual cost or \$80 per acre, whichever is lesser and replace with language that sets incentive payments to landowners from approved projects at 75% of the total cost of the project or an annually determined maximum per acre agreed upon by the Board of Forestry and the State Forester, whichever is less.

Issues: The primary advantages associated with the proposed regulatory action include updating definitions to reflect current terminology used by forestry practitioners and updating forestry practices used by those persons engaged in forestry management. All amendments will reflect the types of forestry practices that are used in modern forest management and qualify for financial incentives to encourage reforestation. These regulations underpin the foundation for sustainable forest resources in Virginia well into the future. The amendments present no known disadvantages to the public.

Small Business Impact Review Report of Findings: This fast-track rulemaking 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. The Board of Forestry (Board) proposes to amend its reforestation

regulations to reword some language, delete several types of trees from the list of ground cover that does not qualify for incentive payments, and change the formula for maximum repayment under the reforestation incentive program.

Result of Analysis. Benefits likely outweigh costs for these regulatory changes.

Estimated Economic Impact. Currently, regulations that govern the Commonwealth's reforestation and timberland incentive program include a list of ground cover plants that do not qualify for reforestation incentive payments. The Board proposes to remove pond pine, Virginia pine and tulip poplar from this list. This change will benefit private landowners who might plant these types of trees in the future as they will be eligible for incentive payments to cover part of their planting and maintenance costs. This program is funded through a tax on forest products and most of the money budgeted each year is expended each year.¹ This being the case, total expenditures on this program are unlikely to increase much on account of this change. It is more likely that the total amount spent on incentives will be approximately the same, but more individual landowners may apply for incentives. This may have the effect of driving down the amount of money that each applicant may get.

Current regulations set the amount of reimbursement under this program at 60% of land owner's actual costs or \$80 per acre, whichever is less. The Board proposes to change reimbursement to 75% of actual costs or a maximum dollar amount per acre to be set annually by the Board of Forestry and the State Forester. This change will benefit individuals who are interested in availing themselves of this program as it will give them a much more realistic picture of how much reimbursement they might be eligible for. From 2005 to 2011, reimbursement rates have ranged between \$22 and \$37 (between 32% and 48% of actual costs). These payments are far below those indicated in current regulations as payments are also constrained by a maximum budget. The new regulatory language directs interested parties to getting information on actual yearly incentives from the Board staff who will be able to give them more accurate information.

Businesses and Entities Affected. Board staff reports that this regulatory action will affect all private forest landowners who seek financial incentives through the reforestation and timberland incentive program. DOF staff also reports that the number of individuals who have submitted applications for reimbursement from the incentive program have ranged between 900 and 1,500 over the past five years.

Localities Particularly Affected. No locality will be particularly affected by these proposed regulations.

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

Effects on the Use and Value of Private Property. By incentivizing reforestation, these proposed regulatory changes will likely lead to affected private property forests being

slightly more valuable than they otherwise would be. Since participation in this program is voluntary, individuals would be unlikely to participate unless they perceived that participation would lead to more valuable forestland than non-participation.

Small Businesses: Costs and Other Effects. No small business is likely to incur any additional expense on account of these regulatory changes.

Small Businesses: Alternative Method that Minimizes Adverse Impact. No small business is likely to incur any additional expense on account of these regulatory changes.

Real Estate Development Costs. This regulatory action will likely have little effect on real estate development costs in the Commonwealth.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

¹ Between 2005 and 2011, the percentage of money budgeted from the tax on forestry products that was actually disbursed in incentive payments ranged between 80% and 96%.

Agency's Response to Economic Impact Analysis: The Department of Forestry concurs with the economic impact analysis.

Summary:

The amendments update language; remove pond pine, Virginia pine, and tulip poplar from the list of ground cover plants that do not qualify for reforestation incentive payments; and change the formula for maximum repayment under the reforestation incentive program to the

Regulations

lesser of (i) 75% of actual costs or (ii) a maximum dollar amount per acre set annually by the Board of Forestry and the State Forester.

Part I Definitions

4VAC10-40-10. Definitions.

The following words and terms when used in this regulation shall have the following meanings unless the context indicates otherwise:

"Acre" means one or more acres or part of an acre or any combination of them.

"Board" means the Reforestation Board of Forestry.

"Department" means the Department of Forestry.

"Forest Products Tax Act" means the tax paid by every person engaged in the Commonwealth in business as a manufacturer or shipper of forest products for sale, profit, or commercial use (§ 58.1-1600 of the Code of Virginia).

~~"Owner" means individual, corporation, partnership, trust, association or any other business unit, device or arrangement owning land to which the Reforestation Act is applicable.~~

"Project" means the reforestation activity, completed or an approved portion of it, on a specific number of acres, in a specific location under one ownership.

"Reforestation Act" means Reforestation of Timberlands Act, Article 10 (§ 10.1-1170 et seq.) of Chapter 11 of Title 10.1 of the Code of Virginia.

"Reforestation assistance" means funds, material, personnel or other assistance made available to a landowner pursuant to § 10.1-1173 of the Reforestation Act and these Reforestation of Timberlands Regulations.

"State Forester" means the chief executive officer of the Department of Forestry.

"Tract" means specific acreage upon which a reforestation project is conducted.

4VAC10-40-50. Nonqualifying type of land cover.

In addition to those acres to which the Reforestation Act does not apply pursuant to the provisions of § 10.1-1171 of the Reforestation Act, reforestation assistance shall not be available with respect to the following:

1. Any acre on which there are present 400 or more well distributed and free-to-grow loblolly pine (*Pinus taeda*), short leaf pine (*Pinus echinata*), ~~pond pine (*Pinus serotina*)~~, white pine (*Pinus strobus*), ~~Virginia pine (*Pinus virginiana*)~~, or pitch pine (*Pinus rigida*); stems or tulip poplar (*Liriodendron tulipifera*) stems, singly or together, four feet or more in height, measured from ground level to tip of stem.

2. Any acre on which loblolly pine (*Pinus Taeda*), short leaf pine (*Pinus echinata*), ~~pond pine (*Pinus serotina*)~~, or white pine (*Pinus strobus*), singly or together, occur and exceed in number 50 live, thrifty trees of the above species

six inches or more in diameter of the point of average thickness measured from outside of bark to outside of bark at a point on the trunk 10 inches above the general ground level.

4VAC10-40-70. Qualifying practices.

The type of forest practices qualifying for reforestation assistance shall include any method approved by the board and State Forester designed to:

1. Prepare land for reforestation, ~~including release, by means of chemical, mechanical or hand methods, of seedlings from overtopping shade of trees, brush, or shrubs;~~

2. Reforest land, ~~either naturally or artificially, by sowing of seed and/or planting of seedlings.~~

3. Conduct post-reforestation cultural treatments.

Part IV Seed Trees

4VAC10-40-80. Seed trees.

After expiration of the number of years that the eight pine and/or two tulip poplar seed trees are required, pursuant to the Seed Tree Trees Act (§ 10.1-1162 et seq. of the Code of Virginia), to be left standing following the date of cutting of the timber, and after release of the tract to the owner, reforestation assistance may be made available with respect to any acre on which seed trees were left standing and uncut as required by the Seed Tree Trees Act, provided such reforestation assistance is not prohibited by the provisions of 4VAC10-40-50.

Part XI Incentive Payments

4VAC10-40-170. Incentive payments.

A. The department may from time to time and upon consultation with the board adjust the levels and manner of incentive payments to be offered to landowners for reforestation projects in accordance with the Reforestation Act. Those changes will be for one fiscal year and may not change within a fiscal year. Any such adjustments shall be announced and publicized as far in advance of their affective dates as practical.

~~B. Effective July 1, 1982, the incentive payments to landowners for approved projects are hereby set at 60% of actual cost or \$80 per acre, whichever is the lesser. The incentive payments to landowners from approved projects are hereby set at 75% of the total cost of the project or an annually determined maximum amount per acre agreed upon by the Board of Forestry and the State Forester, whichever is less.~~

V.A.R. Doc. No. R14-3639; Filed November 4, 2013, 12:24 p.m.

MARINE RESOURCES COMMISSION

Final Regulation

REGISTRAR'S NOTICE: The Marine Resources Commission is claiming an exemption from Article 2 of 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.

Title of Regulation: 4VAC20-270. **Pertaining to Crabbing (amending 4VAC20-270-30, 4VAC20-270-40, 4VAC20-270-51, 4VAC20-270-55).**

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

Effective Date: November 21, 2013.

Agency Contact: Jane Warren, Agency Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248, FAX (757) 247-2002, or email betty.warren@mrc.virginia.gov.

Summary:

The amendments (i) extend the 2013 crab pot season for female and male crabs to December 15, 2013; (ii) establish a 2014 male and female blue crab peeler pot and crab pot season that begins March 17, 2014, and ends November 30, 2014; and (iii) establish 2014 conservation equivalency measures through crab pot, license-category specific, and daily harvest and possession bushel and barrel limits.

4VAC20-270-30. Daily time limits.

A. It shall be unlawful for any person licensed to catch and sell crabs taken by crab pot or peeler pot to take and harvest crabs from any crab pot or peeler pot, or to retrieve, bait, or set any crab pot or peeler pot, except during the lawful daily time periods described in ~~this subsection or subsection C or D~~ subsections A, B, C, and D of this section. The lawful daily time periods for the commercial harvesting of crabs by crab pot or peeler pot shall be from 6 a.m. to 2 p.m. from March 17 through April 30 ~~and in 2013 and 2014~~, September 1 through December 15, ~~2012 2013~~, and September 1 through November 30, 2014, except as described in ~~subsection~~ subsections B and E, C, and D of this section, ~~and~~. The lawful daily time periods for the commercial harvesting of crabs by crab pot or peeler pot shall be from 5 a.m. to 1 p.m. during the months of May, June, July, and August in 2013 and 2014, except as specified in ~~subsection~~ subsections B, C or, and D of this section. Crab pots or peeler pots already on board a boat at the end of the lawful daily time period, as defined in ~~this subsection or subsection~~ subsections A, B, and C or D of this section, may be set ~~during the period starting~~ immediately following the end of lawful daily time period ~~and ending to~~ one hour after the lawful daily time period ends.

~~B. The lawful daily time periods for the commercial harvesting of crabs by crab pot or peeler pot in 2013 shall begin March 16 and end November 30, with the lawful daily~~

~~time periods described in subsection A of this section in effect for March 16 through November 30, 2013.~~

~~C. B.~~ Any licensed crab pot or peeler pot fisherman who provides an opinion and supporting documentation from an attending physician to the commissioner of an existing medical condition that prevents him from adhering to the daily time limit established in subsection A of this section may be permitted by the commissioner or his designee to take and harvest crabs from his crab pot or peeler pot, or to retrieve, bait, or set his crab pot or peeler pot during an alternate eight-hour daily time limit. That alternative eight-hour daily time limit will be prescribed by the commissioner or his designee in accordance with the medical condition that forms a basis for the exception to the daily time limit as described in subsection A of this section.

Nothing in this regulation shall prohibit any licensed crab pot or peeler pot fisherman, who has been granted an exception to the eight-hour work schedule, on a medical basis, from using another licensed crab pot or peeler pot fisherman as a mate; provided, however, during the designated alternate work hours, only the crab pots or peeler pots of the fisherman receiving the exception shall be fished. Further, it shall be unlawful for the licensed crab fisherman, who has been granted an exception, or his mate, who is a licensed crab pot or peeler pot fisherman, to fish, set, retrieve, or bait, during the alternate work hours, any crab pot or peeler pot that is not owned and licensed by the fisherman granted the exception.

~~D. C.~~ Any licensed crab pot or peeler pot fisherman who requests and obtains an alternate eight-hour daily time limit permit shall be authorized to take and harvest crabs from his crab pot or peeler pot or to retrieve, bait, or set his crab pot or peeler pot one hour earlier than described in subsection A of this section, only for the months of June, July, August, and September. During the months of March, April, May, October, and November, and from December 1 through December 15, ~~2012 2013~~, the lawful daily time period described in subsection A of this section applies to any crab pot or peeler pot licensee. The alternate lawful daily time periods for the commercial harvesting of crabs by crab pot or peeler pot shall be from 4 a.m. to 12 noon from June 1 through August 31 and from 5 a.m. to 1 p.m. from September 1 through September 30. Individuals must apply for this permit on an annual basis and shall adhere to the alternate daily time limit from the day the permit is issued through September 30, as well as subdivisions 1, 2, and 3 of this subsection.

1. It shall be unlawful for two or more licensed crab pot or peeler pot fishermen, or their agents, to crab aboard the same vessel if their authorized eight-hour daily time limits are not identical.

2. After January 1, 2012, requests for an alternate eight-hour time limit permit shall be submitted to the Marine Resources Commission annually and prior to May 15.

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Requests submitted on or after May 15 will not be considered.

3. Once any legal crab pot or peeler pot licensee obtains an alternate eight-hour daily time limit permit, that permittee shall be legally bound by the alternate eight-hour daily time limit as described in this subsection.

~~E.~~ D. The lawful daily time periods for the commercial harvest of crabs by crab pot or peeler pot may be rescinded by the Commissioner of Marine Resources when he determines that a pending weather event is sufficient cause for the removal of crab pots from the tidal waters of the Commonwealth.

4VAC20-270-40. Season limits.

A. The lawful ~~season~~ seasons for the harvest of male crabs shall be March 17 through December 15, ~~2012~~ 2013, and March ~~16~~ 17 through November 30, ~~2013~~ 2014. The lawful ~~season~~ seasons for the harvest of female crabs shall be March 17 through December 15, ~~2012~~ 2013, and March ~~16~~ 17 through November ~~20~~ 30, ~~2013~~ 2014.

B. It shall be unlawful for any person to harvest crabs or to possess crabs on board a vessel, except during the lawful season, as described in subsection A of this section.

C. It shall be unlawful for any person knowingly to place, set, fish or leave any hard crab pot or peeler crab pot in any tidal waters of Virginia from December 16, ~~2012~~ 2013, through March ~~15~~ 16, ~~2013~~ 2014.

D. It shall be unlawful for any person knowingly to place, set, fish or leave any fish pot in any tidal waters from March 11 through March ~~15~~ 16, ~~2013~~ 2014, except as provided in subdivisions 1 and 2 of this subsection.

1. It shall be lawful for any person to place, set, or fish any fish pot in those Virginia waters located upriver of the following boundary lines:

- a. In the James River the boundary shall be a line connecting Hog Point and the downstream point at the mouth of College Creek.
- b. In the York River the boundary lines shall be the Route 33 bridges at West Point.
- c. In the Rappahannock River the boundary line shall be the Route 360 bridge at Tappahannock.
- d. In the Potomac River the boundary line shall be the Route 301 bridge that extends from Newberg, Maryland to Dahlgren, Virginia.

2. This subsection shall not apply to lawful eel pots as described in 4VAC20-500-50.

4VAC20-270-51. Daily commercial harvester, vessel, and harvest and possession limits.

A. Any barrel used by a harvester to contain or possess any amount of crabs will be equivalent in volume to no more than 3 bushels of crabs.

B. From March 16, 2013, through November 30, 2013, any ~~harvester~~ Commercial Fisherman Registration Licensee legally licensed for a any crab pot license, as ~~defined~~ described in 4VAC20-270-50 B, shall be limited to the following maximum daily harvest and possession limits ~~shown below~~, for any of the following crab pot license categories:

1. 27 bushels, or 9 barrels, of crabs, if licensed for up to 85 crab pots.
2. 32 bushels, or 10 barrels and 2 bushels, of crabs, if licensed for up to 127 crab pots.
3. 38 bushels, or 12 barrels and 2 bushels, of crabs, if licensed for up to 170 crab pots.
4. 45 bushels, or 15 barrels, of crabs, if licensed for up to 255 crab pots.
5. 55 bushels, or 18 barrels and 1 bushel, of crabs, if licensed for up to 425 crab pots.

~~C.~~ From December 1 through December 15, 2013, and March 17 through November 30, 2014, any Commercial Fisherman Registration Licensee legally licensed for any crab pot license, as described in 4VAC20-270-50 B, shall be limited to the following maximum daily harvest and possession limits, for any of the following crab pot license categories:

1. 16 bushels, or 5 barrels and 1 bushel, of crabs, if licensed for up to 85 crab pots.
2. 21 bushels, or 7 barrels, of crabs, if licensed for up to 127 crab pots.
3. 27 bushels, or 9 barrels, of crabs, if licensed for up to 170 crab pots.
4. 43 bushels, or 14 barrels and 1 bushel, of crabs, if licensed for up to 255 crab pots.
5. 55 bushels, or 18 barrels and 1 bushel, of crabs, if licensed for up to 425 crab pots.

~~C.~~ D. When a single harvester or multiple harvesters are on board any vessel, that vessel's daily harvest and possession limit shall be equal to only one daily harvest and possession limit, as described in ~~4VAC20-270-51~~ subsections B and C of this section, and that daily limit shall correspond to the highest harvest and possession limit of only one licensee on board that vessel.

~~D.~~ E. When transporting or selling one or more legal crab pot licensee's crab harvest in bushels or barrels, any agent shall possess either the crab pot license of that one or more crab pot licensees or a bill of lading indicating each crab pot licensee's name, address, Commercial Fisherman Registration License number, date, and amount of bushels or barrels of crabs to be sold.

~~E.~~ F. If any police officer finds crabs in excess of any lawful daily bushel, barrel, or vessel limit, as described in this section, that excess quantity of crabs shall be returned immediately to the water by the licensee or licensees who

possess that excess over lawful daily harvest or possession limit. The refusal to return crabs, in excess of any lawful daily harvest or possession limit, to the water shall constitute a separate violation of this chapter.

4VAC20-270-55. Minimum size limits.

A. From March 16 through July 15, it shall be unlawful for any person to harvest, possess, sell or offer for sale more than 10 peeler crabs, per United States standard bushel, or 5.0% of peeler crabs in any other container, that measure less than 3-1/4 inches across the shell from tip to tip of the longest spikes. From July 16 through December 15, ~~2012~~ 2013, and July 16 through November 30, ~~2013~~ 2014, it shall be unlawful for any person to harvest, possess, sell or offer for sale more than 10 peeler crabs, per United States standard bushel, or 5.0% of peeler crabs in any other container, that measure less than 3-1/2 inches across the shell from tip to tip of the longest spikes, except as described in subsections B and C of this section.

B. From July 16 through December 15, ~~2012~~ 2013, and July 16 through November 30, ~~2013~~ 2014, it shall be unlawful for any person to harvest, possess, sell or offer for sale more than 10 peeler crabs, per United States standard bushel, or 5.0% of peeler crabs in any other container, that are harvested from waters on the ocean side of Accomack and Northampton counties and measure less than 3-1/4 inches across the shell from tip to tip of the longest spikes, except as described in subsection C of this section.

C. In the enforcement of these peeler crab minimum size limits aboard a vessel, the marine police officer shall select a single container of peeler crabs of his choosing to determine if the contents of that container violate the minimum size and tolerance described in this section. If the officer determines the contents of the container are in violation, then the officer shall return all peeler crabs on board the vessel to the water alive.

D. It shall be unlawful for any person to take, catch, harvest, possess, sell or offer for sale, or to destroy in any manner, any soft crab that measures less than 3-1/2 inches across the shell from tip to tip of the longest spikes.

VA.R. Doc. No. R14-3903; Filed November 18, 2013; 2:06 p.m.

Final Regulation

REGISTRAR'S NOTICE: The Marine Resources Commission is claiming an exemption from Article 2 of 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.

Title of Regulation: **4VAC20-610. Pertaining to Commercial Fishing and Mandatory Harvest Reporting (amending 4VAC20-610-30).**

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

Effective Date: December 1, 2013.

Agency Contact: Jane Warren, Agency Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248, FAX (757) 247-2002, or email betty.warren@mrc.virginia.gov.

Summary:

The amendments establish a 2014 crab agent provision requiring certain crab licensees to submit a 2014 crab agent registration application to the commission by March 1, 2014, to be eligible for one of the 153 agent slots. If the number of applications by eligible licensees as of March 1 is less than the approved 153 agent slots, then any application for a crab agent will be considered on a first-come, first-served basis, starting with those licensees who have registered prior to March 1, 2014.

4VAC20-610-30. Commercial Fisherman Registration License; exceptions and requirements of authorized agents.

A. In accordance with § 28.2-241 C of the Code of Virginia, only persons who hold a valid Commercial Fisherman Registration License may sell, trade, or barter their harvest, or give their harvest to another, in order that it may be sold, traded, or bartered. Only these licensees may sell their harvests from Virginia tidal waters, regardless of the method or manner in which caught. Exceptions to the requirement to register as a commercial fisherman for selling harvest are authorized for the following persons or firms only:

1. Persons taking menhaden under the authority of licenses issued pursuant to § 28.2-402 of the Code of Virginia.
2. Persons independently harvesting and selling, trading, or bartering no more than three gallons of minnows per day who are not part of, hired by, or engaged in a continuing business enterprise.
 - a. Only minnow pots, a cast net or a minnow seine less than 25 feet in length may be used by persons independently harvesting minnows.
 - b. All other marine species taken during the process of harvesting minnows shall be returned to the water immediately.

B. Requirements of authorized agents.

1. No person whose Commercial Fisherman Registration License, fishing gear license, or fishing permit is currently revoked or rescinded by the Marine Resources Commission pursuant to § 28.2-232 of the Code of Virginia is authorized to possess the Commercial Fisherman Registration License, fishing gear license, or fishing permit of any other registered commercial fisherman in order to serve as an agent for fishing the commercial fisherman's gear or selling the harvest.
2. No registered commercial fisherman shall use more than one person as an agent at any time.

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3. Any person serving as an agent shall possess the Commercial Fisherman Registration License and gear license of the commercial fisherman while fishing.

4. When transporting or selling a registered commercial fisherman's harvest, the agent shall possess either the Commercial Fisherman Registration License of that commercial fisherman or a bill of lading indicating that fisherman's name, address, Commercial Fisherman Registration License number, date and amount of product to be sold.

C. Requirements of authorized blue crab fishery agents.

1. Any person licensed to harvest blue crabs commercially shall not be eligible to also serve as an agent.

2. Any person serving as an agent to harvest blue crabs for another licensed fisherman shall be limited to the use of only one registered commercial fisherman's crab license; however, an agent may fish multiple crab traps licensed and owned by the same person.

3. There shall be no more than one person, per vessel, serving as an agent for a commercial crab licensee.

4. Prior to using an agent in any crab fishery, the licensee shall submit a crab agent registration application to the commission. Crab agent registration applications shall be approved by the commissioner, or his designee, for a crab fishery licensee according to the following guidelines:

a. Only 168 agents may participate in the ~~2013~~ 2014 crab fishery, as described in subdivision 4 b of this subsection, unless the commissioner, or his designee, approves a request for agent use because of a non-economic hardship circumstance and

b. 153 of the 168 agents may be utilized by those crab fishery licensees who received approval for agent use in 2012 or who currently are licensed by a transferred crab fishery license from a licensee approved for agent use in 2012, except that should any of these licensees described in this subdivision fail to register for agent use by March 1, 2014, applications for agent use by other ~~2013~~ 2014 licensees shall be approved on a first-come, ~~first-serve~~ first-served basis, starting with those licensees who have registered prior to ~~the effective date of this regulation~~ March 1, 2014.

D. Failure to abide by any of the provisions of this section, shall constitute a violation of this regulation.

E. In accordance with § 28.2-241 H of the Code of Virginia, only persons with a valid Commercial Fisherman Registration License may purchase gear licenses. Beginning with licenses for the 1993 calendar year and for all years thereafter, gear licenses will be sold only upon presentation of evidence of a valid Commercial Fisherman Registration License.

Exceptions to the prerequisite requirement are authorized for the following gears only and under the conditions described below:

1. Menhaden purse seine licenses issued pursuant to § 28.2-402 of the Code of Virginia may be purchased without holding a Commercial Fisherman Registration License.

2. Commercial gear licenses used for recreational purposes and issued pursuant to § 28.2-226.2 of the Code of Virginia may be purchased without holding a Commercial Fisherman Registration License.

F. Exceptions to the two-year delay may be granted by the commissioner if he finds any of the following:

1. The applicant for an exception (i) has demonstrated, to the satisfaction of the commissioner, that the applicant has fished a significant quantity of commercial gear in Virginia waters during at least two of the previous five years; and (ii) can demonstrate, to the satisfaction of the commissioner, that a significant hardship caused by unforeseen circumstances beyond the applicant's control has prevented the applicant from making timely application for registration. The commissioner may require the applicant to provide such documentation as he deems necessary to verify the existence of hardship.

2. The applicant is purchasing another commercial fisherman's gear, and the seller of the gear holds a Commercial Fisherman Registration License and the seller surrenders that license to the commission at the time the gear is sold.

3. An immediate member of the applicant's family, who holds a current registration, has died or is retiring from the commercial fishery and the applicant intends to continue in the fishery.

Any applicant denied an exception may appeal the decision to the commission. The applicant shall provide a request to appeal to the commission 30 days in advance of the meeting at which the commission will hear the request. The commission will hear requests at their March, June, September, and December meetings.

Under no circumstances will an exception be granted solely on the basis of economic hardship.

VA.R. Doc. No. R14-3904; Filed November 18, 2013, 11:55 a.m.

VIRGINIA SOIL AND WATER CONSERVATION BOARD

Notice of Suspension of Regulatory Process

Title of Regulation: **4VAC50-70. Resource Management Plans (adding 4VAC50-70-10 through 4VAC50-70-150).**

Statutory Authority: § 10.1-104.8 of the Code of Virginia.

Notice is hereby given that on November 21, 2013, in accordance with §§ 2.2-4015 A 4 and 10.1-104.9 of the Code of Virginia, the Virginia Soil and Water Conservation Board directed the suspension of the board's Resource Management Plans regulations (4VAC50-70). The regulations were set to become effective on December 6, 2013, as published in the

Virginia Register of Regulations in [29:18 VA.R. 2198-2207 May 6, 2013](#). The effective date of the final regulations is suspended until the Virginia Soil and Water Conservation Board readopts a new effective date. The board indicated its intent to consider a new effective date for the regulations at the board's first regular meeting in 2014.

Agency Contact: David C. Dowling, Policy and Planning Director, Department of Conservation and Recreation, 203 Governor Street, Suite 302, Richmond, VA 23219, telephone (804) 786-2291, FAX (804) 786-6141, or email david.dowling@dcr.virginia.gov.

VA.R. Doc. No. R12-3140; Filed November 22, 2013; 2:57 p.m.

TITLE 6. CRIMINAL JUSTICE AND CORRECTIONS

BOARD OF CORRECTIONS

Final Regulation

Title of Regulation: **6VAC15-26. Regulations for Human Subject Research (amending 6VAC15-26-10, 6VAC15-26-20, 6VAC15-26-30, 6VAC15-26-50, 6VAC15-26-120, 6VAC15-26-130; adding 6VAC15-26-61, 6VAC15-26-71, 6VAC15-26-81, 6VAC15-26-91, 6VAC15-26-101, 6VAC15-26-102; repealing 6VAC15-26-40, 6VAC15-26-60, 6VAC15-26-70, 6VAC15-26-80, 6VAC15-26-90, 6VAC15-26-100, 6VAC15-26-110, 6VAC15-26-140).**

Statutory Authority: §§ 53.1-5 and 53.1-5.1 of the Code of Virginia.

Effective Date: January 1, 2014.

Agency Contact: Jim Bruce, Agency Regulatory Coordinator, Department of Corrections, 6900 Atmore Drive, Richmond, VA 23225, telephone (804) 887-8215, FAX (804) 674-3017, or email james.bruce@vadoc.virginia.gov.

Summary:

The amendments update the regulations governing research to be conducted on human subjects within the Department of Corrections. The amendments define the proposed research project information submitted by the researcher, the review process for approval, the agreements and conditions required for conducting an approved research project, the consent required from research subjects, the security of data collected, and the use of research findings.

The amendments also reduce the number of Human Subject Research Review Committee (HSRRC) members from five to three and establish and define the HSRRC as the Department of Corrections' committee responsible for (i) reviewing all submitted research projects for completeness and compliance with the Regulations for Human Subject Research, with all applicable Department of Corrections'

operating procedures, and with all applicable state and federal regulations pertaining to human subject research; (ii) approving or denying submitted research proposals; (iii) monitoring all approved research projects for adherence to the approved scope of the research; and (iv) reporting on all research projects approved, all research projects denied, and the findings of all approved research projects.

Summary of Public Comments and Agency's Response: A summary of comments made by the public and the agency's response may be obtained from the promulgating agency or viewed at the office of the Registrar of Regulations.

Part I

General Provisions

6VAC15-26-10. Definitions.

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

"Board" means the Board of Corrections.

"Department" means the Department of Corrections.

"Director" means the Director of the Department of Corrections.

"Human research" means any systematic investigation utilizing human subjects which may expose such human subjects to physical or psychological injury as a consequence of participation as subjects and which departs from the application of established and accepted therapeutic methods appropriate to meet the subjects' needs.

"Human Subject Research Review Committee" or "HSRRC" means the Department of Corrections committee responsible for (i) reviewing all submitted research projects for completeness and compliance, with the Regulations for Human Subject Research, with all applicable Department of Corrections operating procedures, and with all applicable state and federal regulations pertaining to human subject research; (ii) approving or denying submitted research proposals; (iii) monitoring all approved research projects for adherence to the scope of the research that was approved; and (iv) reporting on all research projects approved, all research projects denied and the findings of all approved research projects. The composition of the HSRRC and its responsibilities shall be as stated in Part II (6VAC15-26-50 et seq.) of this chapter.

"Legally authorized representative" means (i) the parent or parents having custody of a prospective subject, (ii) the legal guardian of a prospective subject, or (iii) any person or judicial body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this definition, any person authorized by law or regulation to consent on behalf of a prospective participant to his participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney,

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to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, organizational unit or agency conducting the human research and shall not be authorized to consent to nontherapeutic medical research. No official or employee of the organizational unit or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

"Organizational work unit" means any unit, facility, office, or district within the Department of Corrections, such as prisons, correctional centers, correctional field units, correctional work centers, probation and parole districts or offices, detention centers, diversion centers, or units supervised by a manager who reports directly to [~~the Deputy Director of Administration~~ a deputy director]. Each organizational work unit is managed by an organizational unit head such as a warden, superintendent, chief probation and parole officer, or manager.

"Participant" or "human participant" means a living individual whether ~~personnel or inmate, probationer, or parolee~~ employee or offender about whom an investigator or a researcher (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information. "Intervention" includes both physical procedures by which data are gathered and manipulations of the participant or participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between ~~investigator~~ researcher and participant.

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human participants.

"Research" means the systematic development of knowledge essential to effective planning and rational decision making. It involves the assessment of current knowledge on conceptual problems selected, statement of those problems in researchable format, design of methodologies appropriate to the problems, and the application of appropriate analytical

techniques to the data. Research findings should provide valuable information to management for policy options.

"Research agreement" means the document signed by the principal researcher, research project supervisor, or advisor and the HSRRC indicating the principal researcher and research project supervisor or advisor agree to conduct their research project in the manner in which the research project was approved by the HSRRC, including compliance with this chapter, all applicable Department of Corrections' operating procedures, all applicable state and federal laws and regulations, the research project timeline, and any conditions imposed by the HSRRC. The research agreement is governed by and must comply with the provisions of this chapter.

"Researcher" means an individual who has professional standing in the pertinent field or is supervised directly by such an individual.

"Research project" means the systematic collection of information, analysis of data, and preparation of a report of findings.

"Research proposal" means the document or documents completed by the principal researcher outlining: (i) information about the researchers, including contact information, affiliations, and funding sources; (ii) the human research to be performed, including purpose, methodology, informed consent, time frame, and Department of Corrections resources required; and (iii) any endorsements. The research proposal must be submitted to and approved by the HSRRC. Research proposals are to be limited to [~~twenty~~ 20] pages (not including bibliographies, curriculum vitae, letters of endorsement, copies of surveys or instruments to be used, copies of external Institutional Review board approvals, and voluntary informed consent forms.) A suggested template for a research proposal is incorporated by reference with this chapter.

"Voluntary informed consent" means the knowing consent of an individual so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Voluntary informed consent forms shall not include any language through which the human subject waives or appears to waive any of his legal rights, including any release of any individual, facility, agency, or agents thereof, from liability or negligence. The human participant shall sign all voluntary [informed] consent forms confirmed by an acceptable witness. With regard to the conduct of human research, the basic elements of information necessary to such voluntary informed consent shall include:

1. A fair explanation to the individual of any procedures to be followed and their purposes, including identification of any procedures which are experimental;
2. A description of any attendant discomforts and risks reasonably to be expected;
3. A description of any benefits reasonably to be expected;

- 4. A disclosure of any appropriate alternative procedures that might be advantageous for the individual;
- 5. An offer to answer any inquiries by the individual concerning the procedure; and
- 6. An instruction that the individual is free to withdraw [~~his~~ the individual's] voluntary informed consent and to discontinue participation in the human research at any time without prejudice ~~to him~~.

A copy of the Voluntary Informed Consent [to Participate in Research] form is incorporated by reference with this chapter.

6VAC15-26-20. Applicability.

This chapter shall apply to any individual, group, or agency conducting research ~~which that~~ uses human participants within the Virginia Department of Corrections, including any facility, program or organization owned, operated, funded, or licensed by the department.

6VAC15-26-30. Policy.

A. No human research may be conducted without informing the participant or his legally authorized representative in writing of the risks, procedures, and discomforts of the research. The voluntary informed consent of the participant or his legally authorized representative to participate in the research must be documented in writing and supported by signature of a witness not involved in the conduct of the research, except as provided in ~~6VAC15-26-90 F~~ 6VAC15-26-102. Arrangements shall be made for those who need special assistance in understanding the consequences of participating in the research.

~~B. Each human research review activity shall be approved by a committee composed of representatives of varied backgrounds who shall assure the competent, complete and professional review of human research activities. No offender shall be subjected to experimentation or participation in research against his will.~~

C. Nontherapeutic research using institutionalized participants ~~shall be~~ is prohibited unless it is determined by the ~~research review committee~~ HSRRC that such nontherapeutic research will not present greater than minimal risk.

~~D. The individuals conducting the research shall be required to notify all participants of research of the risks caused by the research which are discovered after the research has concluded. Research involving known and substantive physical, mental, or emotional risk to the participants, including the withholding of any prescribed program or treatment, is specifically prohibited.~~

~~E. Department of Corrections studies, program evaluations, and routine data analyses for management purposes are exempt from this policy. Medical research shall only be conducted in accordance with Department of Corrections Operating Procedure 701.1, Health Services Administration, which is incorporated by reference with this chapter.~~

~~F. The burden of proof for review by any committee shall be with the principal researcher. Research shall not interfere with the rights of offenders or Department of Corrections' employees.~~

G. Proper precautions must be exercised for the protection of the research participants rights and for the overall safety and security of the public, the researcher, and the Department of Corrections.

H. Research shall not interfere significantly with ongoing programs or operations of the Department of Corrections.

I. The research findings shall not identify individual participants. The confidentiality and anonymity of all offenders and other parties engaged in the research will be maintained.

J. Researchers are required to notify all participants of risks caused by the research that are discovered after the research has concluded.

K. Each human research activity shall be reviewed and approved by the HSRRC.

L. No human research activity involving the Department of Corrections shall be initiated without a research proposal reviewed and approved by the HSRRC.

M. Each submitted research proposal must be accompanied by a research agreement signed by the principal researcher, or research project supervisor or advisor.

N. All research proposals, research agreements, and accompanying documentation must be submitted to the HSRRC electronically via email.

O. The burden of proof for review by the HSRRC shall be with the principal researcher.

P. Research shall not commence until all procedural and applicable human research reviews and approvals are completed and the [~~director~~ Director of the Department of Corrections] or [~~applicable deputy director~~ designee] signs an approval memorandum on behalf of the department. This approval memorandum and necessary information describing the project shall be sent to the appropriate Department of Corrections organizational unit head, regional [~~director~~ operations chief], and principal researcher.

Q. This chapter does not apply to Department of Corrections studies, program evaluations, and routine data analyses for management purposes.

Part II

Human Research Review Committees

6VAC15-26-40.-Certification process. (Repealed.)

~~A. Organizational units seeking to conduct or sponsor human research are required to submit statements to the department assuring that all human research activities will be reviewed and approved by a human research review committee. Organizational units shall report annually to the director giving assurance that a committee exists and is functioning. These reports should include a list of committee~~

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members, their qualifications for service on the committee, their organizational unit affiliation and a copy of the minutes of committee meetings.

~~B. Prior to the initiation of a human research project, organizational units shall also send to the director a one page summary containing the following information:~~

- ~~1. Name, address, telephone numbers, and title and affiliation of principal researcher;~~
- ~~2. Name of person who will supervise the project, if different from the principal researcher;~~
- ~~3. Funding source, if any;~~
- ~~4. Date the proposal was submitted to the appropriate human research review committee;~~
- ~~5. Title of project;~~
- ~~6. An objectives statement of the proposed project with anticipated results;~~
- ~~7. Methodology describing in a concise manner the research design, sampling strategy, and analytical techniques to be used and indicating the effects of the research methodology, if any, on existing programs and organizational unit operations;~~
- ~~8. The voluntary informed consent statement;~~
- ~~9. Time frame indicating proposed beginning and ending dates;~~
- ~~10. Department resources required, including personnel, supplies and materials, equipment, workspaces, access to participants and files, and any other resources that the researcher will require from the department or its subsidiaries; and~~
- ~~11. Project endorsement for student research. Letters or other documents must be attached to indicate endorsement of the project by the academic advisor or other appropriate persons.~~

~~C. Each person engaged in the conduct of human research or proposing to conduct human research shall associate himself with any organizational unit having a committee, and such human research shall be subject to review and approval by the committee in the manner set forth in this section.~~

~~D. The director may inspect the records of the committee.~~

~~E. The chairman of the committee shall report as soon as possible to the head of the organizational unit and to the director any violation of the research protocol which led the committee to either suspend or terminate the research.~~

Part II

Human Subject Research Review Committee (HSRRC)

6VAC15-26-50. Composition [of] research review committees [the HSRRC].

~~A. Each committee~~ The HSRRC shall have at least five ~~three~~ members, appointed by the ~~organizational unit head~~ [~~director~~ Director of the Department of Corrections] ~~or designee~~, with varying backgrounds to provide complete and

adequate review of activities commonly conducted by the ~~organizational unit researchers~~. The committee HSRRC shall be sufficiently qualified through the experience and diversity of its members, ~~including consideration of race, gender and cultural background. In addition to possessing the professional competence necessary to review specific activities, the committee must be able to ascertain the acceptability of applications and proposals in terms of organizational unit commitments and regulations, if applicable by law; standards of professional conduct and practice; and community attitudes. If a committee regularly reviews research that has an impact on an institutionalized or other vulnerable category of participants, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these participants and who have appropriate experience to serve in that capacity.~~

1. The HSRRC shall not be comprised entirely of men or of women.

2. The HSRRC shall not be comprised entirely of members from one organizational work unit.

3. The HSRRC shall have at least one member who is not otherwise affiliated with the Department of Corrections and is not an immediate family member of a person who is affiliated with the department.

~~B. No committee shall consist entirely of men or women, or entirely of members of one profession. At least one member shall be an individual whose primary concerns are in nonscientific areas (e.g., lawyers, ethicists, members of the clergy). At least three members shall be individuals who are not otherwise connected with the department. In addition to possessing the professional competence necessary to review research proposals, the HSRRC must be able to ascertain the acceptability of research proposals in terms of organizational work unit commitments, this chapter, applicable Department of Corrections [:] operating procedures, any applicable state and federal law or regulation, standards of professional conduct and practice, and community attitudes.~~

~~C. Each committee shall include at least one member who is not otherwise affiliated with the organizational unit and who is not part of the immediate family of a person who is affiliated with the organizational unit.~~

~~D. C.~~ No member of a ~~committee~~ the HSRRC shall participate in the ~~committee's HSRRC's~~ initial or continuing review of any research project in which the member has a conflict of interest (defined as having direct involvement in or department approval authority over the proposed human research or otherwise having a conflict of interest under applicable Virginia law). ~~The committee HSRRC~~ has responsibility for determining whether a member has a conflicting interest.

~~E. A committee~~ D. The HSRRC may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues ~~which that~~ which require expertise beyond or in addition to that available ~~on the committee~~ to the

~~HSRRC. These individuals may not vote with the committee HSRRC.~~

~~F. E. A quorum of the committee HSRRC shall consist of a majority of its members including at least one member whose primary concerns are in nonscientific areas. If a quorum cannot be established (or cannot meet within the established time frames) from the existing committee HSRRC, the organizational unit head director or designee may replace temporarily an active committee member with an alternate to the degree needed to establish a quorum.~~

~~G. One member of the committee shall be designated as secretary of the committee and shall take and prepare formal minutes of each meeting.~~

~~H. The committee and the organizational unit shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.~~

~~**6VAC15-26-60. Elements of each committee's review process. (Repealed.)**~~

~~A. No human research shall be conducted or authorized by an organizational unit or agency unless such committee has reviewed and approved the proposed human research project giving consideration to:~~

- ~~1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;~~
- ~~2. The degree of the risk and, if the research is nontherapeutic, whether it presents greater than minimal risk;~~
- ~~3. Whether the rights and welfare of the participants are adequately protected;~~
- ~~4. Whether the risks to the participants are outweighed by the potential benefits to them;~~
- ~~5. Whether the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and whether the written consent form is adequate and appropriate in both content and language for both the research and participants of the research;~~
- ~~6. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified;~~
- ~~7. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness;~~
- ~~8. Whether the research conforms with such other requirements as the board may establish; and~~
- ~~9. Whether appropriate studies in the nonhuman systems have been conducted prior to the involvement of human participants.~~

~~B. Each committee shall review and approve projects to ensure conformity with the approved proposal at least annually.~~

~~C. Research shall be approved by the committee which has jurisdiction over the participant. When cooperating organizational units conduct some or all of the research involving some or all of the participants, each cooperating organizational unit is responsible for safeguarding the rights and welfare of human participants and for complying with this chapter, except that in complying with this chapter organizational units may enter into joint review, rely upon the review of another qualified committee, or make similar arrangements aimed at avoiding duplication of effort. Such arrangements may be made by the committee chairperson with the approval of a majority of the members present at a meeting of the committee.~~

~~D. The committee shall consider completed research proposals within 60 days after submission to the committee's chairman. In order for the research to be approved, it shall receive the approval of a majority of those members present at a meeting in which a quorum exists. A committee shall notify investigators and the organizational unit in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure committee approval.~~

~~E. The committee shall develop a written procedure to be followed by a participant who has a complaint about a research project in which he is participating or has participated.~~

~~F. Any participant who has a complaint about a research project in which he is participating or has participated shall be referred to the chairperson of the committee who shall refer it to the committee to determine if there has been a violation of the protocol.~~

~~G. The committee shall require periodic reports. The frequency of such reports should reflect the nature and degree of risk of each research project.~~

~~**6VAC15-26-61. Duties and responsibilities.**~~

~~A. The HSRRC shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.~~

~~B. The HSRRC shall review all submitted research proposals for the following:~~

~~1. Completeness, including:~~

~~a. Researcher information.~~

~~(1) Name of principal researcher~~

~~(2) Affiliation~~

~~(3) Mailing address~~

~~(4) Telephone number~~

~~(5) Email address~~

~~(6) Names of all other researchers participating in the research project~~

~~(7) Name of research project supervisor or advisor, if different from [subdivision 1 a (1) of this subsection principal researcher]~~

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(a) Telephone number

(b) Email address

(8) Funding source

(9) Curriculum vitae of principal researcher, all persons named as researchers and research project supervisor or advisor

b. Research proposal information.

(1) Date research proposal submitted to HSRRC

(2) Title of research proposal

(3) Purpose of research proposal

(4) Methodology

(a) Research design

(b) Sampling methods

(c) Methods of analysis

(5) Discussion of the research proposal in the context of relevant literature

(6) Discussion of the benefits to the Department of Corrections as well as the field of study

(7) Copies of any surveys or instruments to be used

(8) Voluntary informed consent forms

(9) Timeline for the research project

(10) Department of Corrections resources required (including personnel, supplies, materials, equipment, workspace, access to participants and files, etc.)

(11) External Institutional Review Board (IRB) approval (including academic IRBs, research group IRBs, and government IRBs); all external IRB approvals must be received before the HSRRC will initiate review of a submitted research proposal

c. Letters of endorsement.

2. Compliance with this chapter [, all applicable Department of Corrections operating procedures,] and all applicable state and federal laws and regulations. Compliance includes, but is not limited to:

a. The researchers' ability to obtain the appropriate security clearances to enter an organizational work unit.

b. The researchers' adherence to an organizational work unit's standards for appropriate attire, including dress or wardrobe, jewelry, hair, grooming, body piercings and tattoos.

c. The researchers' ability to pass an organizational work unit's security screening process for contraband, including weapons of any kind, alcohol, drugs of any kind, cellular phones, other electronic devices, tobacco products (including lighters and matches), and any other items deemed as potentially adversely impacting the safety and security of the Department of Corrections, organizational work unit, department staff, research participants or other offenders, the researchers, or the general public.

3. Adherence to basic research standards, including:

a. Credentials. The principal researcher shall have academic or professional standing in the pertinent field or job-related experience in the areas of study or be directly supervised by such a person.

b. Ethics. The research shall conform to the appropriate standards of ethics of professional societies such as the American Psychological Association, the American Sociological Association, the National Association of Social Workers, or other equivalent society.

c. Protection of rights. The principal researcher is responsible for the conduct of his staff and assumes responsibility for the protection of the rights of participants involved in the research project.

d. Confidentiality or anonymity. Research project information given by participants to the researcher or researchers shall be confidential or anonymous depending on the study design. This does not preclude the reporting of results in aggregated form that protects the identity of individuals, or the giving of raw data to the Department of Corrections for further analysis. The confidentiality of any such raw data shall be monitored by the department. Persons who breach confidentiality or anonymity shall be subject to sanctions in accordance with applicable laws, policies, and procedures.

e. Participant incentives. The opportunity to participate in research is considered sufficient incentive for participation. The offering of additional incentives is prohibited without specific written approval from the [applicable Director of the] Department of Corrections [~~deputy director~~ or designee]. Sentence reduction or pecuniary compensation are always prohibited as incentives.

4. Determination if the research proposal is subject to the human research review requirements of §§ 32.1-162.16 through 32.1-162.20 of the Code of Virginia.

5. Agreement with Department of Corrections research procedures.

a. The principal researcher and research project supervisor or advisor must submit a separate, signed written research agreement when submitting their research proposal indicating that the principal researcher, research project supervisor or advisor, and all other researchers and staff under their supervision who are associated with the research project have read, understand, and agree to abide by Department of Corrections research procedures.

b. The research agreement shall establish a timeline for the research project and the specific date when the principal researcher shall submit the final report to the HSRRC.

c. In the case of student research, the student's academic advisor must sign the research agreement indicating endorsement of the research project.

C. After reviewing each submitted, complete research proposal, research agreement and accompanying documentation, the HSRCC will vote to approve or deny the research proposal.

D. A research proposal shall be approved by the HSRRC when a majority of the quorum of the HSRRC votes to approve the research proposal.

E. ~~[In the event that~~ If] a research proposal is denied, the HSRRC shall notify the principal researcher of the reason or reasons for denial and any requested clarifications, edits, updates, or additions that can be made to the research proposal. The principal researcher may resubmit a revised research proposal with these requested clarifications, edits, updates, or additions. The HSRRC will then review the resubmitted revised, complete research proposal in accordance with 6VAC15-26-50 B.

F. Upon approval of a research proposal by the HSRRC, the HSRRC shall prepare a research brief summarizing the research proposal with any comments. The research brief will be provided to the ~~[director or the appropriate deputy director~~ Director of the Department of Corrections or designee] for review and approval.

G. Upon approval of the research brief by the ~~[director or the appropriate deputy director~~ Director of the Department of Corrections or designee], the HSRRC shall provide an approval memorandum and necessary information describing the research project to the organizational work unit head, regional ~~[director~~ operations chief], and principal researcher.

H. The HSRRC shall retain a separate electronic file for each submitted research proposal. Each electronic file shall contain:

1. The original submitted research proposal.
2. The research agreement.
3. Any accompanying documentation.
4. Any resubmitted revised research proposals.
5. The research brief.
6. The approval memorandum.
7. Any progress reports.
8. The final report.
9. All communication between the HSRRC, principal researcher, research project supervisor or advisor, the [Director of the] Department of Corrections [~~Director, and the applicable deputy director~~ or designee], regional ~~[director~~ operations chief], and organizational unit head pertaining to the research project.

I. At the time the research agreement is signed, the HSRRC shall establish due dates for progress reports to be provided by the principal researcher. These progress reports will

inform the HSRRC of the status of the research project and any difficulties encountered that might delay or preclude completion of the research project.

J. The HSRRC shall establish research priorities consistent with the needs of the Department of Corrections.

K. The HSRRC shall regulate the number and timetable of research projects so as to not disrupt the normal functioning of any Department of Corrections operational work unit.

L. Upon receipt of a complaint from an organizational unit head or participant, the HSRRC will investigate to determine if there has been a violation of these regulations, Department of Corrections operating procedures, the research proposal, the research agreement or any applicable state or federal laws or regulations.

M. If the HSRRC determines that a principal researcher, researcher, research project supervisor or advisor, or staff supervised by them has violated any provisions of this chapter, Department of Corrections operating procedures, the research proposal, the research agreement, or any applicable state or federal laws or regulations, the HSRRC may terminate the research project at any time.

N. The HSRRC shall submit to the Governor, the General Assembly, and the ~~[director~~ Director of the Department of Corrections] or ~~[his]~~ designee [.] at least annually [.] a report on the human research projects reviewed and approved by the HSRRC, including any significant deviations from the approved research projects.

6VAC15-26-70. Kinds of research exempt from committee review. (Repealed.)

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from this chapter unless the research is covered by other sections of this chapter:

1. Research conducted in established or commonly accepted educational settings, involving commonly used educational practices, such as:

 - a. Research on regular and special education instructional strategies; or
 - b. Research on the effectiveness of, or the comparison among, instructional techniques, curriculum or classroom management methods.
2. Research involving solely the use and analysis of the results of standardized psychological, educational, diagnostic, aptitude, or achievement tests, if information taken from these sources is recorded in such a manner that participants cannot be reasonably identified directly or through identifiers linked to the participants.
3. Research involving survey or interview procedures, unless responses are recorded in such a manner that participants can be identified directly or through identifiers linked to the participants, and either:

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a. ~~The participants' responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation; or~~

b. ~~The research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.~~

4. ~~Research involving solely the observation (including observation by participants) of public behavior, unless observations are recorded in such a manner that participants can be identified directly or through identifiers linked to the participants, and either:~~

a. ~~The observations recorded about the individual, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or~~

b. ~~The research deals with sensitive aspects of the participant's own behavior such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.~~

5. ~~Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information taken from these sources is recorded in such a manner that participants cannot be identified directly or through identifiers linked to the participants.~~

6. ~~Research involving solely a combination of any of the activities described in this section.~~

6VAC15-26-71. Reports.

A. The principal researcher must submit progress reports to the HSRRC by the dates agreed upon in the research agreement. These progress reports must be submitted electronically via email.

B. The principal researcher must submit a final report to the HSRRC. The final report must be submitted electronically via email.

C. The HSRRC reserves the right to reproduce the final report for official Department of Corrections use only.

6VAC15-26-80. Expedited review procedures for certain kinds of research involving no more than minimal risk. (Repealed.)

~~A. The committee may conduct an expedited review of a human research project which involves no more than minimal risk to the participants if (i) another institution's or agency's human research review committee has reviewed and approved the project or (ii) the review involves only minor changes in previously approved research and the changes occur during the approved project period. Under an expedited review procedure, the review may be carried out by the committee chairperson or one or more experienced reviewers designated~~

~~by the chairperson from among members of the committee. In reviewing the research, the reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in 6VAC15-26-60.~~

~~B. Each committee which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.~~

~~C. Research activities involving no more than minimal risk and in which the involvement of human participants will only be in one or more of the following categories (carried out through standard methods) may be reviewed by the research review committee through the expedited review procedure:~~

~~1. The study of existing data in the form of records on department personnel or inmates, probationers, or parolees, automated or other records.~~

~~2. Research on individual or group behavior or characteristics of individuals, such as studies of perception, attitudes or interaction patterns, where the investigator does not manipulate participants' behavior and the research will not involve stress to participants.~~

6VAC15-26-81. Records maintenance.

A. The principal researcher shall maintain records adequate to enable the Department of Corrections to ascertain the status of the research project at any given time.

B. The principal researcher shall maintain completed voluntary informed consent forms in a secure location for at least three years.

6VAC15-26-90. Informed consent. (Repealed.)

~~A. No human research may be conducted in the absence of voluntary informed consent subscribed to in writing by the participant or by the participant's legally authorized representative except as provided for in subsection F of this section. If the participant is a minor otherwise capable of rendering voluntary informed consent, the consent shall be subscribed to by both the minor and his legally authorized representative. An investigator shall seek such consent only under circumstances that (i) provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and (ii) minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in understandable language.~~

~~B. No individual shall participate in research unless subsection A of this section is met for each individual. The consent by a legally authorized representative shall be subject to the provisions of subsection C of this section. No voluntary informed consent shall include any language through which the participant waives or appears to waive any of his legal rights, including any release of any individual, institution, agency or any agents thereof from liability for negligence.~~

~~Notwithstanding consent by a legally authorized representative, no person shall be forced to participate in any research project. Each participant shall be given a copy of the signed consent form required by 6VAC15-26-30 A except as provided for in subsection F of this section.~~

~~C. No legally authorized representative may consent to nontherapeutic research unless it is determined by the committee that such nontherapeutic research will present no more than a minor increase over minimal risk to the participant. No nontherapeutic research shall be performed without the consent of the participant.~~

~~D. The committee may approve a consent procedure which omits or alters some or all of the elements of informed consent set forth in 6VAC15-26-10, or waives the requirement to obtain informed consent provided the committee finds and documents that:~~

- ~~1. The research involves no more than minimal risk to the participants;~~
- ~~2. The omission, alteration or waiver will not adversely affect the rights and welfare of the participants;~~
- ~~3. The research could not practicably be performed without the omission, alteration or waiver; and~~
- ~~4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.~~

~~E. Except as provided in subsection F of this section, the consent form may be either of the following:~~

- ~~1. A written consent document that embodies the elements of informed consent required by 6VAC15-26-10. This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or~~
- ~~2. A short form written consent document stating that the elements of informed consent required by 6VAC15-26-10 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the representative in addition to a copy of the short form.~~

~~F. The committee may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds that the only record linking the participant and the research would be the consent document and that the principal risk would be potentially harmful resulting from a breach of confidentiality. Each participant~~

~~will be asked whether he wants documentation linking him to the research, and the participant's wishes will govern. In cases where the documentation requirement is waived, the committee may require the investigator to provide participants with a written statement explaining the research.~~

6VAC15-26-91. Publication rights.

A. Researchers are not permitted to publish beyond the approved research proposal without further review and approval from the HSRRC.

B. The researcher shall furnish the HSRRC with an electronic copy of the published research findings.

C. The Department of Corrections shall be permitted to use the data collected in the research project and to reproduce the materials as they are published.

D. Without the explicit written approval of the researcher, the Department of Corrections should not publicly distribute any dissertation or thesis material that the researcher has not published or presented publicly or professionally.

E. Without prior approval from the HSRRC, research conducted by employees or agents (including but not limited to interns, volunteers, contractors, and vendors) of the [~~department~~ Department of Corrections] is the property of the department and cannot be published without the approval of the [~~director or the appropriate deputy director~~ Director of the Department of Corrections or designee].

6VAC15-26-100. Committee records. (Repealed.)

~~A. Documentation of all committee activities shall be prepared and maintained and shall include the following:~~

- ~~1. Copies of all research proposals reviewed, evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by researchers, reports of injuries to participants, and correspondence related to the research;~~
- ~~2. Minutes of committee meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or for disapproving research; and a written summary of the discussion of controversial issues and their resolution;~~
- ~~3. Records of continuing review activities;~~
- ~~4. Copies of all correspondence between the committee and the investigators;~~
- ~~5. A list of committee members;~~
- ~~6. Written procedures for the committee; and~~
- ~~7. Statements of significant new findings provided to the participants.~~

~~B. The records required by this chapter shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for~~

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inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

6VAC15-26-101. Research exempt from HSRRC review.

The following are exempt from HSRRC review:

1. Department of Corrections' studies, program evaluations and routine data analyses for management purposes.

2. Research conducted by the Department of Corrections, Division of Education in established or commonly accepted educational settings, involving commonly used educational practices, such as:

a. Research on regular and special education instructional strategies.

b. Research on the effectiveness of, or the comparison among, instructional techniques, curriculum or classroom management methods.

3. Research involving required agency survey procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:

a. The participants' responses, if they become known outside the research, could reasonably place a participant at risk of criminal or civil liability or be damaging to a participant's financial standing, employability, or reputation; or

b. The research deals with sensitive aspects of a participant's own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.

4. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publically available or if the information taken from these sources is recorded in such a manner that participants [~~cannot~~] be identified, either directly or through identifiers linked to the participants.

6VAC15-26-102. Waiver of signed voluntary informed consent form.

A. The HSRRC may waive the requirement for the researcher to obtain a signed voluntary informed consent form for some or all participants in a research project if it finds that the only record linking the participant and the research would be the consent form and that the principal risk would be potentially harmful resulting from a breach of confidentiality.

B. Each participant will be asked whether he wants documentation linking him to the research, and the participant's wishes will govern.

C. In cases where the documentation requirement is waived, the HSRRC shall require the researcher to provide participants with a written statement explaining the research.

6VAC15-26-110. Mandatory reporting. (Repealed.)

~~Each research review committee shall submit to the governor, the General Assembly, and the director or his designee at least annually a report on the human research projects reviewed and approved by the committee, including significant deviations from the proposals as approved.~~

Part III

Role of the Department, Director, and the Board

6VAC15-26-120. Role of the department, director, and the board.

A. ~~The [~~director~~ Director of the Department of Corrections], or [~~his~~] designee, shall establish and maintain records of ~~organizational unit~~ the HSRRC assurances, annual reports, and summary descriptions of research projects to be reviewed by the board.~~

B. ~~The [~~director~~ Director of the Department of Corrections], or [~~his~~] designee, shall review communications from ~~committees~~ the HSRRC reporting violations of research protocols which led to suspension or termination of the research to ensure that appropriate steps have been taken for the protection of rights of human research participants. The board shall be kept informed.~~

C. ~~The [~~director~~ Director of the Department of Corrections] shall arrange for the printing and dissemination of copies of this chapter.~~

Part IV

Applicability of State and Federal Policies

6VAC15-26-130. Applicability of state and federal policies.

A. ~~No statement in this chapter shall be construed as limiting in any way the rights of participants in research under regulations promulgated by the board pursuant to §§ 53.1-5 and 53.1-5.1 of the Code of Virginia.~~

B. ~~Human research that is subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempted from this chapter. Annual certification shall be made [to the Director of the Department of Corrections and the Board of Corrections] that exempted projects have complied with the policies and regulations of federal agencies [~~to the director and the board~~].~~

6VAC15-26-140. Applicability of federal policies. (Repealed.)

~~Human research which is subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempted from this chapter. Annual certification shall be made to the director and the board that exempted projects have complied with the policies and regulations of federal agencies.~~

NOTICE: 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 to access a form. 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 (6VAC15-26)

~~[[Research Proposal - Sample \(Operating Procedure 020.1\), Attachment 1, effective April 1, 2010 \(rev. 1/10\).](#)~~

~~[[Research Agreement \(Operating Procedure 020.1\), Attachment 2, effective April 1, 2010 \(rev. 1/10\).](#)~~

~~[[Voluntary Informed Consent to Participate in Research \(Operating Procedure 020.1\), Attachment 3, effective April 1, 2010 \(rev. 1/10\).](#)~~

[Research Agreement, 020 F2 2-13, \(rev. 3/13\)](#)

[Research Proposal - Sample \(Operating Procedure 020.1\), Attachment 1, effective May 1, 2013 \(rev. 3/13\)](#)

[Voluntary Informed Consent to Participate in Research, 020 F3 2-13, \(rev. 3/13\) \]](#)

DOCUMENTS INCORPORATED BY REFERENCE (6VAC15-26)

[Operating Procedure 701.1 - Health Services Administration, Effective Date January 1, 2012, Amended March 29, 2012, Virginia Department of Corrections](#)

VA.R. Doc. No. R11-2246; Filed November 7, 2013, 8:22 a.m.

FORENSIC SCIENCE BOARD

Fast-Track Regulation

Title of Regulation: **6VAC40-20. Regulations for Breath Alcohol Testing (amending 6VAC40-20-140, 6VAC40-20-160).**

Statutory Authority: § 9.1-1110 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 2, 2014.

Effective Date: January 17, 2014.

Agency Contact: Stephanie Merritt, Department Counsel, Department of Forensic Science, 700 North Fifth Street, Richmond, VA 23219, telephone (804) 786-2281, FAX (804) 786-6857, or email stephanie.merritt@dfs.virginia.gov.

Basis: Section 18.2-267 B of the Code of Virginia requires the Department of Forensic Science to determine the proper method and equipment to be used in analyzing breath samples taken pursuant to § 18.2-267 and to advise the respective police and sheriff's departments of the same. Additionally, § 18.2-268.9 of the Code of Virginia requires the department to establish a training program for all individuals who are to administer the breath tests and, upon a person's successful completion of the training program, the department may

license him to conduct breath test analyses. This regulation describes the process for approval of breath test devices, general methods of conducting breath tests, training and licensing procedures for operators, and the use of preliminary breath test devices. Section 9.1-1110 A 1 of the Code of Virginia authorizes the Forensic Science Board to adopt regulations, pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), for the administration of Chapter 11 (§ 9.1-1100 et seq.) of Title 9.1 of the Code of Virginia or §§ 18.2-268.6, 18.2-268.9, 19.2-188.1, and 19.2-310.5 of the Code of Virginia and for any provisions of the Code of Virginia as they relate to the responsibilities of the Department of Forensic Science.

Purpose: The regulations, which describe the process for approval of breath test devices, general methods of conducting breath tests, training and licensing procedures for operators, and the use of preliminary breath test devices, facilitate the protection of the health and safety of the public from the perils of individuals who drive while under the influence of alcohol or other drugs.

Rationale for Using Fast-Track Process: The amendments involving a mail delivery method, striking language regarding a checklist that is no longer applicable to the instruments used the Commonwealth, and updating information about the availability of a form relevant to the current breath instrumentation are minor and do not change any existing, substantive procedures. In September 2012, the department conducted a periodic review of this regulation and received no public comment. Likewise, the Forensic Science Board discussed and voted to adopt these amendments at its January 2013 public meeting, and no member of the public offered a comment. Given these facts, the department does not expect the amendments to be controversial.

Substance: The amendments to 6VAC40-20 make two minor changes to the existing regulations. First, the amendments add the term "or equivalent delivery method" to 6VAC40-20-140. This amendment allows the Department of Forensic Science to deliver notice of the revocation of certain licenses or certificates via certified U.S.P.S. mail as well as other equivalent delivery methods such as signature required Federal Express or UPS delivery. The use of the private carriers for mail delivery is, at times, more cost effective than U.S.P.S. mail. This change will allow the department to utilize the least expensive mail delivery option. Second, the amendments to 6VAC40-20-160 strike language about the preventive maintenance checklist, which was applicable to a breath instrument no longer used in the Commonwealth, and replaces this language with information about the availability of breath test worksheets relevant to the instruments currently in use.

Issues: The amendments are advantageous to the Department of Forensic Science and the Commonwealth to the extent that multiple mail delivery options allow the department to choose the most cost-effective delivery method for certain mailings.

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Furthermore, the amendments clarify the current availability of the breath test worksheet to law-enforcement agencies and eliminate reference to a worksheet that is no longer in use. The department expects these changes will enhance its user agencies' understanding of the regulations. There is no other anticipated public impact and no known disadvantage.

Small Business Impact Report of Findings: This regulatory action serves as the report of 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. The Department of Forensic Science (DFS) proposes to amend its Regulations for Breath Alcohol Testing to: 1) allow DFS to deliver notice of license or certificate revocation to breath instrument operators or instructors by certified USPS mail or by equivalent signature required UPS or Federal Express, 2) remove obsolete language that refers to DFS providing preventative maintenance checklists and requires that a copy of this checklist be filled out for every breath test device assigned to affected agencies and 3) add language that informs agencies that breath test worksheets relevant to instruments currently in use are provided to agencies but may also be accessed and printed from DFS's website.

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

Estimated Economic Impact. Current regulations require that DFS deliver notice of revocation to breath test instructor licensees and breath test operators certificate holders by certified USPS mail. In other areas of practice, however, DFS has found that sending mail by signature required UPS or Federal Express mail tends to be less expensive and also offers the benefit of nearly instant verification that mail has been delivered. Because of this, DFS now proposes to amend these regulations so that mail service that is equivalent to certified mail (in that it requires the recipient to sign for it) may be used to mail notice of revocation to individuals who are losing their department issued licenses or certifications. This change will benefit DFS, and taxpayers who fund DFS, because DFS will have the ability to choose the least costly equivalent mailing service rather than being constrained to only using certified USPS mail. No entity is likely to incur costs on account of this regulatory change.

DFS also proposes to remove language from these regulations that references testing of equipment that is no longer in use in the Commonwealth and to add language that informs localities of breath test worksheets (in use with newer breath test equipment) that will be distributed by DFS and that are also available for download on the department's website. No entity is likely to incur costs on account of these changes. Licensees and certificate holders, as well as other interested parties will likely benefit from changes that remove obsolete language and clarify current practice.

Businesses and Entities Affected. DFS reports that there are 5,000 breath instrument operators and 35 breath instrument instructors all of whom will be affected by these regulatory changes. DFS additionally reports that there are 168 breath instruments that are operated in 165 localities throughout the Commonwealth.

Localities Particularly Affected. No localities will be particularly affected by these proposed regulations.

Projected Impact on Employment. This proposed regulatory action is 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.

Small Businesses: Costs and Other Effects. No small business is likely to incur any additional expense on account of these regulatory changes.

Small Businesses: Alternative Method that Minimizes Adverse Impact. No small business is likely to incur any additional expense on account of these regulatory changes.

Real Estate Development Costs. This regulatory action will likely have no effect on real estate development costs in the Commonwealth.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The Department of Forensic Science concurs with the economic

impact analysis prepared by the Department of Planning and Budget.

Summary:

The amendments (i) allow the Department of Forensic Science to deliver notice of license or certificate revocation to breath instrument operators or instructors by certified USPS mail or by equivalent signature-required delivery service, (ii) remove obsolete language that (a) refers to the department providing preventative maintenance checklists and (b) requires that a copy of this checklist be filled out for every breath test device assigned to affected agencies, and (iii) add language that informs agencies that breath test worksheets relevant to instruments currently in use are provided to agencies but may also be accessed and printed from the department's website.

6VAC40-20-140. Revocation.

Any revocation of a license or instructor certificate shall be by notice sent by registered or certified mail or equivalent delivery method from the department to the licensee or instructor.

6VAC40-20-160. Checklist.

~~A preventive maintenance checklist, if applicable, shall be provided by the department and completed at least once each month for each breath test device assigned to an agency. A copy of this preventive maintenance checklist shall be submitted to the department to be kept on file for at least three years. Breath test worksheets are provided to an agency by the department but may also be accessed and printed from the department's website.~~

NOTICE: 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 (6VAC40-20)

~~Intoxilyzer 5000 Monthly Preventive Maintenance/Simulator Solution Change Checklist, DFS 70-036A (rev. 7/05).~~

~~Operational Checklist for Intoxilyzer 5000, DFS 70-037 (rev. 8/97).~~

[EC/IR II Breath Test Worksheet, DFS Document 250-F115 \(eff. 10/08\)](#)

VA.R. Doc. No. R14-3740; Filed November 7, 2013, 9:10 a.m.



TITLE 12. HEALTH

STATE BOARD OF HEALTH

Fast-Track Regulation

Title of Regulation: 12VAC5-71. Regulations Governing Virginia Newborn Screening Services (amending 12VAC5-71-10, 12VAC5-71-30, 12VAC5-71-70 through 12VAC5-71-100, 12VAC5-71-120 through 12VAC5-71-190; repealing 12VAC5-71-20).

Statutory Authority: §§ 32.1-12 and 32.1-67 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 1, 2014.

Effective Date: January 24, 2014.

Agency Contact: Susan Tlusty, Division of Child and Adolescent Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7686, FAX (804) 864-7647, or email susan.tlusty@vdh.virginia.gov.

Basis: The State Board of Health is authorized to make, adopt, promulgate, and enforce regulations by § 32.1-12 of the Code of Virginia. Section 32.1-65 of the Code of Virginia requires newborn screening to be conducted on every infant born in the Commonwealth of Virginia. Section 32.1-67 of the Code of Virginia requires the State Board of Health to promulgate regulations as necessary to implement newborn screening services. The regulations are required to include a list of newborn screening tests pursuant to § 32.1-65.

Purpose: The regulation needs to be amended as the result of a periodic review conducted pursuant to Executive Order 14 (2010). The regulation is essential to protect the health of citizens as conditions identified through newborn screening can lead to death or permanent disability if left unidentified or untreated.

The regulation provides oversight for the Virginia Newborn Screening Program. The benefits of newborn screening are to identify rare genetic and heritable disorders at birth in order to reduce infant mortality and permanent disabilities that can result from unidentified and untreated disease. The amendments update names and references to programs, state regulations, and federal recommendation entities.

Rationale for Using Fast-Track Process: The fast-track rulemaking process is being utilized as the changes to the regulation update names and references to programs, state regulations, and federal recommendation entities. These changes are not expected to be controversial.

Substance: Definitions in 12VAC5-71-10 for "certified nurse midwife," "child," "hospital," "parent," "pool of funds," and "preterm infants" are updated to be consistent with other regulations or to provide more clarity to the definition. References to Virginia Newborn Screening Services or

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newborn screening services are changed to reflect the current program name, Virginia Newborn Screening Program, throughout the regulation. In 12VAC5-71-30, the reference to the federal newborn screening recommended screening panel is updated, and standardized nomenclature for newborn screening condition names and abbreviations is incorporated into the list of conditions. In 12VAC5-71-70, the term from the hospital is added to the term at the time of discharge for clarity. 12VAC5-71-80 and 12VAC5-71-120 are restructured to be formatted in correct style. In 12VAC5-71-90, the phrase "information relative to" is stricken to clarify what information must be recorded in the record. The reference to the federal regulation for laboratories is clarified in 12VAC5-71-100. In 12VAC5-71-160, the word "protocol" is substituted for "procedure" and the term "resident adults" is added to clarify that persons ages 19 and 20 are covered.

Issues: The primary advantage to the public is that infants in Virginia will continue to be screened for conditions as recommended by the federal government. There are no disadvantages related to the proposed changes.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The State Board of Health (Board) proposes to amend these regulations to: 1) update multiple condition names and abbreviations using national standardized nomenclature, 2) update citations, 3) update definitions, 4) make grammatical changes, and 5) add clarifying language.

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

Estimated Economic Impact. None of the proposed amendments change requirements or have any impact beyond improving clarity.

Businesses and Entities Affected. These regulations affect newborns and their families, as well as hospitals and their staff.

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

Projected Impact on Employment. Since the proposed amendments do not have any impact beyond improving clarity, employment will not be significantly affected.

Effects on the Use and Value of Private Property. Since the proposed amendments do not have any impact beyond improving clarity, the use and value of private property will not be significantly affected.

Small Businesses: Costs and Other Effects. The proposal amendments do not significantly affect costs.

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

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

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The Department of Health concurs with the economic impact analysis conducted by the Department of Planning and Budget.

Summary:

The amendments update condition names and abbreviations, names and references to programs, citations to state regulations, and names of federal recommendation entities.

12VAC5-71-10. Definitions.

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

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN ~~Pool~~ ~~pool~~ of ~~Funds~~ ~~funds~~, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II (18VAC90-30-60 et seq.) of 18VAC90-30 and ~~18VAC90-30-120 and 18VAC90-30-121~~, subject to 18VAC90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, ~~and as well as~~ a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

"Confirmatory testing" means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

"Core panel conditions" means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (i) specific and sensitive screening tests, (ii) a sufficiently well understood natural history, and (iii) available and efficacious treatments.

"Department" means the state Department of Health.

"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

"Healthcare provider" means a person who is licensed to provide health care as part of his job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means ~~a medical care facility licensed as a hospital by the Virginia Department of Health~~ any facility as defined in § 32.1-123 of the Code of Virginia.

"Infant" means a child less than 12 months of age.

"Low protein modified foods" means foods that are (i) specially formulated to have less than one gram of protein per serving, (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, (iii) not natural foods that are naturally low in protein, and (iv) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

"Metabolic formula" means nutritional substances that are (i) prescribed by a health professional with appropriate prescriptive authority; (ii) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (iii) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (iv) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs.

"Metabolic supplements" means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

"Midwife" means a person licensed as a nurse practitioner in the category of certified nurse midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

"Newborn" means an infant who is 28 days old or less.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multistate licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

"Parent" means a biological parent, adoptive parent, or stepparent.

"Pediatric Comprehensive Sickle Cell Clinic Network" means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support services for newborns and children living with sickle cell disease and other genetically related hemoglobinopathies.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state ~~match~~ matching funds.

"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.

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"Preterm infant" means a ~~neonate~~ an infant whose birth occurs ~~through~~ by the end of the last day of the 36th week following the onset of the last menstrual period.

"Repeat specimen" means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Satisfactory specimen" means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

"Screened-abnormal" means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

"Testing laboratory" means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

"Total parenteral nutrition-~~(TPN)~~" or "TPN" means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12VAC5-71-30 D.

"Unsatisfactory specimen" means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

"Virginia Genetics Advisory Committee" means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Services Program and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

"Virginia Sickle Cell Awareness Program" means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related hemoglobinopathies.

12VAC5-71-20. Administration of chapter. (Repealed.)

~~This chapter is administered by the commissioner.~~

~~The commissioner may issue a guidance document that interprets these regulations and provides guidance for their implementation. Such a document shall be reviewed and revised whenever the regulations of this chapter are reviewed and may also be amended or revised as needed to meet changing circumstances.~~

~~Guidance documents shall include procedures for accessing program services including available assistance when not otherwise addressed in these regulations or the Code of Virginia.~~

12VAC5-71-30. Core panel of heritable disorders and genetic diseases.

A. The Virginia Newborn Screening System, which includes Virginia Newborn Screening Services Program and the Virginia Early Hearing Detection and Intervention Program, shall ensure that the core panel of heritable disorders and genetic diseases for which newborn screening is conducted is consistent with but not necessarily identical to the ~~recommendations for screening by the American College of Medical Genetics in its 2005 report "Newborn Screening: Toward a Uniform Screening Panel and System."~~ U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel.

B. The department shall review, at least biennially, national recommendations and guidelines and may propose changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the commissioner on proposed changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

D. Infants under six months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:

1. Argininosuccinic ~~acidemia~~ aciduria (ASA);
2. ~~Beta-ketothiolase~~ Beta-Ketothiolase deficiency (~~±KT~~) (BKT);
3. Biotinidase deficiency (BIOT);
4. Carnitine uptake defect (CUD);
5. Classical galactosemia (galactose-1-phosphate uridylyltransferase deficiency) (GALT);
- ~~5.~~ 6. Citrullinemia (~~CIT~~) type I (CIT-I);
- ~~6.~~ 7. Congenital adrenal hyperplasia (CAH);
- ~~7.~~ Congenital hypothyroidism (CH);
8. Cystic fibrosis (CF);
9. Galactosemia (GALT);
- ~~10.~~ 9. Glutaric acidemia type I (GA I);
11. ~~Hemoglobin Sickle/Beta thalassemia (Hb S/±Th)~~ 10. Hb S beta-thalassemia (Hb F,S,A);
12. ~~Hemoglobin Sickle/C disease (Hb S/C)~~ 11. Hb SC-disease (Hb F,S,C);
12. Hb SS-disease (sickle cell anemia) (Hb F, S);

- 13. Homocystinuria (HCY);
- 14. Isovaleric acidemia (IVA);
- 15. Long chain ~~hydroxyacyl-CoA~~ L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD);
- 16. Maple syrup urine disease (MSUD);
- 17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
- 18. Methylmalonic acidemia (~~mutase deficiency~~) (Methylmalonyl-CoA mutase deficiency) (MUT);
- 19. Methylmalonic acidemia (~~Cbl A,B~~) (Adenosylcobalamin synthesis deficiency) (CBL A, CBL B);
- 20. Multiple carboxylase deficiency (MCD);
- 21. Phenylketonuria (PKU);
- 22. Primary congenital hypothyroidism (CH);
- ~~22.~~ 23. Propionic acidemia (PROP);
- ~~23. Sickle cell anemia (Hb SS disease) (Hb SS)~~;
- 24. Tyrosinemia type I (TYR I);
- 25. Trifunctional protein deficiency (TFP);
- 26. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);
- 27. 3-hydroxy 3-methyl glutaric aciduria (HMG); and
- 28. 3-Methylcrotonyl-CoA carboxylase deficiency (~~3MCC~~) (3-MCC).

E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set forth in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and as governed by 12VAC5-80.

12VAC5-71-70. Newborn dried-blood-spot screening specimen collection, specimen submission, and notification for hospital deliveries.

A. Newborn dried-blood-spot specimen collection and submission shall be done in accordance with requirements that are determined by the department's designated testing laboratory.

B. Newborn dried-blood-spot specimen collection shall occur after 24 hours of age or immediately before the newborn's discharge from the hospital, whichever comes first.

C. If the initial newborn dried-blood-spot specimen is collected before 24 hours of age, a repeat specimen shall be collected at the time of discharge from the hospital or no later than 14 days of age, regardless of earlier test results.

D. If the newborn is a preterm infant, the newborn dried-blood-spot specimen shall be collected at seven days of age or at the time of discharge from the hospital, whichever occurs first.

E. If the newborn requires a blood transfusion or total parenteral nutrition (TPN) or if the newborn is suspected of having a heritable disorder or genetic disease that is listed in 12VAC5-71-30 D:

- 1. The newborn dried-blood-spot specimen may be collected before 24 hours of age and subsequently submitted; and
- 2. A repeat newborn dried-blood-spot specimen shall be collected at the time of discharge from the hospital or no later than 14 days of age, regardless of earlier test results, and subsequently submitted.

F. On notification by the hospital that the infant was discharged before a newborn dried-blood-spot specimen was collected, the healthcare provider in charge of the infant's care or his designee shall:

- 1. Notify the infant's parent that the infant was discharged before a newborn dried-blood-spot specimen was collected;
- 2. Cause the collection of a specimen within 48 hours of that parental notification; and
- 3. Cause the submission of the specimen.

G. If the newborn is to be transferred to another hospital and is less than 24 hours of age:

- 1. The physician or certified nurse midwife in charge of the infant's care at the hospital of birth shall:
 - a. Cause the collection of a newborn dried-blood-spot specimen before the newborn is transferred to another hospital;
 - b. Cause the submission of the specimen; and
 - c. Notify the receiving physician or healthcare provider that a newborn dried-blood-spot specimen was collected before 24 hours of age.
- 2. The receiving physician or healthcare provider shall:
 - a. Cause the collection of a repeat specimen at the time of discharge or no later than 14 days of age, regardless of earlier test results; and
 - b. Cause the submission of the specimen.

H. If the infant is transferred to another hospital and is 24 hours of age or older, the physician in charge of the infant's care at the hospital of birth shall:

- 1. Cause the initial collection and submission of a newborn dried-blood-spot specimen for the infant who is being transferred;
- 2. Notify the receiving physician or physician of record on transfer that the infant's specimen has been collected; and
- 3. Notify the receiving physician or physician of record if a newborn dried-blood-spot specimen needs to be repeated or if confirmatory testing is required.

I. The healthcare provider in charge of the infant's care, on receiving notice from the testing laboratory that the infant's newborn dried-blood-spot specimen is unsatisfactory, shall:

- 1. Cause the collection of a repeat specimen as soon as possible but no later than two business days after notice; and

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2. Cause the submission of the specimen.

J. The healthcare provider in charge of the infant's care, on receiving notice of the results of the infant's newborn dried-blood-spot screening test, shall place or cause to be placed the results in the infant's medical record and cause parental notification of test results.

K. The healthcare provider in charge of the infant's care, on receiving notice of the infant's screened-abnormal result, shall:

1. Cause the collection of a repeat newborn dried-blood-spot specimen for repeat or confirmatory testing as soon as possible but no later than two business days after notice;
2. Cause the submission of the specimen; and
3. Take immediate action, as instructed, when notified of a critically abnormal screening result.

12VAC5-71-80. Newborn dried-blood-spot screening specimen collection, specimen submission, and notification for deliveries outside of the hospital.

A. In the event that the infant is born outside of a hospital, the attending physician or midwife shall ensure that:

1. Newborn dried-blood-spot specimen collection and submission is done in accordance with requirements that are determined by the department's designated testing laboratory.
2. Newborn dried-blood-spot specimen collection occurs after 24 hours of age.
3. If the initial newborn dried-blood-spot specimen is collected before 24 hours of age, a repeat specimen shall be collected no later than 14 days of age, regardless of earlier test results.
4. If the newborn is hospitalized, the infant's healthcare provider shall cause the newborn dried-blood-spot screening specimen collection and submission in accordance with 12VAC5-71-70.

B. The healthcare provider in charge of the infant's care, on receiving notice of the results of the infant's newborn dried-blood-spot screening test, shall place or cause to be placed the results in the infant's medical record and cause parental notification of test results.

C. The healthcare provider in charge of the infant's care, on receiving notice from the testing laboratory that the infant's newborn dried-blood-spot specimen is unsatisfactory, shall:

1. Cause the collection of a repeat specimen as soon as possible but no later than two business days after notice; and
2. Cause the submission of the specimen.

D. The healthcare provider in charge of the infant's care, on receiving notice of the infant's screened-abnormal result, shall:

1. Cause the collection of a repeat newborn dried-blood-spot specimen for repeat or confirmatory testing as soon as possible but no later than two business days after notice;
2. Cause the submission of the specimen; and
3. Take immediate action, as instructed, when notified of a critically abnormal screening result.

E. If a licensed midwife has ordered the newborn dried-blood-spot screening test and is notified that the results are unsatisfactory or abnormal, the infant shall be immediately referred to a physician or health care facility for repeat collection and submission and for care and treatment as necessary.

F. The licensed midwife shall cause the collection and submission of a repeat newborn dried-blood-spot specimen if the specimen is unsatisfactory and referring the infant to a physician or health care facility for repeat collection will result in a delay of more than two business days.

12VAC5-71-90. Responsibilities of the chief executive officer.

The chief executive officer shall assure that the hospital providing birthing services develops and implements policies and procedures to make certain that the following steps take place:

1. Collection of newborn dried-blood-spot screening specimens shall occur after 24 hours of birth, and collection and submission of the specimens shall meet the standards required by the testing laboratory;
2. Notification of the newborn's physician of record or designee shall occur within one business day in the event that the infant is discharged before the newborn dried-blood-spot screening specimen has been collected;
3. Communication of the newborn dried-blood-spot screening test results to the newborn's physician of record or designee shall occur so that test results may become part of the infant's medical record on file with the physician;
4. ~~Information relative to~~ The newborn screening dried-blood-spot results and treatment shall be recorded in the patient's medical record, and retention of the information shall comply with applicable medical record retention requirements; and
5. Training of staff on newborn dried-blood-spot screening specimen collection and submission and parental notification shall be implemented in a way that ensures an adequately trained and knowledgeable workforce is maintained for implementing specimen collection and submission and parental notification according to standards required by the testing laboratory and guidance from the department.

12VAC5-71-100. Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests.

A. Newborn dried-blood-spot screening tests shall be performed by the Division of Consolidated Laboratory

Services or other laboratory the department has contracted with to provide this service in accordance § 32.1-65 of the Code of Virginia.

B. The testing laboratory shall maintain accreditation under the federal Clinical Laboratory Improvement Amendments regulations as defined in 42 CFR Part 493.

C. The testing laboratory shall perform required initial and secondary tests using validated analytical test methods and establish normal ranges and notification protocols as defined in the contract with the department. The testing laboratory may seek the advice of the Newborn Screening Subcommittee of the Virginia Genetics Advisory Committee.

D. On completion of newborn dried-blood-spot screening tests for the infant, the testing laboratory shall provide the completed test results to the submitting facility and to the infant's healthcare provider, as indicated on the newborn screening sample.

E. The testing laboratory shall provide the department's newborn screening services program with the newborn dried-blood-spot screening test data that are necessary to carry out follow-up services.

F. The testing laboratory shall manage the distribution of newborn dried-blood-spot screening specimen collection kits.

G. The testing laboratory is authorized to set the fee charged to birthing hospitals and physicians for purchase of newborn dried-blood-spot screening specimen collection kits in consultation with the department and in accordance with applicable state statutes and regulations.

H. The testing laboratory shall maintain an information management system capable of electronic data exchange between the laboratory and the department's newborn screening services program.

12VAC5-71-120. Scope and content of Virginia Newborn Screening Services Program.

A. The mission of Virginia Newborn Screening Services Program is to prevent ~~mental-retardation~~ intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by those heritable disorders and genetic diseases listed in 12VAC5-71-30 D.

B. The scope of the newborn screening services program shall include the following:

1. Ensure that infants born in the Commonwealth receive newborn dried-blood-spot screening, confirmatory testing, and follow-up services for selected heritable disorders or genetic diseases;
2. Locate and track infants with screened-abnormal results or unsatisfactory results, a short-term process of ensuring that the identified healthcare provider is informed of results, in a timely matter, by at least six months of age, to determine if the infant has a selected heritable disorder or genetic disease;

3. Ensure that the department receives all diagnostic test results, both normal and screened-abnormal results, from healthcare providers;

4. Ensure that appropriate diagnostic data are collected, stored, and organized in a secure data management information system that allows for efficient extraction of appropriate data from the testing laboratory to newborn screening services in accordance with federal and state laws and regulations;

5. Assess and evaluate the newborn screening services program follow-up activities by collecting and reporting data required annually for Title V national performance measures that address how well the system functions;

6. Educate healthcare providers, parents, and the general public by electronic or written materials and educational sessions, as deemed necessary by the department;

7. Facilitate the entry of infants with screened-abnormal results into medical and dietary management services as needed upon receiving notification from the contracted lab of such results;

8. Ensure that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through the newborn screening services program are referred to the Care Connection for Children network for care coordination services; and

9. Provide information to residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through the newborn screening services program regarding available assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements that are medically necessary to manage their diagnosed heritable disorder or genetic disease listed in 12VAC5-71-30 D.

C. To ensure full implementation of the newborn screening services program, the department may establish contracts with, but not be limited to, the following entities, and the established contracts shall comply with all federal assurances:

1. A designated testing laboratory;
2. Medical facilities to provide metabolic treatment and genetic services; and
3. Other entities as needed.

D. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA; Public Law 103-62), shall be used to establish the newborn screening services program goals. The following goals shall change as needed to be consistent with applicable Title V national performance measures:

1. All infants who are born in the Commonwealth and who are residents of Virginia will receive appropriate newborn dried-blood-spot screening, confirmatory testing, and follow-up services.

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2. All infants who are born in the Commonwealth and who are not residents of Virginia will receive appropriate newborn dried-blood-spot screening and be referred to their state of residence for confirmatory testing and follow-up services.

12VAC5-71-130. Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network.

A. Upon notification by the Virginia Newborn Screening Services Program of an infant diagnosed with sickle cell disease, the Virginia Sickle Cell Awareness Program shall track infants identified with sickle cell disease and related hemoglobinopathies to ensure that they receive care and refer the infants to the Pediatric Comprehensive Sickle Cell Clinic Network.

B. The Pediatric Comprehensive Sickle Cell Clinic Network shall provide the following services:

1. Consultation on screened-abnormal results to primary care providers and parents;
2. Family counseling and support;
3. Regularly scheduled clinics, which meet the needs of the population served; and
4. Referral to appropriate inpatient care facilities.

C. The Pediatric Comprehensive Sickle Cell Clinic Network shall provide data as needed by the department's newborn screening services program.

12VAC5-71-140. Responsibilities of metabolic treatment and genetic centers facilities.

A. The department's contracted metabolic treatment and genetic centers facilities shall collaborate with a specialized testing laboratory or laboratories for performing diagnostic testing on infants referred by the department's newborn screening services program in accordance with § 32.1-65 of the Code of Virginia.

B. The department's contracted metabolic treatment and genetic centers facilities shall provide the following clinical services:

1. Consultation on screened-abnormal results to healthcare providers;
2. Family counseling and support;
3. Regularly scheduled clinics;
4. Appropriate inpatient care facilities;
5. Clinical genetic services; and
6. Nutritional counseling and support.

C. The department's contracted metabolic treatment and genetic centers facilities shall provide written diagnostic and other related case information to the department's newborn screening services program.

12VAC5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases and are referred to the network by the Virginia Newborn Screening Services Program.

2. Other network services for eligible individuals in accordance with the § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening services program.

12VAC5-71-160. Availability of assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements.

A. The department shall maintain a procedure protocol to assist eligible persons in obtaining metabolic formula, low protein modified foods, and metabolic supplements.

B. Expenditures shall be limited to available funding.

C. Resident children and resident adults under the age of 21 who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and meet financial eligibility criteria for the Children with Special Health Care Needs Program pool of funds in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to receive metabolic formula at no cost. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have insurance coverage for metabolic formula.

D. Resident children and resident adults under the age of 21 who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and do not meet financial eligibility criteria for the Children with Special Health Care Needs Program pool of funds in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may be eligible to purchase metabolic formula through the Virginia Department of Health.

E. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who have a gross family income at or below 300% of the federal poverty level in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to receive metabolic formula at no cost. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for metabolic formula.

F. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who do not meet financial criteria or other

eligibility criteria in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to purchase metabolic formula through the Virginia Department of Health.

G. Residents who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who have a gross family income at or below of 300% of the federal poverty level in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may be eligible to receive reimbursement from the department up to \$1,500 per year for purchase of low protein modified foods and metabolic supplements. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for low protein modified foods or metabolic supplements for which they are seeking reimbursement.

12VAC5-71-170. Emergency suspension of assistance.

The commissioner may suspend any portion of the assistance plan to ensure the financial integrity of the Virginia Newborn Screening Services Program. The commissioner shall report any action taken under the provisions of this section to the State Board of Health at its next scheduled meeting.

12VAC5-71-180. Use of federal, state, or other resources.

A. The commissioner or his designee may seek, receive, and expend federal, state general, or other nongeneral funds for the department necessary to administer the newborn screening services program.

B. Federal Title V funds received for the Children with Special Health Care Needs Program, authorized by § 32.1-77 of the Code of Virginia, may be used to support the department's newborn screening services program, in accordance with applicable federal and state laws and regulations.

12VAC5-71-190. Confidentiality of information.

The department's newborn screening services program and its contractors shall maintain, store, and safeguard client records from unauthorized access as required by law.

VA.R. Doc. No. R11-2916; Filed November 5, 2013, 2:42 p.m.

Proposed Regulation

Title of Regulation: 12VAC5-105. Rabies Regulations (adding 12VAC5-105-10 through 12VAC5-105-40).

Statutory Authority: §§ 32.1-12 and 3.2-6521 of the Code of Virginia; Chapter 834 of the 2010 Acts of Assembly.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 31, 2014.

Agency Contact: Julia Murphy, DVM, State Epidemiological Veterinarian, Department of Health, 109 Governor Street, 5th

Floor, Richmond, VA 23219, telephone (804) 864-8113, FAX (804) 864-8131, or email julia.murphy@vdh.virginia.gov.

Basis: Section 32.1-12 of the Code of Virginia authorizes the State Board of Health to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia and other laws of the Commonwealth administered by it, the Commissioner of Health, or the Department of Health. Chapter 834 of the 2010 Acts of Assembly clarifies the procedures and responsibilities among the Department of Health, localities, and other entities to prevent and control rabies and the second enactment of Chapter 834 requires the Board of Health to adopt regulations to implement the provisions of the act. Section 3.2-6521 of the Code of Virginia requires the Board of Health to provide, by regulation, an exemption to the requirement that an owner of a dog or cat must have his animal vaccinated for rabies if the veterinarian determines that the dog or cat has an underlying medical condition that is likely to result in a life-threatening condition in response to the vaccination.

Purpose: These regulations are necessary for the protection of public health. Rabies is nearly 100% fatal in mammals and is highly endemic in the Commonwealth. It is very important that human and animal exposures are addressed promptly and correctly. Greater detail than is appropriate for the Code of Virginia is articulated in these regulations to support the implementation of rabies-related sections of the Code of Virginia modified and introduced during the 2010 Session of the General Assembly. In addition, the Board of Health has been specifically instructed to develop regulations addressing rabies exemptions and a model rabies response plan. Goals of the proposed language include (i) defining commonly used terms in the rabies-related sections of the Code of Virginia to increase the likelihood that these terms are interpreted and applied in a consistent way, (ii) improving the recordkeeping associated with rabies clinics to increase the likelihood that an animal's vaccinations status can be verified in response to a rabies exposure, (iii) outlining the procedure a veterinarian must use to apply for a rabies vaccination exemption and the role of local authorities in that process, and (iv) offering a model rabies response plan that localities may use to comply with § 3.2-6562.1 of the Code of Virginia. The proposed language has been developed in cooperation with stakeholders from potentially affected groups such as local health departments, animal control agencies, veterinary associations, humane groups, wildlife agencies, agriculture agencies, the Board of Veterinary Medicine, and local government associations. These stakeholders have been engaged to discuss issues such as the entity that grants rabies exemptions and restrictions placed on animals that are exempt as well as the authority local health directors now have to direct animal control officers in the pursuit of their duties in certain circumstances. This participatory approach was intended to result in proposed language that is clearly written,

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understandable, and functional for all those involved in rabies prevention, control, and response efforts.

Substance: The provisions in these new regulations address commonly used terms in the rabies-related sections of the Code of Virginia, the health department's recordkeeping responsibilities associated with rabies clinics, a mechanism whereby dogs and cats may be granted a rabies vaccination exemption, and fulfill the requirement, as put forward by the 2010 General Assembly, for the Board of Health to develop a model plan that may be used by localities to comply with the requirements of § 3.2-6562.1 of the Code of Virginia.

Issues: The main issues associated with the proposed regulatory action include defining common terms used in the Code of Virginia, rabies vaccination exemptions, recordkeeping associated with rabies clinics, and the development of a model rabies response plan. The primary advantages of these regulations for individual private citizens, veterinarians in private practice, and the Commonwealth include (i) increasing the likelihood that the terms used in the rabies-related sections of the Code of Virginia will be applied and interpreted in a consistent way in all health districts; (ii) increasing the likelihood that the rabies vaccination status of an animal that was vaccinated as part of a rabies clinic can be verified; (iii) providing a mechanism for granting rabies vaccination exemptions that will allow for a dog or cat owner whose animal is likely to have a life-threatening reaction in response to vaccination to be in compliance with local licensing laws, but also contains provisions that will assist local authorities with protecting public health; and (iv) improving coordination and communication among local government authorities in response to a rabies exposure event to ensure that residents living in a locality and their animals receive timely and accurate guidance about rabies by creating a model rabies response plan that can be used by local health departments. A potential disadvantage of these regulations includes the time and effort veterinarians in private practice may need to complete the application for vaccination exemption.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Pursuant to Chapters 182 and 834 of the 2010 Acts of Assembly, the proposed regulations 1) establish a procedure for issuing exemptions for rabies vaccination, and 2) require localities to have a response plan to rabies exposure.

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. Chapter 182 of the 2010 Acts of Assembly requires the Board of Health to provide an exemption for rabies vaccination if the vaccination would endanger the animal's life. According to the Virginia Department of Health (VDH), some animals may develop life

threatening allergic reaction to the rabies vaccination. The proposed regulations will allow a veterinarian to apply to the local health director for an exemption if the animal has a history of severe allergic reaction to the vaccination.¹ Based on data from a neighboring state, on an annual basis, approximately 130 applications may be expected and approximately 100 exemptions may be issued in Virginia.

The main benefit of the proposed change is avoidance of a potentially life threatening allergic reaction the animal may develop. The main cost is the added chances of animal being infected with rabies because it is not vaccinated.

In addition, if an exemption is issued, the owner would not have to incur the cost of the vaccination and realize some savings. Each vaccination is estimated to cost approximately \$15 - \$20. However, VDH estimates a veterinarian would have to spend approximately 1 to 2 hours to gather necessary information to complete an exemption application. If a veterinarian chooses to charge for his or her additional time, the owners compliance costs may increase.

Finally, the local health director would be required to spend some time in reviewing exemption applications.

Another proposed change, pursuant to Chapter 834 of the 2010 Acts of Assembly, requires localities to have a response plan to rabies exposure. VDH estimates that most localities already have a plan to respond to rabies exposure. Nonetheless, the proposed regulations also provide a model plan localities may choose to use in part or in total. This proposed change is expected mainly to improve coordination and communication among local government authorities in responding to rabies exposure.

All of the remaining changes appear to be clarifications of current requirements and are not anticipated to create any significant economic impact.

Businesses and Entities Affected. There are 134 local governments, approximately 130 dog or cat owners who are estimated to apply for an exemption, and over 700 full service veterinary hospitals in Virginia.

Localities Particularly Affected. The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment. Approximately 1 to 2 hours may be required to gather necessary information to complete an exemption application. Also, the local health director would be required to spend some time in reviewing exemption applications. Thus, a small increase in demand for labor may be expected.

Effects on the Use and Value of Private Property. The proposed regulations are not anticipated to have a direct impact on the use and value of private property.

Small Businesses: Costs and Other Effects. The vast majority, if not all, of over 700 full-service veterinary hospitals are believed to be small businesses. As discussed, the proposed exemption may require veterinarians to spend approximately

1 to 2 hours of their time to gather information. Veterinarians will choose whether or not to charge for this additional time.

Small Businesses: Alternative Method that Minimizes Adverse Impact. There is no known alternative that has no effect on veterinarians while accomplishing the same goals.

Real Estate Development Costs. The proposed regulations have no effect on real estate development costs.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

¹ The proposed exemption is for licensing purposes only in that if the animal is exposed to rabies, euthanasia or 6-month strict isolation will still be required.

Agency's Response to Economic Impact Analysis: The Virginia Department of Health has reviewed and agrees with the Virginia Department of Planning and Budget's economic impact analysis.

Summary:

The proposed regulations (i) establish a procedure for issuing exemptions for rabies vaccination, (ii) require localities to have a response plan to rabies exposure, and (iii) establish requirements for recordkeeping associated with rabies clinics.

CHAPTER 105
RABIES REGULATIONS

12VAC5-105-10. Definitions.

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

"Currently vaccinated" means the animal was (i) vaccinated by a licensed veterinarian or a licensed veterinary technician under the direct supervision of a licensed veterinarian on the premises and (ii) the animal was vaccinated and revaccinated in accordance with the current National Association of State Public Health Veterinarian's Compendium of Animal Rabies Prevention and Control or as described on the U.S. Department of Agriculture approved vaccine label. For the purposes of rabies exposure response and § 3.2-6522 of the Code of Virginia, an animal will not be considered currently vaccinated until it has been at least 28 days since the initial vaccination and then immediately after every subsequent vaccination.

"Department" means the Virginia Department of Health.

"Rabid animal" means an animal that has had the diagnosis of rabies confirmed by the Virginia Division of Consolidated Laboratory Services, Fairfax Health Department Laboratory, Centers for Disease Control and Prevention Rabies Laboratory, or a laboratory in any state that is recognized by that state to perform rabies testing for public health purposes. Any suspected rabid animal that has exposed a companion or agricultural animal or a person and is not available for laboratory testing should be presumed to be rabid.

"Rabies exposure" or "exposed to rabies" means any circumstance where saliva or central nervous system tissue from a rabid or suspected rabid animal entered or could have entered a fresh, open wound or come in contact with a mucous membrane of a person or susceptible species of companion or agricultural animal. For the purposes of companion and agricultural animal exposure, the actual witnessing of a bite or attack by a rabid or suspected rabid animal is not necessary to define an exposure; however, a rabid or suspected rabid animal needs to have been witnessed in close proximity to the exposed animal and where, in the judgment of the local health director or his designee, it is reasonable to assume that the rabid or suspected rabid animal could have exposed the susceptible companion or agricultural animal. The department should notify the Virginia Department of Agriculture and Consumer Services when agricultural animals meet exposure criteria and coordinate exposure response with that agency. This definition notwithstanding, decisions regarding the disposition of animals housed or maintained with an agricultural animal that is diagnosed with rabies shall be at the discretion of the local health director.

"Rabies vaccination certificate" means a document provided by a licensed veterinarian or a licensed veterinary establishment indicating a specific animal has been vaccinated or revaccinated in accordance with the National Association of State Public Health Veterinarian's Compendium of Animal Rabies Prevention and Control or as described on the U.S. Department of Agriculture approved vaccine label and includes at least, but is not limited to, the following: signature of the veterinarian, the animal owner's

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name and address, the locality where the animal resides, the species of the animal, the sex, whether or not the animal is spayed or neutered, the age, the color, the primary breed, the certificate expiration date, and the vaccination number, also known as the serial lot number. In lieu of individual certificates, a herd certificate can be issued for livestock other than horses that includes at least the signature of the veterinarian, the owner's name and address, the species of animal, the sex, the approximate age, the primary breed, date of vaccination, the rabies vaccine product name, the vaccination number, identifying information for each animal such as ear tag number, tattoo or other permanent identification, and the name and contact information of the veterinarian who administered the vaccine. In lieu of individual certificates, a certificate of veterinary inspection for use in shipping equine may be generated for horses that includes at least the signature of the veterinarian, the owner's name and address, the sex, the approximate age, the date of vaccination, the rabies vaccine product name, the vaccination number, identifying information for each horse such as name, color, markings, tattoo or brand, and the name and contact information for the veterinarian who administered the vaccine.

"Suspected rabid animal" means any animal that has not been tested for rabies and that the department considers to be a species at high risk for acquiring or transmitting rabies whether or not the animal is exhibiting clinical signs compatible with rabies and any animal the department considers at low risk for acquiring or transmitting rabies that is exhibiting clinical signs compatible with rabies. At the discretion of the local health director, any animal to which an observation period will be applied that may have bitten a person shall be considered a suspected rabid animal until the end of the observation period. The status of animals for which an observation period will not be applied or that the department has not identified as either high or low risk for acquiring or transmitting rabies shall be at the discretion of the local health director.

12VAC5-105-20. Rabies clinics.

The local health department (LHD) will maintain and provide upon request the following information about rabies clinics that it and the local governing body have approved within the previous 48 months:

1. Date.
2. Clinic site.
3. Name of sponsoring organization.
4. Name, address, and phone number of attending veterinarian.

12VAC5-105-30. Rabies vaccine exemptions.

A. The local health director, in consultation with the state public health veterinarian, may grant an exemption to the requirement for rabies vaccination as articulated in § 3.2-6521 of the Code of Virginia if a vaccination would likely

endanger the animal's life due to a previously diagnosed disease or other previously documented medical considerations as documented by a licensed veterinarian.

B. Such exemption may be granted for an individual animal only after the veterinarian has (i) consulted with the local health director and completed and submitted to the LHD an application for exemption from rabies vaccination on a form approved by the department and (ii) submitted other documents or medical records as may be requested by the LHD. After approval of such exemption, the LHD shall issue a rabies vaccination exemption certificate, copies of which shall be provided to the veterinarian, the owner of the dog or cat exempted from rabies vaccination, and the animal control office of the municipality in which the owner of the dog or cat resides. Certification that a dog or cat is exempt from rabies vaccination may be presented in lieu of a rabies vaccination certificate for the purposes of veterinary inspection by designated local authorities and for the purposes of licensing by the locality where the animal resides. Certification that a dog or cat is exempt from rabies vaccination shall be valid for one year, after which time the animal shall be vaccinated against rabies or the application for exemption shall be renewed.

C. The governing body of any locality may require that an exempted animal be confined on the owner's property or kept on a leash, or both, or otherwise restrained if it is thought necessary to protect public health and safety. The governing body of any locality may require that a form of unique identification is associated with an exempted animal. An exempted animal shall be considered unvaccinated by the department in the event of the animal's exposure to a confirmed or suspected rabid animal. Any requirement to vaccinate an exempted animal for rabies in the event of that animal's exposure to a confirmed or suspected rabid animal shall be at the discretion of the local health director.

12VAC5-105-40. Model plan for localities.

A. Localities are required to have a rabies exposure response plan by § 3.2-6562.1 of the Code of Virginia. Pursuant to the second enactment of Chapter 834 of the 2010 Acts of Assembly, the department has developed a model plan that localities may use in part or in total to fulfill this requirement. In addition, localities may want to consider including information that will assist the plan's users with assessing rabies exposure and making post-exposure prophylactic (PEP) recommendations, communication with local authorities involved in rabies exposure response, documenting information associated with rabies exposure, and any other duties associated with response.

B. Model plan.

Title: Human and Companion Animal Rabies Exposure Protocol.

Section I. Purpose. The purpose of this plan is to:

A. Ensure the prompt capture, confinement, isolation, or euthanasia of any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies by standardizing procedures associated with investigating such incidents.

B. Identify the authority and responsibility of the LHD, law-enforcement officers, animal control officers, and any other persons with a duty to control or respond to a risk of rabies exposure.

C. Establish consistent communication and reporting of possible rabies exposure incidents to ensure residents living in the locality receive appropriate guidance and residents and their animals receive protection against rabies infection by including them within the scope of the LHD epidemiology staff, LHD environmental health, LHD nursing staff, and locality animal control staff or any personnel acting in the capacity of a locality animal control officer and locality law enforcement. Officials who have entered into a memorandum of understanding with the LHD agree to employ standard written guidelines in response to possible human and animal rabies exposures.

D. Establish a plan to control the risk of rabies exposure and ensure prompt response to rabies-related incidents in order to minimize companion animal and human morbidity and mortality in the locality.

Section II. Locality Employees to Whom Policy Applies. This policy applies to positions assigned to the LHD environmental health staff, LHD nursing staff, LHD epidemiology staff, and any LHD or locality animal control staff employee who receives an initial report of an animal bite/possible rabies exposure. Further, this policy outlines the roles of locality animal control staff and any personnel who may be acting in the capacity of a locality animal control officer and any locality law-enforcement officials who have entered into a memorandum of understanding with the LHD for this purpose and shall herein be referred to as "locality animal control services."

Section III. Legal Authority. Authority for the local health director to develop a local authority and responsibility plan that shall provide for those within the locality with a duty to control or respond to a risk of rabies exposure and to be directed by the local health director for such purposes is articulated in § 3.2-6562.1 of the Code of Virginia (included below).

§ 3.2-6562.1. Rabies exposure; local authority and responsibility plan.

The local health director, in conjunction with the governing body of the locality, shall adopt a plan to control and respond to the risk of rabies exposure to persons and companion animals. Such plan shall set forth a procedure that promptly ensures the capture, confinement, isolation, or euthanasia of any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies. The plan shall identify the authority and responsibility of

the local health department, law-enforcement officers, animal control officers, and any other persons with a duty to control or respond to a risk of rabies exposure. The plan shall provide for law-enforcement officers, animal control officers, and other persons to report to and be directed by the local health director for such purposes.

Section IV. Maintenance. This plan is a working document. In an effort to maintain a current rabies response plan, which addresses emergent issues and changing knowledge, the plan will be reviewed and supplemented as needed as a result of lessons learned during investigations or to comply with updated guidance and legislative requirements.

Section V. Disclaimer. This plan is meant to be used as a guide. No single set of guidelines applies to all situations involving rabies or can provide all of the information needed. The contents of the plan are meant to offer a framework for response as well as support and complement appropriate, practical public health knowledge and experience.

Section VI. Responsibility of Locality Animal Control Services. As directed by the local health director, it shall be the duty of locality animal control services to capture, confine, isolate, or euthanize any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies. If such personnel is unable to capture, confine, isolate, or euthanize a companion animal that (i) is reasonably suspected to be rabid and (ii) has exposed, or poses an immediate risk of exposing, a person or companion animal to rabies, such personnel shall ensure the humane destruction of such animal.

A. Companion Animal Response. Locality animal control services shall within 24 hours of receiving information about a companion animal exposure:

1. Investigate reports of susceptible companion animals exposed to rabies.
2. Determine if the companion animal has or may have been exposed to a rabid animal, and if the companion animal is currently vaccinated.
3. Evaluate the exposure of the companion animal and prescribe the appropriate action according to state and local regulations.
4. Ensure that exposed, currently vaccinated companion animals receive a booster vaccination.
5. Notify the LHD about any unvaccinated, exposed companion animals, or exposed companion animals with an expired vaccination status in order to relay details of the exposure, vaccination history if applicable, and discussion with the owner concerning the potential options.
6. Notify the LHD about any exposed companion animals that are not dogs, cats, or ferrets.
7. Immediately notify the LHD about any illness associated with any animal in confinement or isolation.

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8. Facilitate the submission of the head of any animal that may have exposed a companion animal to rabies as directed by the LHD.

9. Carry out euthanasia or humane destruction of companion animals and suspected rabid animals that may have exposed companion animals as directed by the state agency with jurisdiction over that species.

10. Submit reports associated with any companion animal exposures to the LHD.

B. Human Exposure Response. In regard to situations involving human exposure, locality animal control services shall:

1. Upon receiving information about a human exposure immediately report the exposure to the LHD by the fastest means possible.

2. Not disclose the identity of any victim of an animal bite or rabies exposure except to a health care provider or official of the LHD.

3. If possible, secure any animal that may have exposed a person, pending advice from the LHD as to how to proceed with either observation or testing.

4. Carry out euthanasia or humane destruction of companion animals and suspected rabid animals that may have exposed a person as directed by the state agency with jurisdiction over that species.

5. Facilitate the submission of the head of any animal that may have exposed a person to rabies as directed by the LHD.

Section VII. Responsibility of the LHD. As directed by the local health director, it shall be the duty of LHD environmental health staff, LHD nursing staff, and LHD epidemiology staff to respond to human and companion animal rabies exposures as detailed below. Any LHD employee who receives a report associated with a companion animal or human rabies exposure shall notify a member of the LHD environmental health staff, LHD nursing staff, or LHD epidemiology staff within 24 hours of receiving the report.

A. LHD Environmental Health Staff. Environmental health staff members are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Interfacing with locality animal control services and ensuring that any animals involved in a possible rabies exposure incident are appropriately managed to control the spread of rabies viral infection.

2. Initiating contact with a human exposure victim and coordinating contact with a companion animal owner with locality animal control services when necessary by phone or site visit within two hours of receiving an exposure report.

3. Conducting a site visit to investigate a human exposure and coordinating a site visit with a companion animal

owner with locality animal control services when necessary within 24 hours of the report.

4. Notifying the LHD nursing staff and the local health director within 24 hours of receiving a report of a human exposure victim.

5. Coordinating with locality animal control services to locate, and contain or retrieve animals, and collect clinical animal specimens as necessary.

6. Coordinating the submission of rabies samples to a laboratory that has been designated by the Commonwealth for rabies testing.

7. Maintaining a record of human and companion animal exposures as well as test results associated with rabies sample submissions.

8. Immediately notifying LHD nursing staff and the local health director of any positive results associated with human exposures.

9. Notifying any human exposure victims of positive results within two hours of receiving the result and referring the victim to the LHD nursing staff in regard to PEP treatment options.

10. Coordinating with locality animal control services the notification of owners of positive results associated with exposed companion animals within 24 hours of receiving the result.

11. Coordinating with locality animal control services the response to exposed companion animals and owner follow up to evaluate the situation for any human exposures.

12. Notifying the local health director, LHD nursing staff, and LHD epidemiology staff within 24 hours of any negative results associated with rabies sample submissions.

13. Notifying the LHD epidemiology staff with 24 hours of any positive results associated with rabies sample submissions.

14. Notifying the local health director, LHD nursing staff, and locality animal control services within 24 hours of any companion animal that has been placed in isolation or confinement that is manifesting clinical signs that could be compatible with rabies.

15. Notifying locality animal control services within 24 hours of a companion animal for which rabies vaccination is required that is not vaccinated or has an expired status.

16. Developing and maintaining a human and companion animal rabies exposure communication plan that is shared with locality animal control services.

17. In coordination with the local health director, LHD nursing staff, and LHD epidemiology staff, developing and maintaining a training program that can be used to review locality rabies control and response procedures

with locality animal control services on an as needed basis and/or as new staff are hired.

B. LHD Nursing Staff. LHD nursing staff members are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Ensuring that any humans involved in a possible rabies exposure incident are appropriately counseled/treated to control the risk of rabies viral infection.
2. Notifying the environmental health staff of a human or companion animal exposure within two hours of receiving a report if the report did not originate with environmental health staff.
3. Coordinating human exposure follow up with environmental health staff and assisting with human exposure assessment interviews within 24 hours of receiving a report of an exposure.
4. Coordinating the notifying of human exposure victims with environmental health staff immediately after receiving a positive test result.
5. Coordinating the notifying of human exposure victims with environmental health staff within 24 hours of receiving a negative test result.
6. Discussing PEP treatment options within the locality with human exposure victim(s).
7. Discussing medical conditions and history with human exposure victims that may affect PEP treatment.
8. Maintaining a record of medical information associated with all human exposure victims interviewed and counseled, including the exposure victim's decision concerning PEP treatment and if treatment was completed.
9. Notifying the LHD epidemiology staff when a human exposure victim initiates PEP treatment and providing any information about the situation necessary for statistical purposes.
10. Coordinating follow up with exposure victims if PEP treatment recommendations are not followed.
11. Coordinating the notification of human exposure victims with environmental health staff in regard to confinement release results within 24 hours after the confinement period.

C. Locality Epidemiology Staff. Locality epidemiology staff members are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Collecting and maintaining the following data in coordination/consultation with the environmental health staff and nursing staff for animal exposures/bites, animal bites to humans, and other human exposures:
2. Demographics of person exposed;
3. Information about the animal and its owner;

4. Details of exposure;

5. PEP recommendations and actions;

6. Animal euthanasia secondary to suspect rabies; and

7. Animal quarantine or confinement

D. Local Health Director. The local health director is primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Developing memoranda of understanding with locality animal control services for the purpose of organizing an integrated response to human and companion animal exposures within the locality and acknowledging the need for locality animal control services to be directed by the local health director in certain rabies related situations.
2. Overseeing companion animal and human exposure response within the locality.
3. Providing medical advice and consultation in regard to human exposure victims to environmental health staff, nursing staff, and human exposure victims within the locality.
4. Providing medical advice and consultation about rabies and rabies PEP treatment with health care providers within the locality.
5. Developing a guidance document for locality animal control services that contains examples of rabies response and control situations requiring locality animal control services staff to be specifically directed by the local health director.

NOTICE: 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 (12VAC5-105)

[Request for Rabies Vaccination Exemption for Licensing and Inspection Purposes \(eff. 3/12\)](#)

VA.R. Doc. No. R11-2637; Filed November 5, 2013, 9:41 a.m.

Fast-Track Regulation

Title of Regulation: 12VAC5-191. State Plan for the Children with Special Health Care Needs Program (amending 12VAC5-191-10, 12VAC5-191-40, 12VAC5-191-80, 12VAC5-191-90, 12VAC5-191-210, 12VAC5-191-250).

Statutory Authority: §§ 32.1-12 and 32.1-77 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 1, 2014.

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Effective Date: January 24, 2014.

Agency Contact: Emily McClellan, Manager, Survey and Analysis Unit, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7249, FAX (804) 864-7647, or email emily.mclellan@vdh.virginia.gov.

Basis: Section 32.1-12 of the Code of Virginia authorizes the State Board of Health to make, adopt, promulgate and enforce regulations. Section 32.1-77 of the Code of Virginia (i) authorizes the board to prepare, amend, and submit state plans for maternal and child health services and children's specialty services pursuant to Title V of the United States Social Security Act to the U.S. Secretary of Health and Human Services and (ii) authorizes the State Health Commissioner to administer the plan and to receive and expend federal funds for the administration of the plan in accordance with applicable federal and state laws and regulations.

Section 32.1-64.1 of the Code of Virginia mandates the commissioner to establish and maintain the Virginia Hearing Impairment Identification and Monitoring System for the purpose of identifying and monitoring infants with hearing impairment to ensure that such infants receive appropriate early intervention through treatment, therapy, and education; § 32.1-64.1 D mandates the board to establish regulations for the screening, and § 32.1-64.1 F authorizes the board to promulgate rules and regulations as may be necessary to implement this identification and monitoring system.

Section 32.1-65 of the Code of Virginia mandates certain newborn screening testing of all infants, except for those exempted from testing by law, for specified disorders.

Section 32.1-66 of the Code of Virginia mandates the commissioner to notify the attending physician of any newborn screening test results that indicate a suspicion of a disorder and to perform or provide for any additional testing required to confirm or disprove the diagnosis of the specified disorders.

Section 32.1-67 of the Code of Virginia mandates the board to recommend procedures for the treatment of disorders identified by a newborn screening test.

Section 32.1-68 of the Code of Virginia mandates the commissioner, in cooperation with local health directors, to establish a voluntary program for the screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related diseases and genetic traits and inborn errors of metabolism as the board may deem necessary. The board shall review the program from time to time to determine the appropriate age and the method of screening for such conditions or traits in the light of technological changes. The screening program shall include provisions for education concerning the nature and treatment of sickle cell anemia, other genetically related diseases, and inborn errors of metabolism and provisions for a post-screening counseling program for the treatment of any person determined to have such a condition. The program may include the provision of laboratory testing.

Section 32.1-69.1 of the Code of Virginia mandates the commissioner to establish and maintain a Virginia Congenital Anomalies Reporting and Education System using data from birth certificates filed with the State Registrar of Vital Records and data obtained from hospital medical records. The chief administrative officer of every hospital, as defined in § 32.1-123 of the Code of Virginia, shall make or cause to be made a report to the commissioner of any person under two years of age diagnosed as having a congenital anomaly. Section 32.1-123 B mandates the board to promulgate regulations as may be necessary to implement this reporting and education system. These regulations may include scope of information to be collected and relationships between the reporting and education system and other agencies.

Section 32.1-89 of the Code of Virginia mandates the board to establish a program for the care and treatment of persons suffering from hemophilia and other related bleeding diseases who cannot pay for the entire cost of their needed medical care. Section 32.1-89 B authorizes the board to provide services through cooperative agreements with medical facilities or other appropriate means. This subsection also states that charges for persons receiving care shall be determined by the board.

All of these authorized and mandated programs serve children with special health care needs. Separate regulations 12VAC5-71, Regulations Governing Virginia Newborn Screening Services, and 12VAC5-80, Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System, exist for these programs. Relationships among the programs are addressed in 12VAC5-191.

Purpose: A periodic review of 12VAC5-191 was conducted starting on April 6, 2011. The public comment period ended on May 30, 2011. An ad hoc regulatory workgroup met on June 2, 2011, to review the regulation and public comments.

The workgroup recommended amending the regulation through the fast-track rulemaking process to correct references to other regulations, laws, and organizational entities that have changed since the regulation went into effect in 2007.

This regulation is essential to outline program services for children with special health care needs that are made available to eligible residents within available appropriations and to help those residents qualify for federal Title V and other available funds for plan administration. Although the program is neither an entitlement nor a federal, state, or local public benefit, the program does offer certain services and assistance, contingent upon adequate funding, which may affect the rights of individuals.

Other state-mandated initiatives, such as the Virginia Newborn Screening System, Virginia Congenital Anomalies Reporting and Education System, Virginia Sickle Cell Awareness Program, and Pediatric Comprehensive Sickle Cell Clinic Network also identify and serve children with special health care needs. These programs, several of which

have separate regulations, are now referenced in this regulation as well.

The amended regulation serves to protect the health and welfare of children with special health care needs.

Rationale for Using Fast-Track Process: Executive Order 14 (2010) allows state agencies to use a fast-track rulemaking process to expedite regulatory changes that are expected to be noncontroversial. The amendments to 12VAC5-191-10, 12VAC5-191-40, 12VAC5-191-80, and 12VAC5-191-210 are not substantive changes. These amendments will update certain terms and references to other regulations, laws, and organizational entities that have changed since 2007. The amendments to 12VAC 5-191-90 and 12VAC 5-191-250 are substantive but are not expected to be controversial.

Substance: The amendments to 12VAC5-191-90 remove multiple specific citations to privacy and confidentiality laws and substitute the term "all applicable federal and state laws and regulations." The amendments to 12VAC5-191-250 reflect changes in organizational structure and functions due to changes in grant funding and activities. Otherwise the amendments are for clarification and to update citations.

Issues: The primary advantage of amending this regulation is to keep references within the regulation current and up to date. There are no primary disadvantages.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The State Board of Health proposes to update references to other regulations, laws, and organizational entities. The proposed changes also reflect the updated functions of genetics and newborn screening services stemming from changes in grant funding.

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

Estimated Economic Impact. The State Board of Health proposes to update references to other regulations, laws, and organizational entities. The proposed changes also reflect the updated functions of genetics and newborn screening services stemming from changes in grant funding.

None of the proposed regulations will have an impact on the current practices followed by Virginia Department of Health. Thus, the proposed changes are not expected to have any significant direct economic impact other than improving the clarity and accuracy of the regulatory language.

Businesses and Entities Affected. Currently, approximately 9,900 children under age 21 are served by the Children with Special Health Care Needs Program.

Localities Particularly Affected. The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment. No significant impact on employment is expected.

Effects on the Use and Value of Private Property. No significant impact on the use and value of private property is expected.

Small Businesses: Costs and Other Effects. No significant costs or other effects on small businesses are expected.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed regulations are not anticipated to have an adverse impact on small businesses.

Real Estate Development Costs. No significant effect on real estate development costs is expected.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The Virginia Department of Health has reviewed the economic impact analysis pertaining to this regulatory action and concurs with its findings.

Summary:

The amendments (i) update references to other regulations and laws and (ii) modify references where organizational structures, names, or functions have changed since the regulation was promulgated in 2007.

12VAC5-191-10. Definitions.

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

"Appeal" means the client's right to seek relief from an unfavorable decision in obtaining services or assistance included in the plan.

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"Applicant" means an individual who applies for the services under this regulation. An application may be filed for or on behalf of a minor or person under a legal disability by a parent, legal guardian, and attorney in fact, or an attorney at law.

"Bleeding disorders" means inherited problems in coagulation caused by missing or poorly functioning proteins in the blood such as hemophilia and von Willebrand Disease.

"Board" means the State Board of Health.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Center" means a unit providing Care Connection for Children services.

"CCC" means Care Connection for Children.

"Children and youth with special health care needs" means individuals who are ages birth to their twenty-first birthday and have, or are at increased risk for, a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally.

"Client" means an individual who meets all the eligibility criteria for a program and has been accepted for services.

"Commissioner" means the Commissioner of Health.

"Community-based" means a framework within which a variety of programs work together to meet the many, varied needs of children, youth, and families in communities.

"CSHCN" means children with special health care needs.

"Culturally-competent" means the ability to provide services to clients that honor different cultural beliefs, interpersonal styles, attitudes and behaviors and the use of multicultural staff in the policy development, administration, and provision of those services.

"Department" means the ~~state~~ Virginia Department of Health and includes the central office, regional offices, health districts, and local health departments.

"Developmental disorder" means a delay(s) in maturation or deviant maturation of physical, language, sensory, motor, cognitive, social, learning or self-help capabilities to the extent that there is a negative impact on a child's ability to adapt to or cope with the typical environmental demands as expected for chronological age.

"Direct health care services" means medically necessary services for the treatment and monitoring of a condition(s) covered by the program. The services are generally delivered one-on-one between a health care professional and a client in an office, home, clinic, outpatient department, or hospital.

"Director" means the Director, Children with Special Health Care Needs Program.

"Division" means the Division of Child and ~~Adolescent~~ Family Health.

"Enabling services" means support services that allow or provide for access to and the receipt of benefits from an array of basic health care services.

"Family" means the client and other such household members who together constitute one economic unit. An economic unit is one or more individuals who generally reside together and share income.

"Family-centered care" means an approach to the planning, delivery, and evaluation of health care whose cornerstone is active participation between families and professionals. Family-centered care recognizes that families are the ultimate decision makers for their children, with children gradually taking on more and more of this decision-making themselves.

"Family-to-family support" means the provision of information and peer support among families having experience with family members having special health care needs.

"Guardian" means a court-appointed guardian of the person.

"Information and referral services" means assisting clients and their families to find available services, responding to inquiries from the general public, and disseminating information for accessing specific services.

"MCH" means maternal and child health.

"Medical home" means a concept in which the child has an ongoing source of health care from a primary care physician who works together with the family to ensure that the child has accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective medical care.

"Parent" means a biological or adoptive parent or a stepparent.

"Plan" means the State Plan for the Children with Special Health Care Needs Program prepared pursuant to Title V of the United States Social Security Act, as amended.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services.

"Population-based services" means preventive interventions and personal health services developed and available for the entire MCH population of the Commonwealth rather than for individuals in a one-on-one situation.

"Program" means the Children with Special Health Care Needs Program.

"Provider" means an individual or agency that provides a service under an agreement between the individual or agency and the Children with Special Health Care Needs Program or its contractors.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Services" means those activities provided or arranged by the various programs within the Children with Special Health Care Needs Program.

"Sickle cell disease" means any inherited hemoglobin pattern with a predominance of hemoglobin (S) in absence of, or greater than normal hemoglobin (A); or hemoglobin S with another hemoglobin variant such as C, D, or E or beta thalassemia.

"Sickle Cell Program Manager" means an employee of the Pediatric Comprehensive Sickle Cell Clinic Network who is designated to be responsible for the administration of the statewide Pediatric Comprehensive Sickle Cell Clinic Network.

"Transition services" means assisting the client and his family in the process of making necessary changes from life as a youth with special health care needs to life as an adult with special health care needs. Aspects to be addressed include health and wellness; education, vocation, and employment; mobility, transportation, and recreation; and legal, insurance, disability benefits, and housing.

"Underinsured" means having medically necessary service needs that exceed an individual's health insurance coverage limits.

"Uninsured" means having no private health insurance or state or federal medical assistance coverage.

12VAC5-191-40. Scope and content of the Children with Special Health Care Needs Program.

A. Mission. The Children with Special Health Care Needs Program promotes the optimal health and development of individuals living in the Commonwealth with special health care needs by working in partnership with families, service providers, and communities.

B. Scope. The scope of the Children with Special Health Care Needs Program includes the following:

1. Direct health care services.
2. Enabling services.
3. Population-based services.
4. Assessment of community health status and available resources.
5. Policy development to support and encourage better health.

C. Networks and Services. The Children with Special Health Care Needs Program administers the following networks and services:

1. Care Connection for Children.
2. Child Development Services.
3. Virginia Bleeding Disorders Program.
4. ~~Pediatric Screening and Genetics Services~~ Genetics and Newborn Screening Services.
 - a. Virginia Newborn Screening System.

- b. Virginia Congenital Anomalies Reporting and Education System.

5. Virginia Sickle Cell Awareness Program.
6. Pediatric Comprehensive Sickle Cell Clinic Network.

~~C.~~ D. Target population. The target population to receive services from the networks and programs within the Children with Special Health Care Needs Program are the following:

1. Residents of the Commonwealth.
2. Individuals between the ages of birth and their twenty-first birthday except that the Virginia Bleeding Disorders Program and the Virginia Sickle Cell Awareness Program serve individuals of all ages.
3. Individuals diagnosed as having, or are at increased risk for having, a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally.

Each network and program within the CSHCN Program has its own specific eligibility criteria.

~~D.~~ E. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals.

12VAC5-191-80. Appeal process.

A. An applicant for or client in receipt of services or assistance, as defined in this plan, may appeal the following actions:

1. Denial of services or assistance.
2. Termination of services or assistance.
3. Adverse determination regarding financial eligibility.

There are no further rights of appeal except as set forth in this section. Applicants or clients have no right of appeal of a denial of services or assistance because of a lack of funds.

B. The applicant or client has the right to receive a written statement of the reasons for denial and be informed in writing of the appeal process, including time limits.

C. If a client already receiving services or assistance is denied those services or assistance, a written notice of termination including the reason of denial shall be given 30 days in advance of discontinuing services.

D. First level of appeal: An individual or his representative may make a written or oral appeal to the employee designated to be responsible for the administration of the different programs (the Care Connection for Children Program Director, Administrative Director for the Child Development Services, Bleeding Disorders Program Coordinator, or Sickle Cell Program Manager) within 30 days of the denial of service. The respective program director, administrative director, program coordinator, or program manager shall review and make a written decision to the individual or his

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representative within 15 days from the date of receipt of the appeal.

E. Second level of appeal: If the individual is not satisfied with the decision provided at the first level of appeal, the individual may appeal the decision in writing to the Director of the Children with Special Health Care Needs Program within 30 days of the denial from the individual program.

F. Upon receipt of the appeal, the director shall review and make written recommendations to the commissioner, or the commissioner's designee, within 15 days. The director shall consider all written information and may confer, as deemed necessary, with the department's adjudication officer ~~in the Office of Family Health Services~~ or other relevant experts.

G. Within 45 days following the date on which an appeal is filed, the commissioner, or commissioner's designee, shall make a final decision.

12VAC5-191-90. Privacy.

A. The Children with Special Health Care Needs Program and program subcontractors shall protect the privacy of the client's personal health information and the confidentiality of medical records in accordance with ~~§§ 2.2-3700 through 2.2-3705.1, 2.2-3705.5, 2.2-3800 through 2.2-3809, 32.1-40, 32.1-41, 32.1-64.2, 32.1-67.1, 32.1-69, 32.1-69.2, 32.1-127.1:03, and 32.1-127.1:04 of the Code of Virginia; the federal Health Insurance Portability and Accountability Act of 1996 (42 USC §§ 1320 d et seq. and 45 CFR Part 164); and Title V of the Social Security Act (42 USC §§ 701-710, Subchapter V, Chapter 7 and 42 CFR 51a.6) all applicable federal and state laws and regulations.~~

B. Access to ~~minor's~~ minors' health records and the authority to consent to surgical and medical treatment for certain minors shall be administered in accordance with §§ 20-124.6 and 54.1-2969 of the Code of Virginia, respectively.

C. Surveillance and investigation shall be consistent with §§ 32.1-39, 32.1-40, 32.1-41 and 32.1-66 of the Code of Virginia.

D. The department's ~~children~~ Children with ~~special health care needs program~~ Special Health Care Needs Program and its contractors shall maintain security and confidentiality of databases in accordance with applicable federal and state laws and regulations.

12VAC5-191-210. ~~Scope~~ Scope and content of the Child Development Services Program.

A. Mission. The Child Development Services Program promotes the optimal physical, language, cognitive, social, learning, self-help, behavioral, and emotional development and well-being of children.

B. Scope of services. The child development clinics provide pediatric services in the specialty area of developmental and behavioral pediatrics. This health care field specializes in the diagnosis and treatment of developmental and psychosocial aspects of pediatric health care including developmental

disorders and emotional, behavioral, and psychosomatic problems.

Services offered at each clinic location may vary according to the needs of the community, expertise of the professional staff, and the overall goals and objectives for the current program.

The Child Development Services network provides the following direct health care services and enabling services:

1. Interdisciplinary evaluations that may include a pediatric medical examination, nurse evaluation, psychosocial history, psychological assessment, and educational evaluation.
2. Treatment planning that may include the evaluation team developing a written report that integrates their findings, establishes diagnoses, and formulates recommendations for each client.
3. Care coordination.
4. Consultation.
5. Screenings for early identification of persons with developmental disorders.
6. Screening services to assist other agencies in their program implementation as may be described in a contract or memorandum of agreement.
7. Information and referral.
8. Intervention services that may include medical, psychosocial, educational, or interdisciplinary treatment services.
9. Training and technical assistance for community providers.

C. Criteria to receive services from Child Development Services. Children and youth are eligible to receive services from Child Development Services if they are:

1. Residents of the Commonwealth.
2. Between the ages of birth and their twenty-first birthday.
3. Suspected to have or diagnosed with developmental, emotional or behavioral disorder or presence of severe or multiple risk factors for these conditions.

No financial eligibility criteria are required for clients to receive the enabling services. However, clients who meet the above criteria must also meet the financial requirements to receive direct health care services based on a sliding scale charge schedule. The amount of the required charge shall be in accordance with the State Board of Health ~~Regulation~~ Regulations Governing Eligibility Standards and Charges for ~~Health~~ Medical Care Services to Individuals, 12VAC5-200.

D. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals. The following goals shall change as needed to be consistent with the Title V national performance measures:

1. Children who are at greatest risk for developmental, emotional and behavioral disorders and in need of related services will receive early screening, diagnosis, and assistance in finding and accessing needed services.

2. Other state and local agencies will receive assistance in providing effective coordinated services for persons with special health care needs.

12VAC5-191-250. ~~Pediatric Screening and Genetics Services~~ **Genetics and Newborn Screening Services.**

~~The Pediatric Screening and Genetics Services unit Genetics and Newborn Screening Services works to improve the health of children and families by preventing birth defects and developmental disabilities, promoting optimal child development, and promoting health and wellness among children and adolescents living with disabilities.~~

~~Pediatric Screening and Genetics Services include several programs, services, and projects, two of which are Genetics and Newborn Screening Services includes the Virginia Newborn Screening System and the Virginia Congenital Anomalies Reporting and Education System.~~

VA.R. Doc. No. R14-2931; Filed November 6, 2013, 10:05 a.m.

Proposed Regulation

Title of Regulation: **12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-10, 12VAC5-481-290, 12VAC5-481-340, 12VAC5-481-350, 12VAC5-481-2110, 12VAC5-481-3410; adding 12VAC5-481-1581, 12VAC5-481-1591, 12VAC5-481-1601, 12VAC5-481-1611, 12VAC5-481-1621, 12VAC5-481-1631, 12VAC5-481-1641, 12VAC5-481-1651, 12VAC5-481-1653, 12VAC5-481-1655, 12VAC5-481-1657; repealing 12VAC5-481-1580, 12VAC5-481-1590, 12VAC5-481-1600, 12VAC5-481-1610, 12VAC5-481-1620, 12VAC5-481-1630, 12VAC5-481-1640, 12VAC5-481-1650).**

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

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 31, 2014.

Agency Contact: Steve Harrison, Acting Director, Division of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7001, FAX (804) 864-7022, or email steve.harrison@vdh.virginia.gov.

Basis: 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 board to promulgate regulations (i) for the registration, inspection, and certification of x-ray machines and (ii) to set the criteria for private inspectors.

Purpose: During the 2006 revision of the Virginia Radiation Protection Regulations, and in order for Virginia to become

an Agreement State, some definitions were deleted to comply with the Nuclear Regulatory Commission's rules (10 CFR). Some of these definitions, however, were used by the x-ray program. The proposed amendments will reinsert these definitions and update their verbiage such that they would apply only to X-ray registrants.

The Conference of Radiation Control Program Directors (CRCPD) has Suggested State Regulations (SSR) upon which individual states may base their regulations. 12VAC5-481 was based upon the SSRs in 2006.

The sections in Part VI were repealed and new sections were inserted that include the 2009 revised CRCPD SSRs to ensure that Virginia's regulations conform to the most recent SSRs.

Substance: The CRCPD SSRs were updated in 2009 to reflect current practices and devices used in the x-ray field. Virginia's x-ray regulations were last updated to conform to the CRCPD SSRs in 2006. 12VAC5-481 is amended to reflect and conform to the current practices and to include regulations that govern all devices used in the x-ray field.

Issues: The advantage of the proposed regulation is that businesses regulated by both federal agencies and the department will operate under identical standards, which will eliminate some confusion, particularly with respect to occupational worker standards and x-ray machine performance standards. Another advantage for 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. The proposed amendments include definitions that were removed in 2006 that pertain to the x-ray program. There are no disadvantages to the public in promulgating the proposed regulation.

The advantage of the proposed regulation to the agency is that fewer interpretations of the regulation will be needed for new radiation machines or materials that were developed since the promulgation of the existing regulation and not addressed. Another advantage is that agency staff will no longer need to take additional time to explain regulatory differences to facilities that are dually regulated by a federal agency. There are no disadvantages to the agency in promulgating the proposed regulation.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The State Board of Health (Board) proposes to amend these regulations to: 1) reflect changes to federal regulations, 2) reflect new X-ray modalities in the medical field, 3) reduce the frequency of required inspections for lower-risk equipment, 4) update definitions, and 5) update formatting and style to meet the current Virginia Register Form, Style, and Procedure Manual.

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

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Estimated Economic Impact. The proposed amendments that reflect federal regulations will not change requirements for the regulated community since they are already required to follow federal rules. Amending the state regulations to reflect the federal rules will be beneficial in that it will improve clarity.

The Board proposes to permit the use of portable hand-held x-ray dental equipment under specified requirements. Currently these are not permitted. The devices are considered safe and are known to be in demand. Thus this proposal should produce a net benefit.

The Board also proposes to change the frequency of the radiation survey requirement for analytical x-ray systems from once every year to once every five years. Due to the nature of the equipment, safety is not expected to be adversely affected. Private inspectors charge approximately \$250 per unit inspection.¹ There are approximately 1250 units in the Commonwealth.² Thus, there would be approximately \$250,000 savings annually.³

Businesses and Entities Affected. Currently, the X-ray program registers approximately 7,500 entities, including medical offices, hospitals, laboratories, courts, etc. Approximately 7,000 of these entities meet the small business criteria.⁴ Also, the proposal to permit the use of portable hand-held x-ray dental equipment under specified requirements will affect the manufacturers and sellers of these devices.

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

Projected Impact on Employment. The proposed amendments are unlikely to significantly affect employment.

Effects on the Use and Value of Private Property. The proposal to change the frequency of the radiation survey requirement for analytical x-ray systems from once every year to once every five years would save private users of analytical x-ray systems \$200 per unit average over each five-year period.⁵ The proposal to permit the use of portable hand-held x-ray dental equipment under specified requirements will increase the use of these devices and likely increase profits for the manufacturers and sellers of the devices.

Small Businesses: Costs and Other Effects. The proposal to change the frequency of the radiation survey requirement for analytical x-ray systems from once every year to once every five years would save small businesses that use analytical x-ray systems \$200 per unit average over each five-year period.⁶

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed regulations do not adversely affect small businesses.

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

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

¹ Source: Interview with a Virginia private inspector

² Source: Virginia Department of Health

³ $\$250 \times 1250 \times 4/5 = \$250,000$

⁴ Source: Virginia Department of Health

⁵ $\$250 \times 4/5 = \250

⁶ Ibid

Agency's Response to Economic Impact Analysis: The Division of Radiological Health has reviewed the economic impact analysis prepared by the Virginia Department of Planning and Budget dated March 17, 2012. The division has the following comments:

1. In the Estimated Economic Impact section on Page 1, it states private inspectors charge approximately \$250 per unit inspection. According to footnote 1 it states source: interview with a Virginia private inspector. The division recommends the sentence be changed to: One private inspector charges approximately \$250 per unit inspection.

2. The next sentence states that there are approximately 1250 units in the Commonwealth. Thus, there would be approximately \$250,000 savings annually. These units are not required to be inspected; thus, this statement is not accurate. DPB's sentence should be amended to include if the units are required to be inspected. This analysis is based upon 12VAC5-481-2110 which states that radiation surveys as required by 12VAC5-481-750. The regulation in 12VAC5-481-750 is a radiation survey

and not an inspection. The division will begin to develop a new regulatory action to address this.

3. The division recommends that a statement be included in the Small Businesses section that this is based upon one private inspector's cost and if the unit was required to be inspected under 12VAC5-481. Currently the regulations for analytical X-ray equipment under Part VIII are not required to be inspected. The division will begin to develop a new regulatory action to address this.

Summary:

The proposed amendments (i) reflect changes to federal regulations, (ii) reflect new x-ray modalities in the medical field, (iii) reduce the frequency of required inspections for lower-risk equipment, (iv) update definitions, and (v) make minor grammatical and clarifying changes.

Part I

General Provisions

12VAC5-481-10. Definitions.

As used in these regulations, these terms have the definitions set forth below.

"A₁" 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.

"A₂" 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.

"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 one-time 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).

~~"Added filtration" means any filtration that is in addition to the inherent filtration.~~

"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.

"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 (K)" or "K" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of De by Dm, where De is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass Dm. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy) 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 air-purifying filter, cartridge, or canister that removes specific air

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

"Analytical ~~X-ray~~ 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" (~~ALI~~) 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.

"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 (~~APF~~)" 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" (~~ALARA~~) 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~~ x-ray system or subsystem. The term includes the owner of an ~~X-ray~~ x-ray system or his or her employee or agent who assembles components into an ~~X-ray~~ 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—~~(AEC)~~" or "AEC" means a device that automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation (includes devices such as phototimers and ion chambers).

"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~~ x-ray fields.

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the ~~X-ray~~ x-ray field.

"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" (~~Bq~~) 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

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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 ~~X-ray~~ x-ray system fluoroscope" means an ~~X-ray~~ x-ray system in which the image receptor and ~~X-ray~~ 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~~ x-ray system" means an ~~X-ray~~ x-ray system with the ~~X-ray~~ x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet ~~X-ray~~ 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~~ 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~~ x-ray tube used within a shielded part of a building, or ~~X-ray~~ x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet ~~X-ray~~ x-ray 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.

~~"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.~~

"Certifiable cabinet ~~X-ray~~ x-ray system" means an existing uncertified ~~X-ray~~ 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-~~(CoC)~~" 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~~ x-ray system" means an ~~X-ray~~ 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~~ 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.

~~"Certified system" means any X-ray system which has one or more certified component(s).~~

"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.

~~"Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.~~

"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 "see-through" type.

"cm" means centimeters.

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

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where:

- s = Standard deviation of the observed values;
- \bar{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" (~~H_{E,50}~~) 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" (~~H_{E,50}~~) 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 ($H_{E,50} = \sum (w_T H_{T,50})$).

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of ~~X-ray~~ 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:

$$CTDI = 1/nT \int_{-7T}^{+7T} D(z) dz$$

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 (dose constraint)~~" or "dose constraint" means a value above which specified licensee actions are required.

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"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_w = Linear attenuation coefficient of the material of interest;

μ_x = Linear attenuation coefficient of water;

\overline{CTN}_x = of the material of interest;

\overline{CTN}_w = of water.

"Control ~~(drive)~~ 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~~ 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.

"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—~~(CSI)~~" 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~~ 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, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

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

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

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.

~~"Dead man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.~~

"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" (~~H_d~~, 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 sections 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 section 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" (~~DAC~~) 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" (~~DAC-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~~ x-ray system" means an ~~X-ray~~ x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

~~"Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image.~~

"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 or 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

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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.

"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 (~~H_T~~)" 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 (~~DMU~~)" 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 (~~H_E~~)" 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 ($H_E = \sum w_T H_T$).

"Elemental area" means the smallest area within a tomogram for which the ~~X-ray~~ 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 (~~ECS~~)" 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 exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.~~

"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").

"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 used.

"Fail-safe characteristics" mean 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 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 (~~dusk mask~~)" 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.

"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 x-ray~~ photons produce a ~~visible image set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor~~. It includes the image receptor(s) ~~such as the image intensifier and spot film device 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 operator-applied 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 (~~actual~~)" or "actual" means the area projected on the anode of the ~~X-ray 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.

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"General purpose radiographic ~~X-ray~~ x-ray system" means any radiographic ~~X-ray~~ x-ray system which, 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 (~~HVL~~)" or "HVL" 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 half of the value measured without the material at the same point~~ 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 A 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~~ 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~~ 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 (~~HIC~~)" 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.

"HVL" (See "Half value layer").

"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~~ x-ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen or, ~~radiographic film,~~ x-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident ~~X-ray~~ x-ray 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 ~~mammography~~ 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").

~~"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.~~

"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.

"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 useful beam axis passes while the gantry moves through its full range of motions when the equipment moves through a full range of rotations about its common center.

"kBq" means kilobecquerels.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus K=dE_{tr}/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 (kV) (kilo electron volt (keV))" 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").

"kW" means kilowatt second.

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"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 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, ~~i.e., 10 milliamperere seconds (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 maximum-rated number of ~~X-ray 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 ~~(LDE)~~" 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 cm (300 mg/cm²).

"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 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.

"Limits" (See "Dose limits").

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a ~~percentage percent~~ of the load line potential. ~~It is calculated using the following equation as follows:~~

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where:

V_n = No-load line potential; and

V_l = Load line potential.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Local components" mean part of an analytical ~~X-ray x-ray~~ system and include areas that are struck by ~~X-rays 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.

"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 ~~(LSA)~~ material" or "LSA" 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 $1.0 \text{ E-}04 \text{ A}_2/\text{g}$ for solids and gases, and $1.0 \text{ E-}05 \text{ A}_2/\text{g}$ 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 (for example: 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 $2.0 \text{ E-}03 \text{ A}_2/\text{g}$.

"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.

~~"Maximum line current" means the root mean square current in the supply line of an X-ray machine operating at its maximum rating.~~

"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-(MV) (mega electron volt (MeV))" 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 nuclear medicine service" means the transportation and medical use of radioactive material.

"Mobile X-ray x-ray equipment" (See "X-ray equipment").

"Mode of operation" means, for fluoroscopy systems, a distinct method of fluoroscopy or radiography provided by

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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 (~~MU~~)" 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.

"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~~ x-ray system that obtains ~~X-ray~~ x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"NARM" means any naturally occurring or accelerator-produced 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 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 (~~tight fitting~~)" or "tight fitting" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"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:

$$S_n = \frac{100 \otimes \overline{CS} \otimes s}{\mu_w}$$

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~~ 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~~ 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 ~~542~~ 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 (~~NRC~~)" 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~~ 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.

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"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~~ 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 wet-source-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~~ x-ray equipment" (See "X-ray equipment").

"Position indicating device" means a device on dental ~~X-ray~~ 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 semi-automatic adjustment of an ~~X-ray~~ x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Positive emission tomography (~~PET~~) radionuclide production facility" or "PET" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

"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—(~~PAPR~~)" or "PAPR" means an air-purifying 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~~ 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; 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~~ 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" ~~(See "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 purpose(s) 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 radiation-attenuating or absorbing materials used to reduce exposure to radiation.

~~"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:~~

- ~~1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam;~~

~~2. "Secondary protective barrier" means the material that attenuates stray 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.

"Qualitative fit test ~~(QLFT)~~" 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" ~~(Q)~~ 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 ~~(QNFT)~~" 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~~ 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

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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—(RSO)" 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~~ 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.

"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~~ 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 imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.~~

"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" (See "~~Industrial 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 permanent retrievable form of an image resulting from ~~X-ray~~ 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 United States 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 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.

"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.

"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~~ x-ray transmission data for the production of a tomogram. Data

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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~~ 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~~ 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.

~~"Sealed Source and Device Registry (SSD)" 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.~~

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

~~"Secondary protective barrier" (See "Protective barrier").~~

"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 (~~SCBA~~) 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 (~~H_s~~) 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 ~~DOF~~ 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" (~~Sv~~) 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 (radiation therapy simulation system)" or~~ "radiation therapy simulation system" means any ~~X-ray~~ 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~~ x-ray system that obtains ~~X-ray~~ 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~~ 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 (~~SSD~~)" or "SSD" means the distance between from the source and the skin entrance plane of the patient 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 section 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:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

"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 position a radiographic image receptor between the ~~X-ray~~ 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~~ 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, "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.

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"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 well-bore or adjacent formation.

"Supplied-air respirator ~~(SAR) or~~ "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" ~~(SCO) 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 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm² (1 E-05 μCi/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 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm² (0.1 μCi/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 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm² (0.1 μCi/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 μCi/cm²) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm² (1 E-03 μCi/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 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/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 8 E+05 becquerel per cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8

E+04 becquerel per cm² (2 μCi/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~~ x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

"Technologically Enhanced Naturally Occurring Radioactive Material" ~~(TENORM) 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 ~~kV~~ kilovolts (kV) and quantity of charge in ~~mAs~~ milliamperere-seconds (mAs);
2. For field emission equipment rated for pulsed operation, peak tube potential in ~~kV~~ kilovolts (kV), and number of ~~X-ray~~ x-ray pulses;
3. For CT ~~X-ray systems~~ equipment designed for pulsed operation, peak tube potential in ~~kV~~ kilovolts (kV), scan time in seconds, and either tube current in ~~Ma~~ milliamperes (mA), ~~X-ray~~ x-ray pulse width in seconds, and the number of ~~X-ray~~ x-ray pulses per scan, or the product of tube current, ~~X-ray~~ x-ray pulse width, and the number of ~~X-ray~~ x-ray pulses in ~~mAs~~ milliamperere-seconds (mAs);
4. For CT ~~X-ray systems~~ equipment not designed for pulsed operation, peak tube potential in ~~kV~~ kilovolts (kV), and either tube current in ~~Ma~~ milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in ~~mAs~~ milliamperere-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 ~~kV~~ kilovolts (kV), and either tube current in ~~Ma~~ milliamperes

(mA) and exposure time in seconds, or the product of tube current and exposure time in ~~mAs~~ milliamperere-seconds (mAs).

"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 XRF use is performed and where licensed material may be stored other than those location(s) of use authorized on the license.

"Tenth-value layer-~~(TVL)~~" 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.

~~"Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.~~

"Test" means the process of verifying compliance with an applicable regulation.

"Therapeutic radiation machine" means ~~X-ray~~ x-ray or electron-producing equipment designed and used for external beam radiation therapy.

"These regulations" mean all parts of these regulations.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

"Tomogram" means the depiction of the ~~X-ray~~ x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose ~~X-ray~~ x-ray attenuation properties are imaged in a tomogram.

"Total effective dose equivalent" ~~(TEDE)~~ 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" ~~(TODE)~~ 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 United States Department of Transportation.

"Transport index-~~(TI)~~" 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)).

"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.

"Tube" means an ~~X-ray~~ x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/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 A₁ for special form radioactive material or A₂ for normal form radioactive material, where A₁ and A₂ 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 related equipment are beneath the surface of the water.

"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 2×10^3 Bq of plutonium per gram of uranium-235, not

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more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-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 ~~emanating from that passes through the tube housing port or the radiation head and passing through and~~ the aperture of the ~~beam limiting beam-limiting~~ device when the exposure controls are in a mode to ~~cause the system to produce radiation~~ switch or timer is activated.

"User seal check (~~fit 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 beam-limiting device which has capacity for stepless adjustment of the ~~X-ray~~ 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 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~~ 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, who (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 persons licensed to dispose of radioactive waste.

"Waste processor" means an entity, operating under a specific license, whose principal purpose is to process, repack, 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 (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

Organ or Tissue	w _T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^{a/}
Whole Body	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 (~~WL~~)" or "WL" means any combination of short-lived 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" (~~WLM~~) 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 below, 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 terminates the radiation exposure. The ~~X-ray x-ray~~ exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an ~~X-ray x-ray~~ system, subsystem, or component thereof. Types of ~~X-ray x-ray~~ equipment are as follows:

1. "Mobile ~~X-ray x-ray~~ equipment" means ~~X-ray x-ray~~ equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
2. "Portable ~~X-ray x-ray~~ equipment" means ~~X-ray x-ray~~ equipment designed to be hand-carried.
3. "Stationary ~~X-ray x-ray~~ equipment" means ~~X-ray 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

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including the plane of the image receptor, whose perimeter is the locus of points at which the ~~exposure rate~~ AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the ~~X-ray~~ 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~~ x-ray tube(s), 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~~ x-rays. It includes minimally an ~~X-ray~~ x-ray high-voltage generator, an ~~X-ray~~ 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 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, ~~image intensifier~~ 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~~ x-ray energy.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. 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.

12VAC5-481-290. Registration of radiation machine facilities.

Each person having a radiation machine facility shall:

1. Apply for registration of such facility with the agency within 30 days following installation of equipment. Application for registration shall be completed on forms furnished by the agency and shall contain all the information required by the form and accompanying instructions. Registrations filed with the agency prior to September 20, 2006, shall remain in effect until a renewal notice is issued by the agency pursuant to ~~12VAC5-481-310~~.
2. Designate on the application form an individual to be responsible for radiation protection;
3. Submit to the agency as part of any application for registration or renewal of registration one copy of each radiation survey or calibration report for which records are required to be maintained pursuant to ~~12VAC5-481-1590~~

~~12VAC5-481-1591~~ A 12 c. Records submitted once need not be submitted again for renewal of registration.

4. Have an initial inspection by a private or state inspector no later than 30 days after the registration of the equipment. Subsequent inspections shall be made periodically in accordance with other parts of these regulations or whenever the equipment is moved to a new location. The agency shall furnish a list of private inspectors.

12VAC5-481-340. Private inspector qualifications.

Any person desiring designation as a private inspector for diagnostic ~~X-ray~~ x-ray, mammographic or therapeutic ~~X-ray~~ x-ray and teletherapy machines must be qualified by training and experience to perform inspections or calibrations according to the following criteria and must submit to the agency a statement on the appropriate form certifying his specific qualifications. In order to maintain designation as a private inspector, the individual must maintain satisfactory performance of work performed in that capacity. The agency shall disqualify ~~individuals~~ any individual from this designation ~~for just cause provided that a show cause hearing has been held and the agency~~ if the agency has determined that the individual has demonstrated unsatisfactory performance as a private inspector. The individual may request an informal hearing.

A. Private inspector, diagnostic ~~X-ray~~ x-ray (except mammography). The person must have adequate knowledge, training and experience to measure ionizing radiation, evaluate safety techniques, and advise regarding radiation protection needs to assure compliance with Virginia Rules and Regulations for Ionizing Radiation as evidenced by all of the following:

1. Initial qualifications: evidenced by one or more of the following:
 - a. Certification by one of the following: American Board of Radiology either in diagnostic or radiological physics, American Board of Health Physics in comprehensive practice, or the American Board of Medical Physics in diagnostic imaging physics.
 - b. Bachelor's degree in one of the physical sciences or engineering and three years of full-time experience in radiation safety including at least one year in diagnostic ~~X-ray~~ x-ray safety. Advanced degrees in related areas may be substituted for experience on an equal time basis, except that no substitution shall be allowed for the required one year of experience in diagnostic ~~X-ray~~ x-ray safety.
 - c. Those individuals listed as private inspectors immediately prior to September 20, 2006, shall be considered grandfathered.

2. Continuing qualifications:

- a. Continuing education. Private inspectors must participate in continuing education programs relating to

diagnostic ~~X-ray~~ x-ray, either by teaching or completing at least 15 continuing education units (CMEs) every three years.

b. Continuing experience. The private inspector must have inspected at least 10 diagnostic ~~X-ray~~ x-ray machines within the preceding 12 months.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform the inspections without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications, as follows:

a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to five continuing education units during the preceding 12 months.

b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of a sufficient number of facilities and machines under the direct supervision of a private inspector who meets the qualifications of this section to bring the number to the required level.

B. Private inspector, therapeutic ~~X-ray~~ x-ray and teletherapy machines. The person must have adequate knowledge, training, and experience to calibrate a therapeutic ~~X-ray~~ x-ray machine or teletherapy machine, perform inspections and to establish procedures for (and review the results of) spot-check measurements as evidenced by all of the following:

1. Initial qualifications: evidenced by one or more of the following:

a. Be certified by the American Board of Radiology in:

- (1) Therapeutic radiological physics;
- (2) Roentgen-ray and gamma-ray physics;
- (3) X-ray and radium physics;
- (4) Radiological physics;

b. Be certified by the American Board of Medical Physics in Radiation Oncology Physics;

c. Be certified by the Canadian College of Medical Physics; or

d. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 12VAC5-481-3400 A₂, 12VAC5-481-3420 P₂, 12VAC5-481-3430 T₂, 12VAC5-481-3420 Q₂, and 12VAC5-481-3430 U under the supervision of a radiation therapy physicist during the year of work experience.

Notwithstanding the provisions of 12VAC5-481-3390 D, certification pursuant to subdivisions B 1 a, b₂ or c of this section shall be required on or before July 1, 2007, for all persons currently qualifying as a radiation therapy physicist pursuant to subdivision B 1 d of this section.

2. Continuing qualifications.

a. ~~Continuing education~~: Private inspectors must participate in continuing education programs relating to therapeutic ~~X-ray~~ x-ray and teletherapy machines, either by teaching or completing at least 15 continuing education units (CEUs) every three years.

b. ~~Continuing experience~~: The private inspector must have inspected at least one therapeutic ~~X-ray~~ x-ray or teletherapy facilities and at least one therapeutic ~~X-ray~~ x-ray or teletherapy machine within the preceding 12 months.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform an inspection without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications, as follows:

a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to five continuing education units during the preceding 12 months.

b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of a sufficient number of facilities and machines under the direct supervision of a private inspector who meets the qualifications of this section to bring the number to the required level.

C. Private inspector, mammography. The person must have adequate knowledge, training, and experience to inspect mammography ~~X-ray~~ x-ray machines and facilities. All mammography private inspector conducting inspections of mammography facilities and providing oversight of the facility quality assurance program must meet one of the following tracks, either through the initial master's degree of higher route or the alternative initial bachelor's degree route:

1. Initial qualifications:

Master Route:

a. Be certified by the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) in:

- (1) Diagnostic radiological physics;
- (2) Radiological physics; or
- (3) Diagnostic imaging physics;

b. A master's degree or higher in a physical science with at least 20 semester hours or equivalent of graduate or undergraduate physics; and

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- c. Twenty contact hours of mammography facility training; and
- d. The experience of conducting inspections of at least one mammography facility and a total of at least 10 mammography units.

Bachelor Route (must have been qualified before April 28, 1999):

- a. A bachelor's degree in a physical science with at least 10 semester hours or equivalent of college level physics;
- b. Forty contact hours of documented specialized training in conducting inspections of mammography facilities; and
- c. The experience of conducting inspections of at least one mammography facility and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.

2. Continuing qualifications.

- a. ~~Continuing education.~~ At all times after the third anniversary of completion of the initial requirements of this section, the private inspector shall have taught or completed at least 15 continuing education units in mammography during the preceding three years.
- b. ~~Continuing experience.~~ At all times after the first anniversary of the completion of the initial requirements of this section, the private inspector shall have inspected at least two mammography facilities and six machines in 24 months.
- c. Before a private inspector may begin independently performing mammographic examinations using a new modality, that is, a modality other than one for which the physicist received training to qualify under this section, the inspector must receive at least eight hours of training in inspecting units with the new modality.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform the mammography inspections without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications as follows:

- a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.
- b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of three mammography facilities under the direct supervision of a private inspector who meets the qualifications of this section.

12VAC5-481-350. Assembler or transfer obligation.

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines or upon significant service or modification thereof of any radiation machine (such as tube inserts, generators, or collimators) in this state shall notify the agency within 15 days of:

1. The name and address of persons who have received these machines;
2. The manufacturer, model, and serial number of each radiation machine transferred; however, in the case of diagnostic x-ray systems that contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with the requirements of the Food and Drug Administration's Federal Diagnostic X-ray Standard (21 CFR 1020.30(d)) shall be submitted and shall suffice in lieu of any other report by the assembler; and
3. The date of transfer of each radiation machine.

B. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

Part VI

Use Of Diagnostic X-Rays In The Healing Arts

12VAC5-481-1580. ~~Purpose and scope. (Repealed.)~~

~~This part establishes requirements, for which a registrant is responsible, for use of diagnostic X ray equipment by, or under the supervision of, an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of Parts I (12VAC5 481 10 et seq.); II (12VAC5 481 260 et seq.); IV (12VAC5 481 600 et seq.); and X (12VAC5 481 2250 et seq.) of this chapter. Some registrants may also be subject to the requirements of Parts IX (12VAC5 481 2140 et seq.) and XV (12VAC5 481 3380 et seq.) of this chapter.~~

12VAC5-481-1581. ~~Purpose and scope.~~

This part establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with Virginia law to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to and not in substitution for other applicable provisions of this chapter.

12VAC5-481-1590. ~~General and administrative requirements. (Repealed.)~~

~~A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the X ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the X ray system(s).~~

1. An X ray system that does not meet the provisions of these regulations shall not be operated for diagnostic purposes.

2. Individuals who will be operating the X ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The agency may use interview, observation and/or testing to determine compliance. The following are areas in which the agency considers it important that an individual have expertise for the competent operation of X-ray equipment:

a. Familiarization with equipment

(1) Identification of controls

(2) Function of each control

(3) How to use a technique chart

b. Radiation protection

(1) Collimation

(2) Filtration

(3) Gonad shielding and other patient protection devices, if used

(4) Restriction of X ray tube radiation to the image receptor

(5) Personnel protection

(6) Grids

c. Image processing

(1) Film speed as related to patient exposure

(2) Image processing parameters

(3) Quality assurance program

d. Emergency procedures—termination of exposure in event of automatic timing device failure

e. Proper use of personnel dosimetry, if required

f. Understanding units of radiation

3. A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel that specifies, for all examinations performed with that system, the following information:

a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

b. Reserved;

c. Reserved;

d. Source to image receptor distance to be used (except for dental intra-oral radiography);

e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

f. For mammography, indication of kVp/target/filter combination.

4. The registrant of a facility shall create and make available to X ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X ray system. The operator shall be able to demonstrate familiarity with these procedures. A copy of the written safety procedures shall be posted near each X-ray machine.

5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

b. The X ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;

c. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers, or protective aprons of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

a. Exposure of an individual for training, demonstration, or other nonhealing arts purposes; and

b. Exposure of an individual for the purpose of healing arts screening except as authorized by subdivision A 11 of this section.

8. When a patient or film must be provided with auxiliary support during a radiation exposure:

a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by subdivision A 4 of this section, shall list individual projections where holding devices cannot be utilized;

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b. Written safety procedures, as required by subdivision A 4 of this section, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision A 5 of this section;

d. No individual shall be used routinely to hold film or patients;

e. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

f. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X ray operations and who are otherwise not shielded.

g. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected by appropriate shielding devices, such as protective glove and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The radiation exposure of and individual used for this purpose shall be monitored and recorded. These records of radiation exposure must be maintained indefinitely for inspection by the agency.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

a. The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

b. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality and, where applicable, shall not exceed the following standards:

EXPOSURE LIMITS FOR SELECTED PROJECTIONS

Using a method acceptable to the agency, the exposure measurement shall be determined in the center of the X ray field at the location of the entrance skin of a standard patient, except for dental intraoral X ray machines in which case the measurement shall be determined at the conetip. The technique factors selected shall be those used for routine radiography for an average size adult patient at that facility for that X ray machine. At least one projection must be tested for each X ray machine unless none of the projections listed

are used. If an X ray machine is used in both the manual and phototimed modes, then only the manual mode shall be tested. If the machine is used only in the phototimed mode, then this test is not required. An average size adult, for purposes of these regulations, is defined as a 5'8", 164 lb. adult male meeting the following anthropometric guidelines for the radiographic examination projection specified: PA Chest—Thorax—23 cm thickness; AP Abdomen and AP Lumbar Spine—Abdomen—23 cm thickness.

The exposure shall not exceed the following maximum exposure limits for the projections below:

Projection	Maximum Exposure
PA Chest	50 mR
AP Lumbar Spine	1400 mR
AP Abdomen	1100 mR
Dental Bitewing Using D Speed Film	
50 kVp	575 mR
55 kVp	500 mR
60 kVp	440 mR
65 kVp	400 mR
70 kVp	350 mR
75 kVp	260 mR
80 kVp	230 mR
85 kVp	200 mR
90 kVp	180 mR
95 kVp	160 mR
100 kVp	140 mR
Using E Speed Film	
50 kVp	320 mR
55 kVp	270 mR
60 kVp	230 mR
65 kVp	200 mR
70 kVp	170 mR
75 kVp	140 mR
80 kVp	120 mR
85 kVp	105 mR
90 kVp	90 mR
95 kVp	80 mR
100 kVp	70 mR

~~e. Portable or mobile X ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X ray installation.~~

~~d. X ray systems subject to 12VAC5 481 1620 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.~~

~~e. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:~~

~~(1) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;~~

~~(2) If of the focused type, be of the proper focal distance for the SID's being used.~~

~~10. All individuals who are associated with the operation of an X ray system are subject to the requirements of 12VAC5 481 640, 12VAC5 481 680, 12VAC5 481 700 and 12VAC5 481 710.~~

~~11. Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the following information. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified.~~

**INFORMATION TO BE SUBMITTED BY PERSONS
PROPOSING TO CONDUCT HEALING ARTS
SCREENING**

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

a. Name and address of the applicant and, where applicable, the names and addresses of agents within this state;

b. Diseases or conditions for which the X ray examinations are to be used in diagnoses;

c. A detailed description of the X ray examinations proposed in the screening program;

d. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;

e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the X ray examinations;

f. An evaluation by a private inspector of the X ray system(s) to be used in the screening program. The evaluation by the private inspector shall show that such system(s) do satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X ray examinations to be performed;

~~g. A description of the diagnostic X ray quality control program;~~

~~h. A copy of the technique chart for the X ray examination procedures to be used;~~

~~i. The qualifications of each individual who will be operating the X ray system(s);~~

~~j. The qualifications of the individual who will be supervising the operators of the X ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;~~

~~k. The name and address of the individual who will interpret the radiograph(s);~~

~~l. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;~~

~~m. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X ray examinations;~~

~~n. An indication of the frequency of screening and the duration of the entire screening program.~~

~~12. Information and maintenance record and associated information. The registrant shall maintain the following information for each X ray system for inspection by the agency:~~

~~a. Model and serial numbers of all major components, and user's manuals for those components;~~

~~b. Tube rating charts and cooling curves;~~

~~c. Records of surveys, calibrations, maintenance, and modifications performed on the X ray system(s); and~~

~~d. A copy of all correspondence with this agency regarding that X ray system.~~

~~13. X ray utilization log. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.~~

~~14. The registrant shall maintain a list of X ray machine operators for each facility. The following information will be maintained on the list:~~

~~The name of the X ray machine operator. Operators must be licensed by the Department of Health Professions where X rays are used within the scope of practice or be certified by the ARRT, or an individual enrolled in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, and if a dental assistant, comply with the Board of Dentistry's radiation certification requirements in 18VAC60 20 195.~~

~~B. X ray film processing facilities and practices.~~

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1. Each installation using a radiographic X ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film:

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time temperature chart that must be posted in the darkroom:

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	22
25.0	77	22
24.4	76	3
23.9	75	3
23.3	74	32
22.8	73	32
22.2	72	4
21.7	71	4
21.1	70	42
20.6	69	42
20.0	68	5
19.4	67	52
18.9	66	52
18.3	65	6
17.8	64	62
17.2	63	7
16.7	62	8
16.1	61	82
15.6	60	92

(3) Devices shall be utilized which will indicate the actual temperature of the developer and signal the

passage of a preset time appropriate to the developing time required.

b. Automatic processors and other closed processing systems:

(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time ^a (Seconds)
°C	°F	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
^a Immersion time only, no crossover time included.		

(2) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

c. Processing deviations from the requirements of subdivision 1 of this subsection shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

2. Other requirements.

a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for

mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

e. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated X ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

h. Living and deceased patient's films (diagnostic images) shall be maintained for a minimum of five years. Films for minors shall be maintained for a minimum of five years beyond their 18th birthday.

C. Information to be submitted to the agency. The registrant shall submit to the agency a copy of all surveys, calibrations and inspections performed by a private inspector within 30 days of completion of the survey or calibration.

D. Information to be submitted by the private inspector to the registrant. The private inspector shall provide the inspection report to the registrant within 14 days of the completion of the inspection. A summary and/or recommendations shall be included with this report. The private inspector shall notify the registrant of any noncompliances that need corrective action.

12VAC5-481-1591 General and administrative requirements

A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the x-ray system under his administrative control. The registrant or the registrant's agent shall assure that the requirements of this chapter are met in the operation of the x-ray system or systems.

1. An x-ray system that does not meet the provisions of this chapter shall not be operated for diagnostic purposes.

2. Individuals who will be operating the x-ray systems shall meet the qualifications of this part to conduct the practice of radiologic technology.

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel that specifies, for all examinations performed with that system, the following information:

a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

b. Type and size of the image receptor to be used;

c. Type and size of the image receptor combination to be used, if any;

d. Source to image receptor distance to be used (except for dental intraoral radiography);

e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

f. For mammography, indication of kVp/target/filter combination.

4. The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;

b. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material; and

c. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 mm lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. Gonad shielding of not less than 0.5 mm lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the

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healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

- a. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and
- b. Exposure of an individual for the purpose of healing arts screening except as authorized by subdivision 11 of this subsection.

8. When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

- a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, as required by subdivision 4 of this subsection, shall list individual projections where holding devices cannot be utilized;
- b. Written safety procedures, as required by subdivision 4 of this subsection, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
- c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 5 of this subsection;
- d. No individual shall be used routinely to hold image receptor or patients;
- e. In those cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and
- f. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with x-ray operations and who are otherwise not shielded.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

- a. The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.
- b. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
- c. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.
- d. X-ray systems subject to 12VAC5-481-1621 shall not be utilized in procedures where the source to patient distance is less than 30 cm, except for veterinary systems.

e. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- (1) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray; and
- (2) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 12VAC5-481-640, 12VAC5-481-700, and 12VAC5-481-710.

11. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

- a. Name and address of the applicant and, where applicable, the names and addresses of agents within this state;
- b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;
- c. A description of the x-ray examinations proposed in the screening program, i.e., type and number of views;
- d. Description of the population to be examined in the screening program, i.e., age range, sex, physical condition, and other appropriate information;
- e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;
- f. An evaluation by a qualified medical physicist of the x-ray system or systems to be used in the screening program. The evaluation shall include the following:
 - (1) Documentation that such systems satisfy all requirements of this chapter; and
 - (2) Measurement of patient exposures from the x-ray examinations to be performed;
- g. A description of the diagnostic x-ray quality control program;
- h. A copy of the technique chart for the x-ray examination procedures to be used;
- i. The qualifications of each individual who will be operating the x-ray system or systems;
- j. The qualifications of the individual who will be supervising the operators of the x-ray system or systems. The extent of supervision and the method of work performance evaluation shall be specified;
- k. The name and address of the practitioner licensed in the state who will interpret the radiograph;

l. Procedures to be used in advising the individuals screened and their practitioners of the healing arts or health care providers of the results of the screening procedure and any further medical needs indicated;

m. Procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;

n. Frequency of screening of individuals; and

o. The duration of the screening program.

12. The registrant shall maintain the following information and maintenance record for each x-ray system for inspection by the agency:

a. Model and serial numbers of all major components, and user's manuals for those components;

b. Tube rating charts and cooling curves;

c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system or systems; and

d. A copy of all correspondence with the agency regarding that x-ray system.

13. Except for veterinary facilities, each facility shall maintain an x-ray utilization log containing the patient's name, the type of examination, and the date the examination was performed.

14. The registrant shall maintain a list of x-ray operators for each facility. Operators must be licensed by the Department of Health Professions where x-rays are used within the scope of practice or be certified by the American Registry of Radiological Technologists (ARRT), or be an individual enrolled in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, and if a dental assistant, comply with the Board of Dentistry's radiation certification requirements in 18VAC60-20-195.

B. X-ray film processing facilities and practices.

1. Each installation using a radiographic x-ray system and analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film.

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2-1/2
25.0	77	2-1/2
24.4	76	3
23.9	75	3
23.3	74	3-1/2
22.8	73	3-1/2
22.2	72	4
21.7	71	4
21.1	70	4-1/2
20.6	69	4-1/2
20.0	68	5
19.4	67	5-1/2
18.9	66	5-1/2
18.3	65	6
17.8	64	6-1/2
17.2	63	7
16.7	62	8
16.1	61	8-1/2
15.6	60	9-1/2

(3) Devices shall be utilized that will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

b. Automatic processors and other closed processing systems. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer. In the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time*
°C	°F	Seconds
35.5	96	19
35	95	20

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<u>34.5</u>	<u>94</u>	<u>21</u>
<u>34</u>	<u>93</u>	<u>22</u>
<u>33.5</u>	<u>92</u>	<u>23</u>
<u>33</u>	<u>91</u>	<u>24</u>
<u>32</u>	<u>90</u>	<u>25</u>
<u>31.5</u>	<u>89</u>	<u>26</u>
<u>31</u>	<u>88</u>	<u>27</u>
<u>30.5</u>	<u>87</u>	<u>28</u>
<u>30</u>	<u>86</u>	<u>29</u>
<u>29.5</u>	<u>85</u>	<u>30</u>
<u>*Immersion time only, no crossover time included.</u>		

Processing deviations from the requirements of this subdivision shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

2. Other requirements.

a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-ray radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

c. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer

and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

h. Living and deceased patients' diagnostic images shall be maintained for a minimum of five years. Diagnostic images for minors shall be maintained for a minimum of five years beyond their 18th birthday.

C. The registrant shall submit to the agency a copy of all surveys, calibrations, and inspections performed by a private inspector within 30 days of completion of the survey, calibration, or inspection.

D. The private inspector shall provide the inspection report to the registrant within 14 days of the completion of the inspection. A summary or recommendation shall be included with this report. The inspector shall notify the registrant of any noncompliances that need corrective action.

E. Violations identified as "serious" must be corrected within 30 days. Certification of the unit will not be issued until the violation is corrected. Violations identified as "non-serious" shall be corrected before the next inspection cycle. Uncorrected "non-serious" violations will become "serious" and require immediate correction.

12VAC5-481-1600. General requirements for all diagnostic X-ray systems. (Repealed.)

In addition to other requirements of this part, all diagnostic X ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. Battery charge indicator. On battery powered X ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 $\mu\text{C}/\text{kg}$ (100 milliroentgens) in one hour when the X ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 $\mu\text{C}/\text{kg}$ (2 milliroentgens) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled X ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an

area of 100 square centimeters with no linear dimension greater than 20 centimeters.

5. Beam quality.

a. Half value layer.

(1) The half value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half value layer at an X ray tube potential that is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (kVp)	Measured Potential (kVp)	Half Value Layer In mm Aluminum	
		Dental Intra-Oral Manufactured Before Aug. 1, 1974, and on or After Dec. 1, 1980	All Other Diagnostic X-ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(2) For capacitor energy storage equipment, compliance with the requirements of subdivision 5 a of this section shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

(3) The required minimal half value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

b. Filtration controls. For X ray systems that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by subdivision 5 a of this section is in the useful beam for the given kVp that has been selected.

6. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to

initiation of the exposure. This indication shall be both on the X ray control panel and at or near the tube housing assembly that has been selected.

7. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X ray system.

8. Technique indicators.

a. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

b. The requirement of subdivision 8 a of this section may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors

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shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

9. ~~Maintaining compliance. Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.~~

10. ~~Locks. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.~~

11. ~~Mechanical timers. The use of a mechanical timer is prohibited.~~

12VAC5-481-1601. General requirements for all diagnostic x-ray systems.

In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

2. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (100 milliroentgen (mR) exposure) in one hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

3. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (two milliroentgens exposure) in one hour at five cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

4. Beam quality half-value layer (HVL).

a. The HVL of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1 (i) under the heading "Specified Dental Systems" for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; (ii) under the heading "I-Other X-Ray Systems" for any dental x-ray system designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and (iii) under the heading "II-Other X-Ray Systems" for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 1, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector that will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 1

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	Measured Operating Potential	Minimum HVL (mm in Aluminum)		
		Specified Dental Systems ¹	I-Other X-Ray Systems ²	II-Other X-Ray Systems ³
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5

	<u>70</u>	<u>1.5</u>	<u>1.5</u>	<u>1.8</u>
<u>Above 70</u>	<u>71</u>	<u>2.1</u>	<u>2.1</u>	<u>2.5</u>
	<u>80</u>	<u>2.3</u>	<u>2.3</u>	<u>2.9</u>
	<u>90</u>	<u>2.5</u>	<u>2.5</u>	<u>3.2</u>
	<u>100</u>	<u>2.7</u>	<u>2.7</u>	<u>3.6</u>
	<u>110</u>	<u>3.0</u>	<u>3.0</u>	<u>3.9</u>
	<u>120</u>	<u>3.2</u>	<u>3.2</u>	<u>4.3</u>
	<u>130</u>	<u>3.5</u>	<u>3.5</u>	<u>4.7</u>
	<u>140</u>	<u>3.8</u>	<u>3.8</u>	<u>5.0</u>
	<u>150</u>	<u>4.1</u>	<u>4.1</u>	<u>5.4</u>

¹ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

² Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

³ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

b. Optional filtration. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube or tubes with a continuous output of one kilowatt or more and an anode heat storage capacity of one million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions in Table 1. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

c. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

5. Aluminum equivalent of material between patient and image receptor. Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table 2, which are used between the patient and the image receptor, shall not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in Table 1 for the potential. This requirement applies to front panel or panels of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

<u>Item</u>	<u>Maximum Aluminum Equivalent (mm)</u>
<u>Front panel(s) of cassette holders (total of all)</u>	<u>1.2</u>
<u>Film panel(s) of film changer (total of all)</u>	<u>1.2</u>
<u>Cradle</u>	<u>2.3</u>
<u>Tabletop, stationary, without articulated joints</u>	<u>1.2</u>
<u>Tabletop, movable, without articulated joints (including stationary subtop)</u>	<u>1.7</u>
<u>Tabletop, with radiolucent panel having one articulated joint</u>	<u>1.7</u>
<u>Tabletop, with radiolucent panel having two or more articulated joints</u>	<u>2.3</u>
<u>Tabletop, cantilevered</u>	<u>2.3</u>
<u>Tabletop, radiation therapy simulator</u>	<u>5.0</u>

6. Battery charge indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

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7. Modification of certified diagnostic x-ray components and systems.

a. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this part.

b. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or a component to comply with the applicable requirements of this part. The owner who causes such modification need not submit the reports required by this part, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with this part.

8. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

9. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

10. Technique indicators.

a. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set prior to the exposure shall be indicated.

b. The requirement of subdivision 10 a of this subsection may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

11. Maintaining compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

12. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

13. Mechanical timers. The use of mechanical timers is prohibited.

12VAC5-481-1610. ~~Fluoroscopic X-ray systems.~~ (Repealed.)

~~All fluoroscopic X-ray systems used shall be image intensified and meet the following requirements:~~

~~1. Limitation of useful beam.~~

~~a. Primary barrier.~~

~~(1) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.~~

~~(2) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.~~

~~b. Fluoroscopic beam limitation.~~

~~(1) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.~~

~~(2) For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.~~

~~(3) For uncertified fluoroscopic systems without a spot film device, the requirements of subdivision b (1) of this section apply.~~

~~(4) Other requirements for fluoroscopic beam limitation:~~

~~(a) Means shall be provided to permit further limitation of the field. Beam limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;~~

~~(b) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;~~

~~(c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;~~

~~(d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;~~

(e) For noncircular X ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X ray field that pass through the center of the visible area of the image receptor.

c. Spot film beam limitation. Spot film devices shall meet the following requirements:

(1) Means shall be provided between the source and the patient for adjustment of the X ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the X ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(2) Neither the length nor the width of the X ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3.0% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4.0% of the SID;

(3) It shall be possible to adjust the X ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;

(4) The center of the X ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2.0% of the SID; and

(5) On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

d. Override. If a means exists to override any of the automatic X ray field size adjustments required in subdivisions 1 b and c of this section that means:

(1) Shall be designed for use only in the event of system failure;

(2) Shall incorporate a signal visible at the fluoroscopist's position that will indicate whenever the automatic field size adjustment is overridden; and

(3) Shall be clearly and durably labeled as follows:

FOR X RAY FIELD LIMITATION SYSTEM FAILURE

2. Activation of the fluoroscopic tube. X ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. Exposure rate limits.

a. Entrance exposure rate allowable limits.

(1) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images; or

(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5.2 mC/kg-min (20 R/min) at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images; or

(b) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) Compliance with the requirements of subdivision 3 of this section shall be determined as follows:

(a) If the source is below the X ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;

(b) If the source is above the X ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam limiting device or

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spacer positioned as closely as possible to the point of measurement;

(c) For a C arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(d) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X ray table and in the direction of the X ray source with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X ray source, with the end of the beam limiting device or spacer no closer than 15 centimeters to the centerline of the X ray table.

b. Periodic measurement of entrance exposure rate shall be performed by a private inspector for both typical and maximum values as follows:

(1) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate;

(2) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 12VAC5-481-1590 A-12-c. The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;

(3) Conditions of periodic measurement of typical entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of subdivision 3-a(3) of this section;

(b) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

(c) The X ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of subdivision 3-b(3)(b) of this section.

(4) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of subdivision 3-a(3) of this section;

(b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

(c) The X ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

4. Barrier transmitted radiation rate limits.

a. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 $\mu\text{R}/\text{hr}$ (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mR/min (roentgen) per minute of entrance exposure rate.

b. Measuring compliance of barrier transmission.

(1) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(3) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(4) Movable grids and compression devices shall be removed from the useful beam during the measurement.

5. Indication of potential and current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

6. Source to skin distance. The SSD shall not be less than:

a. Thirty eight centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

b. Thirty five and one half centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

c. Thirty centimeters on all mobile fluoroscopes;

d. Twenty centimeters for all mobile fluoroscopes when used for specific surgical applications; or

e. Nine centimeters for all portable fluoroscopes when used for special applications.

7. Fluoroscopic timer.

- a. Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
- b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

8. Control of scattered radiation.

- a. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
- b. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:
 - (1) Is at least 120 centimeters from the center of the useful beam; or
 - (2) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12VAC5-481-1590 A 5.
- c. The agency may grant exemptions to subdivision 8 b of this section where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption. The following is a suggested list of fluoroscopic procedures where such exemptions will be automatically granted: angiograms, arthrograms, biliary drainage procedures, fluoroscopic biopsy procedures, myelograms, percutaneous cholangiograms, percutaneous nephrostomies, sinograms or fistulograms, t tube cholangiograms, interventional cardiac catheterization, and interventional special procedures.

9. Spot film exposure reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of 12VAC5 481 1620 D when operating in the spot film mode.

10. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of subdivision 3 of this section. In addition, these systems shall be exempt from:

- a. The requirements of subdivisions 1 and 4 of this section provided such systems are designed and used in

such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

- b. The requirements of subdivision 7 of this section if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

11. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic X-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1611. Fluoroscopic equipment.

A. The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

B. Primary protective barrier.

1. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed $3.34 \times 10^{-3}\%$ of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation.

2. Measuring compliance. The AKR shall be measured in accordance with subsection E of this section. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

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C. Field limitation.

1. Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with subdivisions 4 and 5 of this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of subdivisions 4 and 5 of this subsection. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or capability of a visible area of greater than 300 square cm, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five cm by five cm. This paragraph does not apply to non-image-intensified fluoroscopy.

3. Non-image-intensified fluoroscopy. The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

4. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

a. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

(2) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

b. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

(1) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80% of the area of the x-ray field overlaps the visible area of the image receptor; or

(2) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm.

5. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies:

a. Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

b. The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

"For X-Ray Field Limitation System Failure"

D. Activation of tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure or exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

E. Air kerma rates. For fluoroscopic equipment, the following requirements apply:

1. Fluoroscopic equipment manufactured before May 19, 1995.

a. Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

b. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

c. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

d. Equipment may be modified in accordance with this part to comply with subdivision 2 of this subsection. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

e. Exceptions:

(1) During recording of fluoroscopic images; or

(2) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of any of the rates specified in subdivisions 1 a, b, and c of this subsection at the measurement point specified in subdivision 3 of this subsection, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

2. Fluoroscopic equipment manufactured on or after May 19, 1995.

a. Equipment shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Provision or manual selection of technique factors may be provided.

b. Equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 2 c of this subsection.

c. Exceptions:

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from the fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(2) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image or images after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(3) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

3. Measuring compliance. Compliance with this subsection shall be determined as follows:

a. If the source is below the x-ray table, the AKR shall be measured at one cm above the tabletop or cradle.

b. If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c. In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

d. In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

e. In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

4. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

F. Reserved.

G. Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential

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and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

H. Source-skin distance.

1. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subsection, provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this subsection, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

I. Fluoroscopic irradiation time, display, and signal.

1. Fluoroscopic equipment manufactured before June 10, 2006.

a. Equipment shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of this subdivision. When the equipment is modified, it shall bear a label indicating the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

b. As an alternative to the requirements of this subsection, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

2. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

a. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

(1) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be

continuously displayed and updated at least once every six seconds.

(2) The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.

(3) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

b. A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

J. Mobile and portable fluoroscopes. In addition to the other requirements of this subsection, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

K. Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

3. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with reinitiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

L. Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

1. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

2. The cumulative air kerma in units of mGy shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

3. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

4. The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

a. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in subdivision E 3 a or E 3 e of this section.

b. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

5. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than $\pm 35\%$ over the range of six mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three seconds.

M. Control of scattered radiation.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 centimeters from the center of the useful beam; or

b. The radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12VAC5-481-1591 A 5.

3. The agency may grant exemptions to subdivision 2 of this subsection where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

N. Operator qualifications. The facility shall ensure that only a licensed practitioner of the healing arts or a radiologic

technologist or equivalent be allowed to operate fluoroscopic x-ray systems.

O. Equipment operation.

1. All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. The operation of fluoroscopic x-ray systems by radiologic technologists or equivalent shall be performed under the direct supervision of a licensed practitioner of the healing arts.

3. Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or radiologic technologist as specified in subsection N of this section.

4. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

5. Facilities shall maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

P. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic x-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1620. Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems. (Repealed.)

~~A. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 12VAC5-481-1620 H 2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).~~

~~1. General purpose stationary and mobile X-ray systems, including veterinary systems (other than portable) installed after September 20, 2006.~~

~~a. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.~~

~~b. A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2.0% of the~~

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distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X ray beam.

~~e. The agency may grant an exemption on noncertified X ray systems to subdivisions 1 a and b of this subsection provided the registrant makes a written application for such exemption and in that application:~~

~~(1) Demonstrates it is impractical to comply with subdivisions 1 a and b of this subsection; and~~

~~(2) The purpose of subdivisions 1 a and b of this subsection will be met by other methods.~~

2. Additional requirements for stationary general purpose X ray systems. In addition to the requirements of subdivision 1 of this subsection, stationary general purpose X ray systems, both certified and noncertified, shall meet the following requirements:

a. A method shall be provided to indicate when the axis of the X ray beam is perpendicular to the plane of the image receptor, to align the center of the X ray field with respect to the center of the image receptor to within 2.0% of the SID, and to indicate the SID to within 2.0%;

b. The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

c. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in X ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam limiting device to within 2.0% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X ray field with the center of the image receptor to within 2.0% of the SID, or shall be provided with means to both size and align the X ray field such that the X ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4. X ray systems other than those described in subdivisions 1 through 3 of this subsection, and veterinary systems installed prior to September 20, 2006, and all portable veterinary X ray systems.

a. Means shall be provided to limit the X ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2.0% of the SID when the axis of the X ray beam is perpendicular to the plane of the image receptor.

b. Means shall be provided to align the center of the X ray field with the center of the image receptor to within 2.0% of the SID, or means shall be provided to both size

and align the X ray field such that the X ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X ray beam perpendicular to the plane of the image receptor.

c. Subdivisions 4 a and b of this subsection may be met with a system that meets the requirements for a general purpose X ray system as specified in subdivision 1 of this subsection or, when alignment means are also provided, may be met with either:

(1) An assortment of removable, fixed aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) A beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

B. Radiation exposure control.

1. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

a. Manual exposure control. An X ray control shall be incorporated into each X ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposure of two seconds or less; or

(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

b. Automatic exposure controls. When an automatic exposure control is provided:

(1) Indication shall be made on the control panel when this mode of operation is selected;

(2) If the X ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(3) The minimum exposure time for all equipment other than that specified in subdivision 3 b (2) of this subsection shall be equal to or less than one sixtieth (1/60) second or a time interval required to deliver five mAs, whichever is greater;

(4) Either the product of peak X ray tube potential, current, and exposure time shall be limited to not more than 60 kW-s per exposure, or the product of X ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X ray tube potential is less than 50 kVp, the product of X ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(5) A visible signal shall indicate when an exposure has been terminated at the limits required by subdivision 3 b (4) of this subsection, and manual resetting shall be required before further automatically timed exposures can be made.

4. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C \text{ kg}^{-1} \text{ s}^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average $C \text{ kg}^{-1} \text{ s}^{-1}$ (mR/s) values.

5. Exposure control location. The X ray exposure control shall be so placed that the operator can view the patient while making any exposure.

6. Operator protection, except veterinary systems, bone densitometers, and other self-contained machines whose design was approved by the FDA.

a. Stationary systems. Stationary X ray systems shall be required to have the X ray exposure control permanently mounted behind a protected barrier so that the operator can remain behind that protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, dental panoramic and podiatry X ray systems may, as an alternative, be provided with means to allow the operator to be at least nine feet from the tube housing assembly during exposures.

b. Mobile and portable systems. Mobile and portable X ray systems that are:

(1) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 6 a of this subsection;

(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

7. Operator protection for veterinary systems. All stationary, mobile or portable X ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

C. Source to skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source to skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

D. Reproducibility for Exposure and Time. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.10. This requirement applies to clinically used techniques.

E. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.5 $\mu\text{R}/\text{h}$ (2 milliroentgens) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam limiting device fully open.

F. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value for kVp and 10% for time.

G. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X ray tube potential within the range of 40% to 100% of the maximum rated:

1. Equipment having independent selection of X ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliamperes seconds product ($C \text{ kg}^{-1} \text{ mAs}^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

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2. Equipment having a combined X ray tube current exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliamperere seconds product, in units of $C \cdot kg^{-1} \cdot mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X ray tube manufacturer.

H. Additional requirements. Diagnostic X ray systems shall be required to comply with the following additional requirements.

1. Beam limitation for stationary and mobile general purpose X ray systems:

a. There shall be provided a means of stepless adjustment of the size of the X ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

b. When a light localizer is used to define the X ray field, it shall provide an average illumination of not less than 120 lux or 10 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

2. Beam limitation and alignment on stationary general purpose X ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

a. PBL shall prevent the production of X rays when:

(1) Either the length or width of the X ray field in the plane of the image receptor differs, except as permitted by subdivision 2 c of this subsection, from the corresponding image receptor dimensions by more than 3.0% of the SID; or

(2) The sum of the length and width differences as stated in subdivision 2 a (1) of this subsection without regard to sign exceeds 4.0% of the SID;

b. Compliance with subdivision 2 a of this subsection shall be determined when the equipment indicates that

the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor;

c. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters;

d. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in subdivision 2 a of this subsection, then any change of image receptor size or SID must cause the automatic return.

3. Beam limitation for portable X ray systems. Beam limitation for portable X ray systems shall meet the beam limitation requirements of subdivisions A 1 or H 2 of this section.

I. Tube stands for portable X ray systems. A tube stand or other mechanical support shall be used for portable X ray systems, so that the X ray tube housing assembly need not be hand held during exposures unless the system is specifically designed to be handheld.

J. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all X ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers and X ray machines used in the practice of podiatry or dentistry shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.

12VAC5-481-1621. Radiographic equipment.

A. Control and indication of technique factors.

1. Visual indication. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

2. Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

a. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an

exposure when the timer is set to a zero or off position if either position is provided.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. Automatic exposure controls. When an automatic exposure control is provided:

a. Indication shall be made on the control panel when this mode of operation is selected;

b. When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver five milliamperere-seconds (mAs), whichever is greater;

c. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kW) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

d. A visible signal shall indicate when an exposure has been terminated at the limits described in subdivision 3 c of this subsection, and manual resetting shall be required before further automatically timed exposures can be made.

4. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer. In the absence of manufacturer's limits, the deviation shall not exceed 10% of the indicated value for kVp and time.

B. Reproducibility. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

1. Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.10.

2. Measuring compliance. Determination of compliance shall be based on 10 consecutive measurements taken within a time period of one hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within ± 1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such

that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

C. Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated.

1. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$$|X_1 - X_2| \leq 0.10(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

2. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$$|X_1 - X_2| \leq 0.10(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on 10 exposures, made within one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ± 1 of the mean value for all measurements at these technique factors.

D. Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

1. Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm.

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2. Visual definition.

a. Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2.0% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

b. When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 10 foot-candles at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

c. The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2 , where I_1 is the illuminance three mm from the edge of the light field toward the center of the field, and I_2 is the illuminance three mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one mm.

E. Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in subsection D of this section:

1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2.0% of the SID and to indicate the SID to within 2.0%;

2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in centimeters or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2.0% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13,

18, 24, 30, 35, 40, and 43 cm or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

F. Field limitation on radiographic x-ray equipment other than general purpose radiographic systems.

1. Equipment for use with intraoral image receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

a. If the minimum source-to-skin distance (SSD) is 18 cm or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven cm; and

b. If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six cm.

For dental intraoral uses, an open ended shielded positioning device shall be used.

2. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of image receptor to within 2.0% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

3. Systems designed for mammography.

a. Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

b. Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond

any edge of the image receptor by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. For systems that allow changes in SID, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

c. Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

4. Other x-ray systems. Radiographic systems not specifically covered in subsections D, E, and H of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2.0% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2.0% of the SID, or means shall be provided to both size and alignment the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

a. A system that performs in accordance with subsections D and E of this section; or when alignment means are also provided, may be met with either;

b. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

c. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

G. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems that contain PBL.

1. Field size. When a PBL system is provided, it shall prevent x-ray production when:

a. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3.0% of the SID; or

b. The sum of the length and width differences stated in subdivision 1 a of this subsection without regard to sign exceeds 4.0% of the SID.

c. The beam-limiting device is at an SID for which PBL is not designed for sizing.

2. Conditions for PBL. When provided, the PBL system shall function as described in subdivision 1 of this subsection whenever all the following conditions are met:

a. The image receptor is inserted into a permanently mounted cassette holder;

b. The image receptor length and width are less than 50 cm;

c. The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ± 3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

d. The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees; and

e. Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance. Compliance with the requirements of subdivision 1 of this subsection shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of subdivision 2 of this subsection are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

4. Operator initiated undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm. Return to PBL function as described in subdivision 1 of this subsection shall occur automatically upon any change of image receptor size or SID.

5. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

"For X-Ray Field Limitation System Failure"

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

H. Field limitation and alignment for spot-film devices. The following requirements shall apply to spot-film devices,

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except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3.0% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4.0% of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2.0% of the SID.

4. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

a. For spot-film devices used on fixed-SID fluoroscopic systems that are not required to and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

b. For spot-film devices used on fluoroscopic systems that have a variable SID or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

"For X-ray Field Limitation System Failure"

I. Source-skin distance.

1. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

- a. 18 cm if operable above 50 kVp; or
- b. 10 cm if not operable above 50 kVp.

2. Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 cm.

J. Beam-on indicators. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

K. Reserved.

L. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed:

1. An air kerma of 0.26 microGy (0.03 mR exposure) in one minute at five cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm; and

2. An air kerma of 0.88 mGy (100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in one hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

M. Primary protective barrier for mammography x-ray systems.

1. For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

2. For mammographic x-ray systems manufactured on or after September 30, 1999:

- a. At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

b. The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in subdivision 2 a of this subdivision.

c. The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

3. Compliance with the requirements of subdivisions 1 and 2 c of this subsection for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

N. Reserved.

O. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of subsection G of this section have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

P. Radiation exposure control.

1. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Operator protection, except veterinary systems.

a. Stationary systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator may remain in that protected area during the entire exposure. For dental intraoral systems installed prior to September 20, 2006, if the x-ray control is not permanently mounted behind a protected barrier, then dosimetry is required by all operators of the system.

b. Mobile and portable systems. Mobile and portable x-ray systems that are:

(1) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 3 a of this subsection;

(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

4. Operator protection for veterinary systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during exposures.

Q. Tube stands for portable x-ray systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

R. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all x-ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers, hand-held units, and x-ray machines other than head CT or cone beam units used in the practice of podiatry, dentistry, or veterinary medicine shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.

12VAC5-481-1630. ~~Intraoral dental radiographic systems. (Repealed.)~~

~~In addition to the provisions of 12VAC5 481 1590 and 12VAC5 481 1600, the requirements of 12VAC5 481 1630 apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 12VAC5 481 1620. Only systems meeting the requirements of this section shall be used.~~

~~A. Source to skin distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:~~

~~1. 18 centimeters if operable above 50 kVp; or~~

~~2. 10 centimeters if operable at 50 kVp only.~~

~~B. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.~~

Regulations

C. Radiation exposure control.

1. Exposure initiation.

a. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

b. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Exposure termination.

a. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

b. An X ray exposure control shall be incorporated into each X ray system such that an exposure can be terminated by the operator at any time, except for exposures of two seconds or less.

c. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

4. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of $C\ kg^{-1}\ s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

5. Exposure control location and operator protection.

a. After September 20, 2006, stationary X ray systems shall be required to have the X ray exposure control permanently mounted behind a protected barrier, so that the operator can remain behind that protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, the X ray exposure shall be permanently mounted at least 2.7 meters (9 feet) from the tube housing assembly while making exposures. If an X ray machine was installed prior to September 20, 2006, and if the X ray exposure control is not permanently mounted behind a protected barrier, so that the operator can remain behind that protected barrier during the entire exposure, then dosimetry shall be required by all operators of the X ray system.

b. Mobile and portable X ray systems that are:

(1) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 5 of this subsection;

(2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly while making exposures.

D. Reproducibility for Exposure and Time. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures and times shall be no greater than 0.10, for any specific combination of selected technique factors.

E. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X ray tube potential within the range of 40% to 100% of the maximum rated:

1. Equipment having independent selection of X ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliamperere seconds product, in units of $C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

2. Equipment having a combined X ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere seconds product, in units of $C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X ray tube manufacturer.

F. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently

selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10% of the indicated value for kVp and 10% for time.

G. kVp limitations. Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

H. Administrative controls.

1. Patient and film holding devices shall be used when the techniques permit.
2. The tube housing and the PID shall not be hand held during an exposure.
3. The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subsection B of this section.
4. Dental fluoroscopy without image intensification shall not be used.

I. Radiation safety and equipment performance surveys shall be performed every three years on all dental X-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1631. Intraoral dental radiographic equipment.

In addition to the applicable provisions of 12VAC5-481-1591, 12VAC5-481-1601, and 12VAC5-481-1621, the requirements of this section apply to x-ray equipment and associated facilities used for dental intraoral radiography. Requirements for extraoral dental radiographic systems are in 12VAC5-481-1621.

1. Radiation exposure control. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.
2. Exposure control location and operator protection.
 - a. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and
 - b. Mobile and portable x-ray systems that are:
 - (1) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 1 of this section.
 - (2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

3. kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4. Administrative controls.

- a. Patient and film holding devices shall be used when the techniques permit.
- b. The tube housing and the PID for a permanently mounted intraoral dental system shall not be hand-held during an exposure.
- c. Dental fluoroscopy without image intensification shall not be used.

12VAC5-481-1640. Computed tomography X-ray systems. (Repealed.)

A. Reserved.

B. Requirements for equipment.

1. Termination of exposure.

- a. Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.
- b. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by subdivision 1 a of this subsection.
- c. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one half second duration.

2. Tomographic plane indication and alignment.

- a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
- b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.
- c. If a device using a light source is used to satisfy the requirements of subdivisions 2 a or b of this subsection, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam on and shutter status indicators and control switches.

- a. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

Regulations

b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT conditions of operation. The CT X ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subdivision 3 of 12VAC5-481-1600.

6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional requirements applicable to CT X ray Systems containing a gantry manufactured after September 3, 1985.

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

b. If the X ray production period is less than one half second, the indication of X ray production shall be actuated for at least one half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the X ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

C. Facility design requirements.

1. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing systems.

a. Windows, mirrors, closed circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

D. Surveys, calibrations, spot checks, and operating procedures.

1. Surveys.

a. All CT X ray systems installed after September 20, 2006, and those systems not previously surveyed shall have a survey made by, or under the direct supervision of a private inspector who is physically present at the facility during the inspection. In addition, such surveys shall be done at least annually or after any change in the facility or equipment that might cause a significant increase in radiation hazard, whichever occurs first.

b. The registrant shall obtain a written report of the survey from the private inspector, and a copy of the report shall be sent to the agency within 60 days of the date of the survey.

2. Radiation calibrations.

a. The calibration of the radiation output of the CT X ray system shall be performed by, or under the direction of, a private inspector who is physically present at the facility during such calibration.

b. The calibration of a CT X ray system shall be performed at intervals specified by a private inspector and after any change or replacement of components that, in the opinion of the private inspector, could cause a change in the radiation output.

c. The calibration of the radiation output of a CT X ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

d. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(2) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

~~(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;~~

~~(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.~~

~~e. The calibration shall be required for each type of head, body, or whole body scan performed at the facility.~~

~~f. Calibration shall meet the following requirements:~~

~~(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;~~

~~(2) The CTDI along the two axes specified in subdivision 2-d (2) of this subsection shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;~~

~~(3) The spot checks specified in subdivision 3 of this subsection shall be made.~~

~~g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.~~

3. Spot checks.

~~a. The spot check procedures shall be in writing and shall have been developed by a private inspector.~~

~~b. The spot check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.~~

~~e. All spot checks shall be included in the calibration required by subdivision 2 of this subsection and at time intervals and under system conditions specified by a private inspector.~~

~~d. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by subdivision~~

~~2 of this subsection. The images shall be retained, until a new calibration is performed, in two forms as follows:~~

~~(1) Photographic copies of the images obtained from the image display device; and~~

~~(2) Images stored in digital form on a storage medium compatible with the CT X ray system.~~

~~e. Written records of the spot checks performed shall be maintained for inspection by the agency.~~

4. Operating procedures.

~~a. The CT X ray system shall not be operated except by an individual who has been specifically trained in its operation.~~

~~b. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:~~

~~(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;~~

~~(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;~~

~~(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and~~

~~(4) A current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination.~~

~~e. If the calibration or spot check of the CT X ray system identifies that a system operating parameter has exceeded a tolerance established by the private inspector, use of the CT X ray system on patients shall be limited to those uses permitted by established written instructions of the private inspector.~~

12VAC5-481-1641. Computed tomography equipment.

A. Reserved.

B. Requirements for equipment.

1. Termination of exposure.

a. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.

b. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by subdivision 1 a of this subsection.

Regulations

c. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

2. Tomographic plane indication and alignment.

a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

c. If a device using a light source is used to satisfy the requirements of subdivision 2 a or b of this subsection, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and shutter status indicators and control switches.

a. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT conditions of operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subdivision 3 of 12VAC5-481-1601.

6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985.

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five mm.

b. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to

the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment shall not exceed one millimeter with any mass from 0 to 100 kg resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

C. Facility design requirements.

1. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing systems.

a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

D. Surveys, calibrations, spot checks, and operating procedures.

1. Surveys.

a. All CT x-ray systems installed after September 19, 2006, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

b. The registrant shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the agency upon request.

2. Radiation calibrations.

a. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified medical physicist who is physically present at the facility during such calibration.

b. The calibration of a CT x-ray system shall be performed (i) after initial installation and before use on human patients, (ii) annually or at intervals specified by a qualified medical physicist, and (iii) after any change or replacement of components that in the opinion of the

qualified medical physicist could cause a change in the radiation output.

c. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

d. CT dosimetry phantom shall be used in determining the radiation output of a CT x-ray system. Such phantom shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic cm. The phantom shall be at least 14 cm in length and shall have diameters of 32.0 cm for testing CT x-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(2) CT dosimetry phantom shall provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(2) The CTDI along the two axes specified in subdivision 2 d (2) of this subsection shall be measured. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within

the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and

(3) The spot checks specified in subdivision 3 of this subsection shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

3. Spot checks.

a. The spot-check procedures shall be in writing and shall have been developed by a qualified medical physicist.

b. The spot-check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of (i) providing an indication of contrast scale, noise, nominal tomographic section thickness, and the resolution capability of the system for low and high contrast objects; and (ii) measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by subdivision 2 of this subsection and at time intervals and under system conditions specified by a qualified medical physicist.

d. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom or phantoms using the same processing mode and CT conditions of operation as are used to perform calibrations required by subdivision 2 of this subsection.

e. The results of each spot check shall be maintained for two years.

4. Operating procedures.

a. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

b. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(2) Instructions on the use of the CT dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination.

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c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.

12VAC5-481-1650. Mammography. (Repealed.)

~~A. Equipment standards. Only X ray systems meeting the following standards shall be used:~~

~~1. System design. The X ray system shall be specifically designed for mammography.~~

~~2. Image receptor. The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography.~~

~~3. kVp/target/filter. The X ray system shall have the capability of providing kVp/target/filter combinations compatible with the selected image receptor system.~~

~~4. Beam quality.~~

~~a. When used with screen film image receptors, and when the contribution to filtration made by the compression device is included, the useful beam shall have a half value layer (HVL):~~

~~(1) Between the values of: ((measured kVp)/100) and ((measured kVp)/100 + 0.1) millimeters aluminum for molybdenum targets;~~

~~(2) At least the value of ((measured kVp)/100) millimeters aluminum for rhodium alloy targets.~~

~~b. For xeroradiography, the HVL of the useful beam with the compression device in place shall be at least 1.0 and not greater than 1.6 mm aluminum, measured at 49 kVp with a tungsten target tube.~~

~~5. Resolution. The combination of focal spot size, source-to image receptor distance and magnification shall result in a resolution of at least 12 line pairs per millimeter (cycles/mm) measured when a resolution pattern is positioned 4.2 cm above all breast supports and when the resolution pattern is either perpendicular to or parallel with the chest wall edge of the image receptor support. The measurement shall be made with the kVp in the range of 25-30 and the mA shall be the highest available for the focal spot size selected. The resolution shall be at least 11 line pairs when a high contrast resolution bar test pattern is orientated with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line pairs/mm when the bars are parallel to that axis. The bar pattern must be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within one cm of the chest wall edge of the image receptor. When more than one target material is provided, the measurement must be made using the appropriate focal spot for each target material.~~

~~6. Compression:~~

~~a. The X ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least three minutes.~~

~~b. The chest wall edge of the compression paddle shall extend beyond the chest wall edge of the image receptor by no more than 2.0% of the Source to Image Receptor Distance with the compression paddle placed 4.2 cm above the breast support device. With the compression paddle in this position, the chest wall edge of the compression paddle shall not be visible in the acquired image.~~

~~7. System capabilities. A mammographic X ray system utilizing screen film image receptors shall have:~~

~~a. The capability of using anti scatter grids that are:~~

~~(1) Integral to the X ray system;~~

~~(2) Available for all image receptor sizes used;~~

~~b. The capability of automatic exposure control, for systems installed after September 20, 2006; and~~

~~c. The capability of displaying post exposure mAs after an exposure made using an automatic exposure control device, for systems installed after September 20, 2006.~~

~~8. Milliampere second read out accuracy. For those mammographic X ray systems equipped with automatic exposure control and post exposure mAs read out, the indicated mAs read out shall be within 10% of the actual mAs delivered.~~

~~9. Transmission. For X ray systems manufactured after September 5, 1978, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 25.8 nC/kg (0.1 milliroentgen) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~10. Collimation.~~

~~a. All systems shall have beam limiting devices that allow the entire chest wall edge of the X ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X ray field does not extend beyond any edge of the image receptor by more than 2.0% of the SID.~~

~~b. Means for visually defining the perimeter of the X ray field shall be provided. The total misalignment of the~~

edges of the visually defined field with the respective edges of the X ray field along either the length or width of the visually defined field shall not exceed 2.0% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X ray beam.

11. Accuracy of kVp. Deviation of actual kVp from the indicated kVp shall not exceed the limits specified by the manufacturer of the X ray system, or, the actual kVp shall be within plus or minus 2 kVp of the indicated kVp, whichever limit is more restrictive.

12. Automatic exposure control performance. In addition to 12VAC5 481 1620 D, mammographic systems in the AEC mode shall be able to maintain constant film density to within an optical density of plus or minus 0.3 of the average optical density over the kVp range used clinically, using phantoms of BR 12 or other breast equivalent material thicknesses of two centimeters to six centimeters. If the facility has established a technique chart that utilizes varying technical factors for different breast thicknesses, those adjustments in technique may be used when performing this test.

13. Radiation output minimum. At 28 kVp, with a focal spot meeting the requirements of subdivision A 5 of this section, the mammographic system shall be capable of sustaining a minimum output rate of 130 $\mu\text{C/kg/sec}$ (500 mR/sec) for at least three seconds. This output shall be measured at a point 4.2 centimeters from the surface of the breast support device when the SID is at its maximum and the effect of compression paddle attenuation is included.

14. Screen film contact. Cassettes shall not be used for mammography if poor contact of two or more large areas (>1 cm in diameter) or a section longer than 1 cm and >2 mm in width along the chest wall edge can be seen in a 40 mesh test.

15. Image quality. The mammographic X ray imaging system shall be capable of providing an image of a 0.75 mm fiber, 0.32 mm speck group, and a 0.75 mm mass from the Conference of Radiation Control Program Directors NEXT "92 phantom (or equivalent) on the standard mammographic image receptor system in use at a facility. Mammograms shall not be taken on patients if this minimum is not met. Any fibers, speck groups and masses larger than those specified shall also be imaged.

16. Dose. The mean glandular dose for one craniocaudal view, measured with the phantom referenced in subdivision 15 of this subsection, based on exposure measured at the breast entrance location, and using dose conversion factors specified by the Health Care Financing Administration in their Medicare Mammography Survey Protocols, shall not exceed the following values:

a. 2.0 mGy (200 millirads) for nongrid screen film systems;

b. 3.0 mGy (300 millirads) for screen film systems with grid.

17. Technique settings. The technique settings used for subdivisions 15 and 16 of this subsection shall be those used by the facility for its clinical images of a 50% adipose, 50% glandular, 4.2 cm compressed breast.

B. Quality assurance.

1. Quality assurance program required. The registrant shall have a written, on going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic X ray imaging system, to ensure consistently high quality images with minimum patient exposure. Responsibilities under this requirement include providing qualified individuals who are to:

- Conduct equipment performance monitoring functions;
- Analyze the monitoring results to determine if there are problems requiring correction;
- Carry out or arrange for the necessary corrective actions when results of quality control tests including those specified in subdivision 3 of this subsection indicate the need; and
- Maintain records for a minimum of two years documenting that actions required under subdivisions 1 a through e of this subsection have been completed.

2. Quality assurance program review. At intervals not to exceed 12 months, the registrant shall:

- Have the annual quality control tests specified in subdivision 3 of this subsection performed by a qualified individual and obtain the results of those tests, incorporating them into the records specified in subdivision 1 d of this subsection; and
- Conduct a review of the effectiveness of the quality assurance program required in subdivision 1 of this subsection and maintain a written report of such review. Records of annual reviews shall be maintained for a minimum of two years and shall be available for agency review.

3. Equipment quality control tests. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed, or replaced or serviced (if such servicing affects test results), and performed thereafter at least as often as the frequency specified. The private inspector shall determine the corrective action interval.

- Processor performance by sensitometric means—daily, or day of use, prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as a mobile service, each processor shall be subject to this requirement. Corrective action shall be taken when:

(1) Deviations of 0.15 or more in optical density from established operating levels occur for readings of mid-

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density (MD) and density difference (DD) on the sensitometric control charts;

(2) Base plus fog (B+F) exceeds the established operating level by more than 0.03 in optical density.

b. Resolution upon tube installation or replacement and every 12 months.

c. Focal spot size upon tube installation or tube replacement only or at least every 12 months, whichever occurs first.

d. Half value layer—12 months.

e. kVp accuracy and reproducibility—12 months.

f. Output reproducibility, mA linearity, and mR/mAs—12 months.

g. Automatic exposure control reproducibility and performance (response to kVp and phantom thickness variations)—12 months.

h. Screen film contact and screen artifact detection—six months.

i. Compression device performance (releases, level of force, etc)—six months.

j. Collimator alignment—12 months.

k. Primary/secondary barrier transmission upon initial X ray system installation and significant modification of the system or the facility.

l. Image quality (using a test "phantom," that simulates the composition of the breast and includes simulations of breast structures) weekly for stationary systems, on each day of use for mobile systems, and upon significant service or modification of any mammographic system.

m. Densitometer accuracy check—every 12 months.

n. Glandular dose—every 12 months.

o. Image quality—every 12 months.

p. Artifacts—every 12 months.

4. Additional quality control requirements. The registrant shall perform the following observations and procedures according to the frequency noted and record the results. Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two year period.

a. Retake Analysis—three months.

b. Viewbox uniformity—six months.

c. Darkroom integrity (safelight condition, light leaks, etc.)—six months.

d. Screen cleaning—weekly.

e. Fixer retention—three months.

C. Additional facility requirements.

1. Masks. Masks shall be provided on the viewboxes to block extraneous light from the viewer's eye when the

illuminated surface of the viewbox is larger than the exposed area of the film.

2. Film processing.

a. Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

b. Clinical films and phantom image quality films shall be processed within 10 hours of exposure.

c. Facilities shall offer to process films before the patient leaves the facility. If the patient chooses not to wait; if there is not developing capabilities, the patient will be notified within two business days if additional films are necessary.

3. Instruments and devices. An image quality phantom, sensitometer, and a calibrated densitometer shall be available to each facility in order to comply with the quality control test frequencies specified in subdivision B 3 of this section.

4. Operator qualifications. The operator of the X ray machine shall be certified by the American Registry of Radiologic Technologists and shall have had specialized training in mammography meeting the requirements set forth by the FDA under the MQSA of 1992.

5. Physician qualifications. The physician interpreting the mammograms shall be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or Board eligible, or equivalent, and shall have had specialized training in mammography and image interpretation.

6. Physicist qualifications. The person performing evaluation of mammographic system performance in accordance with these regulations shall meet the requirements set forth in 12VAC5-481-340 C.

7. Image retention. Clinical images shall be retained for a minimum of five years or 10 years if no other clinical images are obtained.

8. Retake rate. Corrective action shall be taken if the retake rate exceeds 5.0%. The retake rate shall be calculated as (repeated + rejected films)/total number of clinical films.

9. Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density when sensitized mammographic film of the type used in the facility is exposed to darkroom conditions with safelight on for two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen or sensitometer so that after processing an optical density of at least 1.0 is achieved.

Facility qualifications. The registrant performing mammography shall be accredited by the American College of Radiology or another agency recognized as a certifying body or have their application pending. The registrant shall

also be certified by the FDA or another agency recognized as an accrediting body under the MQSA of 1992 or have a provisional/interim certificate.

D. Additional state requirements.

~~1. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality.~~

~~2. Agency inspectors may conduct unannounced inspections during normal hours of business.~~

12VAC5-481-1651. Mammography requirements.

A. Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 (Public Law 105-248) and 21 CFR Part 900, shall be used for screening and diagnostic mammography.

B. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

C. A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

D. The operator of the mammography machine shall be certified by the American Registry of Radiologic Technologists (ARRT) and shall have had specialized training in mammography meeting the requirements set forth by the U.S. Food and Drug Administration under the Mammography Quality Standards Reauthorization Act of 1998.

E. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality.

F. Agency inspectors may conduct unannounced inspections during normal business hours.

12VAC5-481-1653. Hand-held radiographic unit.

In addition to the applicable provisions found elsewhere in this chapter, the following provisions apply to a hand-held radiographic unit.

1. A hand-held radiograph unit shall be:

a. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and

Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

b. Registered with the agency in accordance with applicable parts of this chapter.

c. Maintained and operated in accordance with the manufacturer's specifications.

2. For all uses:

a. Operators of a hand-held radiographic unit shall be specifically trained to operate such equipment.

b. When operating a hand-held radiographic unit, operators shall wear dosimetry unless otherwise authorized by the agency.

c. A hand-held radiographic unit shall have the backscatter radiation shield in place to protect the operator during operation.

d. The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held radiograph unit.

e. A hand-held radiographic unit shall not be used in hallways or waiting rooms.

12VAC5-481-1655. Bone densitometry.

A. A bone densitometry system shall be:

1. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

2. Registered with the agency in accordance with applicable parts of this chapter.

3. Maintained and operated in accordance with the manufacturer's specifications.

B. Equipment requirements. A system with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2.0% of the SID.

C. Operators of a bone densitometry system shall meet one of the following:

1. Be certified by the American Registry of Radiologic Technologists (ARRT);

2. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a radiologic technologist or a limited radiologic technologist for bone density operation;

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3. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

4. Be in an accredited program for radiologic technology and under the supervision of an individual who meets one of the criteria listed in subdivisions 1, 2, or 3 of this subsection.

D. During the operation of any bone densitometry system:

1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

E. The registrant shall keep maintenance records for bone densitometry systems as prescribed by subdivision A 3 of this section. These records shall be maintained for inspection by the agency.

F. Bone densitometry on human patients shall be conducted only:

1. Under a prescription of an individual licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

2. Under a screening program approved by the agency.

12VAC5-481-1657. Quality assurance program.

All registrants of diagnostic x-ray imaging equipment may be required by the agency to establish and maintain a quality assurance program consisting of quality control assessments.

12VAC5-481-2110. Area requirements.

A. Radiation Levels. The local components of an analytical ~~X-ray~~ x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group that could result in a dose to an individual present therein in excess of the dose limits given in 12VAC5-481-640. For systems utilizing ~~X-ray~~ x-ray tubes, these levels shall be met at any specified tube rating.

B. Surveys.

1. Radiation surveys, as required by 12VAC5-481-750, of all analytical ~~X-ray~~ x-ray systems sufficient to show compliance with 12VAC5-481-2440 A shall be performed:

- a. Upon installation of the equipment, and at least once every ~~12 months~~ five years thereafter;
- b. Following any change in the initial arrangement, number, or type of local components in the system;
- c. Following any maintenance requiring the disassembly or removal of a local component in the system;
- d. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary ~~X-ray~~ x-ray beam when any local component in the system is disassembled or removed;

e. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

f. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 12VAC5-481-630.

2. Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance with subsection A of this section to the satisfaction of the agency.

C. Posting. Each area or room containing analytical ~~X-ray~~ x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION—X-RAY EQUIPMENT" or words having a similar intent in accordance with 12VAC5-481-660.

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,—a recordable event, and recording written directives.

VA.R. Doc. No. R10-2412; Filed November 5, 2013, 9:35 a.m.

Proposed Regulation

Title of Regulation: 12VAC5-570. Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings (amending 12VAC5-570-10, 12VAC5-570-30 through 12VAC5-570-190; adding 12VAC5-570-200; repealing 12VAC5-570-20).

Statutory Authority: § 32.1-246 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 31, 2014.

Agency Contact: Preston Smith, Manager, Marina Programs, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7468, FAX (804) 864-7475, or email preston.smith@vdh.virginia.gov.

Basis: Sections 32.1-12 and 32.1-246 of the Code of Virginia require the State Board of Health to promulgate regulations establishing minimum requirements for sewerage facilities at marinas and other places where boats are moored. Section 32.1-164 of the Code of Virginia provides that the board's regulations may require that residences, buildings, structures, and other places designed for human occupancy as the board may prescribe be provided with a sewerage system or treatment works.

Purpose: The board's Marina Regulations are intended to protect public health and the environment by ensuring that sewage generated from boats and onshore boating facilities is treated and disposed of properly. The Marina Regulations have not been revised since the board adopted amendments in 1990. Since that time, development has increased dramatically in the Chesapeake Bay watershed and other

tributaries and around Virginia's inland lakes. At the same time the public's awareness of and susceptibility to impaired water quality has increased. Boating has increased in popularity with more than 12 million boats in use nationwide. While the number of large commercial marinas has steadily grown, Virginia has also seen an increase in the number of smaller facilities, such as neighborhood marinas and public boat ramps. The proposed amendments simplify and clarify many regulatory requirements and address the need to modify the regulatory requirements for two facilities in particular: (i) marinas that serve owners who live aboard their boats and (ii) public boating access facilities (boat ramps) that receive heavy use (i.e., that have parking spaces for 50 or more boat trailers). In addition, the proposed amendments reflect the evolution in the methods of conveying and disposing human waste aboard boats; in particular, the proposed amendments address the advent of waste disposal via a marine sanitation device or a portable toilet. In addition to these methods, the Marina Regulations also require pump-outs to safely and properly handle waste disposal. Some of the changes, particularly those that simplify the method for determining sewage flow as a function of the number of slips, are intended to provide marinas and other places where boats are moored with the flexibility to redefine business models regarding the types of boats and boating activities they will service.

Substance: The amendments cover five main areas: (i) definitions of terms; (ii) requirements for sanitary fixtures based on the number of slips and dry storage spaces; (iii) sewerage facility requirements at boating access facilities (boat ramps); (iv) sewage design flows based on the number of slips rather than the type of slip with a specific flow assigned to all slips used as live-aboard slips; (v) a new section for onshore facility requirements; and (vi) an exemption from the requirement for a sewage dump station for any facility that has a sewage pump-out and the correct appurtenance for pumping out portable toilets.

The agency amended 12VAC5-570-10 to define boating access facility as a location consisting of a boat ramp. The agency expanded the definition for dry storage to include different ways boats are stored between uses. The agency added a definition for live-aboard slip. The agency defined regulated facilities as marinas, other places where boats are moored, and boating access facilities with 50 or more parking spaces for boat trailers.

The agency amended 12VAC5-570-150 to provide an allowance for smaller boating facilities to construct unisex bathrooms.

The agency amended 12VAC5-570-160 to require sewerage facilities at boating access facilities that have 50 or more parking spaces for boat trailers.

The agency amended 12VAC5-570-180 to prohibit marinas or other places that provide live-aboard slips or boats with a marine sanitation device to invoke an exemption to provide a pump-out service.

The agency amended 12VAC5-570-190 to allow marinas with a pump-out facility equipped with a specialized device (i.e., porta-potty wand) to use the device to excavate sewage from portable sewage containers instead of installing a dump station.

Issues: The primary advantages to the public of these amendments are improved sewage handling in sensitive waterfront areas and the assurance that when the public visits a regulated facility, there will be adequate sewerage fixtures to meet their needs. Having sewerage facilities available in such locations reduces the potential that human wastes will be improperly dumped into the waters of the Commonwealth. The requirement for smaller-sized marinas to install shower facilities poses an additional economic burden on smaller marina owners. This burden is offset somewhat, however, by the change that allows these smaller facilities to install a unisex bathroom instead of having to construct separate facilities for men and women. The proposed amendments create advantages to the public and the department by simplifying the regulatory program; specifically, the number of sewerage fixtures required at regulated facilities is no longer driven by the type of slip (seasonal or transient) but rather by the total number of slips and dry storage spaces. This proposed amendment allows owners the freedom to accommodate both short-term and long-term boaters without impacting any future growth. The amendments propose a higher sewage flow for live-aboard slips to reflect the higher water usage associated with these residences. While this change may pose economic impacts to owners, it provides public health protection from raw sewage discharge by helping to ensure that sewerage systems and treatment works are sized adequately to handle the wastewater load.

The department worked with an ad hoc group of stakeholders in developing the proposed amendments. While that group was not able to review all of the proposed amendments, it supported the need to update the regulations and generally supported the substantive changes proposed.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Health's Sanitary Regulations for Marinas and Boat Moorings establish minimum standards for sewage handling and disposal at regulated facilities. The regulations are intended to protect public health and the environment by ensuring that sewage generated from boats and onshore boating facilities is treated and disposed of properly. The Marina Regulations have not been revised since the Board adopted amendments in 1990. Among other changes the Board proposes to: 1) require that boating access facilities have at least one privy, 2) eliminate the distinction between transient and seasonal slips as the basis for determining sewerage fixture needs, 3) establish a new category of slip, live-aboard slip, with a higher wastewater flow number, 4) provide owners with facilities that have proper sanitary waste

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pump-out services an alternative to installing a sanitary waste dump station, and 5) allow the use of manually operated pumps at marinas and other places where boats are moored that offer fewer than 26 slips.

Result of Analysis. The benefits likely exceed the costs for one or more proposed changes. There is insufficient data to accurately compare the magnitude of the benefits versus the costs for other changes.

Estimated Economic Impact. The proposed regulations do state that "Marinas, other place(s) where boats are moored, and boating access facilities in operation prior to the effective date of this chapter shall be subject to the regulations in effect at the time the marina, other place(s) where boats are moored or boating access facility was permitted unless such marina, other place(s) where boats are moored or boating access facility is expanded after the effective date of this chapter." So, no marina or other facility will face increased (or decreased) costs due to the proposed changes in these regulations unless they expand after the effective date of the adoption of these proposed amended regulations. Further, federal funding is available to pay 75 percent of the cost of investments in sewage handling infrastructure.¹

The Board proposes to require that boating access facilities have at least one privy (porta john). Boating access facilities are defined as any installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers. The Virginia Department of Health (Department) estimates that purchasing a privy costs from \$500 to \$750;² leasing a privy costs about \$150.00 per week and that includes a weekly service (pump-out and cleaning).³ The benefit of this proposed requirement is reduced risk to public health and the environment. According to the Department there has been a problem with unprocessed sewage being left in the water and on the land at boating access facilities and adjacent properties. The proposed requirement for a privy is intended to reduce such incidences and thus reduce potential harm to public health and the environment.

The Board also proposes to eliminate the distinction between transient and seasonal slips as the basis for determining sewerage fixture needs. In the current regulations the required number of sewerage fixtures per given quantity of transient slips is greater than the required number of sewerage fixtures per given quantity of seasonal slips. Under the proposed regulations where the distinction between transient and seasonal is eliminated, the required number of sewerage fixtures per given quantity of slips is between the required numbers for seasonal and transient under the current regulations. Thus, marina owners with relatively more transient slips may encounter a slight reduction in the number of required sewerage fixtures under the proposed regulations; while marina owners with relatively more seasonal slips may encounter a slight increase in the number of required sewerage fixtures under the proposed regulations. As

indicated earlier, these changes in the number of required sewerage fixtures only apply for facilities which expand after the effective date of the adoption of these proposed amended regulations.

Public or municipal sewerage systems and treatment works should be used if there is reasonable access to sewers. When such municipal means of disposal are not available, the owner shall have designed and installed an approved sewerage system or treatment works. The sewage design flow for each slip shall be 25 gallons per slip per day.

The Board proposes to establish a new category of slip, live-aboard slip, with a higher wastewater flow number. Live-aboard slips are any slip where a boat is moored and used principally as a residence or a place of business. Charter and commercial fishing boats are not included unless used as a residence. The Board proposes to require that the sewage design flow for each live-aboard slip be 50 gallons per slip per day. Users of live-aboard slips are likely to put significantly greater demands on the sewage system given that the slip users are likely to be present at the facility for a much higher percentage of time than other slip users.

The proposed regulations do allow for a reduction in the sewage flow requirements if the owner provides documented flow data sufficient to justify the reduction. The owner could do this by use of a water meter measuring actual discharge into the onsite system. Such meters cost approximately \$500. Expansion of an onsite system would on the other hand cost thousands of dollars.⁴

The Board proposes to provide owners with facilities that have proper sanitary waste pump-out services an alternative to installing a sanitary waste dump station. Marinas and other place(s) where boats are moored that have an operational pump-out facility equipped with a device to pump portable sewage containers would not be required to have a dump station (costs about \$5,000). The wand attachment is now commonly used at boating facilities with sanitary waste pump-out systems because it is easy to use and limits the boaters opportunity to spill sanitary waste into the water thereby protecting the environment. The wand costs approximately \$25.⁵

Under the current regulations manually operated pumps are not permitted. The Board proposes to allow the use of manually operated pumps at marinas and other places where boats are moored that offer fewer than 26 slips. Manually operated pumps cost approximately \$1,500 and could help avoid spending \$15,000.⁶

Businesses and Entities Affected. The proposed amendments potentially affect owners of the 525 marinas, 402 other places where boats are moored, and 25 public access facilities (boat ramps) in the Commonwealth,⁷ as well as the customers and suppliers of such facilities.

Localities Particularly Affected. Localities that own (or propose to own) regulated facilities are regulated under the current regulations and will be affected by the proposed

amendments. These include the Cities of Alexandria, Hampton, Newport News, Norfolk, Portsmouth, Virginia Beach, Suffolk and the counties of Fairfax, Prince William, Stafford, Spotsylvania, James City, and the Northern Neck, Middle Peninsula, and Eastern Shore regions.

Projected Impact on Employment. The proposal to require that boating access facilities have at least one privy may increase demand for firms which supply and service privies. Consequently employment for such firms may modestly increase.

Effects on the Use and Value of Private Property. The proposal to require that boating access facilities have at least one privy may increase demand for firms which supply and service privies. Consequently the value for some such firms may modestly increase.

Small Businesses: Costs and Other Effects. The proposed amendments are unlikely to significantly increase costs for small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed amendments are unlikely to significantly adversely affect small businesses.

Real Estate Development Costs. The proposals to allow the use of manually operated pumps at marinas and other places where boats are moored that offer fewer than 26 slips and to provide owners with facilities that have proper sanitary waste pump-out services an alternative to installing a sanitary waste dump station will modestly reduce develop costs for applicable marinas and other places where boats are moored.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

¹ Source: Virginia Department of Health

² Ibid

³ Ibid

⁴ Ibid

⁵ Ibid

⁶ Ibid

⁷ Ibid

Agency's Response to Economic Impact Analysis: The Virginia Department of Health concurs with the Department of Planning and Budget's economic impact analysis. The benefits of the regulations likely exceed the costs for one or more proposed changes.

Summary:

The Sanitary Regulations for Marinas and Boat Moorings establish minimum standards for sewage handling and disposal at regulated facilities to ensure that sewage generated from boats and onshore boating facilities is treated and disposed of properly. The proposed amendments (i) provide an allowance for smaller boating facilities to construct unisex bathrooms, (ii) eliminate the distinction between transient and seasonal slips as the basis for determining sewerage fixture needs, (iii) establish a new live-aboard slip category with a higher wastewater flow number, (iv) provide an alternative to installing a sanitary waste dump station for owners with facilities that have proper sanitary waste pump-out services, and (v) allow the use of manually operated pumps at marinas and other places where boats are moored that offer fewer than 26 slips.

Part I
Introduction
Article 1
Definitions

12VAC5-570-10. Definitions.

~~As used in this chapter, the~~ The following words and terms ~~hereinafter set forth when used in this chapter~~ shall have the following meanings ~~respectively~~, unless the context clearly ~~requires a different meaning~~. indicates otherwise:

"Board" means the State Board of Health.

"Boat" means any vessel or other watercraft, privately owned or owned by the Commonwealth or any political subdivision thereof, whether moved by oars, paddles, sails, or other power mechanism, inboard or outboard, or any other vessel or structure floating on water in the Commonwealth of Virginia, whether or not capable of self-locomotion, including but not limited to cruisers, cabin cruisers, runabouts, houseboats and barges. Excluded from this definition are commercial, passenger and cargo carrying vessels subject to the Quarantine Regulation of the United States Public Health Service adopted pursuant to Title 42 of the United States Code and ships or vessels of the U.S. Government and boats which are tenders to larger boats moored or stored at the same facility.

Regulations

"Boating access facility" means any installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers.

"Certificate" means a written approval from the ~~Commissioner~~ commissioner or his designated representative indicating that plans for ~~sanitary facilities and sewage sewerage facilities, sewerage system, and treatment works~~ meet or satisfy the minimum requirements of this chapter and § 32.1-246, of the Code of Virginia.

"Commissioner" means the State Health Commissioner whose duties are prescribed in § 32.1-19 of the Code of Virginia.

"Department" means the Virginia Department of Health.

"Division" means the Division of ~~Wastewater Engineering, Department of Health Onsite Sewage and Water Services, Environmental Engineering, and Marina Programs, Office of Environmental Health Services of the department or its administrative successor.~~

"Dry storage" means a boat storage, including boatels, valet storage, pigeon hole storage, stackminiums, or parking space where boats rest on racks or trailers located on land, whether covered or uncovered, at a marina or other place places where boats are moored for the purpose of storing boats on land between use.

"Expanded" means any change to a regulated facility that results in an increase in sewage volume or strength due to the addition of slips, dry storage spaces, boat trailer parking spaces, or ancillary operations.

"Live-aboard slip" means any slip where a boat is moored and used principally as a residence or a place of business. Charter and commercial fishing boats are not included unless used as a residence.

"Local health department" means the branch of the State Health Department, established in accordance with § 32.1-30 of the Code of Virginia, that has jurisdiction in the city or county where the regulated facility is located.

"Marina" means any installation operating, under public or private ownership, which that provides dockage or moorage for boats (exclusive of, other than paddle or rowboats) rowboats, and provides, through sale, rental or, fee, or free basis, any equipment, supply, or service (fuel including fuel, electricity, or water) water for the convenience of the public or its lessee the lessee, renters, or users of its the facilities.

"Marine sanitation device" means any equipment, piping, holding tanks, and appurtenances such as holding tanks for installation on board onboard a boat which is designed to receive, retain, treat, or discharge sewage and any process to treat such sewage.

"No Discharge Zone" means an area where a state has received an affirmative determination from the U.S. Environmental Protection Agency that there are adequate facilities for the removal of sewage from vessels (holding

tank pump-out facilities) in accordance with § 312(f)(3) of the Clean Water Act (33 USC § 1251 et seq.) and where federal approval has been received allowing a complete prohibition of all treated or untreated discharges of sewage from all vessels.

"Office" means the Office of Environmental Health Services.

"Other places where boats are moored" means any installation operating under public or private ownership, which that provides dockage, or moorage or mooring for boats, other than (exclusive of paddle or rowboats) rowboats, either on a free, rental, or fee basis or for the convenience of the public boater.

"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm, or company organized or existing under the laws of this or any other state or county, or any person or group of persons acting individually or as a group who owns or proposes to own a marina, or other place places where boats are moored, or boating access facility.

"Pump-out facilities facility" means any device, equipment, or method of for removing sewage from a marine sanitation device. Also, it shall include and conveying such sewage to a sewerage system or treatment works including any portable, movable, or permanent holding tanks either portable, movable or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats.

"Sanitary facilities "Sewerage facility" means bathrooms, toilets, closets and other enclosures, including portable toilets, where commodes, stools, water closets, lavatories, showers, urinals, sinks, or other such plumbing fixtures are installed.

"Seasonal slips" means any slip which is used, rented, leased, or otherwise made available for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days.

"Sewage" means the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks. water-carried and nonwater-carried human excrement, kitchen, laundry, shower, bath, or lavatory waste, separately or together with such underground, surface, storm, and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, boats, industrial establishments, or other places.

"Sewage dump station" means a facility specifically designed to receive waste from portable sewage containers carried on boats and to convey such sewage to a sewerage system or a treatment works.

"Sewage treatment or disposal systems" means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge to another approved system, or an approved discharge to state waters or disposal through an approved

~~subsurface drainfield or other acceptable method, such as incineration.~~

~~"Sewerage facilities system" means entire sewage collection and disposal system including commodes, toilets, lavatories, showers, sinks and all other plumbing fixtures which are connected to a collection system consisting of sewer pipe, conduit, holding tanks, pumps and all appurtenances, including the sewage treatment or disposal system pipelines or conduits, pump stations and force mains, and all other construction, devices, and appliances used for the collection and conveyance of sewage to a treatment works or point of ultimate disposal.~~

~~"Slip" means a berth or space where a boat may be secured to a fixed or floating structure, including a dock, finger pier, boat lift, or mooring buoy.~~

~~"Transient slips" means temporary docking or mooring space which may be used for short periods of time, including overnight, days, or weeks, but less than 30 days.~~

~~"Treatment works" means any device or system used in the storage, treatment, disposal, or reclamation of sewage or combinations of sewage and industrial wastes, including but not limited to pumping, power and other equipment and appurtenances, septic tanks, and any works, including land, that are or will be (i) an integral part of the treatment process or (ii) used for ultimate disposal of residues or effluents resulting from such treatment.~~

~~"VMRC" means the Virginia Marine Resources Commission.~~

Article 2
General Information

12VAC5-570-20. Authority for regulations. (Repealed.)

~~Section 32.1-12 and 32.1-246 of the Code of Virginia provides that the State Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and places are designed to accommodate, regardless of whether such establishments serve food.~~

Article 2
General Information

12VAC5-570-30. Purpose of regulations.

~~This chapter The board has been promulgated by the State Board of Health this chapter to:~~

~~Ensure~~ 1. Protect public health and water quality by ensuring that adequate sanitary sewerage facilities and pump-out facilities, as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, sewage dump stations, and sewerage systems are provided at all marinas and other places where boats are moored, and boating access facilities.

2. Establish minimum requirements as to the adequacy of sewerage facilities and sewerage systems at all marinas and other places where boats are moored, and boating access facilities.

3. Protect public health and the environment by ensuring that all sewage generated from all regulated facilities is conveyed to an approved sewerage system or treatment works.

~~3.~~ 4. Guide the State Board of Health commissioner or his designee in its his determination of the adequacy of the sewerage systems and sewerage facilities to serve serving all marinas and other places where boats are moored, and boating access facilities.

~~4.~~ 5. Guide the State Board of Health commissioner or his designee in its approval his evaluation of plans and other data and in the issuance of a certificate as to the adequacy of sanitary and sewerage facilities; and sewerage systems.

~~5.~~ Notify the Marine Resources Commission that a certificate has been issued; and

~~6.~~ Assist the owner or his authorized engineer in the preparation of an application and supporting data, as may be required. (See 12VAC5-570-70)

12VAC5-570-40. Administration of regulations.

This chapter is administered by the following parties:

1. ~~The State Board of Health has responsibility for promulgating, amending, and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.~~

2. ~~A.~~ The State Health Commissioner commissioner is the chief executive officer of the Virginia Department of Health. The commissioner has the authority to act for the board when it is not in session. The commissioner may delegate his powers under this chapter with the exception of his power to issue variances under 12VAC5-570-90.

3. ~~B.~~ The Division of Wastewater Engineering division is designated as the primary reviewing agent of the board commissioner for the purpose of administering this chapter. It Upon receipt of the application from the local health department, the division examines and passes upon the technical aspects of all applications, plans and specifications grants or denies the application for sewerage facilities to serve marinas and other places where boats are moored, and boating access facilities. It The division issues all certificates attesting to the adequacy of the sewerage facilities and notifies the Marine Resources Commission VMRC when a certificate is issued or denied.

4. ~~The Deputy Commissioner for Community Health Services directs and supervises the activities of the local health departments in the administration of assigned duties and responsibilities under the chapter.~~

Regulations

~~5. C. The local health department in each jurisdiction, city, town or county in which there exists, or is proposed, a marina or other place where boats are moored shall (i) be responsible for the processing of all applications submitted by owners, (ii) inspect and for inspecting sites and facilities provided, (iii) issue such permits as required by law, rules or regulations for sewerage facilities and, (iv) lacking in authority to issue a permit, will process such applications in accordance with the policies and procedures of the department. The local health department shall conduct a surveillance program and enforce the provisions of this chapter to ensure proper sanitation and cleanliness of the facilities provided for compliance with this chapter.~~

~~6. The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.~~

~~12VAC5-570-50. Application of regulations to marinas and other places where boats are moored~~ Applicability.

~~A. Marinas or other places where boats are moored which are not in compliance with the Rules and Regulations of the Board of Health Governing Sanitary and Sewerage Facilities at Marinas and Other Places Where Boats Are Moored which became effective November 15, 1975 [repealed], shall comply with this chapter. Marinas, other places where boats are moored, and boating access facilities in operation prior to the effective date of this chapter shall be subject to the regulations in effect at the time the marina, other places where boats are moored, or boating access facility was permitted unless such marina, other places where boats are moored, or boating access facility is expanded after (insert the effective date of this chapter).~~

~~B. All planned or new marinas or other places where boats are moored which do not exist This chapter shall apply to all marinas, other places where boats are moored, and boating access facilities placed into operation on or after (insert the effective date of this chapter) shall comply with all provisions of this chapter prior to commencing operation.~~

~~C. All sanitary or sewerage facilities and sewerage systems shall conform to the requirements of this chapter when the marina or other place places where boats are moored are either, or boating access facility that is served by the sewerage facilities and sewerage systems is expanded, altered or modified.~~

~~D. This chapter shall apply to sewerage facilities and sewerage systems (i) serving marinas, other places where boats are moored, or boating access facilities and (ii) located on property owned by the marina, other places where boats are moored, or boating access facility. Sewerage systems or treatment works installed or proposed to be installed on property owned by someone other than the marina, other~~

~~places where boats are moored, or boating access facility owner are regulated by Chapter 6 (§ 32.1-163 et seq.) of Title 32.1 of the Code of Virginia or Title 62.1 of the Code of Virginia, as applicable.~~

Article 3 Procedure

~~12VAC5-570-60. Certification—general~~ Permits and certificate.

~~No owner shall operate construct a marina or other place places where boats are moored, or a boating access facility unless he complies with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and has obtained a construction permit in accordance with this chapter. No owner shall operate a marina, other places where boats are moored, or a boating access facility until the local health department has inspected and approved construction and has issued a certificate to operate. Owners shall have in their possession obtain a permit from the Marine Resources Commission VMRC to operate a marina, or place other places where boats are moored, or a boating access facility when so required by § 62.1-3, of the Code of Virginia. Where state-owned bottom lands are involved, the owner shall submit a plan approved preliminary design and receive approval by the department shall be issued division prior to construction and the issuance of a certificate to operate.~~

~~12VAC5-570-70. Application for certificate~~ construction permit.

~~A. Any owner, or his duly authorized representative, may make application shall apply for a certificate of approval of sanitary or sewerage facilities construction permit by applying submitting an application to the local health department in the jurisdiction where the proposed marina or other place places where boats are moored, or boating access facility is to be located. The application shall be made on a form supplied by the local health department approved by the division. The application shall consist of the following:~~

- ~~1. A completed application form which shall set forth the essential Essential data to determine the sewerage facilities and sewerage system necessary to serve the proposed installation;~~
- ~~2. Maps, plans, and specifications of the sanitary sewerage facilities and sewerage facilities system describing how and what the type of facilities that will be provided and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility. The preliminary design plans shall establish the location of the sanitary sewerage facilities and sewerage system in relation to other facilities; they are intended to serve.~~
- ~~3. A description of the proposed method of sewage or existing offsite sewerage system or treatment works used for the ultimate treatment or and disposal. Approval of sewage. The applicant shall apply for and obtain approval of the new offsite sewerage systems or treatment works or~~

~~disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter.~~

4. Any other data as may be pertinent to show the adequacy of ~~sanitary~~ the sewerage facilities and sewerage system to be provided.

B. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.

12VAC5-570-80. Receipt of ~~data~~ application.

~~Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.~~

~~A. Construction.~~ Upon completion of construction of the sanitary sewerage facilities and sewerage facilities systems at marinas and other places where boats are moored, or boating access facilities, the owner ~~of the facility,~~ or his duly authorized representative; shall notify the local health department so that it may inspect the construction. A certificate to operate shall be issued by the Health Department when it When the division, in consultation with the local health department, has ~~been~~ determined that construction is in compliance with the approved plan, it shall issue a certificate.

~~B. Operation.~~ All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia. The owner shall post the certificate in a place where it is readily observable by members of the public who transact business with the facility.

12VAC5-570-90. Variances.

~~A.~~ The commissioner may grant a variance to any requirement of this chapter if, after investigation, ~~it is determined~~ the commissioner determines that the hardship imposed upon the owner or the public by compliance with this chapter ~~outweigh~~ outweighs the benefits that the chapter confers, ~~or that there is no~~ and that granting a variance will not result in a potential or actual public health hazard.

~~A. Effect of variance.~~ B. A variance is a conditional waiver of a specific regulation ~~which that~~ is granted to a particular or designated marina or other place where boats are moored an owner of a marina, other places where boats are moored, or a boating access facility. It is nontransferable. Variances are not transferable between owners, and if any variance shall be attached to the certificate of the marina or other place places where boats are moored, or boating access facility to which it was granted. The variance is a condition of the certificate, which is revoked if the certificate is revoked.

~~B. Application for a variance.~~ C. Any owner of a marina ~~or,~~ other place places where boats are moored, or a boating access facility may apply in writing for a variance. This

application shall be submitted to the local health department in the jurisdiction in which the marina ~~or,~~ other place places where boats are moored, or boating access facility is located. This application shall include:

1. A citation ~~to~~ referencing the specific requirements of this chapter from which a variance is requested and a statement describing the hardships imposed by the specific requirements of this chapter;
2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted; and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; ~~and~~
3. Facts supporting the need and justification for the variance;
4. The nature and duration of the variance request;
5. Other information, if any, believed by the applicant to be pertinent; and
6. Such other information as the division, local health department, or the commissioner may require.

D. If the commissioner denies any request for a variance, such denial shall be in writing and shall state the reasons for the denial.

12VAC5-570-100. ~~Suspension or revocation~~ Revocation of a certificate.

~~The board~~ Either by emergency order under the authority of § 32.1-13 of the Code of Virginia or following an opportunity for an informal fact-finding proceeding as provided by § 2.2-4019 of the Code of Virginia, the commissioner or his designee may revoke or suspend a certificate for failure to construct and operate the sewerage facilities and sewerage system in accordance with the conditions of the application and certificate issued or for any violation of this chapter.

12VAC5-570-110. ~~Administration appeals~~ Applicability of the Administrative Process Act.

~~Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the The Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia. (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the decision of cases under this chapter.~~

Regulations

Part II

Required Sewerage Facilities and Sewerage Systems for Marinas and Other Places Where Boats are Moored, and Boating Access Facilities and Their Operation

12VAC5-570-120. General.

A. All owners of marinas or other places where boats are moored, and boating access facilities shall provide the minimum number of sanitary sewerage facilities required by this chapter for their patrons. These Owners shall maintain their facilities shall be maintained in a clean and sanitary operable condition. They shall be equipped Owners shall equip their facilities with toilet tissue, lights where electricity is available, and soap and towels where handwashing facilities are required. These Owners shall make their facilities shall be available during normal business hours to patrons and users of these facilities at all times during the normal boating season for that facility.

B. Marinas which are located within 1,000 feet of the shore end of the pier that are operated as part of residential developments, overnight lodging facilities, restaurants, or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted exempt from providing separate sanitary sewerage facilities, as long as the sanitary sewerage facilities at the residence, lodging establishment, restaurant, or commercial establishment are made available to all users of the marina. This The exemption set forth in this subsection does not apply to (i) marinas:

1. Marinas associated with restaurants or commercial establishments which that allow overnight occupancy of boats; and (ii) marinas

2. Marinas associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.

C. Exempt from the requirements of subsection A of this section are other Other places where boats are moored which serve and boating access facilities are exempt from the requirements of subsection A of this section, provided that the other places where boats are moored or boating access facility:

1. Serves residents of homes (houses, condominiums, apartments, or mobile homes), their bona fide house guests, or registered guests of tourist establishments which provide; and

2. Provides adequate sanitary sewerage facilities that are located within 1,000 feet of the shore end of the pier.

D. In order to qualify for an exemption under subsections subsection B or C of this section, the owner of such marinas or a marina, other places where boats are moored, or a boating access facility shall provide to the department division a signed, notarized statement that all conditions set forth in the aforementioned sections this section will be complied with by users of the facilities.

12VAC5-570-130. Location.

Adequate sanitary Owners shall conveniently locate their sewerage facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock they the facilities are intended to serve or within a reasonable. On a case-by-case basis the division may approve a greater distance under if unusual circumstances as determined by the division, such as topography or resource protection areas, prevent compliance with this requirement. The division may be necessary require the owner to provide sanitary sewerage facilities in more than one location in order to meet the needs of the particular site developed. In addition, the division may require additional fixtures, beyond the minimum number specified in Table 1 (12VAC5-570-150), if it determines that additional fixtures are necessary to accommodate the site layout and use of the marina, other places where boats are moored, or boating access facility.

12VAC5-570-140. Availability and marking of sanitary facilities.

The sanitary Owners shall locate the sewerage facilities shall be so that they are available and readily reasonably accessible to all users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities The location and use of all sewerage facilities shall be clearly indicated by appropriate signage.

12VAC5-570-150. Marinas Sewerage facilities for marinas.

A. Minimum The minimum number of sewerage fixtures to be provided in sanitary facilities. It shall be understood that at marinas is found in many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined Table 1.

B. Where dry storage space is provided, each dry storage space is equivalent to one-third of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate sewerage facilities for male and female personnel shall employees may be provided in a structure or structures, but shall not be counted toward the minimum number of fixtures required to accommodate users of the marina.

Table # 1

Number of Seasonal Slips	FIXTURES						
	Commodes		Urinals	Lavatories		Showers	
	Male	Female	Male	Male	Female	Male	Female
0-49	1	1	0	1	1	0	0
50-99	1	2	1	1	1	0	0
100-149	2	3	1	2	2	1	1
150-199	2	4	2	3	3	2	2
200-249	3	5	2	4	4	2	2

Table 1

Number of Slips	SEWERAGE FIXTURES						
	Commodes		Additional Urinal or Commode	Lavatories		Showers	
	Male	Female	Male	Male	Female	Male	Female
1 - 24	1		0	1		1	
25 - 49	1	2	1	2	2	1	1
50 - 99	2	3	1	2	2	1	1
100 - 149	3	4	1	3	3	2	2
150 - 199	3	5	2	4	4	2	2
200 - 249	4	6	2	5	5	3	3

C. When the number of seasonal slips exceeds those above on prescribed by Table No. 1, the owner shall provide additional fixtures shall be provided. ~~One~~ The owner shall provide one commode, lavatory, and shower will be provided for each sex gender for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.

B. Transient slip. When transient slips are available additional sanitary facilities shall be provided. Table No. 2 below shows the minimum number of additional fixtures required. These fixtures may be included in a structure or structures with those fixtures provided for the seasonal slip, provided the accessibility and convenience standards of 12VAC5-570-130 and 12VAC5-570-140 of this chapter are met.

Table # 2

Number of Transient Slips	FIXTURES						
	Commodes		Urinals	Lavatories		Showers	
	Male	Female	Male	Male	Female	Male	Female
0-24	1	1	1	1	1	1	1
25-49	1	2	1	2	2	2	2
50-74	2	3	1	2	2	2	2
75-100	2	4	2	3	3	3	3

Regulations

For each 24 or fraction thereof of transient slips or moorings in excess of those shown in Table No. 2 above, one commode, lavatory, and shower shall be provided for each sex. In addition, one urinal shall be provided for each 50 or fraction thereof transient slips in excess of the number shown in Table No. 2.

12VAC5-570-160. Sanitary Sewerage facilities at other places where boats are moored and boating access facilities.

A. Sewerage facilities are required at other places where boats are moored and boating access facilities in accordance with this section.

B. Where piped potable water is available, sanitary sewerage facilities for other places where boats are moored shall consist of a minimum of one commode and one lavatory, and one shower for females and one commode and one lavatory for males for each gender, for each 100 seasonal slips or fraction thereof and each 50 transient slips or fraction thereof.

C. Requirements for dry storage boat usage shall be identical to those specified in 12VAC5-570-150 for marinas.

D. Where piped potable water is not available, sewerage facilities for other places where boats are moored may consist of privies where piped water is not available.

E. Sewerage facilities at boating access facilities shall consist of at least one privy or portable toilet and shall be sufficient in number to accommodate facility usage.

F. Walking distance to these facilities shall comply with 12VAC5-570-130.

12VAC5-570-170. Sewage treatment.

A. Public or municipal sewage sewerage systems and treatment facilities shall works should be used if there is reasonable access to sewers. When such municipal means of disposal is are not available, the owner shall have designed and installed an approved method of sewage treatment. Approved methods of sewage treatment are set forth in the Sewerage Regulations (1977) (12VAC5 580 10 et seq.) Sewage Handling and Disposal Regulations (1982, as amended), 12VAC5 610 10 et seq. If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division sewerage system or treatment works. An approved sewerage system or treatment works is (i) a system for which a certificate to operate has been issued jointly by the department and the Department of Environmental Quality, (ii) a system approved by the Department of Environmental Quality in accordance with Title 62.1 of the Code of Virginia, or (iii) a system approved by the commissioner in accordance with Title 32.1 of the Code of Virginia.

A. The following shall be used to determine the amount of sewage flow. It is assumed that B. The sewage design flow for each slip or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 40 25 gallons per person slip per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only

~~seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. For dry storage facilities the sewage flow shall be calculated using one third the number of dry storage spaces. Where dry storage is provided, each dry storage space shall be equivalent to one-third of a slip. The sewage design flow for each live-aboard slip shall be 50 gallons per slip per day. When marinas or other places where boats are moored are constructed in conjunction with another structure or facility, the sewage design flows prescribed in this section shall be added to the sewage design flow governing the associated structure or facility.~~

~~In addition, for marinas C. For marinas or other places where boats are moored which have that have a boat launching ramp and provide boat trailer parking spaces only while the boat is in use boating access facility, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.~~

~~B. Where restaurants or motels are operated in connection with a marina or place where boats are moored the following shall be used as a basis for determining the amount of sewage flow:~~

~~Motels—65 gallons per person per day or a minimum of 130 gallons per room per day.~~

~~Restaurant—50 to 180 gallons per seat per day. Each installation will be evaluated according to conditions.~~

~~C. The occupancy level of boats used for design of sewage treatment or disposal facilities will be those levels listed in 12VAC5 570 170 A. It is recognized that the type of activity and utilization of marina or other places where boats are moored varies and, therefore, additional facilities to provide capacity up to maximum may be required if the need arises. The local health director serving the area in which the marina is located shall make such determination.~~

~~D. The division may approve a reduction in the sewage flow requirements specified in subsection B of this section if the owner provides documented flow data sufficient to justify the reduction.~~

12VAC5-570-180. Pump-out.

~~Other A. Owners of other places where boats are moored which that allow overnight docking or mooring of boats and owners of all marinas, regardless of size or number of boat moorings slips, shall provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures, and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other places~~

where boats are moored ~~which that~~ do not have live-aboard slips or allow boats with an installed toilet with a discharge overboard or a sewage holding tank a marine sanitation device to use any of the services provided, ~~including moorage,~~ except in an emergency. In order to qualify for this exemption, the owner of such marina or other ~~place~~ places where boats are moored shall provide the department with a signed, notarized statement indicating that there are no live-aboard slips and that boats with installed toilets with overboard discharges or sewage holding tanks marine sanitation devices shall not be permitted to use the ~~marina or other places facilities~~ facility except in an emergency.

~~A. Availability and operation. Where pump out facilities are required, the owner shall install, maintain in good operating condition and provide pump out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump out service.~~ B. The owner shall make sewage pump-out facilities available to all users of the marina or other places where boats are moored during normal operating hours. The owner shall maintain the pump-out equipment in serviceable condition and shall keep the equipment located in an area convenient for utilization.

C. The owner shall use placards or signs to identify the sewage pump-out location and use restrictions.

~~B. Alternate pump out service.~~ D. Marinas and other places where boats are moored which that provide less fewer than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted exempt from the requirement to install pump-out facilities unless such marinas or other places where boats are moored are located in a No Discharge Zone. Such exemption will shall be granted by the director of the division whenever alternate pump-out service is provided at a nearby marina or other place places where boats are moored, and is as evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the division. Such The division shall only approve such alternate pump-out service will only be approved by the division when in accordance with the following criteria are met:

1. ~~That the~~ The alternate pump-out service ~~will shall~~ not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the ~~boat sewage holding tank marine sanitation device~~ pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed ~~twenty~~ 20 minutes;.
2. ~~That the~~ The alternate pump-out service shall be located within three nautical miles, as measured along the water route, of the ~~exempt facility using the agreement~~ unless the

alternate pump-out service is located along the normal travel route to open water, in which case the exempt facility using the agreement shall be within five nautical miles of the alternate pump-out service;.

3. ~~That the~~ The alternate pump-out service capacity ~~is shall~~ be sufficient to handle the demand for pump-out service, ~~in accordance with subsection C of this section,~~ that is expected for all of the marinas or other places where boats are moored entering into the ~~above mentioned~~ agreement; referenced in this subsection.

4. ~~That a notice shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump out service, that specifies the location of the alternate pump out service; and~~ The owner of the exempt facility shall post in a conspicuous location appropriate signage that specifies the location of the alternate pump-out service and the associated charge for its use.

5. The terms of the agreement shall provide that:

a. ~~That the~~ The alternate pump-out service ~~will shall~~ be available to all boats moored at each facility and ~~it will state that~~ the alternate pump-out facility will furnish pump-out services to ~~anybody~~ boaters referred to it by the establishment using the agreement to provide pump-out service; exempt facility as specified by this chapter; and

b. ~~That the~~ The agreement ~~will shall~~ be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day termination notice to the other and to the director of the division prior to the renewal date.

6. If a termination notice is issued to a an exempt facility ~~using an agreement to provide alternate pump out service,~~ in accordance with ~~12VAC5-570-180 B~~ this subsection, then that facility shall either provide pump-out service or obtain a new written agreement; in accordance with ~~12VAC5-570-180 B,~~ this subsection by the effective date of the termination of alternate pump-out service.

~~C. Minimum design criteria for pump out facilities.~~ E. The purpose of these minimum design criteria is to provide the owner and the Department of Health department with acceptable methods for pumping, storing, and conveying and treatment of the contents from boat holding tanks marine sanitation devices. The owner shall furnish the following information for each proposed pump out facility A proposed pump-out facility shall meet the following minimum design criteria:

1. ~~Pumping equipment.~~ Pump equipment may be fixed or portable; however, this equipment shall be ~~conveniently located for usage and~~ clearly identified or placarded by signs or other notices, indicating any fees, restrictions, or other operating instructions, as necessary. A minimum pump capacity of 10 ~~gpm~~ gallons per minute (gpm) is

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acceptable at the operating head required to transport the flow to the proper collection or treatment location with such residual head as may be required; however, at marinas with 51 or more slips, greater pumping capacity may be required. ~~Pumps To prevent clogging, pumps shall be of a macerator type or have sufficient size suction and discharge openings to prevent clogging the pumps shall be able to pass a 2-inch spherical solid.~~ Manually operated pumps are ~~not permitted acceptable at marinas and other places where boats are moored that offer fewer than 26 slips.~~ Pump data from the manufacturer shall include:

- a. ~~The type of pump (diaphragm or (positive displacement, centrifugal, and power) vacuum, macerator, etc.);~~
- b. ~~Rated capacity (gpm, hp. and head) Pump power source (electric motor, gasoline engine, etc.) and output (HP);~~
- c. ~~Motor type (electric or gas); and Pump capacity, including a performance curve;~~
- d. ~~Suction and discharge opening size. Pump solids-handling ability; and~~
- e. A schematic showing relevant pump dimensions, such as height, size, and location of suction and discharge openings, etc.

2. ~~Location schematic. If fixed pump-out equipment is proposed, a schematic of the location with elevations for subsections a, b, c, d and e, as described below, shall be included, or if portable pump-out equipment is proposed, a schematic shall indicate elevations for subsections a, c, f and g, as described below. A schematic of the proposed facilities shall be provided and include the following minimum information:~~

- a. Mean low water level elevation;
- b. Elevation of dock Suction hose diameter, length, and highest elevation;
- c. Greatest elevation of suction center line of pump Pump elevation;
- d. Elevation of discharge point Discharge hose/pipe diameters, lengths, and highest elevation;
- e. Highest point in discharge line Discharge point elevation;
- f. ~~Type of dock (floating or stationary); and~~
- g. Greatest elevation of any dock; and
- h. Distance between pump-out location and slips.

All elevations shall be measured with respect to mean low water. If the elevation of mean low water is not known, assume it to be zero.

3. ~~Fittings and hose (piping). Fittings This subdivision sets forth the minimum design criteria for fittings and hoses (piping) which are used in the operation of a pump-out facility shall meet the following:~~

a. ~~Suction hose hoses shall meet the following criteria:~~

- (1) A friction nozzle (right angle preferred) or wand-type attachment is to be provided on the end of the suction hose. Adapters shall be provided to fit any discharge connection from ~~1.5~~ 1.25 to 4 2 inches in diameter.
- (2) A check valve shall be provided on the suction hose at the nozzle.
- (3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis by the division.
- (4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for service, a ~~gate~~ full port ball valve shall be provided on the pump end of the suction line.

b. ~~Discharge hose and piping; shall meet the following criteria:~~

- (1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections.
- (2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing.

c. ~~Discharge line lines shall meet the following criteria:~~

- (1) A ~~gate~~ full port ball valve shall be provided on the discharge line at the pump;
- (2) Suitable connections on the end of the discharge line shall be provided to prevent it from ~~coming loose~~ dislodging during discharge; all nozzles and fittings are to be positive locking, male and female.
- (3) The discharge line ~~must~~ shall not be subject to freezing or leaking into the water course.
- (4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (~~12VAC5-590-10 et seq.~~) (12VAC5-590) and the Sewage Handling and Disposal Regulations (~~12VAC5-610-10 et seq.~~) (12VAC5-610).

(5) The discharge line connection to the pump-out receiving facility shall be fixed in place in such a manner as to prevent it from ~~coming loose~~ dislodging during discharge.

d. ~~Pump-out facilities shall include equipment for rinsing the boats' holding tanks associated with marine sanitation devices.~~ Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type vacuum breaker shall be provided.

4. ~~Other devices or methods of removal. Other devices or methods of removal of contents from boat holding tanks~~

marine sanitation devices may be approved by the Commissioner division on an individual case basis.

~~5. Onshore facilities. Contents from boat holding tanks shall be discharged to (i) a public wastewater collection system in which sewage is conveyed to an approved treatment facility; (ii) a holding tank whereby sewage may be stored until it is taken in an approved manner to an approved treatment facility; or (iii) directly to an approved sewage treatment facility.~~

~~a. For discharge to a public wastewater collection system, the following will be required: The owner of the marina or other place where boats are moored shall submit evidence, in writing, (i) of consent from the owner of the system, (ii) from the owner of any conveyance systems located downstream, which may be affected, and (iii) from the owner of the ultimate treatment facility. Verification shall be given that there are satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.~~

~~b. If sewage is to be stored in a holding tank, the holding tanks shall be sized, constructed and located to meet the criteria:~~

~~(1) Size of holding tank.~~

~~Marinas or other places where boats are moored shall size the holding tanks based upon the following tabulations:~~

Total Number of Boats Serviced with Holding Tanks	Required Onshore Holding Tank Volume (gallons) Minimum
1-20	250
21-40	500
41-60	725
61-80	1000
81-100	1200
100+	2000

~~(2) Construction of holding tank.~~

~~(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.~~

~~(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.~~

~~(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.~~

~~(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.~~

~~(e) The holding tank shall be fixed in place unless it is part of an approved mobile pump out unit.~~

~~(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.~~

~~(g) The holding tank shall be adequately vented. Screened, elbows down vents installed at the top of the tank will serve this requirement.~~

~~(h) The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.~~

~~(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.~~

~~(3) Holding tank location.~~

~~Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.)~~

~~(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.)~~

~~e. Sewage treatment plant. Disposal of holding tank wastes shall not be allowed at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewer system of a large sewage treatment facility or transported for eventual treatment at a large plant.~~

12VAC5-570-190. Sewage dump station.

A. All marinas and other places where boats are moored, regardless of size or number of boat moorings, shall have ~~an acceptable a proper and adequate~~ receiving station for sewage from portable toilets containers used on boats. ~~The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision subsection are marinas or other places where boats are moored which that also qualify for the exemption contained in 12VAC5-570-120 B or C exemption, provided that the owner of the sanitary sewerage facility will allow consents to the dumping of the contents of portable toilets sewage containers into the sanitary sewerage facilities.~~

B. ~~Availability and operation.~~ Where a sewage dump station is required, the owner shall install, ~~and maintain in good operating condition, and provide it in a serviceable and~~

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sanitary condition and in compliance with this chapter. The owner shall make the facilities available to users of the marina or other places where boats are moored. The owner shall locate the sewage dump station in an area convenient for use, and the owner shall use placards or signs to identify its location and restrictions.

C. ~~Minimum design criteria for a sewage dump station.~~ The purpose of ~~these~~ the minimum design criteria is to provide the owner and the Department of Health department with acceptable methods of discharging sewage from a portable ~~container~~ containers into a sewage holding tank or a ~~sewage sewerage~~ treatment system works. The same criteria as set forth in ~~12VAC5-570-180 C-5~~ 12VAC5-570-200 A for contents from ~~boat holding tanks~~ will marine sanitation devices shall apply for sewage dump stations. The sewage dump station receiving unit shall be a minimum of 12 inches in diameter and be equipped with a cover that has a lip of sufficient size to ~~prevent it from accidentally being removed~~ prohibit accidental removal. If the unit is designed to drain, the drain shall be a minimum of four inches in diameter and equipped with a fly tight cover.

D. Marinas and other places where boats are moored that have an operational pump-out facility equipped with a device to pump portable sewage containers are exempt from the requirements of subsection C of this section.

12VAC5-570-200. Onshore facilities.

A. Contents from marine sanitation devices and portable sewage containers used on boats shall be discharged to:

1. A public sewerage system for conveyance to an approved treatment works as described in 12VAC5-570-170 A;
2. A holding tank whereby sewage may be stored until it is transported in accordance with the Sewage Handling and Disposal Regulations to an approved treatment works as described in 12VAC5-570-170 A; or
3. An approved sewage treatment works as described in 12VAC5-570-170 A.

B. Disposal of sewage waste from a marine sanitation device shall be prohibited at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewerage system of a large sewage treatment facility or transported for eventual treatment at a large sewage treatment facility.

C. For discharge to a public sewerage system, the owner of the marina or other places where boats are moored shall submit to the division, in writing:

1. Evidence of consent to the discharge from the owner of the conveyance system;
2. Evidence of consent to discharge from the owner of any conveyance systems located downstream that may be affected; and

3. Evidence of consent to discharge from the owner of the treatment works where the sewage is to be disposed.

The owner shall verify that there are satisfactory provisions for emptying the contents from portable sewage containers in a sanitary manner.

D. If sewage is to be stored by the marina or other places where boats are moored in a holding tank, the holding tank or tanks shall be sized, constructed, and located to meet the following criteria:

1. Sewage holding tanks shall be sized in accordance with the requirements of Table 2.

Table 2: Minimum Holding Tank Volume

<u>Total Number of Boats Serviced Annually with Marine Sanitation Devices</u>	<u>Minimum Holding Tank Volume (gallons)</u>
<u>1 - 60</u>	<u>725</u>
<u>61 - 80</u>	<u>1000</u>
<u>81 - 100</u>	<u>1200</u>
<u>100+</u>	<u>2000</u>

2. Holding tanks shall be constructed in accordance with the following criteria:

- a. The holding tank shall be watertight and not subject to any infiltration or leakage.
- b. When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater, and saltwater.
- c. When holding tanks are made of material other than concrete, the external surface of the holding tank shall be protected from corrosion.
- d. The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.
- e. The holding tank shall be located onshore and fixed in place unless it is part of an approved mobile pump-out unit.
- f. Provisions shall be made to the satisfaction of the department to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.
- g. The holding tank shall be adequately vented. This requirement may be met with screened, elbowed down vents installed at the top of the tank.
- h. The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.

i. There shall be provisions for emptying the contents from portable sewage containers in a sanitary manner.

3. The required separation distances between holding tank and various structures and features are contained in Table 4.1 of the Sewage Handling and Disposal Regulations (12VAC5-610-597 D).

4. Any person who removes, or contracts to remove and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the commissioner in accordance with the Sewage Handling and Disposal Regulations (12VAC5-610).

VA.R. Doc. No. R11-2688; Filed November 7, 2013, 12:24 p.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Emergency Regulation

Title of Regulation: **12VAC30-20. Administration of Medical Assistance Services (amending 12VAC30-20-500, 12VAC30-20-520, 12VAC30-20-540, 12VAC30-20-560).**

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq.

Effective Dates: January 1, 2014, through June 30, 2015.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

Preamble:

Section 2.2-4011 of the Administrative Process Act states that an agency may adopt emergency regulations in situations in which Virginia statutory law, the Virginia appropriation act, or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia. Item 307 III of Chapter 3 of the 2012 Acts of Assembly, Special Session I, authorizes the Department of Medical Assistance Services to promulgate regulations to implement changes related to appeals administered by and for the department as described in Item 307 III within 280 days or less from its enactment date.

The purpose of this regulatory action is to comply with the legislative mandate and address recent case law and administrative decisions that have created the need to clarify existing appeals processes and codify emerging processes made urgent by court and administrative case decisions and the increasing volume of appeals generated by provider audits and other utilization review mandates. Specifically, recent case decisions such as Virginia Department of Medical Assistance Services v. Patient Transportation System, 58 Va. App.328, 709 S. E. 2d 188 (2011) and its predecessor appeal in circuit court have necessitated clarifying the means by which documentation

can be transmitted and the manner in which alleged deficiencies in case summaries can be addressed. The volume of appeals has left outdated appeal timelines established a decade ago and requires immediate clarification and updating to reflect the realities that the hearing officers and all parties to the appeal process face in attempting to meet outdated timelines that were originally established when the volume of appeals was less than one third of the current volume.

This regulation is necessary to comply with the requirements set out in Item 307 III of Chapter 3 of the 2012 Acts of Assembly, Special Session I, and is not expected to have direct impact on the health, safety, or welfare of the citizens of the Commonwealth.

Section 32.1-325.1 of the Code of Virginia requires the agency to provide the right of appeal to Medicaid service providers and to do so within established timeframes that are more specifically contained in the regulations subject to this regulatory action. The mandate must be fulfilled and, in order to do so, the timeframes and requirements must adapt to and reflect the growing volume and complexity of appeals. Protecting the agency's right to collect overpayments of public funds, while assuring the provider's right to a timely appeal, requires clarifying existing processes and codifying processes that court and administrative proceedings have placed in practice to deal with the increasing volume of appeals. It is in the interest of all parties to clarify and to amend the appeal regulation to reflect current needs and practices.

The amendments (i) address the Department of Medical Assistance Services (DMAS) timeframes and specification for filing required documentation, including the sufficiency of the contents of case summaries; and (ii) clarify DMAS' authority to administratively invalidate untimely filed appeals.

**Part XII
Provider Appeals**

12VAC30-20-500. Definitions.

The following words, when used in this part, shall have the following meanings:

"Administrative dismissal" means a dismissal that requires only the issuance of a decision with appeal rights but that does not require the submission of a case summary or any further proceedings.

"Day" means a calendar day unless otherwise stated.

"DMAS" means the Virginia Department of Medical Assistance Services or its agents or contractors.

"Hearing officer" means an individual selected by the Executive Secretary of the Supreme Court of Virginia to conduct the formal appeal in an impartial manner pursuant to §§ 2.2-4020 and 32.1-325.1 of the Code of Virginia and this part.

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"Informal appeals agent" means a DMAS employee who conducts the informal appeal in an impartial manner pursuant to §§ 2.2-4019 and 32.1-325.1 of the Code of Virginia and this part.

"Provider" means an individual or entity that has a contract with DMAS to provide covered services and that is not operated by the Commonwealth of Virginia.

"Transmit" means send by means of the U.S. Postal Service, courier or other hand delivery, facsimile, electronic mail, or electronic submission.

12VAC30-20-520. Provider appeals: general provisions.

A. This part governs all DMAS informal and formal provider appeals and shall supersede any other provider appeals regulations.

B. A provider may appeal any DMAS action that is subject to appeal under the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), including DMAS' interpretation and application of payment methodologies. A provider may not appeal the actual payment methodologies.

C. DMAS shall ~~mail~~ transmit all items to the last known address of the provider. It is presumed that DMAS ~~mails~~ transmits items on the date noted on the item. It is presumed that providers receive items ~~mailed~~ sent by U.S. mail to their last known address within three days after DMAS ~~mails~~ sends the item by U.S. mail. It is presumed that providers receive items sent by email or facsimile, to their last known email address or facsimile number, on the date sent.

D. Whenever DMAS or a provider is required to file a document, the document shall be considered filed when it is date stamped by the DMAS Appeals Division in Richmond, Virginia.

E. Whenever the last day specified for the filing of any document or the performance of any other act falls on a day on which DMAS is officially closed, for the full or partial day, the time period shall be extended to the next day on which DMAS is officially open.

F. Conferences and hearings shall be conducted at DMAS' main office in Richmond, Virginia, or at such other place as agreed to by the parties.

G. Whenever DMAS or a provider is required to attend a conference or hearing, failure by one of the parties to attend the conference or hearing shall result in dismissal of the appeal in favor of the other party.

H. DMAS shall reimburse a provider for reasonable and necessary attorneys' fees and costs associated with an informal or formal administrative appeal if the provider substantially prevails on the merits of the appeal and DMAS' position is not substantially justified, unless special circumstances would make an award unjust. In order to substantially prevail on the merits of the appeal, the provider must be successful on more than 50% of the dollar amount

involved in the issues identified in the provider's notice of appeal.

I. Documents that are filed with the DMAS Appeals Division or the hearing officer after 5 p.m. eastern time on the due date shall be untimely.

12VAC30-20-540. Informal appeals.

A. Providers appealing a DMAS decision shall file a written notice of informal appeal with the DMAS Appeals Division within 30 days of the provider's receipt of the decision. Providers appealing the termination or denial of their Medicaid agreement pursuant to § 32.1-325 D of the Code of Virginia shall file a written notice of informal appeal with the DMAS Appeals Division within 15 days of the provider's receipt of the notice of termination or denial. Providers appealing adjustments to a cost report shall file a written notice of informal appeal with the DMAS Appeals Division within 90 days of the provider's receipt of the notice of program reimbursement. The notice of informal appeal shall identify the issues being appealed. Failure to file a written notice of informal appeal that identifies the issues being appealed within 30 days of receipt of the decision ~~or within 90 days of receipt of the notice of program reimbursement~~ shall result in an administrative dismissal of the appeal. Failure to file a written notice of informal appeal that identifies the issues being appealed for termination or denial of a Medicaid agreement pursuant to § 32.1-325 D of the Code of Virginia within 15 days of receipt of the notice of termination or denial shall result in an administrative dismissal of the appeal. Failure to file a written notice of informal appeal that identifies the issues being appealed within 90 days of receipt of the notice of program reimbursement shall result in an administrative dismissal of the appeal.

B. DMAS shall file a written case summary with the DMAS Appeals Division within 30 days of the filing of the provider's notice of informal appeal. DMAS shall ~~mail~~ transmit a complete copy of the case summary to the provider on the same day that the case summary is filed with the DMAS Appeals Division. The case summary shall address each disputed adjustment, patient, service date, or other ~~disputed matter~~ appealable issue identified by the provider in its notice of informal appeal and shall state DMAS' position for each disputed adjustment, patient, service date, or other ~~disputed matter~~ appealable issue identified by the provider in its notice of informal appeal. The case summary shall contain the factual basis for each disputed adjustment, patient, service date, or other ~~disputed matter~~ appealable issue identified by the provider in its notice of informal appeal and any other information, authority, or documentation DMAS relied upon in taking its action or making its decision on the appealable issues identified by the provider in its notice of informal appeal. Failure to file a written case summary with the DMAS Appeals Division in the detail specified within 30 days of the filing of the provider's notice of informal appeal

shall result in dismissal in favor of the provider on those appealable issues not addressed in the detail specified. If the provider alleges any nonsubstantive deficiencies with the case summary, defined as being other than the factual basis for each disputed adjustment, patient, service date, or other appealable issue identified by the provider in its notice of informal appeal, the provider shall adhere to the following procedure: the provider shall have 12 days following the due date of the case summary to file with the DMAS Appeals Division and transmit to the author of the case summary a written notice of any alleged nonsubstantive deficiencies that the provider knows or reasonably should know exist. DMAS shall have 12 days after the DMAS Appeals Division's receipt of the provider's written notice to address or cure any alleged deficiencies. Failure of the provider to timely file a written notice with the DMAS Appeals Division pursuant to this procedure shall be deemed a waiver of any alleged nonsubstantive deficiencies with the case summary. Any remaining dispute regarding the sufficiency of the case summary not resolved through the procedure herein shall be addressed by the informal appeals agent as part of the informal appeal decision.

C. The informal appeals agent shall conduct the conference within 90 days from the filing of the notice of informal appeal. If DMAS and the provider and the informal appeals agent agree, the conference may be conducted by way of written submissions. If the conference is conducted by way of written submissions, the informal appeals agent shall specify the time within which the provider may file written submissions, not to exceed 90 days from the filing of the notice of informal appeal. Only written submissions filed within the time specified by the informal appeals agent shall be considered.

D. The conference may be recorded for the convenience of the informal appeals agent. Since the conference is not an adversarial or evidentiary proceeding, recordings shall not be made part of the administrative record and shall not be made available to anyone other than the informal appeals agent.

E. Upon completion of the conference, the informal appeals agent shall specify the time within which the provider may file additional documentation or information, if any, not to exceed 30 days. Only documentation or information filed within the time specified by the informal appeals agent shall be considered.

F. The informal appeal decision shall be issued within 180 days of receipt of the notice of informal appeal.

G. Whenever an informal appeal is required pursuant to a remand by court order, final agency decision, agreement of the parties, or otherwise, all time periods set forth in this section shall begin to run effective with the date of the remand, unless otherwise specified within the remand.

12VAC30-20-560. Formal appeals.

A. Any provider appealing a DMAS informal appeal decision shall file a written notice of formal appeal with the

DMAS Appeals Division within 30 days of the provider's receipt of the informal appeal decision. The notice of formal appeal shall identify the issues being appealed. Failure to file a written notice of formal appeal that identifies the issues being appealed within 30 days of receipt of the informal appeal decision shall result in dismissal of the appeal.

B. DMAS and the provider shall ~~exchange~~ transmit to the other party and file with the hearing officer all documentary evidence on which DMAS or the provider relies within 21 days of the filing of the notice of formal appeal. Only documents filed within 21 days of the filing of the notice of formal appeal shall be considered. DMAS and the provider shall ~~file~~ transmit to the other party and file with the hearing officer any objections to the admissibility of documentary evidence within seven days of the filing of the documentary evidence. Only objections filed within seven days of the filing of the documentary evidence shall be considered. The hearing officer shall rule on any objections within seven days of the filing of the objections.

C. The hearing officer shall conduct the hearing within 45 days from the filing of the notice of formal appeal, unless the hearing officer, DMAS, and the provider all mutually agree to extend the time for conducting the hearing. Notwithstanding the foregoing, the due date for the hearing officer to submit the recommended decision to the DMAS director shall not be extended or otherwise changed.

D. Hearings shall be transcribed by a court reporter retained by DMAS.

E. Upon completion of the hearing, DMAS and the provider shall have 30 days to ~~exchange~~ transmit to the other party and file with the hearing officer an opening brief. Only opening briefs filed within 30 days after the hearing shall be considered. DMAS and the provider shall have 10 days to ~~exchange~~ transmit to the other party and file with the hearing officer a reply brief after the opening brief has been filed. Only reply briefs filed within 10 days after the opening brief has been filed shall be considered. Notwithstanding the foregoing, if there has been an extension to the time for conducting the hearing pursuant to subsection C of this section, the hearing officer is authorized to alter the time periods for briefs set forth herein so that the hearing officer complies with the due date set forth in subsection F of this section.

F. The hearing officer shall submit a recommended decision to the DMAS director with a copy to the provider within 120 days of receipt of the formal appeal request. If the hearing officer does not submit a recommended decision within 120 days, then DMAS shall give written notice to the hearing officer and the Executive Secretary of the Supreme Court that a recommended decision is due.

G. Upon receipt of the hearing officer's recommended decision, the DMAS director shall notify DMAS and the provider in writing that any written exceptions to the hearing officer's recommended decision shall be filed with the DMAS

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director within 30 14 days of receipt of the DMAS director's letter. Only exceptions filed within 30 14 days of receipt of the DMAS director's letter shall be considered. The DMAS director shall issue the final agency decision within 60 days of receipt of the hearing officer's recommended decision.

VA.R. Doc. No. R14-3105; Filed November 1, 2013, 2:51 p.m.

Fast-Track Regulation

Titles of Regulations: 12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-210).

12VAC30-80. Methods and Standards for Establishing Payment Rates; Other Types of Care (amending 12VAC30-80-40).

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 1, 2014.

Effective Date: January 16, 2014.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmass.virginia.gov.

Basis: Section 32.1-325 of the Code of Virginia grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. Section 32.1-324 of the Code of Virginia authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the board's requirements. The Medicaid authority as established by § 1902(a) of the Social Security Act (42 USC § 1396 et seq.) provides governing authority for payments for services.

Supplemental Rebates - Section 4401 of the federal Omnibus Budget Reconciliation Act of 1990 added § 1927 to the Social Security Act (42 USC § 1396r-8). This provided for the Commonwealth to receive supplemental rebates on pharmaceutical products purchased by Medicaid for fee-for-service recipients, in addition to the rebates received under the manufacturers' CMS agreement. Payments of supplemental rebates by the pharmaceutical manufacturers to the Commonwealth does not affect DMAS payment methodology for pharmacy services.

Unit Dose Drugs Dispensing Fee - Chapter 890, Item 297 NNNN of the 2011 Acts of Assembly directed DMAS to discontinue paying the dispensing fee of \$5.00 to nursing facilities for drugs dispensed to residents via unit dose systems.

Drug Threshold Program - The need for regulations controlling the use of high numbers of prescription drugs

no longer exists. DMAS' authority for this change derives from its general authority set out in § 32.1-325 of the Code of Virginia, which provides for administering and amending the State Plan for Medical Assistance.

Purpose: This suggested regulatory action will not affect the health, safety, or welfare of the citizens of the Commonwealth. The federally mandated drug rebate program does benefit the Commonwealth by permitting DMAS to recover some of its expenditures for legend drugs.

Supplemental Rebates - The supplemental rebate program, implemented by DMAS in 2004, saves the Commonwealth of Virginia millions of dollars per year in the cost of legend drugs provided to fee-for-service Medicaid recipients. This rebate program helps DMAS offset some of its expenditures while at the same time assuring that fee-for-service Medicaid recipients have access to clinically appropriate medications in all covered therapeutic drug classes. The proposed changes to the supplemental rebate agreement described in 12VAC30-80-40 A 9 reduce the time necessary to execute new contracts and renew existing contracts, and increase the flexibility of DMAS and its pharmaceutical manufacturing partners in the contracting process, thereby enhancing a cost effective and clinically appropriate pharmacy program that saves the Commonwealth money.

Unit Dose Drugs Dispensing Fee - The discontinuing of the dispensing fee for unit dose drugs dispensed by nursing facility pharmacies will save DMAS a small expenditure.

Drug Threshold Program - The need for the provisions establishing prior authorization requirements when high numbers of prescription drugs is monitored by the Drug Utilization Review Board.

Rationale for Using Fast-Track Process: This proposed regulatory change is being promulgated through the fast-track rulemaking process because it is noncontroversial: (i) it reduces the time and effort needed to execute contracts and revisions to these contracts without reducing or modifying existing terms or conditions of the supplemental rebate agreements between DMAS and pharmaceutical manufacturers; (ii) it eliminates a dispensing fee that is no longer necessary; and (iii) it removes prior authorization requirements for using high numbers of prescription drugs because it has been replaced with the Drug Utilization Review program. No opposition is expected as a result of this suggested fast-track regulatory action.

Substance: The sections of the State Plan that are affected by this action are the Methods and Standards for Establishing Payment Rates; Other Types of Care: Fee for Services Reimbursement for Pharmacy Services (12VAC30-80-40) and the Amount, Duration, and Scope of Services: Pharmacy Services (12VAC30-50-210).

Supplemental Rebates - Prior to 2004, DMAS did not collect rebates for expenditures for legend drugs and spent almost \$499 million for this service. In 2005, DMAS' gross

expenditures for prescribed drugs were almost \$612 million with almost \$11 million in manufacturers' rebates. In 2007, with the implementation of the federal Medicare Part D program (which reimburses for a significant amount of the legend drugs required by Virginia Medicaid individuals), DMAS saw its gross expenditures for prescribed drugs decrease to almost \$228 million with a concomitant decrease in the manufacturers' rebates to slightly more than \$2 million.

The current supplemental rebate contracting policy requires DMAS and pharmaceutical manufacturers to execute an 18-page to 20-page contract each time there is a change in the types of supplemental drugs to be included in the supplemental rebate program by a specific pharmaceutical manufacturer. The supplemental rebate contracts and amendments in current regulation are the model supplemental rebate contracts A, B, and C and amendments 1 and 2.

DMAS proposes to develop one Supplemental Drug Rebate Agreement and one Supplemental Drug Rebate Amendment. Additional changes to these documents by either the manufacturer or DMAS would be made through addenda to the original agreement. Renewals to the agreement would be made through an amendment to the original agreement.

Unit Dose Drugs Dispensing Fee - In 2003, DMAS implemented a unit dose dispensing fee of \$5.00 per member per month as a means of reimbursing nursing home pharmacies for the packaging of individual doses of medication for their Medicaid residents. This dispensing fee compensated nursing facility pharmacies for the time and materials to perform in-house packaging as was the practice at the time.

Community pharmacies are also paid a dispensing fee for their pharmacy services for individuals who live in their communities. Community pharmacies do not use unit dose packaging systems for drugs dispensed to individuals who are not institutionalized.

With the implementation of the Medicare Part D prescription drug program in 2006, the vast majority of Medicaid recipients residing in nursing facilities became eligible for Medicare Part D prescription drug benefits. As a result, the payment of the dispensing fee for unit dose prescription drugs covered by DMAS was no longer necessary. Although DMAS still covers drugs not covered by Medicare Part D (benzodiazepines, barbiturates, and over the counter medications) and prescription drugs for nursing facility residents enrolled in the Medicaid program but not eligible for Medicare Part D, the vast majority by volume of unit dose prescriptions are provided by Medicare Part D plans.

Additionally, DMAS determined in a recent analysis of pharmacy reimbursement that nursing facility pharmacies are no longer packaging unit dose prescriptions in-house

but are receiving prepackaged unit dose prescriptions directly from external pharmacies thereby making the unit dose dispensing fee no longer necessary. DMAS estimates that the elimination of this unnecessary unit dose dispensing fee will save the agency approximately \$323,708 in General Fund dollars for the state fiscal year 2012.

Drug Threshold Program - DMAS is proposing the removal of the pharmacy threshold program. This program, adopted by DMAS in 2004, required prior authorization for fee-for-service non-institutionalized Medicaid patients whose volume of prescriptions for legend drugs exceeded nine unique prescriptions within 180 days and institutionalized Medicaid patients whose volume of legend drugs exceeded nine unique prescriptions within 30 days. The definition of prior authorization as it relates to the pharmacy threshold program is eliminated as is the description of the program in 12VAC30-50-210 A 7 d (1) through (4).

The elimination of the pharmacy threshold program in current state regulation is proposed in this regulatory change because this function has been assumed by the Virginia Drug Utilization Review Board (DUR Board), and therefore is no longer needed. The DUR Board carries out reviews at least semiannually of high prescription use by patients and targets prescribers of these patients through individual notifications that includes relevant peer-reviewed clinical standards specific to these patients' diagnoses.

In addition, pharmacists are informed at the point of sale through prospective DUR (Pro-DUR) edits if prescriptions have exceeded nine unique prescriptions within 180 days or 30 days, depending on the non-institutional or institutional status of patients. This DUR Board function achieves the objectives of the pharmacy threshold program by reducing over-prescribing without clinical justification and informs prescribers and pharmacists about patients who have received excessive, clinically questionable prescriptions.

Issues: The issues are as follows:

Supplemental Rebates - The primary advantages to this regulatory change are to decrease the time and paperwork and increase the flexibility of DMAS and its pharmaceutical manufacturing partners by modifying the supplemental rebate agreement and amendment. There are no known disadvantages to this regulatory change.

Unit Dose Drugs Dispensing Fee - This change has a small advantage for the agency in that it will save slightly more than \$300,000 in expenditures. It would be a slight disadvantage to the nursing facilities that have been receiving these dispensing fees.

Drug Threshold Program - There are no advantages or disadvantages to anyone regarding the removal of this text. This function has been assumed by the Drug Utilization Review Board so this additional service limit text is not necessary.

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Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed changes 1) discontinue the \$5 per individual per month unit dose fee paid to nursing home pharmacies by Virginia Medicaid, 2) modify the supplemental rebate contracting process, and 3) repeal the regulatory language regarding the pharmacy threshold program.

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. Pursuant to Chapter 890 Item 297 NNNN of the 2011 Appropriation Act, one of the proposed changes permanently discontinues the \$5 per individual per month unit dose fee paid by Medicaid for individuals residing in a nursing facility. This dispensing fee is to compensate nursing home pharmacies for time and material costs associated with performing in-house packaging. This change was implemented in July 2011.

According to the Department of Medical Assistance Services (DMAS), a majority of nursing home residents became eligible for the Medicare Part D prescription drug program that was implemented in 2006. As a result, the need for the Medicaid unit dose dispensing fee was significantly reduced. In addition, DMAS reports that nursing facility pharmacies no longer package unit dose prescriptions in-house, but receive pre-packaged unit dose prescriptions directly from external pharmacies thereby making the payment of this dispensing fee unnecessary.

The main economic effect of this change will be on pharmacies that used to package unit dose prescriptions in house prior to July 2011. They are expected to lose \$647,416 per year in revenues as a result of this change. One half of this amount (\$323,708) represents savings to the Commonwealth and the other half represents savings to the federal government, as currently 50% of Virginia Medicaid is paid by federal matching funds. In addition, a reduction in federal funds coming in to the Commonwealth will likely have additional a contractionary economic impact beyond the initial \$323,708 reduction in economic activity due to repercussion effects.

Additionally, one of the proposed changes will modify the supplemental rebate contracting process. DMAS collects rebates from manufacturers for expenditures for legend drugs provided to Medicaid fee-for-service recipients. The current rules require DMAS and pharmaceutical manufacturers to execute an 18-20 pages model contract each time there is a change in the types of drugs included in the rebate program. The proposed changes will allow DMAS and pharmaceutical manufacturers to execute an initial contract and effectuate changes through an addendum to the original agreement. This change is expected to reduce the time necessary to execute new contracts and renew existing ones. It will also provide

additional flexibility to DMAS and to pharmaceutical manufacturers in the contracting process.

Finally, the proposed changes will repeal the regulatory language regarding the pharmacy threshold program.¹ The pharmacy threshold program aims to reduce excessive prescription of drugs without clinical justification. According to DMAS; however, the program has never been implemented as written in regulations. This function has been assumed by the Drug Utilization Review (DUR) Board since August 2005. The DUR Board is reported to have been carrying out reviews, at least semi-annually, of high prescription use by patients and is targeting prescribers of these patients through individual notifications that include relevant peer-reviewed clinical standards specific to these patients' diagnoses. In addition, pharmacists are informed at the point of sale through prospective DUR edits if prescriptions have exceeded the thresholds. This DUR Board review function is expected to achieve the objectives of the pharmacy threshold program by reducing over-prescriptions without clinical justification and to inform prescribers and pharmacists about patients who have received excessive, clinically questionable prescriptions. Since there does not appear to be any operational differences as a result of this change, no significant economic effect is expected other than achieving consistency between the regulatory language and the practice.

Businesses and Entities Affected. The proposed repeal of unit dose dispensing fee is expected to primarily affect 76 nursing facility pharmacies. The proposed supplemental rebate contract change is expected to primarily affect approximately 20 pharmaceutical manufacturers providing rebates and the Virginia Medicaid program. The drug threshold program applies to all of the approximately 1,857 pharmacies enrolled in Medicaid.

Localities Particularly Affected. The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment. The proposed repeal of the unit dose dispensing fee is expected to reduce revenues of nursing facility pharmacies which may have a negative impact on their demand for labor. Also, simplification of the supplemental rebate contracting process may reduce demand for legal professionals by a small margin.

Effects on the Use and Value of Private Property. The proposed changes are not anticipated to have a direct impact on the use and value of private property. However, a reduction in revenues of nursing facility pharmacies may have a negative impact on their asset values.

Small Businesses: Costs and Other Effects. Only the repeal of unit dose dispensing fee is expected to have a small business impact as most of the nursing home pharmacies are believed to be small businesses. Anticipated economic effects on nursing home pharmacies are discussed above.

Small Businesses: Alternative Method that Minimizes Adverse Impact. There does not seem to be an alternative

method that minimizes the adverse impact while achieving the same goals.

Real Estate Development Costs. No impact on real estate development costs is expected.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

¹ Current regulatory language requires prior authorization for prescriptions for legend drugs that exceed nine unique prescriptions within 180 days for non-institutionalized Medicaid fee-for-service patients and within 30 days for institutionalized patients.

Agency's Response to Economic Impact Analysis: The agency concurs with the economic impact analysis prepared by the Department of Planning and Budget.

Summary:

The amendments (i) discontinue the \$5.00 per individual per month unit dose fee paid to nursing home pharmacies by Virginia Medicaid, (ii) modify the supplemental drug rebate contracting process, and (iii) repeal the regulatory language regarding the pharmacy threshold program.

12VAC30-50-210. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs.

1. Drugs for which Federal Financial Participation is not available, pursuant to the requirements of § 1927 of the Social Security Act (OBRA 90 § 4401), shall not be covered.

2. Nonlegend drugs shall be covered by Medicaid in the following situations:
 - a. Insulin, syringes, and needles for diabetic patients;
 - b. Diabetic test strips for Medicaid recipients under 21 years of age;
 - c. Family planning supplies;
 - d. Designated categories of nonlegend drugs for Medicaid recipients in nursing homes; and
 - e. Designated drugs prescribed by a licensed prescriber to be used as less expensive therapeutic alternatives to covered legend drugs.

3. Legend drugs are covered for a maximum of a 34-day supply per prescription per patient with the exception of the drugs or classes of drugs identified in 12VAC30-50-520. FDA-approved drug therapies and agents for weight loss, when preauthorized, will be covered for recipients who meet the strict disability standards for obesity established by the Social Security Administration in effect on April 7, 1999, and whose condition is certified as life threatening, consistent with Department of Medical Assistance Services' medical necessity requirements, by the treating physician. For prescription orders for which quantity exceeds a 34-day supply, refills may be dispensed in sufficient quantity to fulfill the prescription order within the limits of federal and state laws and regulations.

4. Prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products unless the physician or other practitioners so licensed and certified to prescribe drugs certifies in his own handwriting "brand necessary" for the prescription to be dispensed as written or unless the drug class is subject to the Preferred Drug List.

5. New drugs shall be covered in accordance with the Social Security Act § 1927(d) (OBRA 90 § 4401).

6. The number of refills shall be limited pursuant to § 54.1-3411 of the Drug Control Act.

7. Drug prior authorization.
 - a. Definitions. The following words and terms used in these regulations shall have the following meaning meanings unless the context clearly indicates otherwise:
 - "Clinical data" means drug monographs as well as any pertinent clinical studies, including peer review literature.
 - "Complex drug regimen" means treatment or course of therapy that typically includes multiple medications, comorbidities and/or caregivers.
 - "Department" or "DMAS" means the Department of Medical Assistance Services.
 - "Drug" shall have the same meaning, unless the context otherwise dictates or the board otherwise provides by regulation, as provided in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia).

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"Emergency supply" means 72-hour supplies of the prescribed medication that may be dispensed if the prescriber cannot readily obtain authorization, or if the physician is not available to consult with the pharmacist, including after hours, weekends, holidays and the pharmacist, in his professional judgment consistent with current standards of practice, feels that the patient's health would be compromised without the benefit of the drug, or other criteria defined by the Pharmacy and Therapeutics Committee and DMAS.

"Nonpreferred drugs" means those drugs that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Nonpreferred drugs may be prescribed but require authorization prior to dispensing to the patient.

"Pharmacy and Therapeutics Committee," "P&T Committee" or "committee" means the committee formulated to review therapeutic classes, conduct clinical reviews of specific drugs, recommend additions or deletions to the preferred drug list, and perform other functions as required by the department.

"Preferred drug list ~~(PDL)~~" or "PDL" means the list of drugs that meet the safety, clinical efficacy, and pricing standards employed by the P&T Committee and adopted by the department for the Virginia Medicaid fee-for-service program. Most drugs on the PDL may be prescribed and dispensed in the Virginia Medicaid fee-for-service program without prior authorization; however, some drugs as recommended by the Pharmacy and Therapeutics Committee may require authorization prior to dispensing to the patient.

"Prior authorization," as it relates to the PDL, means the process of review by a clinical pharmacist of legend drugs that are not on the preferred drug list, or other drugs as recommended by the Pharmacy and Therapeutics Committee, to determine if medically justified.

~~"Prior authorization," as it relates to the threshold program, means the process of review by a clinical pharmacist of legend drugs with respect to established limits or criteria to determine the appropriateness of all existing prescriptions and newly prescribed medications to help ensure appropriate, quality, and cost-effective prescription drug treatments. The process is also designed to prevent waste and abuse of the pharmacy program by assisting providers and the department in identifying clients who may be accessing multiple physicians and pharmacies.~~

"State supplemental rebate" means any cash rebate that offsets Virginia Medicaid expenditure and that supplements the federal rebate. State supplemental rebate amounts shall be calculated in accordance with the Virginia Supplemental Drug Rebate Agreement Contract and Addenda.

"Therapeutic class" means a grouping of medications sharing the same Specific Therapeutic Class Code (GC3) within the Federal Drug Data File published by First Data Bank, Inc.

"Utilization review" means the prospective and retrospective processes employed by the agency to evaluate the medical necessity of reimbursing for certain covered services.

b. Medicaid Pharmacy and Therapeutics Committee.

(1) The department shall utilize a Pharmacy and Therapeutics Committee to assist in the development and ongoing administration of the preferred drug list and other pharmacy program issues. The committee may adopt bylaws that set out its make-up and functioning. A quorum for action of the committee shall consist of seven members.

(2) Vacancies on the committee shall be filled in the same manner as original appointments. DMAS shall appoint individuals for the committee that assures a cross-section of the physician and pharmacy community and remains compliant with General Assembly membership guidelines.

(3) Duties of the committee. The committee shall receive and review clinical and pricing data related to the drug classes. The committee's medical and pharmacy experts shall make recommendations to DMAS regarding various aspects of the pharmacy program. For the preferred drug list program, the committee shall select those drugs to be deemed preferred that are safe, clinically effective, as supported by available clinical data, and meet pricing standards. Cost effectiveness or any pricing standard shall be considered only after a drug is determined to be safe and clinically effective.

(4) As the United States Food and Drug Administration (FDA) approves new drug products, the department shall ensure that the Pharmacy and Therapeutics Committee will evaluate the drug for clinical effectiveness and safety. Based on clinical information and pricing standards, the P&T Committee will determine if the drug will be included in the PDL or require prior authorization.

(a) If the new drug product falls within a drug class previously reviewed by the P&T Committee, until the review of the new drug is completed, it will be classified as nonpreferred, requiring prior authorization in order to be dispensed. The new drug will be evaluated for inclusion in the PDL no later than at the next review of the drug class.

(b) If the new drug product does not fall within a drug class previously reviewed by the P&T Committee, the new drug shall be treated in the same manner as the other drugs in its class.

(5) To the extent feasible, the Pharmacy and Therapeutics Committee shall review all drug classes included in the preferred drug list at least every 12 months and may recommend additions to and deletions from the PDL.

(6) In formulating its recommendations to the department, the committee shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

(7) Immunity. The members of the committee and the staff of the department and the contractor shall be immune, individually and jointly, from civil liability for any act, decision, or omission done or made in performance of their duties pursuant to this subsection while serving as a member of such board, committee, or staff provided that such act, decision, or omission is not done or made in bad faith or with malicious intent.

c. Pharmacy prior authorization program. Pursuant to § 1927 of the Act and 42 CFR 440.230, the department shall require the prior authorization of certain specified legend drugs. For those therapeutic classes of drugs subject to the PDL program, drugs with nonpreferred status included in the DMAS drug list shall be subject to prior authorization. The department also may require prior authorization of other drugs only if recommended by the P&T Committee. Providers who are licensed to prescribe legend drugs shall be required to obtain prior authorization for all nonpreferred drugs or other drugs as recommended by the P&T Committee.

(1) Prior authorization shall consist of prescription review by a licensed pharmacist or pharmacy technician to ensure that all predetermined clinically appropriate criteria, as established by the P&T Committee relative to each therapeutic class, have been met before the prescription may be dispensed. Prior authorization shall be obtained through a call center staffed with appropriate clinicians, or through written or electronic communications (e.g., faxes, mail). Responses by telephone or other telecommunications device within 24 hours of a request for prior authorization shall be provided. The dispensing of 72-hour emergency supplies of the prescribed drug may be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.

(2) The preferred drug list program shall include: (i) provisions for an expedited review process of denials of requested prior authorization by the department; (ii) consumer and provider education; (iii) training and information regarding the preferred drug list both prior to implementation as well as ongoing communications, to include computer and website access to information and multilingual material.

(3) Exclusion of protected groups from pharmacy preferred drug list prior authorization requirements. The following groups of Medicaid eligibles shall be excluded from pharmacy prior authorization requirements: individuals enrolled in hospice care, services through PACE or pre-PACE programs; persons having comprehensive third party insurance coverage; minor children who are the responsibility of the juvenile justice system; and refugees who are not otherwise eligible in a Medicaid covered group.

~~d. Other pharmacy prior authorization programs. Pursuant to § 1927 of the Act and 42 CFR 440.230, the department shall require the prior authorization of legend drugs when both institutionalized and noninstitutionalized recipients are prescribed high numbers of legend drugs. Over the counter drugs and legend drug refills shall not count as a unique prescription for the purposes of prior authorization as it relates to the threshold program.~~

~~(1) Prior authorization shall be required for noninstitutionalized Medicaid recipients whose current volume of prescriptions of legend drugs exceeds nine unique prescriptions within 180 days and as may be further defined by the agency's guidance documents for pharmacy utilization review, limitations, and the prior authorization program. This prior authorization shall be required regardless of whether the prescribed drug appears on the preferred drug list of legend drugs. All recipients subject to these prior authorization limits shall be advised of their rights to appeal. Such appeals shall be considered and responded to pursuant to 12VAC30-110.~~

~~(2) Prior authorization shall be required for institutionalized Medicaid recipients whose current volume of prescriptions of legend drugs exceeds nine unique prescriptions within 30 days and as may be further defined by the agency's guidance documents for pharmacy utilization review, limitations, and prior authorization program. The prior authorization shall be required regardless of whether the drug is listed on the PDL of legend drugs. All recipients subject to these prior authorization limits shall be advised of their rights to appeal. Such appeals shall be considered and responded to pursuant to 12VAC30-110.~~

~~(3) Prior authorization shall consist of prospective and retrospective drug therapy review by a licensed pharmacist to ensure that all predetermined clinically appropriate criteria, as established by the department, have been met before the prescription may be dispensed. Prior authorization shall be obtained through a call center staffed with appropriate clinicians, or through written or electronic communications (e.g., faxes, mail). Responses by telephone or other telecommunications device within 24 hours of a request for prior authorization shall be provided. The dispensing of 72-hour emergency supplies~~

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~~of the prescribed drug may be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.~~

~~(4) Exclusion of protected institutions from pharmacy threshold prior authorization. For the purposes of threshold prior authorization, nursing facility residents do not include residents of the Commonwealth's mental retardation training centers. For the purposes of threshold prior authorization, noninstitutionalized recipients do not include recipients of services at Hiram Davis Medical Center.~~

~~e. d.~~ State supplemental rebates. The department has the authority to seek supplemental rebates from pharmaceutical manufacturers. The contract regarding supplemental rebates shall exist between the manufacturer and the Commonwealth. Rebate agreements between the Commonwealth and a pharmaceutical manufacturer shall be separate from the federal rebates and in compliance with federal law, §§ 1927(a)(1) and 1927(a)(4) of the Social Security Act. All rebates collected on behalf of the Commonwealth shall be collected for the sole benefit of the state share of costs. One hundred percent of the supplemental rebates collected on behalf of the state shall be remitted to the state. Supplemental drug rebates received by the Commonwealth in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.

~~f. e.~~ Pursuant to 42 USC § 1396r-8(b)(3)(D), information disclosed to the department or to the committee by a pharmaceutical manufacturer or wholesaler which discloses the identity of a specific manufacturer or wholesaler and the pricing information regarding the drugs by such manufacturer or wholesaler is confidential and shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

~~g. f.~~ Appeals for denials of prior authorization shall be addressed pursuant to 12VAC30-110, Part I, Client Appeals.

8. Coverage of home infusion therapy. This service shall be covered consistent with the limits and requirements set out within home health services (12VAC30-50-160). Multiple applications of the same therapy (e.g., two antibiotics on the same day) shall be covered under one service day rate of reimbursement. Multiple applications of different therapies (e.g., chemotherapy, hydration, and pain management on the same day) shall be a full service day rate methodology as provided in pharmacy services reimbursement.

B. Dentures. Dentures are provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

C. Prosthetic devices.

1. Prosthetic services shall mean the replacement of missing arms, legs, eyes, and breasts and the provision of any internal (implant) body part. Nothing in this regulation shall be construed to refer to orthotic services or devices or organ transplantation services.

2. Artificial arms and legs, and their necessary supportive attachments, implants and breasts are provided when prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional licenses as defined by state law. This service, when provided by an authorized vendor, must be medically necessary and preauthorized for the minimum applicable component necessary for the activities of daily living.

3. Eye prostheses are provided when eyeballs are missing regardless of the age of the recipient or the cause of the loss of the eyeball. Eye prostheses are provided regardless of the function of the eye.

D. Eyeglasses. Eyeglasses shall be reimbursed for all recipients younger than 21 years of age according to medical necessity when provided by practitioners as licensed under the Code of Virginia.

12VAC30-80-40. Fee-for-service providers: pharmacy.

Payment for pharmacy services shall be the lowest of ~~items~~ subdivisions 1 through 5 of this section (except that ~~items~~ subdivisions 1 and 2 of this section will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.512(c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

1. The upper limit established by the CMS for multiple source drugs pursuant to 42 CFR 447.512 and 447.514, as determined by the CMS Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the HCFA Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. The methodology used to reimburse for generic drug products shall be the higher of either (i) the lowest Wholesale Acquisition Cost (WAC) plus 10% or (ii) the second lowest WAC plus 6.0%. This methodology shall reimburse for products' costs based on a Maximum Allowable Cost (VMAC) list to be established by the single state agency.

a. In developing the maximum allowable reimbursement rate for generic pharmaceuticals, the department or its designated contractor shall:

(1) Identify three different suppliers, including manufacturers that are able to supply pharmaceutical products in sufficient quantities. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the Food and Drug Administration's most

recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Pharmaceutical products that are not available from three different suppliers, including manufacturers, shall not be subject to the VMAC list.

(2) Identify that the use of a VMAC rate is lower than the Federal Upper Limit (FUL) for the drug. The FUL is a known, widely published price provided by CMS; and

(3) Distribute the list of state VMAC rates to pharmacy providers in a timely manner prior to the implementation of VMAC rates and subsequent modifications. DMAS shall publish on its website, each month, the information used to set the Commonwealth's prospective VMAC rates, including, but not necessarily limited to:

(a) The identity of applicable reference products used to set the VMAC rates;

(b) The Generic Code Number (GCN) or National Drug Code (NDC), as may be appropriate, of reference products;

(c) The difference by which the VMAC rate exceeds the appropriate WAC price; and

(d) The identity and date of the published compendia used to determine reference products and set the VMAC rate. The difference by which the VMAC rate exceeds the appropriate WAC price shall be at least or equal to 10% above the lowest-published wholesale acquisition cost for products widely available for purchase in the Commonwealth and shall be included in national pricing compendia.

b. Development of a VMAC rate that does not have a FUL rate shall not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program.

c. DMAS or its designated contractor shall:

(1) Implement and maintain a procedure to add or eliminate products from the list, or modify VMAC rates, consistent with changes in the fluctuating marketplace. DMAS or its designated contractor will regularly review manufacturers' pricing and monitor drug availability in the marketplace to determine the inclusion or exclusion of drugs on the VMAC list; and

(2) Provide a pricing dispute resolution procedure to allow a dispensing provider to contest a listed VMAC rate. DMAS or its designated contractor shall confirm receipt of pricing disputes within 24 hours, via telephone or facsimile, with the appropriate documentation of relevant information, e.g., invoices. Disputes shall be resolved within three business days of confirmation. The pricing dispute resolution process will include DMAS' or the contractor's verification of accurate pricing to ensure consistency with marketplace pricing and drug availability. Providers will be reimbursed, as appropriate, based on findings. Providers shall be required to use this

dispute resolution process prior to exercising any applicable appeal rights.

3. The provider's usual and customary charge to the public, as identified by the claim charge.

4. The Estimated Acquisition Cost (EAC), which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the General Assembly (as set forth in subdivision 7 of this section) or, in the absence thereof, by the following methodology set out in subdivisions a through c of this subdivision.

a. Percentage discount shall be determined by a statewide survey of providers' acquisition cost.

b. The survey shall reflect statistical analysis of actual provider purchase invoices.

c. The agency will conduct surveys at intervals deemed necessary by DMAS.

5. MAC methodology for specialty drugs. Payment for drug products designated by DMAS as specialty drugs shall be the lesser of subdivisions 1 through 4 of this section or the following method, whichever is least:

a. The methodology used to reimburse for designated specialty drug products shall be the WAC price plus the WAC percentage. The WAC percentage is a constant percentage identified each year for all GCNs.

b. Designated specialty drug products are certain products used to treat chronic, high-cost, or rare diseases; the drugs subject to this pricing methodology and their current reimbursement rates are listed on the DMAS website at the following internet address: http://www.dmas.virginia.gov/downloads/pdfs/pharm-special_mac_list.pdf.

c. The MAC reimbursement methodology for specialty drugs shall be subject to the pricing review and dispute resolution procedures described in subdivisions 2 c (1) and 2 c (2) of this section.

6. Payment for pharmacy services will be as described above; however, payment for legend drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The dispensing fee for brand name and generic drugs is \$3.75.

~~7. The Program pays additional reimbursement for unit dose dispensing systems of dispensing drugs. DMAS defines its unit dose dispensing system coverage consistent with that of the Board of Pharmacy of the Department of Health Professions (18VAC110-20-420). This service is paid only for patients residing in nursing facilities. Reimbursements are based on the allowed payments described above plus the unit dose per capita fee to be calculated by DMAS' fiscal agent based on monthly per nursing home resident service per pharmacy provider. Only~~

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one service fee per month may be paid to the pharmacy for each patient receiving unit dose dispensing services. Multisource drugs will be reimbursed at the maximum allowed drug cost for specific multiple source drugs as identified by the state agency or CMS' upper limits as applicable. All other drugs will be reimbursed at drug costs not to exceed the estimated acquisition cost determined by the state agency. The original per capita fee shall be determined by a DMAS analysis of costs related to such dispensing, and shall be reevaluated at periodic intervals for appropriate adjustment. The unit dose dispensing fee is \$5.00 per recipient per month per pharmacy provider. An EAC of AWP minus 13.1% shall become effective July 1, 2011. The dispensing fee for brand name and generic drugs of \$3.75 shall remain in effect, creating a payment methodology based on the previous algorithm (least of subdivisions of this section) plus a dispensing fee where applicable.

8. Home infusion therapy.

a. The following therapy categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basic components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the CMS 1500 claim form.

b. The cost of the active ingredient or ingredients for chemotherapy, pain management and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.

9. Supplemental rebate agreement. ~~Based on the requirements in § 1927 of the Social Security Act, the Commonwealth of Virginia has the following policies for the supplemental drug rebate program for Medicaid recipients. The Commonwealth complies with the requirements of § 1927 of the Social Security Act and Subpart I (42 CFR 447.500 et seq.) of 42 CFR Part 447 with regard to supplemental drug rebates. In addition, the following requirements are also met:~~

~~a. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for legend drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract A and~~

~~Amendment #2 to Contract A has been authorized by CMS.~~

~~b. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract B and Amendment #2 to Contract B has been authorized by CMS.~~

~~c. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract C, and Amendments #1 and #2 to Contract C has been authorized by CMS.~~

~~d. a. Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.~~

~~e. b. Prior authorization requirements found in § 1927(d)(5) of the Social Security Act have been met.~~

~~f. c. Nonpreferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Nonpreferred drugs will be made available to Medicaid beneficiaries through prior authorization.~~

~~g. d. Payment of supplemental rebates may result in a product's inclusion on the PDL.~~

VA.R. Doc. No. R14-3130; Filed October 30, 2013, 4:36 p.m.

Emergency Regulation

Title of Regulation: 12VAC30-80. Methods and Standards for Establishing Payment Rates; Other Types of Care (amending 12VAC30-80-20, 12VAC30-80-40; adding 12VAC30-80-36).

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396.

Effective Dates: January 1, 2014, through June 30, 2015.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

Preamble:

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which 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 and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Administrative Process Act. Item 307 XX of Chapter 806 of the 2013 Acts of Assembly authorizes the Department of Medical Assistance Services (DMAS) to (i)

amend the State Plan for Medical Assistance to convert the current cost-based reimbursement methodology for outpatient hospitals to an Enhanced Ambulatory Patient Group (EAPG) methodology and (ii) promulgate regulations to be effective within 280 days of enactment of the act.

The purpose of this action is to implement a prospective payment methodology for outpatient hospital services. The current cost-based methodology is out of date, inefficient, and costly. DMAS is implementing the EAPG methodology, which is deemed to be a more efficient and predictable reimbursement methodology for DMAS to pay hospitals that furnish services to Medicaid recipients in an outpatient hospital setting.

12VAC30-80-20. Services that are reimbursed on a cost basis.

A. Payments for services listed below shall be on the basis of reasonable cost following the standards and principles applicable to the Title XVIII Program with the exception provided for in subdivision D 1 d of this section. The upper limit for reimbursement shall be no higher than payments for Medicare patients on a facility by facility basis in accordance with 42 CFR 447.321 and 42 CFR 447.325. In no instance, however, shall charges for beneficiaries of the program be in excess of charges for private patients receiving services from the provider. The professional component for emergency room physicians shall continue to be uncovered as a component of the payment to the facility.

B. Reasonable costs will be determined from the filing of a uniform cost report by participating providers. The cost reports are due not later than 150 days after the provider's fiscal year end. If a complete cost report is not received within 150 days after the end of the provider's fiscal year, the Program shall take action in accordance with its policies to assure that an overpayment is not being made. The cost report will be judged complete when DMAS has all of the following:

1. Completed cost reporting form(s) provided by DMAS, with signed certification(s);
2. The provider's trial balance showing adjusting journal entries;
3. The provider's financial statements including, but not limited to, a balance sheet, a statement of income and expenses, a statement of retained earnings (or fund balance), and a statement of changes in financial position;
4. Schedules that reconcile financial statements and trial balance to expenses claimed in the cost report;
5. Depreciation schedule or summary;
6. Home office cost report, if applicable; and
7. Such other analytical information or supporting documents requested by DMAS when the cost reporting forms are sent to the provider.

C. Item 398 D of the 1987 Appropriation Act (as amended), effective April 8, 1987, eliminated reimbursement of return on equity capital to proprietary providers.

D. The services that are cost reimbursed are:

1. ~~Outpatient~~ For dates of service prior to January 1, 2014, ~~outpatient~~ hospital services including rehabilitation hospital outpatient services and excluding laboratory.

a. Definitions. The following words and terms when used in this regulation shall have the following meanings when applied to emergency services unless the context clearly indicates otherwise:

"All-inclusive" means all emergency department and ancillary service charges claimed in association with the emergency room visit, with the exception of laboratory services.

"DMAS" means the Department of Medical Assistance Services consistent with Chapter 10 (§ 32.1-323 et seq.) of Title 32.1 of the Code of Virginia.

"Emergency hospital services" means services that are necessary to prevent the death or serious impairment of the health of the recipient. The threat to the life or health of the recipient necessitates the use of the most accessible hospital available that is equipped to furnish the services.

"Recent injury" means an injury that has occurred less than 72 hours prior to the emergency department visit.

b. Scope. DMAS shall differentiate, as determined by the attending physician's diagnosis, the kinds of care routinely rendered in emergency departments and reimburse for nonemergency care rendered in emergency departments at a reduced rate.

(1) With the exception of laboratory services, DMAS shall reimburse at a reduced and all-inclusive reimbursement rate for all services, including those obstetric and pediatric procedures contained in 12VAC30-80-160, rendered in emergency departments that DMAS determines were nonemergency care.

(2) Services determined by the attending physician to be emergencies shall be reimbursed under the existing methodologies and at the existing rates.

(3) Services performed by the attending physician that may be emergencies shall be manually reviewed. If such services meet certain criteria, they shall be paid under the methodology for subdivision 1 b (2) of this subsection. Services not meeting certain criteria shall be paid under the methodology of subdivision 1 b (1) of this subsection. Such criteria shall include, but not be limited to:

(a) The initial treatment following a recent obvious injury.

(b) Treatment related to an injury sustained more than 72 hours prior to the visit with the deterioration of the

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symptoms to the point of requiring medical treatment for stabilization.

(c) The initial treatment for medical emergencies including indications of severe chest pain, dyspnea, gastrointestinal hemorrhage, spontaneous abortion, loss of consciousness, status epilepticus, or other conditions considered life threatening.

(d) A visit in which the recipient's condition requires immediate hospital admission or the transfer to another facility for further treatment or a visit in which the recipient dies.

(e) Services provided for acute vital sign changes as specified in the provider manual.

(f) Services provided for severe pain when combined with one or more of the other guidelines.

(4) Payment shall be determined based on ICD-9-CM diagnosis codes and necessary supporting documentation.

(5) DMAS shall review on an ongoing basis the effectiveness of this program in achieving its objectives and for its effect on recipients, physicians, and hospitals. Program components may be revised subject to achieving program intent, the accuracy and effectiveness of the ICD-9-CM code designations, and the impact on recipients and providers.

c. Limitation of allowable cost. Effective for services on and after July 1, 2003, reimbursement of ~~Type Two~~ hospitals for outpatient services shall be at various percentages as noted in subdivisions 1 c (1) and (2) of this subsection of allowable cost, with cost to be determined as provided in subsections A, B, and C of this section. For hospitals with fiscal years that do not begin on July 1, outpatient costs, both operating and capital, for the fiscal year in progress on that date shall be apportioned between the time period before and the time period after that date, based on the number of calendar months in the cost reporting period, falling before and after that date.

(1) Type One hospitals.

(a) Effective July 1, 2003, through June 30, 2010, hospital outpatient operating reimbursement shall be at 94.2% of allowable cost and capital reimbursement shall be at 90% of allowable cost.

(b) Effective July 1, 2010, through September 30, 2010, hospital outpatient operating reimbursement shall be at 91.2% of allowable cost and capital reimbursement shall be at 87% of allowable cost.

(c) Effective October 1, 2010, through June 30, 2011, hospital outpatient operating reimbursement shall be at 94.2% of allowable cost and capital reimbursement shall be at 90% of allowable cost.

(d) Effective July 1, 2011, hospital outpatient operating reimbursement shall be at 90.2% of allowable cost and capital reimbursement shall be at 86% of allowable cost.

(2) Type Two hospitals.

(a) Effective July 1, 2003, through June 30, 2010, hospital outpatient operating and capital reimbursement shall be 80% of allowable cost.

(b) Effective July 1, 2010, through September 30, 2010, hospital outpatient operating and capital reimbursement shall be 77% of allowable cost.

(c) Effective October 1, 2010, through June 30, 2011, hospital outpatient operating and capital reimbursement shall be 80% of allowable cost.

(d) Effective July 1, 2011, hospital outpatient operating and capital reimbursement shall be 76% of allowable cost.

d. The last cost report with a fiscal year end on or after December 31, 2013, shall be used for reimbursement for dates of service through December 31, 2013, based on this section. Reimbursement shall be prorated based on the number of cost report months prior to January 1, 2014, as a percentage of total months in the cost report. Settlement will be based on four months of runout from the end of the provider's fiscal year. Claims for services paid after the cost report runout period will not be settled.

~~d.~~ e. Payment for direct medical education costs of nursing schools, paramedical programs and graduate medical education for interns and residents.

(1) Direct medical education costs of nursing schools and paramedical programs shall continue to be paid on an allowable cost basis.

(2) Effective with cost reporting periods beginning on or after July 1, 2002, direct graduate medical education (GME) costs for interns and residents shall be reimbursed on a per-resident prospective basis. See [12VAC30-70-281](#) for prospective payment methodology for graduate medical education for interns and residents.

2. Rehabilitation agencies or comprehensive outpatient rehabilitation.

a. Effective July 1, 2009, rehabilitation agencies or comprehensive outpatient rehabilitation facilities that are operated by community services boards or state agencies shall be reimbursed their costs. For reimbursement methodology applicable to all other rehabilitation agencies, see [12VAC30-80-200](#).

b. Effective October 1, 2009, rehabilitation agencies or comprehensive outpatient rehabilitation facilities operated by state agencies shall be reimbursed their costs. For reimbursement methodology applicable to all other rehabilitation agencies, see [12VAC30-80-200](#).

12VAC30-80-36. Fee-for-service: outpatient hospitals.

A. Definitions. The following words and terms when used in this section shall have the following meanings unless the context clearly indicates otherwise:

"Enhanced Ambulatory Patient Group" or "EAPG" means a defined group of outpatient procedures, encounters, or ancillary services that incorporates International Classification of Diseases (ICD) diagnosis codes, Current Procedural Terminology (CPT) codes, and Healthcare Common Procedure Coding System (HCPCS) codes.

"EAPG relative weight" means the expected average costs for each EAPG divided by the relative expected average costs for visits assigned to all EAPGs.

"Base year" means the state fiscal year for which data is used to establish the EAPG base rate. The base year will change when the EAPG payment system is rebased and recalibrated. In subsequent rebasings, the Commonwealth shall notify affected providers of the base year to be used in this calculation.

"Cost" means the reported cost as defined in 12VAC30-80-20 A.

"Medicare wage index" is published annually in the Federal Register by the Centers for Medicare and Medicaid Services. The indices used in this section shall be those in effect in the base year.

"Cost-to-charge ratio" equals the hospital's total costs divided by the hospital's total charges. The cost-to-charge ratio shall be calculated using data from cost reports from hospital fiscal years ending in the state fiscal year used as the base year.

B. Effective January 1, 2014, the prospective Enhanced Ambulatory Patient Group (EAPG) based payment system described as follows shall apply to reimbursement for outpatient hospital services with the exception of laboratory services referred to the hospital but not associated with an outpatient hospital visit, which will be reimbursed according to the laboratory fee schedule:

1. The payments for outpatient hospital visits shall be determined on the basis of a hospital-specific base rate per visit times the relative weight of the EAPG (and the payment action) assigned for each of the service performed during a hospital visit.

2. The EAPG relative weights shall be the weights determined and published periodically by DMAS and shall be consistent with applicable Medicaid reimbursement limits and policies. The weights shall be updated at least every three years.

3. The statewide base rate shall be equal to the total costs described below divided by the wage-adjusted sum of the EAPG weights for each facility. The wage-adjusted sum of the EAPG weights shall equal the sum of the EAPG weights times the labor percentage times the hospital's Medicare wage index plus the sum of the EAPG weights

times the nonlabor percentage. The base rate shall be determined for outpatient hospital services at least every three years so that total expenditures will equal the following:

a. When using base years prior to January 1, 2014, for all services, excluding all laboratory services and emergency services described in subdivision 3 c of this subsection, a percentage of costs as reported in the available cost reports for the base period for each type of hospital as defined in 12VAC30-70-221.

(1) Type One hospitals. Effective January 1, 2014, hospital outpatient operating reimbursement shall be calculated at 90.2% of cost and capital reimbursement shall be at 86% of cost inflated to the rate year.

(2) Type Two hospitals. Effective January 1, 2014, hospital outpatient operating and capital reimbursement shall be calculated at 76% of cost inflated to the rate year.

When using base years after January 1, 2014, the percentages described in subdivision 3 a of this subsection shall be adjusted according to subdivision 3 c of this subsection.

b. Laboratory services (excluding laboratory services referred to the hospital but not associated with an outpatient hospital visit) calculated at the fee schedule in effect for the rate year.

c. Services rendered in emergency departments determined to be nonemergencies as prescribed in 12VAC30-80-20 D 1 b shall be calculated at the nonemergency reduced rate reported in the base year for base years prior to January 1, 2014. For base years after January 1, 2014, the cost percentages in subdivision 3 a of this subsection shall be adjusted to reflect services paid at the non-emergency reduced rate in the last base year prior to January 1, 2014.

4. Inflation adjustment to base year costs. Each July, the Virginia moving average values as compiled and published by Global Insight (or its successor), under contract with the DMAS, shall be used to update the base year costs to the midpoint of the rate year. The most current table available prior to the effective date of the new rates shall be used to inflate base year amounts to the upcoming rate year. Thus, corrections made by Global Insight (or its successor) in the moving averages that were used to update rates for previous state fiscal years shall be automatically incorporated into the moving averages that are being used to update rates for the upcoming state fiscal year. Inflation shall be applied to the costs identified in subdivision 3 a of this subsection.

5. Hospital-specific base rate. The hospital-specific base rate per case shall be adjusted for geographic variation. The hospital-specific base rate shall be equal to the labor portion of the statewide base rate times the hospital's

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Medicare wage index plus the nonlabor percentage of the statewide base rate. The labor percentage shall be determined at each rebasing based on the most recently reliable data. For rural hospitals, the hospital's Medicare wage index used to calculate the base rate shall be the Medicare wage index of the nearest metropolitan wage area or the effective Medicare wage index, whichever is higher. A base rate differential of 5.0% shall be established for freestanding Type Two children's hospitals. The base rate for non-cost-reporting hospitals shall be the average of the hospital-specific base rates of in-state Type Two hospitals.

6. The total payment shall represent the total allowable amount for a visit including ancillary services and capital.

7. The transition from cost-based reimbursement to EAPG reimbursement shall be transitioned over a four-year period. DMAS shall calculate a cost-based base rate at January 1, 2014, and at each rebasing during the transition.

a. Effective for dates of service on or after January 1, 2014, DMAS shall calculate the hospital-specific base rate as the sum of 75% of the cost-based base rate and 25% of the EAPG base rate.

b. Effective for dates of service on or after July 1, 2014, DMAS shall calculate the hospital-specific base rate as the sum of 50% of the cost-based base rate and 50% of the EAPG base rate.

c. Effective for dates of service on or after July 1, 2015, DMAS shall calculate the hospital-specific base rate as the sum of 25% of the cost-based base rate and 75% of the EAPG base rate.

d. Effective for dates of service on or after July 1, 2016, DMAS shall calculate the hospital-specific base rate as the EAPG base rate.

8. To maintain budget neutrality during the first six years, DMAS shall compare the total reimbursement of hospital claims based on the parameters in subdivision 3 of this subsection to EAPG reimbursement every six months based on the six months of claims ending three months prior to the potential adjustment. If the percentage difference between the reimbursement target in subdivision 3 of this subsection and EAPG reimbursement is greater than 1.0%, plus or minus, DMAS shall adjust the statewide base rate by the percentage difference the following July 1 or January 1. The first possible adjustment would be July 1, 2014, using reimbursement between January 1, 2014, and March 31, 2014.

C. The Enhanced Ambulatory Patient Group (EAPG) grouper version used for outpatient hospital services shall be determined by DMAS. Providers or provider representatives shall be given notice prior to implementing a new grouper.

D. The primary data sources used in the development of the EAPG payment methodology are the DMAS' hospital computerized claims history file and the cost report file. The

claims history file captures available claims data from all enrolled, cost-reporting general acute care hospitals. The cost report file captures audited cost and charge data from all enrolled general acute care hospitals. The following table identifies key data elements that are used to develop the EAPG payment methodology. DMAS may supplement this data with similar data for Medicaid services furnished by managed care organizations if DMAS determines that it is reliable.

Data Elements for EAPG Payment Methodology	
Data Elements	Source
Total charges for each outpatient hospital visit	Claims history file
Number of groupable claims lines in each EAPG	Claims history file
Total number of groupable claim lines	Claims history file
Total charges for each outpatient hospital revenue line	Claims history file
Total number of EAPG assignments	Claims history file
Cost-to-charge ratio for each hospital	Cost report file
Medicare wage index for each hospital	Federal Register

12VAC30-80-40. Fee-for-service providers: pharmacy.

Payment for pharmacy services (excluding outpatient hospital) shall be the lowest of items subdivisions 1 through 5 of this section (except that items subdivisions 1 and 2 of this section will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.512(c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

1. The upper limit established by the CMS for multiple source drugs pursuant to 42 CFR 447.512 and 447.514, as determined by the CMS Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the HCFA Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. The methodology used to reimburse for generic drug products shall be the higher of either (i) the lowest Wholesale Acquisition Cost (WAC) plus 10% or (ii) the second lowest WAC plus 6.0%. This methodology shall reimburse for products' costs based on a Maximum Allowable Cost (VMAC) list to be established by the single state agency.

a. In developing the maximum allowable reimbursement rate for generic pharmaceuticals, the department or its designated contractor shall:

(1) Identify three different suppliers, including manufacturers that are able to supply pharmaceutical products in sufficient quantities. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Pharmaceutical products that are not available from three different suppliers, including manufacturers, shall not be subject to the VMAC list.

(2) Identify that the use of a VMAC rate is lower than the Federal Upper Limit (FUL) for the drug. The FUL is a known, widely published price provided by CMS; and

(3) Distribute the list of state VMAC rates to pharmacy providers in a timely manner prior to the implementation of VMAC rates and subsequent modifications. DMAS shall publish on its website, each month, the information used to set the Commonwealth's prospective VMAC rates, including, but not necessarily limited to:

(a) The identity of applicable reference products used to set the VMAC rates;

(b) The Generic Code Number (GCN) or National Drug Code (NDC), as may be appropriate, of reference products;

(c) The difference by which the VMAC rate exceeds the appropriate WAC price; and

(d) The identity and date of the published compendia used to determine reference products and set the VMAC rate. The difference by which the VMAC rate exceeds the appropriate WAC price shall be at least or equal to 10% above the lowest-published wholesale acquisition cost for products widely available for purchase in the Commonwealth and shall be included in national pricing compendia.

b. Development of a VMAC rate that does not have a FUL rate shall not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program.

c. DMAS or its designated contractor shall:

(1) Implement and maintain a procedure to add or eliminate products from the list, or modify VMAC rates, consistent with changes in the fluctuating marketplace. DMAS or its designated contractor will regularly review manufacturers' pricing and monitor drug availability in the marketplace to determine the inclusion or exclusion of drugs on the VMAC list; and

(2) Provide a pricing dispute resolution procedure to allow a dispensing provider to contest a listed VMAC rate. DMAS or its designated contractor shall confirm receipt of pricing disputes within 24 hours, via telephone

or facsimile, with the appropriate documentation of relevant information, e.g., invoices. Disputes shall be resolved within three business days of confirmation. The pricing dispute resolution process will include DMAS' or the contractor's verification of accurate pricing to ensure consistency with marketplace pricing and drug availability. Providers will be reimbursed, as appropriate, based on findings. Providers shall be required to use this dispute resolution process prior to exercising any applicable appeal rights.

3. The provider's usual and customary charge to the public, as identified by the claim charge.

4. The Estimated Acquisition Cost (EAC), which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the General Assembly (as set forth in subdivision 7 of this section) or, in the absence thereof, by the following methodology set out in subdivisions a through c of this subdivision.

a. Percentage discount shall be determined by a statewide survey of providers' acquisition cost.

b. The survey shall reflect statistical analysis of actual provider purchase invoices.

c. The agency will conduct surveys at intervals deemed necessary by DMAS.

5. MAC methodology for specialty drugs. Payment for drug products designated by DMAS as specialty drugs shall be the lesser of subdivisions 1 through 4 of this section or the following method, whichever is least:

a. The methodology used to reimburse for designated specialty drug products shall be the WAC price plus the WAC percentage. The WAC percentage is a constant percentage identified each year for all GCNs.

b. Designated specialty drug products are certain products used to treat chronic, high-cost, or rare diseases; the drugs subject to this pricing methodology and their current reimbursement rates are listed on the DMAS website at the following internet address: http://www.dmas.virginia.gov/downloads/pdfs/pharm-special_mac_list.pdf.

c. The MAC reimbursement methodology for specialty drugs shall be subject to the pricing review and dispute resolution procedures described in subdivisions 2 c (1) and 2 c (2) of this section.

6. Payment for pharmacy services will be as described above; however, payment for legend drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The dispensing fee for brand name and generic drugs is \$3.75.

7. The Program pays additional reimbursement for unit dose dispensing systems of dispensing drugs. DMAS

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defines its unit dose dispensing system coverage consistent with that of the Board of Pharmacy of the Department of Health Professions (18VAC110-20-420). This service is paid only for patients residing in nursing facilities. Reimbursements are based on the allowed payments described above plus the unit dose per capita fee to be calculated by DMAS' fiscal agent based on monthly per nursing home resident service per pharmacy provider. Only one service fee per month may be paid to the pharmacy for each patient receiving unit dose dispensing services. Multisource drugs will be reimbursed at the maximum allowed drug cost for specific multiple source drugs as identified by the state agency or CMS' upper limits as applicable. All other drugs will be reimbursed at drug costs not to exceed the estimated acquisition cost determined by the state agency. The original per capita fee shall be determined by a DMAS analysis of costs related to such dispensing, and shall be reevaluated at periodic intervals for appropriate adjustment. The unit dose dispensing fee is \$5.00 per recipient per month per pharmacy provider.

An EAC of AWP minus 13.1% shall become effective July 1, 2011. The dispensing fee for brand name and generic drugs of \$3.75 shall remain in effect, creating a payment methodology based on the previous algorithm (least of subdivisions of this section) plus a dispensing fee where applicable.

8. Home infusion therapy.

a. The following therapy categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basic components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the CMS 1500 claim form.

b. The cost of the active ingredient or ingredients for chemotherapy, pain management and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.

9. Supplemental rebate agreement. Based on the requirements in § 1927 of the Social Security Act, the Commonwealth of Virginia has the following policies for the supplemental drug rebate program for Medicaid recipients:

a. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for legend drugs provided to Medicaid recipients, submitted

to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract A and Amendment #2 to Contract A has been authorized by CMS.

b. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract B and Amendment #2 to Contract B has been authorized by CMS.

c. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract C, and Amendments #1 and #2 to Contract C has been authorized by CMS.

d. Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.

e. Prior authorization requirements found in § 1927(d)(5) of the Social Security Act have been met.

f. Nonpreferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Nonpreferred drugs will be made available to Medicaid beneficiaries through prior authorization.

g. Payment of supplemental rebates may result in a product's inclusion on the PDL.

10. Each drug administered in an outpatient hospital setting and reimbursed based on the Enhanced Ambulatory Patient Group methodology as described in 12VAC30-80-36 shall be reimbursed separately at a rate greater than zero to be eligible for drug rebate claiming.

VA.R. Doc. No. R14-3799; Filed November 6, 2013; 3:23 p.m.

Final Regulation

Title of Regulation: 12VAC30-120. Waivered Services (amending 12VAC30-120-360, 12VAC30-120-370, 12VAC30-120-380).

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq.

Effective Date: January 2, 2014.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

Summary:

This regulatory action incorporates changes that have been approved by the Centers for Medicare and Medicaid Services to the Virginia Medicaid managed

care waiver program, Medallion II. The amendments add the rural exception to the Medallion II program in areas federally designated as "rural" where there is only one contracted managed care organization.

Summary of Public Comments and Agency's Response: No public comments were received by the promulgating agency.

Part VI
Medallion II

12VAC30-120-360. Definitions.

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

"Action" means the denial or limited authorization of a requested service, including the type or level of service; the reduction, suspension, or termination of a previously authorized service; the denial, in whole or in part, of payment for a service; the failure to provide services in a timely manner, as defined by the state; or the failure of an MCO to act within the timeframes provided in 42 CFR 438.408(b).

"Appeal" means a request for review of an action, as "action" is defined in this section.

"Area of residence" means the recipient's address in the Medicaid eligibility file.

"Capitation payment" means a payment the department makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State Plan, regardless of whether the particular recipient receives services during the period covered by the payment.

"Client," "clients," "recipient," "enrollee," or "participant" means an individual or individuals having current Medicaid eligibility who shall be authorized by DMAS to be a member or members of Medallion II.

"Covered services" means Medicaid services as defined in the State Plan for Medical Assistance.

"Disenrollment" means the process of changing enrollment from one Medallion II Managed Care Organization (MCO) plan to another MCO or to the Primary Care Case Management (PCCM) program, if applicable.

"DMAS" means the Department of Medical Assistance Services.

"Early Intervention" means EPSDT Early Intervention services provided pursuant to Part C of the Individuals with Disabilities Education Act (IDEA) of 2004 as set forth in 12VAC30-50-131.

"Eligible person" means any person eligible for Virginia Medicaid in accordance with the State Plan for Medical Assistance under Title XIX of the Social Security Act.

"Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine,

could reasonably expect the absence of immediate medical attention to result in the following:

1. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,
2. Serious impairment to bodily functions, or
3. Serious dysfunction of any bodily organ or part.

"Emergency services" means covered inpatient and outpatient services that are furnished by a provider that is qualified to furnish these services and that are needed to evaluate or stabilize an emergency medical condition.

"Enrollment broker" means an independent contractor that enrolls recipients in the contractor's plan and is responsible for the operation and documentation of a toll-free recipient service helpline. The responsibilities of the enrollment broker include, but shall not be limited to, recipient education and MCO enrollment, assistance with and tracking of recipients' complaints resolutions, and may include recipient marketing and outreach.

"Exclusion from Medallion II" means the removal of an enrollee from the Medallion II program on a temporary or permanent basis.

"External [~~Quality Review Organization~~ (EQRO) is quality review organization or "EQRO" means] an organization that meets the competence and independence requirements set forth in 42 CFR 438.354 and performs external quality reviews, other [~~EQRO~~ external quality review] related activities as set forth in 42 CFR 438.358, or both.

"Foster care" is a program in which a child receives either foster care assistance under Title IV-E of the Social Security Act or state and local foster care assistance.

"Grievance" means an expression of dissatisfaction about any matter other than an action, as "action" is defined in this section.

"Health care plan" means any arrangement in which any managed care organization undertakes to provide, arrange for, pay for, or reimburse any part of the cost of any health care services.

"Health care professional" means a provider as defined in 42 CFR 438.2.

"Managed care organization" or "MCO" means an entity that meets the participation and solvency criteria defined in 42 CFR Part 438 and has an executed contractual agreement with DMAS to provide services covered under the Medallion II program. Covered services for Medallion II individuals must be as accessible (in terms of timeliness, amount, duration, and scope) as compared to other Medicaid recipients served within the area.

"Network" means doctors, hospitals or other health care providers who participate or contract with an MCO and, as a result, agree to accept a mutually-agreed upon sum or fee

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schedule as payment in full for covered services that are rendered to eligible participants.

"Newborn enrollment period" means the period from the child's date of birth plus the next two calendar months.

"Nonparticipating provider" means a health care entity or health care professional not in the contractor's participating provider network.

"PCP of record" means a primary care physician of record with whom the recipient has an established history and such history is documented in the individual's records.

"Post-stabilization care services" means covered services related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the stabilized condition or to improve or resolve the enrollee's condition.

"Potential enrollee" means a Medicaid recipient who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO or PCCM.

"Primary care case management" or "PCCM" means a system under which a primary care case manager contracts with the Commonwealth to furnish case management services (which include the location, coordination, and monitoring of primary health care services) to Medicaid recipients.

"Retractions" means the departure of an enrolled managed care organization from any one or more localities as provided for in 12VAC30-120-370.

"Rural exception" means a rural area designated in the § 1915(b) managed care waiver, pursuant to § 1932(a)(3)(B) of the Social Security Act and 42 CFR § 438.52(b) and recognized by the Centers for Medicare and Medicaid Services, wherein qualifying Medallion II members are mandated to enroll in the one available contracted MCO.

"School health services" means those physical therapy, occupational therapy, speech therapy, nursing, psychiatric and psychological services rendered to children who qualify for these services under the federal Individuals with Disabilities Education Act (20 USC § 1471 et seq.) by (i) employees of the school divisions or (ii) providers that subcontract with school divisions, as described in [~~12VAC30-50-229.1~~ 12VAC30-50-130].

"Spend-down" means the process of reducing countable income by deducting incurred medical expenses for medically needy individuals, as determined in the State Plan for Medical Assistance.

12VAC30-120-370. Medallion II enrollees.

A. DMAS shall determine enrollment in Medallion II. Medicaid eligible persons not meeting the exclusion criteria set out in this section must participate in the Medallion II program. Enrollment in Medallion II is not a guarantee of continuing eligibility for services and benefits under the Virginia Medical Assistance Services Program. DMAS

reserves the right to exclude from participation in the Medallion II managed care program any recipient who has been consistently noncompliant with the policies and procedures of managed care or who is threatening to providers, MCOs, or DMAS. There must be sufficient documentation from various providers, the MCO, and DMAS of these noncompliance issues and any attempts at resolution. Recipients excluded from Medallion II through this provision may appeal the decision to DMAS.

B. The following individuals shall be excluded (as defined in 12VAC30-120-360) from participating in Medallion II ~~or will be disenrolled from Medallion II if any of the following apply. Individuals not meeting the exclusion criteria must participate in the Medallion II program.~~ as defined in the § 1915(b) managed care waiver. Individuals excluded from Medallion II include the following:

1. Individuals who are inpatients in state mental hospitals;
2. Individuals who are approved by DMAS as inpatients in long-stay hospitals, nursing facilities, or intermediate care facilities for the [~~mentally-retarded~~ intellectually disabled];
3. Individuals who are placed on spend-down;
4. Individuals who are participating in the family planning waiver, or in federal waiver programs for home-based and community-based Medicaid coverage prior to managed care enrollment;
5. Individuals who are participating in foster care or subsidized adoption programs;
6. Individuals under age 21 who are either enrolled in DMAS authorized treatment foster care programs as defined in 12VAC30-60-170 A, or who are approved for DMAS residential facility Level C programs as defined in 12VAC30-130-860;
7. Newly eligible individuals who are in the third trimester of pregnancy and who request exclusion within a department-specified timeframe of the effective date of their MCO enrollment. Exclusion may be granted only if the member's obstetrical provider (e.g., physician, hospital, midwife) does not participate with the enrollee's assigned MCO. Exclusion requests made during the third trimester may be made by the recipient, MCO, or provider. DMAS shall determine if the request meets the criteria for exclusion. Following the end of the pregnancy, these individuals shall be required to enroll to the extent they remain eligible for Medicaid;
8. Individuals, other than students, who permanently live outside their area of residence for greater than 60 consecutive days except those individuals placed there for medically necessary services funded by the MCO;
9. Individuals who receive hospice services in accordance with DMAS criteria;
10. Individuals with other comprehensive group or individual health insurance coverage, including Medicare,

insurance provided to military dependents, and any other insurance purchased through the Health Insurance Premium Payment Program (HIPP);

11. Individuals requesting exclusion who are inpatients in hospitals, other than those listed in subdivisions 1 and 2 of this subsection, at the scheduled time of MCO enrollment or who are scheduled for inpatient hospital stay or surgery within 30 calendar days of the MCO enrollment effective date. The exclusion shall remain effective until the first day of the month following discharge. This exclusion reason shall not apply to recipients admitted to the hospital while already enrolled in a department-contracted MCO;

12. Individuals who request exclusion during preassignment to an MCO or within a time set by DMAS from the effective date of their MCO enrollment, who have been diagnosed with a terminal condition and who have a life expectancy of six months or less. The client's physician must certify the life expectancy;

13. Certain individuals between birth and age three certified by the Department of ~~Mental Health, Mental Retardation and Substance Abuse~~ Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 USC § 1471 et seq.) who are granted an exception by DMAS to the mandatory Medallion II enrollment;

14. Individuals who have an eligibility period that is less than three months;

15. Individuals who are enrolled in the Commonwealth's Title XXI SCHIP program;

16. Individuals who have an eligibility period that is only retroactive; and

17. Children enrolled in the Virginia Birth-Related Neurological Injury Compensation Program established pursuant to Chapter 50 (§ 38.2-5000 et seq.) of Title 38.2 of the Code of Virginia.

C. Individuals enrolled with a MCO who subsequently meet one or more of the aforementioned criteria during MCO enrollment shall be excluded from MCO participation as determined by DMAS, with the exception of those who subsequently become recipients in the federal long-term care waiver programs, as otherwise defined elsewhere in this chapter, for home-based and community-based Medicaid coverage (AIDS, IFDDS, MR, EDCD, Day Support, or ~~Alzheimer's~~ Alzheimer's, or as may be amended from time to time). These individuals shall receive acute and primary medical services via the MCO and shall receive waiver services and related transportation to waiver services via the fee-for-service program.

Individuals excluded from mandatory managed care enrollment shall receive Medicaid services under the current fee-for-service system. When enrollees no longer meet the criteria for exclusion, they shall be required to enroll in the appropriate managed care program.

D. Individuals who are enrolled in localities that qualify for the rural exception may meet exclusion criteria if their PCP of record, as defined in 12VAC30-120-360, cannot or will not participate with the one MCO in the locality. Individual requests to be excluded from MCO participation in localities meeting the qualification for the rural exception must be made to DMAS for consideration on a case-by-case basis. Recipients enrolled in MCO rural exception areas shall not have open enrollment periods and shall not be afforded the 90-day window after initial enrollment during which they may make a health plan or program change.

Individuals excluded from mandatory managed care enrollment shall receive Medicaid services under the current fee-for-service system. When enrollees no longer meet the criteria for exclusion, they shall be required to enroll in the appropriate managed care program.

~~D.~~ E. Medallion II managed care plans shall be offered to recipients, and recipients shall be enrolled in those plans, exclusively through an independent enrollment broker under contract to DMAS.

~~E.~~ F. Clients shall be enrolled as follows:

1. All eligible persons, except those meeting one of the exclusions of subsection B of this section, shall be enrolled in Medallion II.

2. Clients shall receive a Medicaid card from DMAS, and shall be provided authorized medical care in accordance with DMAS' procedures after Medicaid eligibility has been determined to exist.

3. Once individuals are enrolled in Medicaid, they will receive a letter indicating that they may select one of the contracted MCOs. These letters shall indicate a preassigned MCO, determined as provided in subsection F of this section, in which the client will be enrolled if he does not make a selection within a period specified by DMAS of not less than 30 days. Recipients who are enrolled in one mandatory MCO program who immediately become eligible for another mandatory MCO program are able to maintain consistent enrollment with their currently assigned MCO, if available. These recipients will receive a notification letter including information regarding their ability to change health plans under the new program.

4. Any newborn whose mother is enrolled with an MCO at the time of birth shall be considered an enrollee of that same MCO for the newborn enrollment period. ~~The newborn enrollment period is defined as the birth month plus two months following the birth month.~~ This requirement does not preclude the enrollee, once he is assigned a Medicaid identification number, from disenrolling from one MCO to another in accordance with subdivision ~~G~~ H 1 of this section.

The newborn's continued enrollment with the MCO is not contingent upon the mother's enrollment. Additionally, if

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the MCO's contract is terminated in whole or in part, the MCO shall continue newborn coverage if the child is born while the contract is active, until the newborn receives a Medicaid number or for the newborn enrollment period, whichever timeframe is earlier. Infants who do not receive a Medicaid identification number prior to the end of the newborn enrollment period will be disenrolled. Newborns who remain eligible for participation in Medallion II will be reenrolled in an MCO through the preassignment process upon receiving a Medicaid identification number.

5. Individuals who lose then regain eligibility for Medallion II within 60 days will be reenrolled into their previous MCO without going through preassignment and selection.

~~F. G.~~ F. G. Clients who do not select an MCO as described in subdivision ~~E-3~~ F 3 of this section shall be assigned to an MCO as follows:

1. Clients are assigned through a system algorithm based upon the client's history with a contracted MCO.

2. Clients not assigned pursuant to subdivision 1 of this subsection shall be assigned to the MCO of another family member, if applicable.

3. Clients who live in rural exception areas as defined in 12VAC30-120-360 must enroll with the one available MCO. These persons shall receive a preassignment notification for enrollment into the MCO. Individuals in rural exception areas who are assigned to the one MCO may request exclusion from MCO participation if their PCP of record, as defined in 12VAC30-120-360, cannot or will not participate with the one MCO in the locality. Individual requests to be excluded from MCO participation in rural exception localities must be made to DMAS for consideration on a case-by-case basis.

~~3.~~ 4. All other clients shall be assigned to an MCO on a basis of approximately equal number by MCO in each locality.

~~4. In areas where there is only one contracted MCO, recipients have a choice of enrolling with the contracted MCO or the PCCM program. All eligible recipients in areas where one contracted MCO exists, however, are automatically assigned to the contracted MCO. Individuals are allowed 90 days after the effective date of new or initial enrollment to change from either the contracted MCO to the PCCM program or vice versa.~~

5. Recipients in areas where there is only one contracted MCO and the PCCM program are automatically assigned to the contracted MCO, but are allowed 90 days after the effective date of new or initial enrollment to change from either the contracted MCO to the PCCM program, or vice versa. Recipients residing in localities qualifying for rural exception shall not be afforded the 90-day window after initial enrollment during which they may make a health plan or program change.

~~5.~~ 6. DMAS shall have the discretion to utilize an alternate strategy for enrollment or transition of enrollment from the method described in this section for expansions, retractions, or changes to ~~new~~ client populations, ~~new~~ geographical areas, ~~expansion through procurement procurements~~, or any or all of these; such alternate strategy shall comply with federal waiver requirements.

~~G. H.~~ H. Following their initial enrollment into an MCO or PCCM program, recipients shall be restricted to the MCO or PCCM program until the next open enrollment period, unless appropriately disenrolled or excluded by the department (as defined in 12VAC30-120-360).

1. During the first 90 calendar days of enrollment in a new or initial MCO, a client may disenroll from that MCO to enroll into another MCO or into PCCM, if applicable, for any reason. Such disenrollment shall be effective no later than the first day of the second month after the month in which the client requests disenrollment.

2. During the remainder of the enrollment period, the client may only disenroll from one MCO into another MCO or PCCM, if applicable, upon determination by DMAS that good cause exists as determined under subsection I of this section.

~~H. I.~~ I. The department shall conduct an annual open enrollment for all Medallion II participants with the exception of those clients who live in a designated rural exception area. The open enrollment period shall be the 60 calendar days before the end of the enrollment period. Prior to the open enrollment period, DMAS will inform the recipient of the opportunity to remain with the current MCO or change to another MCO, without cause, for the following year. In areas with only one contracted MCO and where the PCCM program is available, recipients will be given the opportunity to select either the MCO or the PCCM program. Enrollment selections will be effective on the first day of the next month following the open enrollment period. Recipients who do not make a choice during the open enrollment period will remain with their current MCO selection.

~~I. J.~~ J. Disenrollment for cause may be requested at any time.

1. After the first 90 days of enrollment in an MCO, clients must request disenrollment from DMAS based on cause. The request may be made orally or in writing to DMAS and must cite the reasons why the client wishes to disenroll. Cause for disenrollment shall include the following:

a. A recipient's desire to seek services from a federally qualified health center which is not under contract with the recipient's current MCO, and the recipient (i) requests a change to another MCO that subcontracts with the desired federally qualified health center or (ii) requests a change to the PCCM, if the federally qualified health center is contracting directly with DMAS as a PCCM;

- b. Performance or nonperformance of service to the recipient by an MCO or one or more of its providers which is deemed by the department's external quality review organizations to be below the generally accepted community practice of health care. This may include poor quality care;
 - c. Lack of access to a PCP or necessary specialty services covered under the State Plan or lack of access to providers experienced in dealing with the enrollee's health care needs;
 - d. A client has a combination of complex medical factors that, in the sole discretion of DMAS, would be better served under another contracted MCO or PCCM program, if applicable, or provider;
 - e. The enrollee moves out of the MCO's service area;
 - f. The MCO does not, because of moral or religious objections, cover the service the enrollee seeks;
 - g. The enrollee needs related services to be performed at the same time; not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk; or
 - h. Other reasons as determined by DMAS through written policy directives.
2. DMAS shall determine whether cause exists for disenrollment. Written responses shall be provided within a timeframe set by department policy; however, the effective date of an approved disenrollment shall be no later than the first day of the second month following the month in which the enrollee files the request, in compliance with 42 CFR 438.56.
 3. Cause for disenrollment shall be deemed to exist and the disenrollment shall be granted if DMAS fails to take final action on a valid request prior to the first day of the second month after the request.
 4. The DMAS determination concerning cause for disenrollment may be appealed by the client in accordance with the department's client appeals process at 12VAC30-110-10 through 12VAC30-110-380.
 5. The current MCO shall provide, within two working days of a request from DMAS, information necessary to determine cause.
 6. Individuals enrolled with a MCO who subsequently meet one or more of the exclusions in subsection B of this section during MCO enrollment shall be ~~disenrolled~~ excluded as appropriate by DMAS, with the exception of those who subsequently become recipients into the AIDS, IFDDS, ~~MR~~ MR/ID, EDCD, Day Support, or Alzheimer's federal waiver programs for home-based and community-based Medicaid coverage. These individuals shall receive acute and primary medical services via the MCO and shall

receive waiver services and related transportation to waiver services via the fee-for-service program.

~~Individuals excluded from mandatory managed care enrollment shall receive Medicaid services under the current fee for service system. When enrollees no longer meet the criteria for exclusion, they shall be required to enroll in the appropriate managed care program.~~

12VAC30-120-380. Medallion II MCO responsibilities.

A. The MCO shall provide, at a minimum, all medically necessary covered services provided under the State Plan for Medical Assistance and further defined by written DMAS regulations, policies and instructions, except as otherwise modified or excluded in this part.

1. Nonemergency services provided by hospital emergency departments shall be covered by MCOs in accordance with rates negotiated between the MCOs and the emergency departments.

2. Services that shall be provided outside the MCO network shall include, but are not limited to, those services identified and defined by the contract between DMAS and the MCO. Services reimbursed by DMAS include, but shall not be limited to, dental and orthodontic services for children up to age 21; for all others, dental services (as described in 12VAC30-50-190), school health services (as defined in 12VAC30-120-360), community mental health services (rehabilitative, targeted case management and the following substance abuse treatment services: emergency services (crisis); intensive outpatient services; day treatment services; substance abuse case management services; and opioid treatment services), as defined in 12VAC30-50-228 and 12VAC30-50-491, EPSDT Early Intervention services provided pursuant to Part C of the Individuals with Disabilities Education Act (IDEA) of 2004 (as defined in 12VAC30-50-131), and long-term care services provided under the § 1915(c) home-based and community-based waivers including related transportation to such authorized waiver services.

3. The MCOs shall pay for emergency services and family planning services and supplies whether they are provided inside or outside the MCO network.

~~B. Except for those services specifically carved out in subsection A of this section,~~ EPSDT services shall be covered by the MCO and defined by the contract between DMAS and the MCO. The MCO shall have the authority to determine the provider of service for EPSDT screenings.

C. The MCOs shall report data to DMAS under the contract requirements, which may include data reports, report cards for clients, and ad hoc quality studies performed by the MCO or third parties.

D. Documentation requirements.

1. The MCO shall maintain records as required by federal and state law and regulation and by DMAS policy. The MCO shall furnish such required information to DMAS,

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the Attorney General of Virginia or his authorized representatives, or the State Medicaid Fraud Control Unit on request and in the form requested.

2. Each MCO shall have written policies regarding enrollee rights and shall comply with any applicable federal and state laws that pertain to enrollee rights and shall ensure that its staff and affiliated providers take those rights into account when furnishing services to enrollees in accordance with 42 CFR 438.100.

E. The MCO shall ensure that the health care provided to its clients meets all applicable federal and state mandates, community standards for quality, and standards developed pursuant to the DMAS managed care quality program.

F. The MCOs shall promptly provide or arrange for the provision of all required services as specified in the contract between the state and the contractor. Medical evaluations shall be available within 48 hours for urgent care and within 30 calendar days for routine care. On-call clinicians shall be available 24 hours per day, seven days per week.

G. The MCOs must meet standards specified by DMAS for sufficiency of provider networks as specified in the contract between the state and the contractor.

H. Each MCO and its subcontractors shall have in place, and follow, written policies and procedures for processing requests for initial and continuing authorizations of service. Each MCO and its subcontractors shall ensure that any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease. Each MCO and its subcontractors shall have in effect mechanisms to ensure consistent application of review criteria for authorization decisions and shall consult with the requesting provider when appropriate.

I. In accordance with 42 CFR 447.50 through 42 CFR 447.60, MCOs shall not impose any cost sharing obligations on enrollees except as set forth in 12VAC30-20-150 and 12VAC30-20-160.

J. An MCO may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his patient in accordance with 42 CFR 438.102.

K. An MCO that would otherwise be required to reimburse for or provide coverage of a counseling or referral service is not required to do so if the MCO objects to the service on moral or religious grounds and furnishes information about the service it does not cover in accordance with 42 CFR 438.102.

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Final Regulation

REGISTRAR'S NOTICE: The Department of Medical Assistance Services is claiming an exclusion from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 a of the Code of Virginia, which excludes regulations that are necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved. The Department of Medical Assistance Services will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 12VAC30-120. Waivered Services (amending 12VAC30-120-760, 12VAC30-120-1020).

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396.

Effective Date: January 2, 2014.

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Summary:

Pursuant to Item 307 QQQQ of Chapter 806 of the 2013 Acts of Assembly, the amendments change the unit of service for skilled nursing services from hourly to 15-minute increments. The amendments affect the Intellectual Disability Waiver and the Individual and Family Developmental Disabilities Support Waiver.

12VAC30-120-760. Skilled nursing services.

A. Service description. Skilled nursing services shall be provided for individuals with serious medical conditions and complex health care needs who require specific skilled nursing services that cannot be provided by non-nursing personnel. Skilled nursing may be provided in the home or other community setting. It may include consultation and training for other providers.

B. Criteria. In order to qualify for these services, the individual must have demonstrated complex health care needs that require specific skilled nursing services ordered by a physician and that cannot be otherwise accessed under the Title XIX State Plan for Medical Assistance. The individual's plan of care must stipulate that this service is necessary in order to prevent institutionalization and is not available under the State Plan for Medical Assistance.

C. Service units and service limitations. Skilled nursing services to be rendered by either registered or licensed practical nurses are provided in ~~hourly~~ 15-minute units. Services must be explicitly detailed in the CSP and must be specifically ordered by a physician.

D. Provider requirements. Skilled nursing services shall be provided by a DMAS-enrolled home care organization provider or a home health provider, or licensed registered

nurse or a licensed practical nurse under the supervision of a licensed registered nurse who is contracted or employed by a DMHMRSAS licensed day support, respite, or residential provider. In addition to meeting the general conditions and requirements for home and community-based waiver participating providers as specified in 12VAC30-120-730 and 12VAC30-120-740, in order to be enrolled as a skilled nursing provider, the provider must:

1. If a home health agency, be certified by the VDH for Medicaid participation and have a current DMAS provider participation agreement for private duty nursing;
2. Demonstrate a prior successful health care delivery business or practice;
3. Operate from a business office; and
4. If community services boards or behavioral health authority employ or subcontract with and directly supervise a registered nurse (RN) or a licensed practical nurse (LPN) with a current and valid license issued by the Virginia State Board of Nursing, the RN or LPN must have at least two years of related clinical nursing experience that may include work in an acute care hospital, public health clinic, home health agency, or nursing home.

12VAC30-120-1020. Covered services; limits on covered services.

A. Covered services in the ID Waiver include: assistive technology, companion services (both consumer-directed and agency-directed), crisis stabilization, day support, environmental modifications, personal assistance services (both consumer-directed and agency-directed), personal emergency response systems (PERS), prevocational services, residential support services, respite services (both consumer-directed and agency-directed), services facilitation (only for consumer-directed services), skilled nursing services, supported employment, therapeutic consultation, and transition services.

1. There shall be separate supporting documentation for each service and each shall be clearly differentiated in documentation and corresponding billing.
2. The need of each individual enrolled in the waiver for each service shall be clearly set out in the Individual Support Plan containing the providers' Plans for Supports.
3. Claims for payment that are not supported by their related documentation shall be subject to recovery by DMAS or its designated contractor as a result of utilization reviews or audits.
4. Individuals enrolled in the waiver may choose between the agency-directed model of service delivery or the consumer-directed model when DMAS makes this alternative model available for care. The only services provided in this waiver that permit the consumer-directed model of service delivery shall be: (i) personal assistance services; (ii) respite services; and (iii) companion services. An individual enrolled in the waiver shall not receive

consumer-directed services if at least one of the following conditions exists:

- (a) The individual enrolled in the waiver is younger than 18 years of age or is unable to be the employer of record and no one else can assume this role;
- (b) The health, safety, or welfare of the individual enrolled in the waiver cannot be assured or a back-up emergency plan cannot be developed; or
- (c) The individual enrolled in the waiver has medication or skilled nursing needs or medical/behavioral conditions that cannot be safely met via the consumer-directed model of service delivery.

5. Voluntary/involuntary disenrollment of consumer-directed services. Either voluntary or involuntary disenrollment of consumer-directed services may occur. In either voluntary or involuntary situations, the individual enrolled in the waiver shall be permitted to select an agency from which to receive his personal assistance, respite, or companion services.

a. An individual who has chosen consumer direction may choose, at any time, to change to the agency-directed services model as long as he continues to qualify for the specific services. The services facilitator or case manager, as appropriate, shall assist the individual with the change of services from consumer-directed to agency-directed.

b. The services facilitator or case manager, as appropriate, shall initiate involuntary disenrollment from consumer direction of the individual enrolled in the waiver when any of the following conditions occur:

- (1) The health, safety, or welfare of the individual enrolled in the waiver is at risk;
- (2) The individual or EOR, as appropriate, demonstrates consistent inability to hire and retain a personal assistant; or
- (3) The individual or EOR, as appropriate, is consistently unable to manage the assistant, as may be demonstrated by, but shall not necessarily be limited to, a pattern of serious discrepancies with timesheets.

c. Prior to involuntary disenrollment, the services facilitator or case manager, as appropriate, shall:

- (1) Verify that essential training has been provided to the individual or EOR, as appropriate, to improve the problem condition or conditions;
- (2) Document in the individual's record the conditions creating the necessity for the involuntary disenrollment and actions taken by the services facilitator or case manager, as appropriate;
- (3) Discuss with the individual or the EOR, as appropriate, the agency directed option that is available and the actions needed to arrange for such services while providing a list of potential providers; and

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(4) Provide written notice to the individual and EOR, as appropriate, of the right to appeal, pursuant to 12VAC30-110, such involuntary termination of consumer direction. Such notice shall be given at least 10 business days prior to the effective date of this action.

d. If the services facilitator initiates the involuntary disenrollment from consumer direction, then he shall inform the case manager.

6. All requests for this waiver's services shall be submitted to either DMAS or the service authorization contractor for service (prior) authorization.

B. Assistive technology (AT). Service description. This service shall entail the provision of specialized medical equipment and supplies including those devices, controls, or appliances, specified in the Individual Support Plan but which are not available under the State Plan for Medical Assistance, that (i) enable individuals to increase their abilities to perform activities of daily living (ADLs); (ii) enable individuals to perceive, control, or communicate with the environment in which they live; or (iii) are necessary for life support, including the ancillary supplies and equipment necessary to the proper functioning of such technology.

1. Criteria. In order to qualify for these services, the individual shall have a demonstrated need for equipment or modification for remedial or direct medical benefit primarily in the individual's home, vehicle, community activity setting, or day program to specifically improve the individual's personal functioning. AT shall be covered in the least expensive, most cost-effective manner.

2. Service units and service limitations. AT shall be available to individuals who are receiving at least one other waiver service and may be provided in a residential or nonresidential setting. Only the AT services set out in the Plan for Supports shall be covered by DMAS. AT shall be prior authorized by the state-designated agency or its contractor for each calendar year with no carry-over across calendar years.

a. The maximum funded expenditure per individual for all AT covered procedure codes (combined total of AT items and labor related to these items) shall be \$5,000 per calendar year for individuals regardless of waiver for which AT is approved. The service unit shall always be one for the total cost of all AT being requested for a specific timeframe.

b. Costs for AT shall not be carried over from calendar year to calendar year and shall be prior authorized by the state-designated agency or its contractor each calendar year. AT shall not be approved for purposes of convenience of the caregiver or restraint of the individual.

3. An independent professional consultation shall be obtained from staff knowledgeable of that item for each AT request prior to approval by the state-designated

agency or its contractor. Equipment, supplies, or technology not available as durable medical equipment through the State Plan may be purchased and billed as AT as long as the request for such equipment, supplies, or technology is documented and justified in the individual's Plan for Supports, recommended by the case manager, prior authorized by the state-designated agency or its contractor, and provided in the least expensive, most cost-effective manner possible.

4. All AT items to be covered shall meet applicable standards of manufacture, design, and installation.

5. The AT provider shall obtain, install, and demonstrate, as necessary, such AT prior to submitting his claim to DMAS for reimbursement. The provider shall provide all warranties or guarantees from the AT's manufacturer to the individual and family/caregiver, as appropriate.

6. AT providers shall not be the spouse or parents of the individual enrolled in the waiver.

C. Companion (both consumer-directed and agency-directed) services. Service description. These services provide nonmedical care, socialization, or support to an adult (ages 18 or older). Companions may assist or support the individual enrolled in the waiver with such tasks as meal preparation, community access and activities, laundry, and shopping, but companions do not perform these activities as discrete services. Companions may also perform light housekeeping tasks (such as bed-making, dusting and vacuuming, laundry, grocery shopping, etc.) when such services are specified in the individual's Plan for Supports and essential to the individual's health and welfare in the context of providing nonmedical care, socialization, or support, as may be needed in order to maintain the individual's home environment in an orderly and clean manner. Companion services shall be provided in accordance with a therapeutic outcome in the Plan for Supports and shall not be purely recreational in nature. This service may be provided and reimbursed either through an agency-directed or a consumer-directed model.

1. In order to qualify for companion services, the individual enrolled in the waiver shall have demonstrated a need for assistance with IADLs, light housekeeping (such as cleaning the bathroom used by the individual, washing his dishes, preparing his meals, or washing his clothes), community access, reminders for medication self-administration, or support to assure safety. The provision of companion services shall not entail routine hands-on care.

2. Individuals choosing the consumer-directed option shall meet requirements for consumer direction as described herein.

3. Service units and service limitations.

a. The unit of service for companion services shall be one hour and the amount that may be included in the Plan for Supports shall not exceed eight hours per 24-hour day

regardless of whether it is an agency-directed or consumer-directed service model, or both.

b. A companion shall not be permitted to provide nursing care procedures such as, but not limited to, ventilators, tube feedings, suctioning of airways, or wound care.

c. The hours that can be authorized shall be based on documented individual need. No more than two unrelated individuals who are receiving waiver services and who live in the same home shall be permitted to share the authorized work hours of the companion.

4. This consumer directed service shall be available to individuals enrolled in the waiver who receive congregate residential services. These services shall be available when individuals enrolled in the waiver are not receiving congregate residential services such as, but not necessarily limited to, when they are on vacation or are visiting with family members.

D. Crisis stabilization. Service description. These services shall involve direct interventions that provide temporary intensive services and support that avert emergency psychiatric hospitalization or institutional placement of individuals with ID who are experiencing serious psychiatric or behavioral problems that jeopardize their current community living situation. Crisis stabilization services shall have two components: (i) intervention and (ii) supervision. Crisis stabilization services shall include, as appropriate, neuropsychiatric, psychiatric, psychological, and other assessments and stabilization techniques, medication management and monitoring, behavior assessment and positive behavioral support, and intensive service coordination with other agencies and providers. This service shall be designed to stabilize the individual and strengthen the current living situation, so that the individual remains in the community during and beyond the crisis period.

1. These services shall be provided to:

a. Assist with planning and delivery of services and supports to enable the individual to remain in the community;

b. Train family/caregivers and service providers in positive behavioral supports to maintain the individual in the community; and

c. Provide temporary crisis supervision to ensure the safety of the individual and others.

2. In order to receive crisis stabilization services, the individual shall:

a. Meet at least one of the following: (i) the individual shall be experiencing a marked reduction in psychiatric, adaptive, or behavioral functioning; (ii) the individual shall be experiencing an increase in extreme emotional distress; (iii) the individual shall need continuous intervention to maintain stability; or (iv) the individual shall be causing harm to himself or others; and

b. Be at risk of at least one of the following: (i) psychiatric hospitalization; (ii) emergency ICF/ID placement; (iii) immediate threat of loss of a community service due to a severe situational reaction; or (iv) causing harm to self or others.

3. Service units and service limitations. Crisis stabilization services shall only be authorized following a documented face-to-face assessment conducted by a qualified mental retardation professional (QMRP).

a. The unit for either intervention or supervision of this covered service shall be one hour. This service shall only be authorized in 15-day increments but no more than 60 days in a calendar year shall be approved. The actual service units per episode shall be based on the documented clinical needs of the individual being served. Extension of services, beyond the 15-day limit per authorization, shall only be authorized following a documented face-to-face reassessment conducted by a QMRP.

b. Crisis stabilization services shall be provided directly in the following settings, but shall not be limited to:

(1) The home of an individual who lives with family, friends, or other primary caregiver or caregivers;

(2) The home of an individual who lives independently or semi-independently to augment any current services and supports; or

(3) Either a community-based residential program, a day program, or a respite care setting to augment ongoing current services and supports.

4. Crisis supervision shall be an optional component of crisis stabilization in which one-to-one supervision of the individual who is in crisis shall be provided by agency staff in order to ensure the safety of the individual and others in the environment. Crisis supervision may be provided as a component of crisis stabilization only if clinical or behavioral interventions allowed under this service are also provided during the authorized period. Crisis supervision must be provided one-to-one and face-to-face with the individual. Crisis supervision, if provided as a part of this service, shall be separately billed in hourly service units.

5. Crisis stabilization services shall not be used for continuous long-term care. Room, board, and general supervision shall not be components of this service.

6. If appropriate, the assessment and any reassessments may be conducted jointly with a licensed mental health professional or other appropriate professional or professionals.

E. Day support services. Service description. These services shall include skill-building, supports, and safety supports for the acquisition, retention, or improvement of self-help, socialization, community integration, and adaptive skills. These services shall be typically offered in a nonresidential setting that provides opportunities for peer interactions,

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community integration, and enhancement of social networks. There shall be two levels of this service: (i) intensive and (ii) regular.

1. **Criteria.** For day support services, individuals shall demonstrate the need for skill-building or supports offered primarily in settings other than the individual's own residence that allows him an opportunity for being a productive and contributing member of his community.

2. **Types of day support.** The amount and type of day support included in the individual's Plan for Supports shall be determined by what is required for that individual. There are two types of day support: center-based, which is provided primarily at one location/building; or noncenter-based, which is provided primarily in community settings. Both types of day support may be provided at either intensive or regular levels.

3. **Levels of day support.** There shall be two levels of day support, intensive and regular. To be authorized at the intensive level, the individual shall meet at least one of the following criteria: (i) the individual requires physical assistance to meet the basic personal care needs (such as but not limited to toileting, eating/feeding); (ii) the individual requires additional, ongoing support to fully participate in programming and to accomplish the individual's desired outcomes due to extensive disability-related difficulties; or (iii) the individual requires extensive constant supervision to reduce or eliminate behaviors that preclude full participation in the program. In this case, written behavioral support activities shall be required to address behaviors such as, but not limited to, withdrawal, self-injury, aggression, or self-stimulation. Individuals not meeting these specified criteria for intensive day support shall be provided with regular day support.

4. **Service units and service limitations.**

a. This service shall be limited to 780 blocks, or its equivalent under the DMAS fee schedule, per Individual Support Plan year. A block shall be defined as a period of time from one hour through three hours and 59 minutes. Two blocks are defined as four hours to six hours and 59 minutes. Three blocks are defined as seven hours to nine hours and 59 minutes. If this service is used in combination with prevocational, or group supported employment services, or both, the combined total units for day support, prevocational, or group supported employment services shall not exceed 780 units, or its equivalent under the DMAS fee schedule, per Individual Support Plan year.

b. Day support services shall be billed according to the DMAS fee schedule.

c. Day support shall not be regularly or temporarily provided in an individual's home setting or other residential setting (e.g., due to inclement weather or individual illness) without prior written approval from the state-designated agency or its contractor.

d. Noncenter-based day support services shall be separate and distinguishable from either residential support services or personal assistance services. The supporting documentation shall provide an estimate of the amount of day support required by the individual.

5. Service providers shall be reimbursed only for the amount and level of day support services included in the individual's approved Plan for Supports based on the setting, intensity, and duration of the service to be delivered.

F. **Environmental modifications (EM).** Service description. This service shall be defined, as set out in 12VAC30-120-1000, as those physical adaptations to the individual's primary home, primary vehicle, or work site that shall be required by the individual's Individual Support Plan, that are necessary to ensure the health and welfare of the individual, or that enable the individual to function with greater independence. Environmental modifications reimbursed by DMAS may only be made to an individual's work site when the modification exceeds the reasonable accommodation requirements of the Americans with Disabilities Act. Such adaptations may include, but shall not necessarily be limited to, the installation of ramps and grab-bars, widening of doorways, modification of bathroom facilities, or installation of specialized electric and plumbing systems that are necessary to accommodate the medical equipment and supplies that are necessary for the individual. Modifications may be made to a primary automotive vehicle in which the individual is transported if it is owned by the individual, a family member with whom the individual lives or has consistent and ongoing contact, or a nonrelative who provides primary long-term support to the individual and is not a paid provider of services.

1. In order to qualify for these services, the individual enrolled in the waiver shall have a demonstrated need for equipment or modifications of a remedial or medical benefit offered in an individual's primary home, the primary vehicle used by the individual, community activity setting, or day program to specifically improve the individual's personal functioning. This service shall encompass those items not otherwise covered in the State Plan for Medical Assistance or through another program.

2. **Service units and service limitations.**

a. Environmental modifications shall be provided in the least expensive manner possible that will accomplish the modification required by the individual enrolled in the waiver and shall be completed within the calendar year consistent with the Plan of Supports' requirements.

b. The maximum funded expenditure per individual for all EM covered procedure codes (combined total of EM items and labor related to these items) shall be \$5,000 per calendar year for individuals regardless of waiver for which EM is approved. The service unit shall always be one, for the total cost of all EM being requested for a specific timeframe.

EM shall be available to individuals enrolled in the waiver who are receiving at least one other waiver service and may be provided in a residential or nonresidential setting. EM shall be prior authorized by the state-designated agency or its contractor for each calendar year with no carry-over across calendar years.

c. Modifications shall not be used to bring a substandard dwelling up to minimum habitation standards.

d. Providers shall be reimbursed for their actual cost of material and labor and no additional mark-ups shall be permitted.

e. Providers of EM services shall not be the spouse or parents of the individual enrolled in the waiver.

f. Excluded from coverage under this waiver service shall be those adaptations or improvements to the home that are of general utility and that are not of direct medical or remedial benefit to the individual enrolled in the waiver, such as, but not necessarily limited to, carpeting, roof repairs, and central air conditioning. Also excluded shall be modifications that are reasonable accommodation requirements of the Americans with Disabilities Act, the Virginians with Disabilities Act, and the Rehabilitation Act. Adaptations that add to the total square footage of the home shall be excluded from this service. Except when EM services are furnished in the individual's own home, such services shall not be provided to individuals who receive residential support services.

3. Modifications shall not be prior authorized or covered to adapt living arrangements that are owned or leased by providers of waiver services or those living arrangements that are sponsored by a DBHDS-licensed residential support provider. Specifically, provider-owned or leased settings where residential support services are furnished shall already be compliant with the Americans with Disabilities Act.

4. Modifications to a primary vehicle that shall be specifically excluded from this benefit shall be:

a. Adaptations or improvements to the vehicle that are of general utility and are not of direct medical or remedial benefit to the individual;

b. Purchase or lease of a vehicle; and

c. Regularly scheduled upkeep and maintenance of a vehicle, except upkeep and maintenance of the modifications that were covered under this waiver benefit.

G. Personal assistance services. Service description. These services may be provided either through an agency-directed or consumer-directed (CD) model.

1. Personal assistance shall be provided to individuals in the areas of activities of daily living (ADLs), instrumental activities of daily living (IADLs), access to the community, monitoring of self-administered medications or other medical needs, monitoring of health status and physical

condition, and work-related personal assistance. Such services, as set out in the Plan for Supports, may be provided and reimbursed in home and community settings to enable an individual to maintain the health status and functional skills necessary to live in the community or participate in community activities. When specified, such supportive services may include assistance with IADLs. Personal assistance shall not include either practical or professional nursing services or those practices regulated in Chapters 30 (§ 54.1-3000 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia, as appropriate. This service shall not include skilled nursing services with the exception of skilled nursing tasks that may be delegated pursuant to 18VAC90-20-420 through 18VAC90-20-460.

2. Criteria. In order to qualify for personal assistance, the individual shall demonstrate a need for assistance with ADLs, community access, self-administration of medications or other medical needs, or monitoring of health status or physical condition.

3. Service units and service limitations.

a. The unit of service shall be one hour.

b. Each individual, family, or caregiver shall have a back-up plan for the individual's needed supports in case the personal assistant does not report for work as expected or terminates employment without prior notice.

c. Personal assistance shall not be available to individuals who (i) receive congregate residential services or who live in assisted living facilities, (ii) would benefit from ADL or IADL skill development as identified by the case manager, or (iii) receive comparable services provided through another program or service.

d. The hours to be authorized shall be based on the individual's need. No more than two unrelated individuals who live in the same home shall be permitted to share the authorized work hours of the assistant.

H. Personal Emergency Response System (PERS). Service description. This service shall be a service that monitors individuals' safety in their homes, and provides access to emergency assistance for medical or environmental emergencies through the provision of a two-way voice communication system that dials a 24-hour response or monitoring center upon activation and via the individuals' home telephone system. PERS may also include medication monitoring devices.

1. PERS may be authorized when there is no one else in the home with the individual enrolled in the waiver who is competent or continuously available to call for help in an emergency.

2. Service units and service limitations.

a. A unit of service shall include administrative costs, time, labor, and supplies associated with the installation, maintenance, monitoring, and adjustments of the PERS.

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A unit of service is the one-month rental price set by DMAS. The one-time installation of the unit shall include installation, account activation, individual and caregiver instruction, and removal of PERS equipment.

b. PERS services shall be capable of being activated by a remote wireless device and shall be connected to the individual's telephone system. The PERS console unit must provide hands-free voice-to-voice communication with the response center. The activating device must be waterproof, automatically transmit to the response center an activator low battery alert signal prior to the battery losing power, and be able to be worn by the individual.

c. PERS services shall not be used as a substitute for providing adequate supervision for the individual enrolled in the waiver.

I. Prevocational services. Service description. These services shall be intended to prepare an individual enrolled in the waiver for paid or unpaid employment but shall not be job-task oriented. Prevocational services shall be provided to individuals who are not expected to be able to join the general work force without supports or to participate in a transitional sheltered workshop within one year of beginning waiver services. Activities included in this service shall not be directed at teaching specific job skills but at underlying habilitative outcomes such as accepting supervision, regular job attendance, task completion, problem solving, and safety. There shall be two levels of this covered service: (i) intensive and (ii) regular.

1. In order to qualify for prevocational services, the individual enrolled in the waiver shall have a demonstrated need for support in skills that are aimed toward preparation of paid employment that may be offered in a variety of community settings.

2. Service units and service limitations. Billing shall be in accordance with the DMAS fee schedule.

a. This service shall be limited to 780 blocks, or its equivalent under the DMAS fee schedule, per Individual Support Plan year. A block shall be defined as a period of time from one hour through three hours and 59 minutes. Two blocks are defined as four hours to six hours and 59 minutes. Three blocks are defined as seven hours to nine hours and 59 minutes. If this service is used in combination with day support or group-supported employment services, or both, the combined total units for prevocational services, day support and group supported employment services shall not exceed 780 blocks, or its equivalent under the DMAS fee schedule, per Individual Support Plan year. A block shall be defined as a period of time from one hour through three hours and 59 minutes.

b. Prevocational services may be provided in center-based or noncenter-based settings. Center-based settings means services shall be provided primarily at one

location or building and noncenter-based means services shall be provided primarily in community settings.

c. For prevocational services to be authorized at the intensive level, the individual must meet at least one of the following criteria: (i) require physical assistance to meet the basic personal care needs (such as, but not limited to, toileting, eating/feeding); (ii) require additional, ongoing support to fully participate in services and to accomplish desired outcomes due to extensive disability-related difficulties; or (iii) require extensive constant supervision to reduce or eliminate behaviors that preclude full participation in the program. In this case, written behavioral support activities shall be required to address behaviors such as, but not limited to, withdrawal, self-injury, aggression, or self-stimulation. Individuals not meeting these specified criteria for intensive prevocational services shall be provided with regular prevocational services.

3. There shall be documentation regarding whether prevocational services are available in vocational rehabilitation agencies through § 110 of the Rehabilitation Act of 1973 or through the Individuals with Disabilities Education Act (IDEA). If the individual is not eligible for services through the IDEA due to his age, documentation shall be required only for lack of DRS funding. When these services are provided through these alternative funding sources, the Plan for Supports shall not authorize prevocational services as waiver expenditures.

4. Prevocational services shall only be provided when the individual's compensation for work performed is less than 50% of the minimum wage.

J. Residential support services. Service description. These services shall consist of skill-building, supports, and safety supports, provided primarily in an individual's home or in a licensed or approved residence, that enable an individual to acquire, retain, or improve the self-help, socialization, and adaptive skills necessary to reside successfully in home and community-based settings. Service providers shall be reimbursed only for the amount and type of residential support services that are included in the individual's approved Plan for Supports. There shall be two types of this service: congregate residential support and in-home supports. Residential support services shall be authorized for Medicaid reimbursement in the Plan for Supports only when the individual requires these services and when such needs exceed the services included in the individual's room and board arrangements with the service provider, or if these services exceed supports provided by the family/caregiver. Only in exceptional instances shall residential support services be routinely reimbursed up to a 24-hour period.

1. Criteria.

a. In order for DMAS to reimburse for congregate residential support services, the individual shall have a

demonstrated need for supports to be provided by staff who shall be paid by the residential support provider.

b. To qualify for this service in a congregate setting, the individual shall have a demonstrated need for continuous skill-building, supports, and safety supports for up to 24 hours per day.

c. Providers shall participate as requested in the completion of the DBHDS-approved SIS form or its approved substitute form.

d. The residential support Plan for Supports shall indicate the necessary amount and type of activities required by the individual, the schedule of residential support services, and the total number of projected hours per week of waiver reimbursed residential support.

e. In-home residential supports shall be supplemental to the primary care provided by the individual, his family member or members, and other caregivers. In-home residential supports shall not replace this primary care.

f. In-home residential supports shall be delivered on an individual basis, typically for less than a continuous 24-hour period. This service shall be delivered with a ~~1:1~~ one-to-one staff-to-individual ratio except when skill building supports require interaction with another person.

2. Service units and service limitations. Total billing shall not exceed the amount authorized in the Plan for Supports. The provider must maintain documentation of the date and times that services have been provided, and specific circumstances that prevented provision of all of the scheduled services, should that occur.

a. This service shall be provided on an individual-specific basis according to the Plan for Supports and service setting requirements;

b. Congregate residential support shall not be provided to any individual enrolled in the waiver who receives personal assistance services under the ID Waiver or other residential services that provide a comparable level of care. Residential support services shall be permitted to be provided to the individual enrolled in the waiver in conjunction with respite services for unpaid caregivers;

c. Room, board, and general supervision shall not be components of this service;

d. This service shall not be used solely to provide routine or emergency respite care for the family/caregiver with whom the individual lives; and

e. Medicaid reimbursement shall be available only for residential support services provided when the individual is present and when an enrolled Medicaid provider is providing the services.

K. Respite services. Service description. These services may be provided either through an agency-directed or consumer-directed (CD) model.

1. Respite services shall be provided to individuals in the areas of activities of daily living (ADLs), instrumental activities of daily living (IADLs), access to the community, monitoring of self-administered medications or other medical needs, and monitoring of health status and physical condition in the absence of the primary caregiver or to relieve the primary caregiver from the duties of caregiving. Such services may be provided in home and community settings to enable an individual to maintain the health status and functional skills necessary to live in the community or participate in community activities. When specified, such supportive services may include assistance with IADLs. Respite assistance shall not include either practical or professional nursing services or those practices regulated in Chapters 30 (§ 54.1-3000 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia, as appropriate. This service shall not include skilled nursing services with the exception of skilled nursing tasks that may be delegated pursuant to 18VAC90-20-420 through 18VAC90-20-460.

2. Respite services shall be those that are normally provided by the individual's family or other unpaid primary caregiver. These covered services shall be furnished on a short-term, episodic, or periodic basis because of the absence of the unpaid caregiver or need for relief of the unpaid caregiver or caregivers who normally provide care for the individual.

3. Criteria.

a. In order to qualify for respite services, the individual shall demonstrate a need for assistance with ADLs, community access, self-administration of medications or other medical needs, or monitoring of health status or physical condition.

b. Respite services shall only be offered to individuals who have an unpaid primary caregiver or caregivers who require temporary relief. Such need for relief may be either episodic, intermittent, or periodic.

4. Service units and service limitations.

a. The unit of service shall be one hour. Respite services shall be limited to 480 hours per individual per state fiscal year. If an individual changes waiver programs, this same maximum number of respite hours shall apply. No additional respite hours beyond the 480 maximum limit shall be approved for payment. Individuals who are receiving respite services in this waiver through both the agency-directed and CD models shall not exceed 480 hours per year combined.

b. Each individual, family, or caregiver shall have a back-up plan for the individual's care in case the respite assistant does not report for work as expected or terminates employment without prior notice.

c. Respite services shall not be provided to relieve staff of either group homes, pursuant to 12VAC35-105-20, or

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assisted living facilities, pursuant to 22VAC40-72-10, where residential supports are provided in shifts. Respite services shall not be provided for DMAS reimbursement by adult foster care providers for an individual residing in that foster home.

d. Skill development shall not be provided with respite services.

e. The hours to be authorized shall be based on the individual's need. No more than two unrelated individuals who live in the same home shall be permitted to share the authorized work hours of the respite assistant.

5. Consumer-directed and agency-directed respite services shall meet the same standards for service limits and authorizations.

L. Services facilitation and consumer-directed service model. Service description. Individuals enrolled in the waiver may be approved to select consumer directed (CD) models of service delivery, absent any of the specified conditions that precludes such a choice, and may also receive support from a services facilitator. Persons functioning as services facilitators shall be enrolled Medicaid providers. This shall be a separate waiver service to be used in conjunction with CD personal assistance, respite, or companion services and shall not be covered for an individual absent one of these consumer directed services.

1. Services facilitators shall train individuals enrolled in the waiver, family/caregiver, or EOR, as appropriate, to direct (such as select, hire, train, supervise, and authorize timesheets of) their own assistants who are rendering personal assistance, respite services, and companion services.

2. The services facilitator shall assess the individual's particular needs for a requested CD service, assisting in the development of the Plan for Supports, provide management training for the individual or the EOR, as appropriate, on his responsibilities as employer, and provide ongoing support of the CD model of services. The service authorization for receipt of consumer directed services shall be based on the approved Plan for Supports.

3. The services facilitator shall make an initial comprehensive home visit to collaborate with the individual and the individual's family/caregiver, as appropriate, to identify the individual's needs, assist in the development of the Plan for Supports with the individual and the individual's family/caregiver, as appropriate, and provide employer management training to the individual and the family/caregiver, as appropriate, on his responsibilities as an employer, and providing ongoing support of the consumer-directed model of services. Individuals or EORs who are unable to receive employer management training at the time of the initial visit shall receive management training within seven days of the initial visit.

a. The initial comprehensive home visit shall be completed only once upon the individual's entry into the CD model of service regardless of the number or type of CD services that an individual requests.

b. If an individual changes services facilitators, the new services facilitator shall complete a reassessment visit in lieu of a comprehensive visit.

c. This employer management training shall be completed before the individual or EOR may hire an assistant who is to be reimbursed by DMAS.

4. After the initial visit, the services facilitator shall continue to monitor the individual's Plan for Supports quarterly (i.e., every 90 days) and more often as-needed. If CD respite services are provided, the services facilitator shall review the utilization of CD respite services either every six months or upon the use of 240 respite services hours, whichever comes first.

5. A face-to-face meeting shall occur between the services facilitator and the individual at least every six months to reassess the individual's needs and to ensure appropriateness of any CD services received by the individual. During these visits with the individual, the services facilitator shall observe, evaluate, and consult with the individual, EOR, and the individual's family/caregiver, as appropriate, for the purpose of documenting the adequacy and appropriateness of CD services with regard to the individual's current functioning and cognitive status, medical needs, and social needs. The services facilitator's written summary of the visit shall include, but shall not necessarily be limited to:

a. Discussion with the individual and EOR or family/caregiver, as appropriate, whether the particular consumer directed service is adequate to meet the individual's needs;

b. Any suspected abuse, neglect, or exploitation and to whom it was reported;

c. Any special tasks performed by the assistant and the assistant's qualifications to perform these tasks;

d. Individual's and EOR's or family/caregiver's, as appropriate, satisfaction with the assistant's service;

e. Any hospitalization or change in medical condition, functioning, or cognitive status;

f. The presence or absence of the assistant in the home during the services facilitator's visit; and

g. Any other services received and the amount.

6. The services facilitator, during routine visits, shall also review and verify timesheets as needed to ensure that the number of hours approved in the Plan for Supports is not exceeded. If discrepancies are identified, the services facilitator shall discuss these with the individual or the EOR to resolve discrepancies and shall notify the fiscal/employer agent. If an individual is consistently

identified as having discrepancies in his timesheets, the services facilitator shall contact the case manager to resolve the situation.

7. The services facilitator shall maintain a record of each individual containing elements as set out in 12VAC30-120-1060.

8. The services facilitator shall be available during standard business hours to the individual or EOR by telephone.

9. If a services facilitator is not selected by the individual, the individual or the family/caregiver serving as the EOR shall perform all of the duties and meet all of the requirements, including documentation requirements, identified for services facilitation. However, the individual or family/caregiver shall not be reimbursed by DMAS for performing these duties or meeting these requirements.

10. If an individual enrolled in consumer-directed services has a lapse in services facilitator duties for more than 90 consecutive days, and the individual or family/caregiver is not willing or able to assume the service facilitation duties, then the case manager shall notify DMAS or its designated prior authorization contractor and the consumer-directed services shall be discontinued once the required 10 days notice of this change has been observed. The individual whose consumer-directed services have been discontinued shall have the right to appeal this discontinuation action pursuant to 12VAC30-110. The individual shall be given his choice of an agency for the alternative personal care, respite, or companion services that he was previously obtaining through consumer direction.

11. The CD services facilitator, who is to be reimbursed by DMAS, shall not be the individual enrolled in the waiver, the individual's case manager, a direct service provider, the individual's spouse, a parent of the individual who is a minor child, or the EOR who is employing the assistant/companion.

12. The services facilitator shall document what constitutes the individual's back-up plan in case the assistant/companion does not report for work as expected or terminates employment without prior notice.

13. Should the assistant/companion not report for work or terminate his employment without notice, then the services facilitator shall, upon the individual's or EOR's request, provide management training to ensure that the individual or the EOR is able to recruit and employ a new assistant/companion.

14. The limits and requirements for individuals' selection of consumer directed services shall be as follows:

a. In order to be approved to use the CD model of services, the individual enrolled in the waiver, or if the individual is unable, the designated EOR, shall have the capability to hire, train, and fire his own assistants and supervise the assistants' performance. Case managers

shall document in the Individual Support Plan the individual's choice for the CD model and whether or not the individual chooses services facilitation. The case manager shall document in this individual's record that the individual can serve as the EOR or if there is a need for another person to serve as the EOR on behalf of the individual.

b. An individual enrolled in the waiver who is younger than 18 years of age shall be required to have an adult responsible for functioning in the capacity of an EOR.

c. Specific employer duties shall include checking references of assistants, determining that assistants meet specified qualifications, timely and accurate completion of hiring packets, training the assistants, supervising assistants' performance, and submitting complete and accurate timesheets to the fiscal/employer agent on a consistent and timely basis.

M. Skilled nursing services. Service description. These services shall be provided for individuals enrolled in the waiver having serious medical conditions and complex health care needs who do not meet home health criteria but who require specific skilled nursing services which cannot be provided by non-nursing personnel. Skilled nursing services may be provided in the individual's home or other community setting on a regularly scheduled or intermittent basis. It may include consultation, nurse delegation as appropriate, oversight of direct support staff as appropriate, and training for other providers.

1. In order to qualify for these services, the individual enrolled in the waiver shall have demonstrated complex health care needs that require specific skilled nursing services as ordered by a physician that cannot be otherwise provided under the Title XIX State Plan for Medical Assistance, such as under the home health care benefit.

2. Service units and service limitations. Skilled nursing services shall be rendered by a registered nurse or licensed practical nurse as defined in 12VAC30-120-1000 and shall be provided in ~~hourly~~ 15-minute units in accordance with the DMAS fee schedule as set out in DMAS guidance documents. The services shall be explicitly detailed in a Plan for Supports and shall be specifically ordered by a physician as medically necessary.

N. Supported employment services. Service description. These services shall consist of ongoing supports that enable individuals to be employed in an integrated work setting and may include assisting the individual to locate a job or develop a job on behalf of the individual, as well as activities needed to sustain paid work by the individual including skill-building supports and safety supports on a job site. These services shall be provided in work settings where persons without disabilities are employed. Supported employment services shall be especially designed for individuals with developmental disabilities, including individuals with ID, who face severe impediments to employment due to the

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nature and complexity of their disabilities, irrespective of age or vocational potential (i.e., the individual's ability to perform work).

1. Supported employment services shall be available to individuals for whom competitive employment at or above the minimum wage is unlikely without ongoing supports and who because of their disabilities need ongoing support to perform in a work setting. The individual's assessment and Individual Support Plan must clearly reflect the individual's need for employment-related skill building.

2. Supported employment shall be provided in one of two models: individual or group.

a. Individual supported employment shall be defined as support, usually provided one-on-one by a job coach to an individual in a supported employment position. For this service, reimbursement of supported employment shall be limited to actual documented interventions or collateral contacts by the provider, not the amount of time the individual enrolled in the waiver is in the supported employment situation.

b. Group supported employment shall be defined as continuous support provided by staff to eight or fewer individuals with disabilities who work in an enclave, work crew, bench work, or in an entrepreneurial model.

3. Criteria.

a. Only job development tasks that specifically pertain to the individual shall be allowable activities under the ID Waiver supported employment service and DMAS shall cover this service only after determining that this service is not available from DRS for this individual enrolled in the waiver.

b. In order to qualify for these services, the individual shall have demonstrated that competitive employment at or above the minimum wage is unlikely without ongoing supports and, that because of his disability, he needs ongoing support to perform in a work setting.

c. Providers shall participate as requested in the completion of the DBHDS-approved assessment.

d. The Plan for Supports shall document the amount of supported employment required by the individual.

4. Service units and service limitations.

a. Service providers shall be reimbursed only for the amount and type of supported employment included in the individual's Plan for Supports, which must be based on the intensity and duration of the service delivered.

b. The unit of service for individual job placement supported employment shall be one hour. This service shall be limited to 40 hours per week per individual.

c. Group models of supported employment shall be billed according to the DMAS fee schedule.

d. Group supported employment shall be limited to 780 blocks per individual, or its equivalent under the DMAS

fee schedule, per Individual Support Plan year. A block shall be defined as a period of time from one hour through three hours and 59 minutes. Two blocks are defined as four hours to six hours and 59 minutes. Three blocks are defined as seven hours to nine hours and 59 minutes. If this service is used in combination with prevocational and day support services, the combined total unit blocks for these three services shall not exceed 780 units, or its equivalent under the DMAS fee schedule, per Individual Support Plan year.

O. Therapeutic consultation. Service description. This service shall provide expertise, training, and technical assistance in any of the following specialty areas to assist family members, caregivers, and other service providers in supporting the individual enrolled in the waiver. The specialty areas shall be (i) psychology, (ii) behavioral consultation, (iii) therapeutic recreation, (iv) speech and language pathology, (v) occupational therapy, (vi) physical therapy, and (vii) rehabilitation engineering. The need for any of these services shall be based on the individuals' Individual Support Plans, and shall be provided to those individuals for whom specialized consultation is clinically necessary and who have additional challenges restricting their abilities to function in the community. Therapeutic consultation services may be provided in individuals' homes, and in appropriate community settings (such as licensed or approved homes or day support programs) as long as they are intended to facilitate implementation of individuals' desired outcomes as identified in their Individual Support Plans.

1. In order to qualify for these services, the individual shall have a demonstrated need for consultation in any of these services. Documented need must indicate that the Individual Support Plan cannot be implemented effectively and efficiently without such consultation as provided by this covered service.

a. The individual's therapeutic consultation Plan for Supports shall clearly reflect the individual's needs, as documented in the assessment information, for specialized consultation provided to family/caregivers and providers in order to effectively implement the Plan for Supports.

b. Therapeutic consultation services shall not include direct therapy provided to individuals enrolled in the waiver and shall not duplicate the activities of other services that are available to the individual through the State Plan for Medical Assistance.

2. The unit of service shall be one hour. The services must be explicitly detailed in the Plan for Supports. Travel time, written preparation, and telephone communication shall be considered as in-kind expenses within this service and shall not be reimbursed as separate items. Therapeutic consultation shall not be billed solely for purposes of monitoring the individual.

3. Only behavioral consultation in this therapeutic consultation service may be offered in the absence of any other waiver service when the consultation is determined to be necessary.

P. Transition services. Transition services, as defined at and controlled by 12VAC30-120-2000 and 12VAC30-120-2010, provide for set-up expenses for qualifying applicants. The ID case manager shall coordinate with the discharge planner to ensure that ID Waiver eligibility criteria shall be met. Transition services shall be prior authorized by DMAS or its designated agent in order for reimbursement to occur.

VA.R. Doc. No. R14-3681; Filed November 1, 2013, 2:41 p.m.

STATE BOARD OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

Fast-Track Regulation

Title of Regulation: 12VAC35-230. Operation of the Individual and Family Support Program (adding 12VAC35-230-10 through 12VAC35-230-110).

Statutory Authority: § 37.2-203 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: January 1, 2014.

Effective Date: January 16, 2014.

Agency Contact: Linda B. Grasewicz, Senior Planner, Department of Behavioral Health and Developmental Services, Jefferson Building, 1220 Bank Street, 12th Floor, Richmond, VA 23219, telephone (804) 786-0040, FAX (804) 371-0092, or email linda.grasewicz@dbhds.virginia.gov.

Basis: The State Board of Behavioral Health and Developmental Services has the authority under § 37.2-203 of the Code of Virginia "to adopt regulations that may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by the Commissioner or the Department."

Purpose: The purpose of the regulations is to establish a support program (i) for individuals who are living in their own homes or a family home and are on the statewide waiting list for Intellectual Disability (ID) Medicaid Waiver or the Individual and Family Developmental Disabilities Support (IFDDS) Medicaid Waiver and (ii) for the family members who are supporting these individuals. This program promotes and protects the public welfare.

Rationale for Using Fast-Track Process: The Governor released emergency regulations governing the operations of the Individual and Family Support Program (IFSP) in January 2013. In March, the Department of Behavioral Health and Developmental Services (DBHDS) mailed letters to all the individuals on the ID or IFDDS statewide waiting lists and posted a notice on the DBHDS website that the program was operational. In addition to these two communication strategies, program guidelines, along with applications for

support, were distributed to community services boards (CSBs), providers, and advocates. By the end of fiscal year (FY) 2013, DBHDS had received more than 1,700 applications, with 825 individuals and families receiving financial support through the program.

The emergency regulations authorizing this program will expire in January 2014. The FY 2014 funding round is scheduled to begin September 3, 2013, and should conclude before the expiration of these emergency regulations. In the settlement agreement with the Department of Justice, the Commonwealth agreed to provide financial support through the program until at least 2021, which will require that the proposed permanent regulations be in place by July 1, 2014. There are no changes from the emergency regulations establishing the IFSP to what is being proposed in the permanent IFSP regulations, which is one of the reasons that fast-track rulemaking process is being sought.

The extraordinary demand for IFSP resources initially overwhelmed DBHDS resources. In two months, the entire fiscal year allocation was distributed to individuals on either the ID or developmental disability (DD) waiver wait list with little controversy. It is important that permanent regulations are in place by July 1, 2014, so that DBHDS can continue to provide supports to this vulnerable population in subsequent state fiscal years.

Substance: The section number and intent and likely impact of proposed requirements are as follows:

12VAC35-230-10. Definitions: Assures that the terms used in the regulation are understood.

12VAC35-230-20. Program description: Describes the objectives and service population of the program being established.

12VAC35-230-30. Program eligibility requirements: Identifies who is eligible to receive program support.

12VAC35-230-40. Program implementation: Explains how the program will be implemented.

12VAC35-230-50. Covered services and supports: Details the specific activities and supports that will be covered.

12VAC35-230-60. Application for funding: Provides details on how to request program support.

12VAC35-230-70. Application review criteria: Explains how DBHDS will evaluate funding requests.

12VAC35-230-80. Funding decision-making process: Establishes the conditions for DBHDS to deny or reduce the amount of an individual funding request and requires that the department provide applicants with a written notice regarding funding decisions.

12VAC35-230-90. Requests for reconsideration: Provides applicants with an opportunity to provide additional information prior to initiating the formal APA review process.

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12VAC35-230-100. Post-funding review: Explains for successful applicants what their responsibilities are with respect to any utilization review.

12VAC35-230-110. Termination of funding for services, supports, or other assistance: Ensures applicants understand how and when funding will be terminated.

The IFSP is designed to support individuals with ID or DD and their family members and help such individuals access needed person-centered and family-centered resources, supports, services, and other assistance. Individual and Family Support Program funds will be distributed directly to the requesting individual or family member or a third party designated by the individual or family member. Program funds can be used to provide services such as (i) professionally provided services and supports, such as respite, transportation services, behavioral consultation, and behavior management; (ii) assistive technology and home modifications, goods, or products that directly support the individual; (iii) temporary rental assistance or deposits; (iv) fees for summer camp and other recreation services; (v) temporary assistance with utilities or deposits; (vi) dental or medical expenses of the individual; (vii) family education, information, and training; (viii) peer mentoring and family-to-family supports; (ix) emergency assistance and crisis support; or (x) other direct support services as approved by the department.

Issues: The IFSP provides short term support that will enable individuals who are living in their own homes or a family home and are on the statewide waiting list for ID Medicaid Waiver or the IFDDS Medicaid Waiver and the family members who are supporting these individuals to continue to remain in their own homes or a family home. The resources provided through the IFSP will benefit individual private citizens and the businesses from which they purchase goods and services. The IFSP benefits local CSBs, DBHDS, and the public by assuring that individuals most at risk of institutionalization continue to maintain their community residence.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed regulations establish the Individual and Family Support Program to provide financial support to individuals with intellectual disability or developmental disabilities and their family members.

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. In a settlement agreement with the Department of Justice (DOJ), the Commonwealth agreed to provide financial support to individuals with intellectual disability or developmental disabilities and their family members until at least 2021. The proposed regulations

establish Individual and Family Support Program (IFSP) to accomplish this goal. IFSP has become operational in March 2013 under emergency regulations. The proposed regulations will permanently replace the emergency regulations currently in place.

IFSP provides short term support that enables individuals who are living in their own homes or a family home and are on the statewide waiting list for Intellectual Disability Medicaid Waiver or Developmental Disabilities Medicaid Waiver and their family members who are supporting these individuals to continue to remain in their own homes or a family home. The support services and items provided may include respite care, transportation services, behavioral consultation and management services; assistive technology, home modifications, goods and products that directly support the individual; temporary assistance with rent, utilities and deposits; fees for summer camp and other recreation services; dental or medical expenses of the individual; family education, information, and training; peer mentoring and family-to-family supports, emergency assistance and crisis support.

IFSP will provide limited relief to a minimum of 1,000 individuals and their families each year over the next nine years in accordance with DOJ settlement agreement requirements. The funds available to the program are limited by the budget appropriation. In fiscal year (FY) 2014, \$3.2 million is appropriated for this program. Since the demand for these services are much greater than the available funds, individuals are served on a first-come-first-serve basis. In FY 2013, there were 1,654 applications and the entire funding was distributed in just two months. As of September 5, 2013, 350 applications were received for FY 2014 funding. The average support amount is estimated to be about \$2,000 with a range from \$50 to \$3,000.

The main benefit of IFSP is providing services and goods to individuals and their families in need so that they can stay in their communities. These individuals would not be able to receive these services without this program or they would have to pay for them from their own resources. In addition, supporting these individuals to keep them in their communities helps avoid institutionalization. According to the Department of Behavioral Health and Developmental Services (DBHDS), caring for an individual in an institutional setting may cost up to \$120,000 per year. Furthermore, failure to permanently implement this program may constitute a breach of the settlement agreement with DOJ and expose the Commonwealth to litigation risks.

On the other hand, IFSP expenditures are paid 100% by state funds. Since the Commonwealth is required to maintain a balanced budget, the funding for this program has to reduce funding elsewhere. Thus, while IFSP recipients and businesses that cater to IFSP recipients enjoy positive economic effects, a corresponding economic effect in the opposite direction would likely take place elsewhere. In

addition, there will be additional costs associated with administration of this program. DBHDS estimates that slightly fewer than three full time personnel would be sufficient to operate the program. Also, there would be other costs associated with office supplies, debit card fees, postage, etc in order to administer this program.

Businesses and Entities Affected. IFSP will provide limited relief to a minimum of 1,000 individuals and their families each year over the next nine years in accordance with DOJ settlement agreement requirements.

Localities Particularly Affected. The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment. The proposed regulations will increase state spending and have positive impact in labor demand in certain sectors that provide support services and goods to keep individuals with intellectual or developmental disabilities in their communities. However, due to balanced budget requirement, state spending will have been reduced somewhere else, having a negative effect on labor demand in different sectors. The net impact of these opposing effects is not known.

Effects on the Use and Value of Private Property. Similarly, while businesses in certain sectors may see a positive impact on their asset values due to increased state spending, businesses in other sectors may see a corresponding decrease in their asset values due to reduced revenues.

Small Businesses: Costs and Other Effects. As discussed above reduced state spending elsewhere to finance IFSP would have negative impact on businesses in those areas. At least some of those businesses may be expected to be small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact. There is no known alternative to minimize adverse impact on small businesses that accomplish the same goal.

Real Estate Development Costs. No direct impact on real estate development costs is expected.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and

estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The agency concurs with the economic impact analysis prepared by the Department of Planning and Budget.

Summary:

Chapter 3, Item 315 V 3 of the 2012 Acts of Assembly, Special Session I, requires the Department of Behavioral Health and Developmental Services to promulgate regulations to establish an Individual and Family Support Program (IFSP). The regulations establish an IFSP for individuals with intellectual disability (ID) or developmental disability (DD) who are on the waiting list for either an ID or a DD waiver. This program is required by a settlement agreement with the U.S. Department of Justice, which also stipulates that this program will be operational before the end of fiscal year 2013.

This regulation establishes a support program for (i) individuals who are living in their own homes or a family home and are on the statewide waiting list for ID Medicaid Waiver or the Individual and Family Developmental Disabilities Support Medicaid Waiver and (ii) for the family members who are supporting these individuals. The regulation provides (i) who is eligible for the program, (iii) how the program is implemented, (iii) what services and supports are covered by the program, (iv) application process, (v) how applications are evaluated and funds approved, (vi) how to appeal the denial of funds, and (vii) when the program terminates.

CHAPTER 230

OPERATION OF THE INDIVIDUAL AND FAMILY SUPPORT PROGRAM

12VAC35-230-10. Definitions.

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

"Commissioner" means the Commissioner of the Department of Behavioral Health and Developmental Services.

"Department" means the Department of Behavioral Health and Developmental Services.

"Developmental disability" or "DD" means a severe, chronic disability of an individual that:

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1. Is attributable to a mental or physical impairment or combination of mental and physical impairments;
2. Is manifested before the individual attains age 22;
3. Is likely to continue indefinitely;
4. Results in substantial functional limitations in three or more of the following areas of major life activity: (i) self-care; (ii) receptive and expressive language; (iii) learning; (iv) mobility; (v) self-direction; (vi) capacity for independent living; and (vii) economic self-sufficiency; and
5. Reflects the individual's need for a combination and sequence of special, interdisciplinary or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated. (42 USC § 15002)

"Family member" means an immediate family member of an individual receiving services or the principal caregiver of that individual. A principal caregiver is a person who acts in the place of an immediate family member, including other relatives and foster care providers, but does not have a proprietary interest in the care of the individual receiving services. (§ 37.2-100 of the Code of Virginia)

"Individual and Family Support" means an array of individualized items and services that are intended to support the continued residence of an individual with intellectual or developmental disabilities (ID/DD) in his own or the family home.

"Intellectual disability" or "ID" means a disability, originating before the age of 18 years, characterized concurrently by (i) significantly subaverage intellectual functioning as demonstrated by performance on a standardized measure of intellectual functioning, administered in conformity with accepted professional practice, that is at least two standard deviations below the mean; and (ii) significant limitations in adaptive behavior as expressed in conceptual, social, and practical adaptive skills. (§ 37.2-100 of the Code of Virginia)

12VAC35-230-20. Program description.

A. The Individual and Family Support Program assists individuals with intellectual disability or developmental disabilities and their family members to access needed person-centered and family-centered resources, supports, services and other assistance as approved by the department. As such, Individual and Family Support Program funds shall be distributed directly to the requesting individual or family member or a third party designated by the individual or family member.

B. The overall objective of the Individual and Family Support Program is to support the continued residence of an individual with intellectual or developmental disabilities in his own home or the family home, which include the home of a principal caregiver.

C. Individual and Family Support Program funds shall not supplant or in any way limit the availability of services provided through a Medicaid Home and Community-Based Waiver, Early and Periodic Screening, Diagnosis and Treatment, or similar programs.

12VAC35-230-30. Program eligibility requirements.

Eligibility for Individual and Family Support Program funds shall be limited to individuals who are living in their own or a family home and are on the statewide waiting list for the Intellectual Disability (ID) Medicaid Waiver or the Individual and Family Developmental Disabilities Support (IFDDS) Medicaid Waiver and family members who are assisting those individuals.

12VAC35-230-40. Program implementation.

A. Individual and Family Support Program funds shall be limited by the amount of funds allocated to the program by the General Assembly. Department approval of funding requests shall not exceed the funding available for the fiscal year.

B. Based on funding availability, the department shall establish an annual individual financial support limit, which is the maximum annual amount of funding that can be provided to support an eligible individual during the applicable fiscal year.

C. Individual and Family Support Program funds may be provided to individuals or family members in varying amounts, as requested and approved by the department, up to the established annual individual financial support limit.

D. On an annual basis, the department shall announce Individual and Family Support Program total funding availability and the annual individual financial support limit for the applicable fiscal year. This announcement shall include a summary of covered services, the application, and the application review criteria.

E. Individuals and family members may submit applications for Individual and Family Support Program funding as needs arise throughout the year. Applications shall be considered by the department on a first-come, first-served basis until the annual allocation appropriated to the program by the General Assembly for the applicable fiscal year has been expended.

F. Individuals and their family members may apply for Individual and Family Support Program funding each year and may submit more than one application in a single year; however, the total amount approved during the year shall not exceed the annual individual financial support limit.

12VAC35-230-50. Covered services and supports.

Services and items funded through the Individual and Family Support Program are intended to support the continued residence of an individual in his own or the family home and may include:

1. Professionally provided services and supports, such as respite, transportation services, behavioral consultation, and behavior management;
2. Assistive technology and home modifications, goods, or products that directly support the individual;
3. Temporary rental assistance or deposits;
4. Fees for summer camp and other recreation services;
5. Temporary assistance with utilities or deposits;
6. Dental or medical expenses of the individual;
7. Family education, information, and training;
8. Peer mentoring and family-to-family supports;
9. Emergency assistance and crisis support; or
10. Other direct support services as approved by the department.

12VAC35-230-60. Application for funding.

A. Eligible individuals or family members who choose to apply for Individual and Family Support Program funds shall submit a completed application to the department.

B. Completed applications shall include the following information:

1. A detailed description of the services or items for which funding is requested;
2. Documentation that the requested services or items are needed to support the continued residence of the individual with ID/DD in his own or the family home and no other public funding sources are available;
3. The requested funding amount and frequency of payment; and
4. A statement in which the individual or family member:
 - a. Agrees to provide the department with documentation to establish that the requested funds were used to purchase only approved services or items; and
 - b. Acknowledges that failure to provide documentation that the requested funds were used to purchase only approved services or items may result in recovery of such funds and denial of subsequent funding requests.

C. The application shall be signed by the individual or family member requesting the funding.

12VAC35-230-70. Application review criteria.

Upon receipt of a completed application, the department shall:

1. Verify that the individual is on the statewide ID or IFDDS Medicaid Waiver waiting list;
2. Confirm that the services or items for which funding is requested are eligible for funding in accordance with 12VAC35-230-50;
3. Determine that the services or items for which funding is requested are needed to support the continued residence of the individual with ID/DD in his own or the family home;

4. Determine that other public funding sources have been fully explored and utilized and are not available to purchase or provide the requested services or items;
5. Evaluate the cost of the requested services or items; and
6. Consider past performance of the individual and family members regarding compliance with this chapter.

12VAC35-230-80. Funding decision-making process.

A. Applications may be approved at a reduced amount when the amount requested exceeds a reasonable amount as determined by department staff as being necessary to purchase the services or items.

B. Applications shall be denied if the department determines that:

1. The service or item for which funding is requested is not eligible for funding in accordance with 12VAC35-230-50;
2. The request exceeds the maximum annual individual financial support limit for the applicable fiscal year;
3. Other viable public funding sources have not been fully explored or utilized;
4. The requesting individual or family member has not used previously received Individual and Family Support Program funds in accordance with the department's written notice approving the request or has failed to comply with these regulations; or
5. The total annual Individual and Family Support Program funding appropriated by the General Assembly has been expended for the applicable fiscal year.

C. The department shall provide a written notice to the individual or family member who submitted the application indicating the funding decision.

1. Approval notices shall include:

- a. The services, supports, or other items for which funding is approved;
- b. The amount and time frame of the financial allocation;
- c. The expected date that the funds should be released; and
- d. Financial expenditure documentation requirements, and the date or dates by which this documentation shall be provided to the department.

2. For applications where funding is denied or approved at a reduced amount, the department's notice shall state the reason or reasons why the requested services, supports, or other items were denied or were approved at a reduced amount and the process for requesting the department to reconsider its funding decision.

12VAC35-230-90. Requests for reconsideration.

A. Individuals or family members who disagree with the determination of the department may submit a written request for reconsideration to the commissioner, or his designee, within 30 days of the date of the written notice of denial or approval at a reduced amount.

Regulations

B. The commissioner, or his designee, shall provide an opportunity for the person requesting reconsideration to submit for review any additional information or reasons why the funding should be approved as originally requested.

C. The commissioner, or his designee, after reviewing all submitted materials shall render a written decision on the request for reconsideration within 30 calendar days of the receipt of the request and shall notify all involved parties in writing. The commissioner's decision shall be binding.

D. Applicants may obtain further review of the decision in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

12VAC35-230-100. Post-funding review.

A. Utilization review of documentation or verification of funds expended may be undertaken by department staff. Reviews may include home visits to view items purchased or services delivered.

B. Individuals and family members receiving Individual and Family Support Program funds shall permit the department representatives to conduct utilization reviews, including home visits.

C. Individuals and family members receiving Individual and Family Support Program funds shall fully cooperate with such reviews and provide all information requested by the department.

D. Failure to use funds in accordance with the department's written notice or provide documentation that the funds were used to purchase only approved services or items may result in recovery of such by the department.

12VAC35-230-110. Termination of funding for services, supports, or other assistance.

Funding through the Individual and Family Support Program shall be terminated when the individual is enrolled in the ID or IFDDS Medicaid Waiver or if approved funds are used for purposes not approved by the department in its written notice. Any funds approved, but not released, will be forfeited in such circumstances.

VA.R. Doc. No. R13-3439; Filed October 30, 2013, 1:58 p.m.

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TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

VIRGINIA BOARD FOR ASBESTOS, LEAD, AND HOME INSPECTORS

Proposed Regulation

Title of Regulation: **18VAC15-20. Virginia Asbestos Licensing Regulations (amending 18VAC15-20-52, 18VAC15-20-53).**

Statutory Authority: §§ 54.1-201 and 54.1-501 of the Code of Virginia.

Public Hearing Information:

December 2, 2013 - 10:40 a.m. - Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 200, Board Room 4, Richmond, VA 23233

Public Comment Deadline: January 31, 2014.

Agency Contact: Trisha Henshaw, Executive Director, Virginia Board for Asbestos, Lead, and Home Inspectors, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8595, FAX (866) 350-5354, or email alhi@dpor.virginia.gov.

Basis: Section 54.1-113 of the Code of Virginia (commonly referred to as the Callahan Act) requires regulatory boards to periodically review and adjust fees. Section 54.1-201 A 4 of the Code of Virginia provides the authority to regulatory boards to levy and collect fees, and § 54.1-304.3 of the Code of Virginia describes the authority of the Department of Professional and Occupational Regulation (DPOR) to collect and account for fees. Section 54.1-308 of the Code of Virginia requires costs to be paid by regulatory boards, of which the Board for Asbestos, Lead, and Home Inspectors is one.

Purpose: The intent of the proposed changes is to increase licensing fees for regulants of the Board for Asbestos, Lead, and Home Inspectors. The board must establish fees adequate to support the costs of board operations and a proportionate share of DPOR's operations. By the close of the next biennium, fees will not provide adequate revenue for the costs.

The intent of the proposed amendments is to increase licensing fees for regulants of the Board for Asbestos, Lead, and Home Inspectors. The board must establish fees adequate to support the costs of board operations and a proportionate share of the DPOR's operations. By the close of the next biennium, fees will not provide adequate revenue for those costs. The board provides protection to the safety and welfare of the citizens of the Commonwealth by ensuring that only those individuals and firms that meet specific criteria set forth in the statutes and regulations are eligible to receive an asbestos worker, asbestos supervisor, asbestos inspector, asbestos management planner, asbestos project designer, asbestos project monitor, asbestos contractor, asbestos analytical laboratory license, or an accredited asbestos training program approval. The board is also tasked with ensuring that its regulants meet standards of practice that are set forth in the regulations. Without adequate funding, citizen complaints against regulants could not be investigated and processed in a timely manner. This could provide an opportunity for a dishonest individual or firm, waiting for action to be taken by the board, to continue to operate, harming additional citizens. DPOR receives no general fund money but, instead, is funded almost entirely from revenue collected for license and certificate application fees, renewal

fees, examination fees, and other licensing fees. DPOR is self-supporting and must collect adequate revenue to support its mandated and approved activities and operations. Fees must be established at amounts that will provide that revenue. Fee revenue collected on behalf of the various boards funds the DPOR's authorized special revenue appropriation. The Board for Asbestos, Lead, and Home Inspectors has no other source of revenue from which to fund its operations.

Substance: The Board for Asbestos, Lead, and Home Inspectors reviewed the fees listed in 18VAC15-20-52 and 18VAC15-20-53 and, based on projected revenues and expenses, developed a fee schedule that meets the requirements of the applicable statutes while being the least burdensome to the regulant population.

Fee Type		Current Fees	Proposed Fees
Application	Individuals	25	80
Application	Contractors	40	110
Application	Labs	40	120
Application	Training courses	400/day	500/day
Renewal	Individuals	25	45
Renewal	Contractors	40	70
Renewal	Labs	40	75
Renewal	Training courses	50	125
Late Renewal	Individuals	25	35
Late Renewal	Contractors	25	35
Late Renewal	Labs	25	35
Late Renewal	Training courses	25	35

Issues: Section 54.1-113 of the Code of Virginia requires DPOR to review each board's expenditures at the close of each biennium and adjust fees if necessary. The Board for Asbestos, Lead, and Home Inspectors is expected to incur a deficit of \$82,268 by the end of the 2012-2014 biennium and a Callahan Act percentage of -11.5%.

The regulatory review process generally takes a minimum of 18 months, so it is essential to consider fee increases now to avoid a greater deficit than currently projected. In order to address the deficit as currently projected, new fees will need to become effective by late in fiscal year 2014. Otherwise, the board's deficit will increase to the point that the new fees would be inadequate to provide sufficient revenue for

upcoming operating cycles, which could result in the board having to consider additional fee increases in the near future.

The advantage of proposed amendments is that the regulatory program will be able to continue to function in order to protect the public. The disadvantage is that these changes will increase the cost of the license to the regulated population; however, the impact of these changes on the income of the regulated population should not be of a great significance compared to their level of income.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Asbestos, Lead, and Home Inspectors (Board) proposes to increase all fees paid by licensees, certificate holders and registrants that are subject to the Board's authority.

Result of Analysis. There is insufficient information to accurately gauge whether benefits are likely to outweigh costs for these proposed changes.

Estimated Economic Impact. Under current regulations, asbestos removal workers, supervisors, inspectors, management planners, project designers and project managers pay an initial licensure fee of \$25, an annual renewal fee of \$25 and a late renewal fee of \$50 (if they renew between 30 days and 6 months after the renewal date). Asbestos contractors currently pay \$40 for initial licensure, \$40 annually for license renewal and \$65 for late renewal. Asbestos analytical laboratories currently pay \$40 for initial licensure, \$40 for license renewal and \$65 for late renewal. Asbestos training programs currently pay \$400 per day of training for program approval, \$50 for renewal of program approval and \$75 for late renewal of program approval. The Board now proposes to increase all of these fees.

Below is a comparison table for current and proposed fees:

FEE TYPE	CURRENT FEE	PROPOSED FEE	% INCREASE
Fee for Worker, Supervisor, Inspector, Management Planner, Project Designer or Project Monitor Initial Licensure	\$25	\$80	220%
Asbestos Analytical Laboratory Initial Licensure	\$40	\$120	200%

Regulations

Asbestos Contractor Initial Licensure	\$40	\$110	175%	Late Renewal of Asbestos Contractor Licensure	\$65	\$105	61.5%
Accredited Asbestos Training Program Initial Approval (per day of training)	\$400	\$500	25% per day	Late Renewal of Accredited Asbestos Training Program Approval	\$75	\$160	113%
Renewal of Worker, Supervisor, Inspector, Management Planner, Project Designer or Project Monitor Licensure	\$25	\$45	80%	<p>Board staff reports that fees were reduced in 2000 because they were set at a level that was too high to be justified by Board expenditures. As a consequence of high fees prior to 2000, the Board had a large surplus that has offset fees that since then were too low to cover all Board expenses. Absent some fee increase, Board staff reports that the Board will run a deficit in the next biennium. In addition to a large surplus finally being depleted, Board staff reports that fees will need to be raised because expenses for developing Department of Professional and Occupational Regulation's (DPOR's) new customer support and licensure software have greatly increased information technology costs over the last several years.</p> <p>While the number of entities that the Board regulates has increased, other things being equal, the fees from additional regulants would be expected to cover application costs, customer support services costs and any other expenses that the Board might incur in regulating them. Because fees have been kept artificially low for the last decade so that the Board could use up the very large surplus that it had accrued, fees from each new licensee, certificate holder or registrant may not, in this instance, been enough to cover the per person application and customer support costs. This notwithstanding, it is likely that the necessity of raising fees would not be as urgent as it now is without large and continuing increases in information technology (IT) expenses over the last few years.</p> <p>Board staff reports that DPOR has already paid \$3.6 million, and expects to pay an additional \$1.6 million, for its new automated licensure system. These costs are additional to other IT (VITA) costs which have increased for all state agencies. It is likely that most of the per regulant expenditure increase in the last decade is due to these increased information systems costs. In FY2005, the Board spent \$32.13 per regulant; in FY2006, per regulant spending was \$31.40 and in FY2007 it was \$29.07. In FY2008 per regulant spending jumped to \$45.45. During FY2012, per regulant spending was to \$50.37. Board staff expect per regulant spending to increase further in FY2013 (to \$57.07). Given this information, it is not at all clear that these increased information systems costs represent a net benefit for the Board's regulated entities.</p> <p>Increasing fees will increase the cost of being licensed, certified or registered, and so may slightly decrease the number of people who choose to remain in these jobs or</p>			
Renewal of Asbestos Analytical Laboratory Licensure	\$40	\$75	87.5%				
Renewal of Asbestos Contractor Licensure	\$40	\$70	75%				
Renewal of Accredited Asbestos Training Program Approval	\$50	\$125	150%				
Late Renewal of Worker, Supervisor, Inspector, Management Planner, Project Designer or Project Monitor Licensure	\$50	\$80	60%				
Late Renewal of Asbestos Analytical Laboratory Licensure	\$65	\$110	69.2%				

businesses. To the extent that the public benefits from the Board regulating these professional populations, they will also likely benefit from the Board's proposed action given that the regulating will continue. There is insufficient information to ascertain whether the benefits of the continued regulation will outweigh the costs with higher fees.

Businesses and Entities Affected. Board staff reports that the Board currently regulates 5,808 individuals, contractors, labs and training programs.

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

Projected Impact on Employment. Fee increases in this regulatory action may marginally decrease the number of individuals who choose to work in professional fields that are regulated by the Board. Individuals who work part time or whose earnings are only slightly higher in these regulated fields than they would be in other jobs that do not require licensure or registration will be more likely to be affected.

Effects on the Use and Value of Private Property. Fee increases will likely slightly decrease business profits and make affected businesses slightly less valuable.

Small Businesses: Costs and Other Effects. Board staff reports that most of the entities regulated by the Board likely qualify as small businesses. Affected small businesses will bear the costs of proposed increased fees.

Small Businesses: Alternative Method that Minimizes Adverse Impact. Outside of increasing the efficiency of the business practices of DPOR or lowering other expenses charged to the department, particularly information technology related, there are no clear alternative methods that would reduce the adverse impact on small businesses from the proposed fee increases.

Real Estate Development Costs. This regulatory action will likely have no effect on real estate development costs in the Commonwealth.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs

required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The Board for Asbestos, Lead, and Home Inspectors concurs with the approval of the economic impact analysis done by the Department of Planning and Budget. However, the board would like to address the statement regarding the efficiency of the Department of Professional and Occupational Regulation's (DPOR's) business practices.

DPOR serves to protect the health, safety, and welfare of the public by establishing and administering regulatory programs for certain professions or occupations that are deemed by the General Assembly as needing to be regulated. Such programs are designed to ensure minimum competency of practitioners who elect to enter these professions by verifying applicants compliance with specified entry standards (education, experience, and examination).

DPOR is mindful of the need to keep costs to a minimum while still maintaining its charge of allowing minimally competent individuals and companies to begin working in their chosen fields as quickly as possible and resolving complaints against licensees in a timely manner. DPOR's staff continuously strives to improve its processes to find more efficient methods of conducting its work. In addition, staff works with its regulatory boards to develop regulations and policies that minimize burdens on its regulants, including minimizing costs associated with licensure, certification, and registration.

Summary:

The proposed amendments increase fees of the Board for Asbestos, Lead, and Home Inspectors to ensure that revenues are sufficient, but not excessive, to cover its ongoing operating expenses. Without the proposed fee increases, the board will incur a deficit by the end of the 2012-2014 biennium.

18VAC15-20-52. Application fees.

Application fees are set out in this section.

Fee Type	Fee Amount	When Due
Application for worker, supervisor, inspector, management planner, project designer or project monitor license	\$25 \$80	With application

Regulations

Application for asbestos analytical laboratory license	\$40 <u>\$120</u>	With application	\$35 late renewal fee in addition to the regular \$40 <u>\$70</u> renewal fee)		
Application for an asbestos contractor license	\$40 <u>\$110</u>	With application	Late renewal for accredited asbestos training program approval (includes a \$25 <u>\$35</u> late renewal fee in addition to the regular \$50 <u>\$125</u> renewal fee)	\$75 <u>\$160</u>	With renewal application
Application for accredited asbestos training program approval	\$400 <u>\$500</u> per day of training	With application			

18VAC15-20-53. Renewal and late renewal fees.

VA.R. Doc. No. R12-3169; Filed October 31, 2013, 8:25 a.m.

Renewal and late renewal fees are set out in this section.

AUCTIONEERS BOARD

Proposed Regulation

Fee Type	Fee Amount	When Due
Renewal for worker, supervisor, inspector, management planner, project designer or project monitor license	\$25 <u>\$45</u>	With renewal application
Renewal for asbestos analytical laboratory license	\$40 <u>\$75</u>	With renewal application
Renewal for asbestos contractor's license	\$40 <u>\$70</u>	With renewal application
Renewal for accredited asbestos training program approval	\$50 <u>\$125</u>	With renewal application
Late renewal for worker, supervisor, inspector, management planner, project designer or project monitor license (includes a \$25 <u>\$35</u> late renewal fee in addition to the regular \$25 <u>\$45</u> renewal fee)	\$50 <u>\$80</u>	With renewal application
Late renewal for asbestos analytical laboratory license (includes a \$25 <u>\$35</u> late renewal fee in addition to the regular \$40 <u>\$75</u> renewal fee)	\$65 <u>\$110</u>	With renewal application
Late renewal for asbestos contractor's license (includes a \$25 <u>\$45</u> renewal fee)	\$65 <u>\$105</u>	With renewal application

Title of Regulation: **18VAC25-21. Regulations of the Virginia Auctioneers Board (amending 18VAC25-21-10, 18VAC25-21-50, 18VAC25-21-70, 18VAC25-21-80, 18VAC25-21-90, 18VAC25-21-110, 18VAC25-21-120, 18VAC25-21-140 through 18VAC25-21-185, 18VAC25-21-220, 18VAC25-21-250, 18VAC25-21-280; adding 18VAC25-21-95).**

Statutory Authority: §§ 54.1-201 and 54.1-602 of the Code of Virginia.

Public Hearing Information:

December 2, 2013 - 11:30 a.m. - Department of Professional and Occupational Regulation, 9960 Mayland Drive, Board Room 4, Richmond, VA 23233

Public Comment Deadline: January 31, 2014.

Agency Contact: Marian H. Brooks, Regulatory Board Administrator, Auctioneers Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email auctioneers@dpor.virginia.gov.

Basis: Section 54.1-201 of the Code of Virginia authorizes the regulatory boards of the Department of Professional and Occupational Regulation to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) necessary to assure continued competency, to prevent deceptive or misleading practices by practitioners, and to effectively administer the regulatory system administered by the regulatory board. Section 54.1-602 of the Code of Virginia authorizes the Board of Auctioneers to establish regulations to obtain and retain licensure of auctioneers.

Purpose: The purpose of the amendments is to improve the clarity of the regulations and thereby better protect the citizens of the Commonwealth.

Substance: The amendments provide clarification to the existing regulations and allow licensees to use continuing education hours gained in reciprocating states to meet continuing education requirements in Virginia.

Issues: The primary advantage to the public and the Commonwealth is that the licensed auctioneers and consumers will have clearer and more comprehensible regulations, which should permit a positive outcome for all parties. In addition, the changes will assist with disciplinary actions and the compliance of such actions.

No disadvantage to the public or the Commonwealth could be identified.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Auctioneers Board (Board) proposes to amend its regulations to allow licensees to use continuing education hours gained in other, reciprocating states to meet continuing education requirements in Virginia.

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

Estimated Economic Impact. Most of the changes that the Board proposes for these regulations are meant to clarify parts of the regulatory text. For instance, current regulatory text says that the Department of Professional and Occupational Regulation (DPOR) mails out renewal notices to licensees when it is actually Board staff that is responsible for this task. The Board proposes to change the regulatory text so that it is clear that the Board will mail out renewal notices. No affected entity is likely to incur any costs on account of changes such as these. To the extent that some regulated entities may find the current regulatory text confusing, these changes will provide the benefit of additional clarity.

Current regulations do not allow individuals who are licensed in Virginia and in another state to count continuing education classes that they may have taken in that other state to count toward Board renewal requirements. The Board proposes to allow licensees to do this so long as the state where the continuing education is completed has a reciprocal agreement with Virginia that allows the same thing. No entity is likely to incur additional costs on account of this regulatory change. Licensees who are licensed in several states will likely benefit from rules that allow them to eliminate the time and expense of duplicating continuing education classes in each of the states in which they are licensed.

Current regulations are silent on whether the Board has discretion to deny renewal of licensure. The Board proposes to add language to these regulations that would allow denial of renewal for any of the same reasons that it can deny initial licensure or discipline licensees.

Businesses and Entities Affected. DPOR reports that there are 1,356 individual auctioneers and 253 auctioneer firms currently licensed by the Board. All of these entities will be affected by these regulatory changes.

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

Projected Impact on Employment. This regulatory action will likely have no impact on employment in the Commonwealth.

Effects on the Use and Value of Private Property. This regulatory action will likely have no effect on the use or value of private property in the Commonwealth.

Small Businesses: Costs and Other Effects. The proposed amendments are unlikely to significantly affect small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed amendments are unlikely to significantly adversely affect small businesses.

Real Estate Development Costs. This regulatory action will likely have no effect on real estate development costs in the Commonwealth.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to Economic Impact Analysis: The Auctioneers Board concurs with the approval.

Summary:

The proposed amendments (i) replace the \$40 examination and reexamination fees with language making such fees subject to competitively negotiated contracts, (ii) allow licensees to use continuing education hours gained in reciprocating states to meet continuing education requirements in Virginia, and (iii) clarify existing regulatory language.

Regulations

Part I Definitions

18VAC25-21-10. Definitions.

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

"Owner" means the bona fide owner or any lawfully designated agent of the real or personal property being offered for sale; in the case of a corporation, partnership, or other entity, except a sole proprietorship, an authorized officer, director, or partner may be deemed to be "owner" of the real or personal property being offered for sale, provided such entity is licensed to do business in the Commonwealth of Virginia.

18VAC25-21-50. Application.

A. All applicants seeking licensure ~~by reciprocity or examination~~ shall submit a fully executed application with the appropriate fee or fees attached. Applicants will be notified if their application is incomplete.

Applications for licensure by examination must comply with the requirements of the board's designee as to the deadline for submission of the application to the board's designee.

B. 1. If a corporation, limited liability company, or other entity, the application shall include copies of the certificate of incorporation or certificate of organization issued by the Virginia State Corporation Commission, articles and bylaws.

2. If a foreign corporation, foreign limited liability company, or other entity, the application shall include copies of the certificate of authority to conduct business issued by the Virginia State Corporation Commission, which shall be required in lieu of the certificates as required by subdivision 1 of this subsection.

3. Any firm applicant shall not have been previously found by any regulatory board or agency to have violated any applicable regulations or laws in the course of performing auctioneer duties or been convicted or found guilty, regardless of the manner of adjudication, in any jurisdiction of the United States of a misdemeanor involving moral turpitude or any felony, there being no appeal pending therefrom or the time for appeal having elapsed. Any plea of nolo contendere shall be considered a conviction for purposes of this subdivision. A certified copy of a final order, decree or case decision by a court or regulatory agency with the lawful authority to issue such order shall be admissible as prima facie evidence of such conviction or discipline. Applicants for licensure who do not meet requirements set forth in this section may be approved for licensure following consideration by the board in accordance with § 54.1-204 of the Code of Virginia.

C. All applications will be reviewed by the Auctioneers Board staff, or the board's designee, to determine eligibility for examination and licensure within 30 days of receipt at the

offices of the Department of Professional and Occupational Regulation or the board's designee. However, failure to review an application within 30 days of receipt shall not imply or result in the automatic approval of the application. No applicant will be approved for licensure unless all requirements of this part of this chapter are met.

18VAC25-21-70. Fees.

Fees are nonrefundable and shall not be prorated. The following fees shall apply:

1. Individual auctioneer license	\$25
2. Auctioneer firm license	\$55
3. Examination	\$40
4. Reexamination fee	\$40
5. 3. Renewal for individual auctioneer's license	\$55
6. 4. Renewal for firm or corporation license	\$65
7. 5. Late renewal for an individual auctioneer's license	\$80
8. 6. Late renewal for an auction firm or corporate license	\$90
9. 7. Reinstatement of the individual auctioneer's license	\$105
10. 8. Reinstatement of the firm or corporate license	\$115

The fee for examination or reexamination 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.

Part III Renewal/Reinstatement

18VAC25-21-80. Notice of renewal.

The ~~Department of Professional and Occupational Regulation board~~ will mail a renewal notice to the licensee outlining the amount due and procedures for renewal to the last known mailing address of record. Failure to receive this notice shall not relieve the individual or firm licensee of the obligation to renew.

Licenses issued under this chapter shall be issued for a two-year period. Each license holder, corporation or firm shall be required to renew the license by submitting the proper fee made payable to the Treasurer of Virginia, with verification of current surety bond coverage as detailed in 18VAC25-21-30. ~~In addition, individual license holders applying for renewal are required to certify that they comply with the continuing education requirements as contained in this chapter. By renewing the license, the licensee is certifying~~

continued compliance with the Standards of Practice in Part IV (18VAC25-21-100 et seq.) and Standards of Conduct in Part V (18VAC25-21-180 et seq.), as well as Continuing Education Requirements in Part VII (18VAC25-21-230 et seq.) of this chapter.

18VAC25-21-90. Failure to renew.

A. Any ~~individual or firm~~ licensee who fails to renew a license within 30 days after the license expires, shall be required to pay a late renewal fee.

B. Any ~~individual or firm~~ licensee, including individuals initially licensed pursuant to § 54.1-603 A of the Code of Virginia, who fails to renew his license within six calendar months after the expiration date of the license shall be required to apply for reinstatement of the license. The applicant shall submit to the ~~Department of Professional and Occupational Regulation~~ board a reinstatement application and fee and comply with the following paragraph.

If the license has expired for six months or more, but less than two years, the applicant shall be required to submit a reinstatement application, which shall be evaluated by the board to determine if the applicant meets the renewal requirements. In addition, individual license holders applying for reinstatement are required to provide evidence of compliance with the continuing education requirements as contained in this chapter. A license that is reinstated shall be deemed as having been continuous without interruption. Nothing in these regulations shall divest the board of its authority to discipline a license holder for a violation of the law or regulation during the period of time for which the ~~regulant licensee~~ licensee was licensed.

C. If the license has expired for two years or more, the applicant shall be required to submit a new application and meet current entry requirements that are in effect as of the date the application is received by the board office. The applicant shall be required to submit the examination fee and sit for and pass the Virginia Licensed Auctioneer's Examination or comply with the provisions contained in 18VAC25-21-40. Any auctioneering activity conducted between the time the previous license expired and the effective date of the new license shall be considered unlicensed activity.

D. The date that the complete renewal application, including fees and all required documentation, is received by the ~~Department of Professional and Occupational Regulation~~ board or its agent will determine whether a license will be renewed without penalty or will be subject to reinstatement requirements.

E. ~~Auctioneer individual and firm licenses~~ Licenses issued under this regulation shall expire 24 months from the last day of the month in which the license was issued. The expiration date of the license will be included on the license.

18VAC25-21-95. Board discretion to deny renewal or reinstatement.

The board may deny renewal or reinstatement of a license for the same reason as it may refuse initial licensure or discipline a licensee. The licensee has the right to request further review of any such action by the board under the Administrative Process Act (§ 2.2-4000 et. seq. of the Code of Virginia).

18VAC25-21-110. Contracts.

A. When ~~an auctioneer or auction firm~~ a licensee agrees to conduct an auction, a contract shall be drawn setting forth the particulars of the terms and conditions under which the auctioneer or auction firm received the real or personal property for auction and particulars for the disbursement of the proceeds. Each contract for auction shall include the following:

1. a. A detailed list of the real or personal property received for sale with adequate descriptions of the property so that the personal property can be readily identified. If a list cannot be made at the time of signing of the contract, then a list must be signed and dated by the owner and made a part of the contract (and attached) prior to auction of the real or personal property for that day; or
 - b. If the auctioneer or auction firm enters into a contract to sell items on a consignment basis where the total value of all the items to be sold at any one action does not exceed \$500, and the owner of the items agrees to waive this requirement in writing on a document separate from, but made a part of, the contract, then the requirement contained in subdivision 1 a of this subsection is not applicable.
2. The name, address, telephone number, and license number of the ~~Virginia auctioneer or auction firm~~ licensee entering into the contract.
3. The name, address and telephone number of the property owner.
4. The date, time and place of the auction or auctions at which the real or personal property is scheduled to be auctioned. The date by which the property is to be returned or otherwise disposed of in accordance with the terms of the contract if it is not sold.
5. The fee or percentage of gross sales the auctioneer or auction firm will charge the owner and what services are included in the fee, such as preparation, travel, labor, advertising and any other auction related expenses.
6. By what date the owner is to be paid and who is responsible for disbursing the funds.
7. A statement that the clerk sheets, or other evidence to properly account for all items sold, shall be given or made available for inspection by the owner on a daily basis.
8. The following statement above the owner's signature line: "I have read and accepted the terms of this contract."

Regulations

B. A legible executed copy of the contract and any addendums shall be given to the owner at the time of execution.

18VAC25-21-120. Conduct at auctions.

No ~~auctioneer or auction firm~~ licensee shall attempt to escalate bidding through false bids, or through collusion with another (shills). The ~~auctioneer or auction firm~~ licensee shall not bid on the owner's behalf nor knowingly accept a bid made by the owner or made on the owner's behalf unless notice has been given that liberty for such bidding has been reserved. The ~~auctioneer or auction firm~~ licensee shall ~~not~~ neither bid on his own behalf nor knowingly accept a bid made on his behalf unless notice has been given that such bidding will be permitted.

18VAC25-21-140. Documentation.

Upon completion of the ~~auctioneer's or auction firm's~~ licensee's service, each owner shall be given legible copies of bills of sale, clerk sheets, consignment sheets, settlement papers, balance sheets or other evidence to properly account for all items sold at auction.

18VAC25-21-150. Escrow funds.

A. Proceeds of a personal property auction not disbursed to the owner on auction day shall be deposited in an auction escrow account by the ~~auctioneer/auction firm~~ licensee no later than the next banking day following the date of auction or sale of the goods, whichever occurs first.

B. Notwithstanding the provisions of subsection A of this section ~~for~~, proceeds that are paid via credit card, ~~the payment of such proceeds from the credit card issuer~~ debit card, check card, or any other electronic funds transfer (EFT) method shall be deposited into an auction escrow account upon receipt from the ~~credit card issuer~~ originating source.

C. The auction escrow account shall be used solely for the preservation and guarantee of auction proceeds until disbursed at settlement. Funds for any other purpose shall not be commingled with the auction escrow account. Contingency accounts established to guarantee checks accepted on the owner's behalf shall not be considered commingling of funds. Moneys due to the licensee shall not be withdrawn from the auction escrow account until final settlement is made with the owner.

D. Funds to be deposited in the escrow account may include moneys that shall ultimately belong to the licensee for incidental expenses per the terms of the contract. Such moneys shall be separately identified in the escrow account records and shall be paid to the licensee by a check drawn on the escrow account when the funds become due to the licensee. The fact that an escrow account contains money that may ultimately belong to the licensee does not constitute "commingling of funds" provided that there are periodic withdrawals of said funds at intervals of not more than six months and that the licensee can at all times accurately

identify the total funds in that account that belong to the licensee.

E. On funds placed in an account bearing interest, written disclosure in the contract of sale or lease at the time of contract or lease writing shall be made to the principals to the transaction regarding the disbursement of interest.

~~C. Auctioneers/auction firms~~ F. Auctioneers and auction firms shall use federally insured depositories in the Commonwealth of Virginia. All accounts, checks, and bank statements shall be labeled "escrow" and the accounts shall be designated as "escrow" accounts with the financial institution where such accounts are established.

~~D. G.~~ Proceeds due from the sale of goods other than real property shall be disbursed to the owner no later than 30 days after the date of each auction.

~~E. H.~~ Funds from a real estate auction shall be held in escrow until settlement in accordance with the agreement of sale.

~~F. I.~~ If the ~~owners'~~ owner's goods are not sold in a single auction, proceeds due shall be disbursed to the owner within 30 days after each auction for goods other than real property, or in accordance with the agreement of sale for the sale of real property. Notice must be given to the owner of tentative date of auction, or date of return to the owner, of the remaining goods.

~~G. The auction escrow account shall be used solely for the preservation and guarantee of auction proceeds until disbursed at settlement. Funds for any other purpose shall not be commingled with the auction escrow account. Contingency accounts established to guarantee checks accepted on the owner's behalf shall not be considered commingling of funds. Moneys due to the licensee shall not be withdrawn from the auction escrow account until final settlement is made with the owner.~~

~~H. J.~~ The balance in the escrow accounts shall be sufficient at all times to account for all funds that are designated to be held by the licensee. A licensee shall not disburse or cause to be disbursed moneys from an escrow account unless sufficient money is on deposit in that account to the credit of the individual client or property involved.

~~I. Funds to be deposited in the escrow account may include moneys that shall ultimately belong to the licensee for incidental expenses per the terms of the contract. Such moneys shall be separately identified in the escrow account records and shall be paid to the licensee by a check drawn on the escrow account when the funds become due to the licensee. The fact that an escrow account contains money that may ultimately belong to the licensee does not constitute "commingling of funds" provided that there are periodic withdrawals of said funds at intervals of not more than six months, and that the licensee can at all times accurately identify the total funds in that account that belong to the licensee.~~

~~J. On funds placed in an account bearing interest, written disclosure in the contract of sale or lease at the time of contract or lease writing shall be made to the principals to the transaction regarding the disbursement of interest.~~

18VAC25-21-160. Records.

~~The licensee is required to maintain, for a period of four years from the date of settlement, written records of the following: the contract drawn with each owner; auction records, including but not limited to lists of buyers and their addresses; and clerk sheets showing the items sold including the buyers' numbers or names and the selling prices and the final settlement papers shall be retained for a period of four years from the date of settlement.~~ These business records shall be available for inspection by the board or its designees as deemed appropriate and necessary.

18VAC25-21-170. Change of address.

A. ~~An auctioneer's or auction firm's license~~ Licenses shall not be transferable and shall bear the same name and physical address as the business. Upon dissolution or change in the form of the business entity of an auction firm, the auction firm license shall become void.

B. ~~Written notice shall be given within 30 days~~ A licensee shall report all changes of address to the board by each individual or firm licensee of any change of physical business address or location in writing, within 30 calendar days of the change, whereupon the board shall issue an amended license without fee for the unexpired portion of the biennial period.

C. A post office box is ~~not an acceptable~~ only when a physical business address is also provided. If the licensee holds more than one license, certificate, or registration, the licensee shall inform the board of all licenses, certificates, and registrations affected by the address change.

Part V Standards of Conduct

18VAC25-21-180. Discipline.

The board has the power to fine any individual or firm licensee, or to suspend or revoke any license issued under the provisions of Chapter 6 (§ 54.1-600 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the board pursuant to the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) if it finds that:

1. The license was obtained, renewed or reinstated through fraud or misrepresentation;
2. The ~~licensed auctioneer or firm licensee~~ has been convicted or found guilty, regardless of the manner of adjudication, in any jurisdiction of the United States of a misdemeanor involving moral turpitude or any felony, there being no appeal pending therefrom or the time for appeal having elapsed. Review of prior criminal convictions shall be subject to the requirements of § 54.1-204 of the Code of Virginia. A certified copy of a final order, decree or case decision by a court with the lawful

authority to issue such order shall be admissible as prima facie evidence of such conviction or discipline;

3. The ~~licensed auctioneer or firm licensee~~ has been found by any regulatory board, agency, or jurisdiction where licensed to have had a license or registration suspended, revoked or surrendered in connection with a disciplinary action, who has been the subject of discipline in another jurisdiction or to have violated any applicable regulations or laws in the course of performing auctioneer duties. A certified copy of a final order, decree or case decision by a court or regulatory agency with the lawful authority to issue such order shall be admissible as prima facie evidence of such conviction or discipline;

4. The ~~licensed auctioneer or firm licensee~~ has not demonstrated reasonable care, judgment, or application of his knowledge and ability in the performance of auctioneering duties;

5. The ~~license auctioneer or firm licensee~~ violated or ~~induced~~ assisted another person to violate any provisions of ~~Chapters~~ Chapter 1 (§ 54.1-100 et seq.), 2 (§ 54.1-200 et seq.), 3 (§ 54.1-300 et seq.), or 6 of Title 54.1 of the Code of Virginia, ~~or any provision of this chapter,~~ or combined or conspired with or acted as agent, partner, or associate for another; or

6. The licensee fails to comply, or misrepresents any information pertaining to his compliance, with any of the continuing education requirements as contained in this chapter.

18VAC25-21-185. Cooperation with board.

A. The licensee shall, upon request or demand, produce to the board, or any of its agents, within 10 days any plan, document, book, record or copy thereof in his possession concerning a transaction covered by this chapter, and shall cooperate in the investigation of a complaint filed with the board.

B. A ~~professional licensee~~ who has direct knowledge that any individual, including himself, or firm may be violating any of these provisions, or the provisions of Chapters 1 (§ 54.1-100 et seq.) through 3 (§ 54.1-300 et seq.) or Chapter 6 (§ 54.1-600 et seq.) of Title 54.1 of the Code of Virginia, shall immediately inform the secretary of the board in writing and shall cooperate in furnishing any further information or assistance that may be required.

~~C. The board, in its discretion, may refuse to grant the renewal or reinstatement of a license of any person for any of the reasons specified in subsection A of this section.~~

18VAC25-21-220. Periodic requalification for continued course approval.

~~At times established by the board, the~~ The board may require that schools that have previously obtained course approval provide the board with evidence, in a form set forth by the board, that they continue to comply with the requirements of 18VAC25-21-190 and 18VAC25-21-200.

Regulations

Failure to continue to comply with the board's requirements or respond to such a request may result in the board withdrawing its approval.

18VAC25-21-250. Continuing education requirements for renewal or reinstatement.

A. ~~Individuals~~ Licensees whose licenses expire, or apply to reinstate, after February 1, 2008, shall be required to comply with the continuing education provisions of this chapter.

~~B. Individuals are required to complete at least six continuing education credit hours of board-approved continuing education courses for any license renewal or reinstatement.~~

B. Licensees are required to complete at least six continuing education credit hours of board-approved continuing education courses for any license renewal or reinstatement.

A Virginia licensee that is also licensed in another state with which the board shares a reciprocal agreement may use board-approved continuing education in that state to meet the required six hours of continuing education for Virginia, provided that the reciprocal jurisdiction affords the same privilege to Virginia licensees.

C. 1. Each ~~individual~~ licensee applying for renewal shall certify that he has met the continuing education requirements of this chapter. Only continuing education courses completed during the license period immediately prior to the expiration date of the license shall be acceptable in order to renew the license.

2. ~~Individuals~~ Licensees shall maintain records of completion of continuing education credit hours for two years from the date of expiration of the license for which the continuing education credit hours are being used to renew the license. Individuals shall provide such records to the board or its duly authorized agents upon request.

3. Continuing education credit hours utilized to satisfy the continuing education requirements to renew a license shall be valid only for that renewal and shall not be accepted for any subsequent renewal cycles or reinstatement.

D. 1. Each individual applying for reinstatement shall provide, as part of his reinstatement application, evidence of compliance with the continuing education requirements of this chapter. The completion date of continuing education courses submitted in support of a reinstatement application shall not be more than two years old as of the date a complete reinstatement application is received by the board.

2. Continuing education credit hours utilized to satisfy the continuing education requirements in order to reinstate a license shall be valid only for that reinstatement and shall not be accepted for any subsequent renewal cycles or reinstatement.

E. Notwithstanding the provisions of subsection C of this section, continuing education hours earned during a licensing renewal cycle to satisfy the continuing education requirements of the preceding licensing renewal cycle shall

be valid only for that preceding license renewal cycle and shall not be accepted for any subsequent renewal cycles or reinstatement.

18VAC25-21-280. Periodic requalification for continued course approval.

~~At times established by the board, the~~ The board may require that course providers that have previously obtained course approval provide the board with evidence, in a form set forth by the board, that they continue to comply with the requirements of 18VAC25-21-230 A and 18VAC25-21-240. Failure to continue to comply with the board's requirements or respond to such a request may result in the board withdrawing its approval.

NOTICE: 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 (18VAC25-21)

~~Auctioneer License By Examination Application, 2907EXLIC (rev. 11/08)~~

~~Auctioneer Surety Bond Form, 2905_07BOND (rev. 11/08)~~

[Auctioneer License By Examination Application, 2907EXLIC \(rev. 3/13\)](#)

[Auctioneer Surety Bond Form, 2905_07BOND \(rev. 4/10\)](#)

[Auctioneer Firm License Application, 2908LIC \(rev. 11/08\)](#)

[Auction Firm Surety Bond Form, 2906_08BOND \(rev. 11/08\)](#)

~~States with Approved Reciprocal Agreements, 29RECST (rev. 11/08)~~

~~Virginia Approved Auctioneering Schools, 29SCHLST (rev. 11/08)~~

[States with Approved Reciprocal Agreements, 29RECLST \(rev. 2/12\)](#)

[Virginia Approved Auctioneering Schools, 29SCHLST \(rev. 9/13\)](#)

[Auctioneering School Application for Course Approval, 29CRS \(rev. 11/08\)](#)

[Auctioneer License By Reciprocity Application, 2907RECLIC \(rev. 11/08\)](#)

[Auctioneer License Reinstatement Application, 2905_07REI \(rev. 11/08\)](#)

[Application for Continuing Education Course Approval, 29CECRS \(rev. 11/08\)](#)

[Auctioneer Firm License Renewal Form, 2906_08REN \(eff. 11/08\)](#)

[Individual Auctioneer License Renewal Form, 2905_07REN \(eff. 11/08\)](#)

[Continuing Education Medical Exemption Request, 2905_07CEXMP \(eff. 11/08\)](#)

VA.R. Doc. No. R09-2002; Filed November 8, 2013, 12:51 p.m.

BOARD OF MEDICINE

Emergency Regulation

Title of Regulation: **18VAC85-50. Regulations Governing the Practice of Physician Assistants (adding 18VAC85-50-117).**

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Effective Dates: November 12, 2013, through May 11, 2015.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4558, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

Preamble:

Chapter 81 of the 2012 Acts of Assembly requires the Board of Medicine to promulgate regulations to implement provisions of the act with 280 days of its enactment. Therefore, the board is authorized to adopt emergency regulations establishing the criteria for use of fluoroscopy by physician assistants.

Fluoroscopy is a radiological procedure that emits high levels of ionizing radiation and is used for diagnostic and therapeutic purposes. Performed improperly, it can harm a patient or cause a misdiagnosis that can harm a patient. Since fluoroscopy typically is outside the scope of practice for a physician assistant and not covered in prelicensure educational programs and examinations, additional qualifications must be established to assure minimal competency to perform the procedure with safety and effectiveness.

The emergency regulation establishes the qualifications of a physician assistant who may use fluoroscopy for guidance of diagnostic and therapeutic procedures under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology. The additional education, training, and testing is consistent with the qualifications recommended by the American Academy of Physician Assistants and the American Society of Radiologic Technologists.

18VAC85-50-117. Authorization to use fluoroscopy.

A physician assistant working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology is authorized to use fluoroscopy for guidance of diagnostic and therapeutic procedures provided such activity is specified in his protocol and he has met the following qualifications:

1. Completion of at least 40 hours of structured didactic educational instruction and at least 40 hours of supervised

clinical experience as set forth in the Fluoroscopy Educational Framework for the Physician Assistant created by the American Academy of Physician Assistants (AAPA) and the American Society of Radiologic Technologists (ASRT); and

2. Successful passage of the American Registry of Radiologic Technologists (ARRT) Fluoroscopy Examination.

DOCUMENTS INCORPORATED BY REFERENCE (18VAC85-50)

[Fluoroscopy Educational Framework for the Physician Assistant, December 2009, American Academy of Physician Assistants, 950 North Washington Street, Alexandria, VA 22314 and the American Society of Radiologic Technologists, 15000 Central Avenue, SE, Albuquerque, NM 87123](#)

VA.R. Doc. No. R14-3348; Filed November 12, 2013, 3:45 p.m.

TITLE 20. PUBLIC UTILITIES AND TELECOMMUNICATIONS

STATE CORPORATION COMMISSION

Final Regulation

REGISTRAR'S NOTICE: The State Corporation Commission is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts courts, any agency of the Supreme Court, and any agency that by the Constitution is expressly granted any of the powers of a court of record.

Title of Regulation: **20VAC5-309. Rules for Enforcement of the Underground Utility Damage Prevention Act (adding 20VAC5-309-205).**

Statutory Authority: §§ 12.1-13 and 56-265.30 of the Code of Virginia.

Effective Date: December 1, 2013.

Agency Contact: Massoud Tahamtani, Director, Utility and Railroad Safety Division, State Corporation Commission, P.O. Box 1197, Richmond, VA 23218, telephone (804) 371-9264, FAX (804) 371-9734, or email massoud.tahamtani@scc.virginia.gov.

Summary:

The amendments provide the State Corporation Commission increased flexibility in its enforcement of the Underground Utility Damage Prevention Act by including a provision by which the rules may be waived by the commission upon a finding supported by clear and convincing evidence that such a waiver is in the public interest. Since the initial rules were promulgated in 1994,

Regulations

enhanced technology and methods employed in locating underground utility lines and the protection of such lines from excavation damage have given rise to the need for flexibility in the commission's enforcement of the Underground Utility Damage Prevention Act that recognizes the evolution of excavation and demolition practices in the Commonwealth of Virginia.

AT RICHMOND, NOVEMBER 15, 2013

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. URS-2013-00312

Ex Parte: In the matter concerning Rules implementing the State Corporation Commission's authority to enforce the Underground Utility Damage Prevention Act

ORDER ADOPTING REGULATIONS

On July 22, 2013, the State Corporation Commission ("Commission") initiated a rulemaking pursuant to § 56-265.30 of the Code of Virginia ("Code"), which authorizes the Commission to enforce the provisions of Chapter 10.3 of Title 56 of the Code,¹ also known as the Underground Utility Damage Prevention Act ("Act"). Section 56-265.30 of the Code also authorizes the Commission to promulgate any rules or regulations necessary to implement the Commission's authority to enforce the Act.

The Commission's Division of Utility and Railroad Safety ("Division") proposed that the Commission adopt an additional rule that includes a general waiver provision in the Commission's Rules for Enforcement of the Underground Utility Damage Prevention Act, 20 VAC 5-309-10 et seq. ("Rules"), by which the Rules may be waived by the Commission upon a finding supported by clear and convincing evidence that such a waiver is in the public interest ("Proposed Rule"). This additional rule was proposed to provide the Commission with increased flexibility in its enforcement of the Act.

The Commission's July 22, 2013 Order for Notice and Comment ("July 22, 2013 Order") set out the rule proposed by the Division and provided that public notice of the Proposed Rule be given so as to afford any interested person or entity an opportunity to comment on or to request a hearing on the Proposed Rule.

Notice of the proceeding was published in the Virginia Register on August 12, 2013, and in newspapers of general circulation throughout the Commonwealth of Virginia.² Interested persons were directed to file any comments and requests for hearing on the Proposed Rule on or before August 26, 2013.

Comments in this proceeding were submitted by Washington Gas Light Company ("WGL") and Columbia Gas of Virginia, Inc. ("Columbia Gas"). The Commission did not receive a request for hearing on the Proposed Rule.

On August 23, 2013, WGL submitted comments in this proceeding with a suggested modification to the Proposed Rule.³ Specifically, WGL proposed a modification to the Proposed Rule that would permit the Commission to modify or eliminate a waiver granted pursuant to the Proposed Rule upon a finding that such waiver is "adverse to the public interest" as opposed to the Division's proposal that a finding be made that the waiver is "no longer required by the public interest." On August 26, 2013, Columbia Gas submitted comments supporting the adoption of the Proposed Rule.⁴

As directed by the July 22, 2013 Order, the Division filed a report on September 10, 2013, responding to the comments received on the Proposed Rule. The Division opposed WGL's modification to the Proposed Rule, stating that "a showing of why the waiver is 'no longer in the public interest' is adequate to return to the status quo under the Damage Prevention Rules."⁵ Accordingly, the Division recommended that the Commission adopt the Proposed Rule without modification.

NOW THE COMMISSION, upon consideration of this matter, is of the opinion and finds that the proposed regulation should be adopted without modification.

Accordingly, IT IS ORDERED THAT:

- (1) The Commission's regulations regarding Rules for Enforcement of the Underground Utility Damage Prevention Act, 20 VAC 5-309-10 et seq., are hereby adopted as shown in Attachment A to this Order and shall become effective as of December 1, 2013.
- (2) A copy of these regulations as set out in Attachment A of this Order shall be forwarded to the Registrar of Regulations for publication in the Virginia Register.
- (3) There being nothing further to come before the Commission, this case hereby is dismissed from the Commission's docket.

AN ATTESTED COPY hereof shall be sent by the Clerk of the Commission to: Meera Ahamed, Senior Legal Counsel, Office of General Counsel, Washington Gas Light Company, 101 Constitution Avenue, N.W., Washington, D.C. 20080; and James S. Copenhaver, Assistant General Counsel, NiSource Corporate Services Company, 1809 Coyote Drive, Chester, Virginia 23836; and a copy shall be delivered to the Commission's Office of General Counsel and Division of Utility and Railroad Safety.

¹ Va. Code §§ 56-265.14 et seq.

² See Memoranda from Laura S. Martin of the Commission's Division of Information Services, filed in this docket on August 7, 2013, and August 26, 2013.

³ Comments of WGL at 2.

⁴ Comments of Columbia Gas at 1.

⁵ Response at 2.

20VAC5-309-205. Commission authority.

Upon a finding that the public interest so requires, the commission may, upon motion, grant exemptions from any of the provisions of this chapter. The burden of proof shall be

upon the movant to demonstrate, by clear and convincing evidence, that such exemption is in the public interest. The commission may, by order, require modification or elimination of any granted exemption no longer required by the public interest.

VA.R. Doc. No. R13-3817; Filed November 18, 2013, 3:48 p.m.

GENERAL NOTICES/ERRATA

DEPARTMENT OF HEALTH

Drinking Water State Revolving Fund Program

Intended Use Plan for Fiscal Year 2014

Under the Safe Drinking Water Act, Congress authorizes capitalization grants to the states through the Drinking Water State Revolving Loan Fund Program (DWSRF). As part of the annual DWSRF grant application process, Virginia seeks meaningful public involvement through input, review, and comments. The Virginia Department of Health's Office of Drinking Water (ODW) has prepared a draft intended use plan (IUP) that explains the goals of the program, funding priorities, how the Virginia Department of Health (VDH) intends to use the grant funds, and other important information submitted from the funding requests and set-aside suggestions.

VDH received numerous funding requests and set-aside suggestions following the January 2013 DWSRF funding solicitation announcement. The draft 2014 IUP and draft project lists (available on the VDH website) are open for review and comment by the public for a period of 60 days. The document entitled "Virginia Drinking Water State Revolving Fund Program Design Manual" (dated January, 2013) is a part of the intended use plan and was mailed in the January announcement and placed on the VDH website. The Program Design Manual provides information on VDH's project prioritization criteria and methodologies.

VDH will hold a public meeting to solicit comments and recommendations regarding the 2014 IUP on Wednesday, January 15, 2014, from 9 a.m. to 11 a.m. at the ODW's East Central Field Office, 300 Turner Road, Richmond, VA 23225. Those individuals planning to attend the public meeting should contact Theresa Hewlett at (804) 864-7501 by the close of business on January 3, 2014.

Any written comments from the public are to be submitted by January 31, 2014, the close of the public comment period. VDH will consider all meaningful public input and comments and make revisions to the IUP and project priority lists if necessary. Please direct requests for information and forward written comments to Steven Pellei, PE, Virginia Department of Health, Office of Drinking Water, James Madison Building, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7500, FAX (804) 864-7521.

The following information is provided at VDH's website at <http://www.vdh.virginia.gov/ODW/financial/IntendedUsePlan14.htm>.

[VDH's 2014 Preliminary Project Priority List/2014 Comprehensive Project List](#)

[VDH's 2014 Draft Intended Use Plan \(IUP\)](#)

The IUP is subject to change depending on EPA's 2014 award allocations.

[VDH's 2014 Planning Grant Award List](#)

The projects listed will be awarded grants in the amounts indicated on the table.

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; FAX (804) 692-0625; *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.

ERRATA

DEPARTMENT OF MINES, MINERALS AND ENERGY

Title of Regulation: **4VAC25-31. Reclamation Regulations for Mineral Mining.**

Publication: 30:6 VA.R. 646-654 November 18, 2013

Correction to Final Regulation:

Page 648, 4VAC25-31-150 B 5, after "identified" insert "[in the initial application]"

VA.R. Doc. No. R09-1913; Filed November 20, 2013 1:57 p.m.

LONGWOOD UNIVERSITY

Title of Regulation: **8VAC50-11. Motor Vehicle Parking and Traffic Regulation.**

Publication: 30:2 VA.R. 97-99 September 23, 2013

Correction to Title of Regulation:

Page 97, change "Title of Regulation:" to "Titles of Regulations:" and add "**8VAC50-10. Motor Vehicle Parking and Traffic Rules and Regulations (repealing 8VAC50-10-10 through 8VAC50-10-50).**"

V.A.R. Doc. No. R14-3757; Filed November 22, 2013 4:16 p.m.

