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Virginia Code Commission

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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 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.

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

<u>Staff of the Virginia Register:</u> Jane D. Chaffin, Registrar of Regulations; Karen Perrine, Assistant Registrar; Anne Bloomsburg, Regulations Analyst; Rhonda Dyer, Publications Assistant; Terri Edwards, Operations Staff Assistant.

PUBLICATION SCHEDULE AND DEADLINES

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

July 2015 through August 2016

Volume: Issue	Material Submitted By Noon*	Will Be Published On	
31:24	July 8, 2015	July 27, 2015	
31:25	July 22, 2015	August 10, 2015	
31:26	August 5, 2015	August 24, 2015	
32:1	August 19, 2015	September 7, 2015	
32:2	September 2, 2015	September 21, 2015	
32:3	September 16, 2015	October 5, 2015	
32:4	September 30, 2015	October 19, 2015	
32:5	October 14, 2015	November 2, 2015	
32:6	October 28, 2015	November 16, 2015	
32:7	November 10, 2015 (Tuesday)	November 30, 2015	
32:8	November 24, 2015 (Tuesday)	December 14, 2015	
32:9	December 9, 2015	December 28, 2015	
32:10	December 21, 2015 (Monday)	January 11, 2016	
32:11	January 6, 2016	January 25, 2016	
32:12	January 20, 2016	February 8, 2016	
32:13	February 3, 2016	February 22, 2016	
32:14	February 17, 2016	March 7, 2016	
32:15	March 2, 2016	March 21, 2016	
32:16	March 16, 2016	April 4, 2016	
32:17	March 30, 2016	April 18, 2016	
32:18	April 13, 2016	May 2, 2016	
32:19	April 27, 2016	May 16, 2016	
32:20	May 11, 2016	May 30, 2016	
32:21	May 25, 2016	June 13, 2016	
32:22	June 8, 2016	June 27, 2016	
32:23	June 22, 2016	July 11, 2016	
32:24	July 6, 2016	July 25, 2016	
32:25	July 20, 2016	August 8, 2016	
32:26	August 3, 2016	August 22, 2016	
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*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF MEDICINE

Agency Decision

<u>Title of Regulation:</u> 18VAC85-50. Regulations Governing the Practice of Physician Assistants.

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

Name of Petitioner: Cara English.

<u>Nature of Petitioner's Request:</u> Replace requirement for National Commission on Certification of Physician Assistants (NCCPA) certification with other measure(s) of continuing competency for renewal of physician assistant licensure.

Agency Decision: Request denied.

<u>Statement of Reason for Decision:</u> At its meeting on June 4, 2015, the Advisory Board on Physician Assistants recommended that the petition be denied because members believe NCCPA certification continues to be the best measure of continued competency and because physician assistants have multiple opportunities to pass the examination prior to expiration of their certifications. On June 18, 2015, the Board of Medicine accepted the recommendation and rationale of the advisory board and voted to deny the petition.

<u>Agency Contact:</u> Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Richmond, VA 23233, telephone (804) 367-4688, or email elaine.yeatts@dhp.virginia.gov.

VA.R. Doc. No. R15-28; Filed July 1, 2015, 10:48 a.m.

NOTICES OF INTENDED REGULATORY ACTION

TITLE 8. EDUCATION

STATE BOARD OF EDUCATION

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Education intends to consider promulgating the following regulations: 8VAC20-750, Regulations Governing the Use of Seclusion and Restraint in Public Elementary and Secondary Schools in Virginia. The purpose of the proposed action is to adopt regulations in accordance with § 22.1-279.1:1 of the Code of Virginia relating to the use of seclusion and restraint in public elementary and secondary schools. The regulations will (i) be consistent with the board's Guidelines for the Development of Policies and Procedures for Managing Student Behavior in Emergency Situations and the Fifteen Principles contained in the U.S. Department of Education's Restraint and Seclusion: Resource Document; (ii) include definitions, criteria for use, restrictions for use, training requirements, notification requirements, reporting requirements, and follow-up requirements; and (iii) address distinctions, including distinctions in emotional and physical development, between (a) the general student population and the special education student population and (b) elementary school students and secondary school students.

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

Statutory Authority: §§ 22.1-16 and 22.1-279.1:1 of the Code of Virginia.

Public Comment Deadline: August 26, 2015.

<u>Agency Contact:</u> Melissa Luchau, Director for Board Relations, Department of Education, P.O. Box 2120, 101 North 14th Street, 25th Floor, Richmond, VA 23219, telephone (804) 225-2924, FAX (804) 225-2524, or email melissa.luchau@doe.virginia.gov.

VA.R. Doc. No. R15-4323; Filed July 2, 2015, 9:15 a.m.

REGULATIONS

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

Symbol Key

Roman type indicates existing text of regulations. Underscored language indicates proposed new text.

Language that has been stricken indicates proposed text for deletion. Brackets are used in final regulations to indicate changes from the proposed regulation.

TITLE 8. EDUCATION

STATE BOARD OF EDUCATION

Proposed Regulation

<u>Title of Regulation:</u> 8VAC20-131. Regulations Establishing Standards for Accrediting Public Schools in Virginia (amending 8VAC20-131-5; adding 8VAC20-131-185).

<u>Statutory Authority:</u> §§ 22.1-16 and 22.1-253.13:3 of the Code of Virginia.

Public Hearing Information:

September 10, 2015 - 11 a.m. - James Monroe Building, 101 North 14th Street, 22nd Floor, Conference Room, Richmond, Virginia 23219. The public hearing will begin immediately following adjournment of the Board of Education business meeting.

Public Comment Deadline: September 25, 2015.

<u>Agency Contact:</u> Anne Wescott, Assistant Superintendent, Policy and Communications, Department of Education, P.O. Box 2120, Richmond, VA 23218-2120, telephone (804) 225-2403, FAX (804) 225-2524, or email anne.wescott@doe.virginia.gov.

<u>Basis</u>: The Board of Education's authority for promulgating regulations governing standards for accrediting public schools may be found in § 22.1-253.13:3 of the Code of Virginia and includes promulgating regulations establishing standards for accreditation of public virtual schools under the authority of the local school board that enroll students full time. The Board of Education's overall regulatory authority is found in § 22.1-16 of the Code of Virginia, which provides that the board may adopt bylaws for its own government and promulgate such regulations as may be necessary to carry out its powers and duties and the provisions of this title.

<u>Purpose</u>: This regulatory action is necessary to protect the health, safety, and welfare of citizens, particularly those of school age. This regulatory action is essential to comport with the Code of Virginia and to ensure that an effective educational program is established and maintained in all of Virginia's public schools, including Virginia's public virtual schools. These regulations will further ensure that public virtual schools meet the same accreditation requirements as the brick-and-mortar public school. It is important that all public schools adhere to the same rigorous standards so that all students receive an effective education that helps them to become career and college ready.

<u>Substance:</u> The proposed amendments define a public virtual school as a school under the authority of the local school

board where a student is enrolled full time and receives instruction primarily electronically using the Internet or other computer-based methods.

The proposed amendments are designed to provide public virtual schools with an alternative way of meeting the requirements that are currently in place for public brick-andmortar schools, or an exemption from any requirement that would not be reasonable for a public virtual school. Specifically, the proposed amendments provide for the following:

1. Licensed personnel employed either by the school division or the public virtual school provider would be required to supervise student testing for the Virginia assessment program.

2. If a student enrolled in a public virtual school participates in a career and technical education course that requires cooperative education or work-based experience, the safety training provided in the virtual classroom would be required to be equivalent to the safety training given at a worksite.

3. Any teacher providing instruction in a full-time virtual school in Virginia shall hold a valid Virginia teaching license and shall be appropriately endorsed by the Board of Education for that teacher's assignment.

4. Each student enrolled in a public virtual school must have access to the necessary technology for participation in public virtual school courses, including a computer and printer, as well as a broadband Internet connection for school work purposes.

5. The local school board shall develop a policy that students who are unable to afford the necessary technology, including the hardware, software, and the broadband connection to the Internet, shall be provided with these items.

6. Students and teachers would be required to have the necessary technical security to ensure student safety while using the computer for school work.

7. Technical support services and training must be provided to assist in the resolution of technical problems for teachers and students.

8. New and experienced online teachers employed to instruct students in the public virtual school must participate annually in professional development for online teaching.

9. The requirement for 140 clock hours of instruction to earn a standard unit of credit may be waived if the content of the course is comparable to a course that

would otherwise require 140 clock hours of instruction in a non-virtual setting and, upon completion, the student would be able to demonstrate mastery of the course.

10. The school board would be required to develop a written policy to ensure that all students receiving instruction in a public virtual school setting have access to adequate and appropriate library resources.

11. Guidance counseling and other student support services are required to be available to students in the public virtual school from appropriately licensed and endorsed personnel.

12. Extracurricular activities and eligibility requirements for students in virtual school settings shall be established and approved by the superintendent and the school board.

13. Public virtual schools would be exempt from the school facilities and safety requirements unless the public virtual school is operated in a stand-alone facility.

14. A full time public virtual school shall have a learning management system that provides secure and appropriate access to the virtual learning environment; supports the creation and management of content and assessments; provides communication tools that facilitate synchronous and asynchronous discussion and collaboration among learners and teachers; and supports the collection, management, and reporting of data on learning outcomes.

15. Student engagement shall be monitored. If a student fails to interact with the learning management system every school day, the public virtual school principal or designee shall contact the students parent or guardian.

16. Public virtual schools would be required to provide all policies and procedures unique to enrollment and matriculation in the public virtual school to parents prior to enrollment and post such information for the public on the school division's website.

<u>Issues:</u> There are no disadvantages to the public, the Commonwealth, or the agency. The primary advantage to the public is in ensuring that the same standards apply to all public schools, both virtual and bricks-and-mortar, which will mean that all students receive a quality public education. The primary advantage to the Commonwealth, the agency, and local school divisions is that there will now be standards that are applicable to virtual public schools, which will assist local school boards in developing, establishing, and maintaining an effective educational program in schools.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Chapter 183 of the 2012 Acts of Assembly amends Virginia Code § 22.1-253.13:3 by requiring the Board of Education (Board) to promulgate regulations establishing standards for the accreditation of public virtual schools that enroll full-time students. Consequently, the Board proposes to promulgate these regulations, Regulations Establishing Standards for Accrediting Public Schools in Virginia, to satisfy the statutory requirement.

Result of Analysis. The benefits likely exceed the costs for some changes. For other amendments, whether the benefits exceed the costs depend on the policy views of the observer.

Estimated Economic Impact. There is currently one public virtual school in Virginia, in Carroll County. The school is accredited, having been granted waivers by the Board from certain provisions in these regulations that were not applicable to virtual schools. The requirements for virtual schools under the proposed regulations are consistent with the status quo with one exception. The local school board would be required to develop a policy that students who are unable to afford the necessary technology, including the hardware, software, and the broadband connection to the Internet, shall be provided with these items.

This would increase costs for establishing and maintaining a virtual school. Currently local school divisions are not specifically required to provide hardware, software, and broadband connections to the Internet for students from low-income families. The additional cost for local divisions if they choose to have a virtual school would likely be in the hundreds of dollars per low-income student who qualified for the virtual school. The total cost would depend on the cost of the specific software needed for the particular virtual instruction program, the hardware attributes needed to handle the software, and the number of low-income students who qualify.

Specifying the requirements for virtual schools in regulations is advantageous for local school boards in that it reduces uncertainty. Requiring that the local school board develop a policy that students who are unable to afford the necessary technology, including the hardware, software, and the broadband connection to the Internet, be provided with these items is beneficial in that enables lower socioeconomic students to have the same opportunity to attend a virtual school as middle and upper socioeconomic students. On the other hand, it significantly increases costs for local divisions which may result in cuts to other areas of educational spending or make it too expensive to have an otherwise planned virtual school. Whether the benefit of increased potential opportunity for some low-income students exceeds the potential cost of cuts to other areas depends on the policy views of the observer.

Businesses and Entities Affected. The proposed amendments potentially affect the 132 public school divisions in the Commonwealth, their staff, and their students, as well providers of software, hardware, and Internet service.

Localities Particularly Affected. The proposed regulations potentially affect all localities.

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

Effects on the Use and Value of Private Property. The proposed regulations are unlikely to have a large impact on the use and value of private property.

Small Businesses: Costs and Other Effects. The proposed regulations are unlikely to have a large impact on small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed regulations are unlikely to have a large impact on small businesses.

Real Estate Development Costs. The proposed amendments will 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.

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

Summary:

The proposed amendments (i) define a public virtual school; (ii) specify those provisions in the current regulations that are not applicable to public virtual schools, such as exempting the school from school facilities and safety requirements unless the school is in a stand-alone facility, and providing appropriate options for library services, counseling and student services, and extracurricular activities; and (iii) add provisions applicable only to public virtual schools, such as ensuring that students have access to the necessary technology and monitoring student engagement online.

Part I Definitions and Purpose

8VAC20-131-5. Definitions.

The following words and terms apply only to these regulations this chapter and do not supersede those definitions used for federal reporting purposes or for the calculation of costs related to the Standards of Quality (§ 22.1-253.13:1 et seq. of the Code of Virginia). When used in these regulations this chapter, these words shall have the following meanings, unless the context clearly indicates otherwise:

"Accreditation" means a process used by the Virginia Department of Education (hereinafter "department") to evaluate the educational performance of public schools in accordance with these regulations this chapter.

"Additional test" means a test, including substitute tests approved by the Board of Education that students may use in lieu of a Standards of Learning test to obtain verified credit.

"Class period" means a segment of time in the school day that is approximately 1/6 of the instructional day.

"Combined school" means a public school that contains any combination of or all of the grade levels from kindergarten through grade 12. This definition does not include those schools defined as elementary, middle, or secondary schools.

"Credit accommodations" means adjustments to meet the standard and verified credit requirements for earning a Standard Diploma for students with disabilities.

"Elementary school" means a public school with any grades kindergarten through five.

"Eligible students" means the total number of students of school age enrolled in the school at a grade or course for which a Standards of Learning test is required unless excluded under the provisions of 8VAC20-131-30 G and 8VAC20-131-280 D relative to limited English proficient (LEP) students.

"Enrollment" means the act of complying with state and local requirements relative to the registration or admission of a child for attendance in a school within a local school division. This term also means registration for courses within the student's home school or within related schools or programs.

"First time" means the student has not been enrolled in the school at any time during the current school year (for purposes of 8VAC20-131-60 with reference to students who transfer in during the school year).

"Four core areas" or "four core academic areas" means English, mathematics, science, and history and social science for purposes of testing for the Standards of Learning.

"Graduate" means a student who has earned a Board of Education recognized diploma, which includes the Advanced Studies Diploma, the Standard Diploma, and the Special Diploma.

"Homebound instruction" means academic instruction provided to students who are confined at home or in a health care facility for periods that would prevent normal school attendance based upon certification of need by a licensed physician or a licensed clinical psychologist.

"Learning management system" or "LMS" means a technology platform through which online courses are accessed by students and teachers. The LMS facilitates delivery, management, tracking, and reporting of content, student and teacher interactions, and learner progress.

"Locally awarded verified credit" means a verified unit of credit awarded by a local school board in accordance with 8VAC20-131-110.

"Middle school" means a public school with any grades 6 through 8.

"Planning period" means one class period per day or the equivalent unencumbered of any teaching or supervisory duties.

"Public virtual school" means a school under the authority of the local school board where a student is enrolled full time and receives instruction primarily electronically, using the Internet or other computer-based methods.

"Recess" means a segment of free time exclusive of time provided for meals during the standard school day in which students are given a break from instruction.

"Reconstitution" means a process that may be used to initiate a range of accountability actions to improve pupil performance, curriculum, and instruction to address deficiencies that caused a school to be rated Accreditation Denied that may include, but not be limited to, restructuring a school's governance, instructional program, staff or student population.

"School" means a publicly funded institution where students are enrolled for all or a majority of the instructional day and:

1. Those students are reported in fall membership at the institution; and

2. At a minimum, the institution meets the preaccreditation eligibility requirements of these regulations as adopted by the Board of Education.

"Secondary school" means a public school with any grades 9 through 12.

"Standard school day" means a calendar day that averages at least five and one-half instructional hours for students in grades 1 through 12, excluding breaks for meals and recess, and a minimum of three instructional hours for students in kindergarten.

"Standard school year" means a school year of at least 180 teaching days or a total of at least 990 teaching hours per year.

"Standard unit of credit" or "standard credit" means credit awarded for a course in which the student successfully completes 140 clock hours of instruction and the requirements of the course. Local school boards may develop alternatives to the requirement for 140 clock hours of instruction as provided for in 8VAC20-131-110.

"Standards of Learning tests" or "SOL tests" means those criterion referenced assessments approved by the Board of Education for use in the Virginia assessment program that measure attainment of knowledge and skills required by the Standards of Learning.

"Student" means a person of school age as defined by § 22.1-1 of the Code of Virginia, a child with disabilities as defined in § 22.1-213 of the Code of Virginia, and a person with limited English proficiency in accordance with § 22.1-5 of the Code of Virginia.

"Student periods" means the number of students a teacher instructs per class period multiplied by the number of class periods taught.

"Verified unit of credit" or "verified credit" means credit awarded for a course in which a student earns a standard unit of credit and achieves a passing score on a corresponding end-of-course SOL test or an additional test approved by the Board of Education as part of the Virginia assessment program.

"Virginia assessment program" means a system used to evaluate student achievement that includes Standards of Learning tests and additional tests that may be approved from time to time by the Board of Education.

8VAC20-131-185. Public virtual schools.

<u>A. Public virtual schools shall meet all of the laws and regulations required of all other public schools, unless otherwise specified in this section.</u>

Instruction in a public virtual school shall be designed to accommodate all students, including those identified with disabilities in accordance with the Individuals with Disabilities Education Act (20 USC § 1431 et seq.) or § 504 of the Rehabilitation Act, as amended (29 USC § 794); those identified as gifted; and those who have limited English proficiency. Any school division providing instruction to students in a virtual school setting must have written policies and procedures that address service delivery to accommodate all students. Instruction provided by a public virtual school must comport with the requirements of the Standards of Learning and career and technical education competencies and must be provided by teachers licensed by the Board of Education and endorsed in the subjects in which they provide instruction.

Students enrolled in a public virtual school shall be required to take all applicable Virginia assessment program tests in a secure, controlled, and proctored environment under the supervision of licensed personnel employed by a local school division or the public virtual school provider and trained in administering the tests.

If a student enrolled in a public virtual school participates in a career and technical education course that requires

cooperative education work-based experience, the safety training provided in the virtual classroom must be equivalent and related to the safety training given at a worksite. To achieve the competencies related to the use of equipment and machinery may require on-site instruction during the course, which may be conducted in a classroom laboratory or in a work-based instructional environment in which any safety requirements would apply.

<u>B. Any teacher providing instruction in a full-time public</u> virtual school in Virginia shall hold a valid Virginia teaching license and shall be appropriately endorsed for his assignment by the Board of Education.

C. Each student enrolled in a public virtual school shall have access to the necessary technology for participation in public virtual school courses, such as a computer and printer, and to a broadband Internet connection for school work purposes. The local school board shall develop a policy that students who are unable to afford the necessary technology, including the hardware, software, and the broadband connection to the Internet, shall be provided with these items. In addition, students and teachers shall have the necessary technical security to ensure student safety while using the computer for school work.

<u>Technical support services and training shall be provided to</u> <u>assist in the resolution of technical problems for teachers and</u> <u>students.</u>

<u>New and experienced online teachers employed to instruct</u> <u>students in the public virtual school shall participate annually</u> <u>in professional development for online teaching.</u>

D. The requirement for 140 clock hours of instruction to earn a standard unit of credit may be waived if the content of the course is comparable to a course that would otherwise require 140 clock hours of instruction in a non-virtual school setting and, upon completion, the student will be able to demonstrate mastery of the course.

E. Section 22.1-98 of the Code of Virginia requires the length of the school term to be not less than 180 teaching days or 990 teaching hours in any school year unless there are severe weather conditions or other emergency situations resulting in the closing of the school. Furthermore, students who complete their course requirements in fewer than 180 days or 990 hours (a standard school year) are still subject to § 22.1-254 of the Code of Virginia, compulsory attendance. The school division shall develop policies and procedures to ensure that the student is in compliance with § 22.1-254 of the Code of Virginia throughout the school year.

Where a student has mastered the course content and completed all course requirements in fewer than 180 days or 990 hours, the school shall enroll the student in the next course level or in another course, provide remediation if needed, focus on increasing the student's academic proficiency, provide enrichment, or meet the student's academic needs in another way as determined by school board policies. <u>F. Each local school board that authorizes a public virtual school must develop a written policy to ensure that all students receiving instruction in a public virtual school setting have access to adequate and appropriate library resources sufficient to meet research, inquiry, and reading requirements of the instructional program and general student interest.</u>

<u>G. Guidance counseling and other student support services</u> shall be available to students in the public virtual school from appropriately licensed and endorsed personnel.

<u>H. Extracurricular activities and eligibility requirements for</u> <u>students in virtual school settings shall be established and</u> <u>approved by the superintendent and the school board.</u>

I. Public virtual schools are exempt from the requirements in 8VAC20-131-260, related to school facilities and safety, unless the public virtual school is operated in a stand-alone facility.

J. A full-time public virtual school shall have a learning management system that provides secure and appropriate access to the virtual learning environment; supports the creation and management of content and assessments; provides communication tools that facilitate synchronous and asynchronous discussion and collaboration among learners and teachers; and supports the collection, management, and reporting of data on learning outcomes.

K. Student engagement shall be monitored. If a student fails to interact with the learning management system every school day, the public virtual school principal or designee shall contact the student's parent or guardian.

<u>L. The public virtual school principal or designee shall be</u> responsible for:

1. Analyzing the school's test scores annually, by grade and by discipline, to:

a. Direct and require appropriate prevention, intervention, remediation, or any combination thereof to those students performing below grade level or not passing the SOL tests;

b. Involve the staff of the school in identifying the types of staff development needed to improve student achievement and ensure that the staff participate in those activities; and

c. Analyze classroom practices and methods for improvement of online instruction;

2. Ensuring that student records are maintained and that criteria used in making placement and promotion decisions, as well as any instructional interventions used to improve the student's performance, are included in the record;

3. Monitoring and evaluating the quality of instruction, providing staff development, providing support that is designed to improve instruction, and seeking to ensure the successful attainment of the knowledge and skills required

for students by the SOL tests and for college and career readiness;

4. Maintaining records of students who drop out of school, including their reasons for dropping out and actions taken to prevent these students from dropping out;

5. Notifying the parents of rising eleventh-grade and twelfth-grade students of:

a. The number of standard and verified units of credit required for graduation; and

b. The remaining number of such units of credit the individual student requires for graduation;

6. Maintaining a current record of licensure, endorsement, and in-service training completed by staff; and

7. Maintaining records of receipts and disbursements of all funds handled. These records shall be audited annually by a professional accountant approved by the local school board.

All of the records, reports, and other information maintained by the public virtual school related to these documents, student scholastic records, and any other record or document maintained by the public virtual school shall be made available as may be necessary to the school board, superintendent, and school board employees.

M. Public virtual schools shall provide all policies and procedures unique to enrollment and matriculation in the public virtual school to parents prior to enrollment and post such information for the public on the school division's website.

N. Public virtual schools shall develop policies and procedures regarding the monitoring of student attendance, notification of parents and students regarding attendance issues and related disciplinary actions, and maintenance of records of attendance. This information shall be provided to parents prior to enrollment.

O. Information regarding student accountability and assessment shall be provided to the parents prior to enrollment. Public virtual schools shall develop policies and procedures to ensure that each student shall be assessed annually to determine what remediation and other support structures are needed to help the student achieve academic success. As determined by the school division, traditional and nontraditional assessments, such as state assessments and portfolios, may be used as part of this annual assessment process.

VA.R. Doc. No. R12-3261; Filed July 2, 2015, 12:19 p.m.

Final Regulation

<u>Titles of Regulations:</u> 8VAC20-670. Regulations Governing the Operation of Private Day Schools for Students with Disabilities (repealing 8VAC20-670-10 through 8VAC20-670-440).

8VAC20-671. Regulations Governing the Operation of Private Schools for Students with Disabilities (adding 8VAC20-671-10 through 8VAC20-671-780).

Statutory Authority: §§ 22.1-16 and 22.1-321 of the Code of Virginia.

Effective Date: August 26, 2015.

<u>Agency Contact</u>: John Eisenberg, Assistant Superintendent for Special Education and Student Services, Department of Education, P.O. Box 2120, Richmond, VA 23218, telephone (804) 786-8079 or email john.eisenberg@doe.virginia.gov.

Summary:

In response to Chapter 873 of the 2008 Acts of Assembly, the regulatory action repeals the Regulations Governing the Operation of Private Day Schools for Students with Disabilities (8VAC20-670) and creates a new chapter, Regulations Governing the Operation of Private Schools for Students with Disabilities (8VAC20-671), to address all applicable requirements for both private day schools and education programs in residential facilities, including group homes. The new chapter clarifies provisions for obtaining a license to operate, the management and conduct of schools, and the standards for programs offered by schools. Requirements of the new chapter include (i) programs of instruction that promote individual student academic achievement in the essential academic disciplines, (ii) development of policies and procedures by schools to ensure safe learning environments for and the protection of children in their care, and (iii) a change in the amount of the required guaranty instrument.

<u>Summary of Public Comments and Agency's Response:</u> 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.

CHAPTER 671

REGULATIONS GOVERNING THE OPERATION OF PRIVATE SCHOOLS FOR STUDENTS WITH DISABILITIES

8VAC20-671-10. Definitions.

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

[<u>"504 Plan" means a written plan required under § 504 of the Rehabilitation Act of 1973 (29 USC § 701 et seq.), as amended. A student's 504 Plan details modifications, accommodations, and services that are needed for the student with a disability to participate in and enjoy the benefits of school programs at the same level as his peers without disabilities.]</u>

"Applicant" means the person, partnership, corporation, or association that has completed and submitted an application to the [<u>licensing agency</u> department] for approval for a license to operate a school for students with disabilities in Virginia. "Autism" means a developmental disability significantly affecting verbal and nonverbal communication and social interaction, generally evident before age three, that adversely affects a child's educational performance. Other characteristics often associated with autism are engagement in repetitive activities and stereotyped movements, resistance to environmental change or change in daily routines, and unusual responses to sensory experiences. Autism does not apply if a child's educational performance is adversely affected primarily because the child has an emotional disturbance. A child who manifests the characteristics of autism after age three could be identified as having autism if the criteria in this definition are satisfied. [(34 CFR 300.8(c) (1))]

[<u>"Aversive stimuli" means any action used to punish a</u> student or to eliminate, reduce, or discourage the problem behavior by use of any of the following or any other actions that are painful, humiliating, degrading, or abusive:

1. Noxious odors and tastes.

2. Water and other mists or sprays.

3. Blasts of air.

4. Corporal punishment as defined in § 22.1-279.1 of the Code of Virginia.

5. Verbal and mental abuse.

6. Placement of a student alone in a room, where the door is locked or held shut and the student is prevented from leaving the room.

7. Forced exercise where:

a. The student's behavior is related to his disability;

b. The exercise would have a harmful effect on the student's health; or

c. The student's disability prevents participation in activities.

8. Deprivation of necessities, including:

a. Food or liquid at a time when it is customarily served;

b. Medication; or

c. Use of restroom.]

<u>"Behavioral intervention plan" means a plan that utilizes</u> positive behavioral interventions and supports to address [(i)] behaviors that [(i)] interfere with the learning of students with disabilities or with the learning of others or (ii) [behaviors that] require disciplinary action.

[<u>"Behavioral support" means those principles and methods</u> employed by a school to help a student achieve positive behavior and to address and correct a student's behavior in a constructive and safe manner in accordance with written policies and procedures governing program expectations, educational and treatment goals, safety and security, and the student's Individualized Education Program (IEP) or Individual Instruction Plan (IIP).] <u>"Board" means the State Board of Education</u> [, which has general supervision of the public school system].

"Business day" means Monday through Friday, 12 months of the year, exclusive of federal and state holidays (unless holidays are specifically included in the designation of business days).

"Calendar days" means consecutive days, inclusive of Saturdays and Sundays. Whenever any period of time fixed by this chapter shall expire on a Saturday, Sunday, or federal or state holiday, the period of time for taking such action under this chapter shall be extended to the next day that is not a Saturday, Sunday, or federal or state holiday.

"Complaint" means an accusation that a school has violated one or more of the requirements of this chapter or other applicable regulation.

"Consent" means:

<u>1. The parent(s) or eligible student has been fully informed</u> of all information relevant to the activity for which consent is sought in the parent's or eligible student's native language or other mode of communication;

2. The parent(s) or eligible student understands and agrees in writing to the carrying out of the activity for which consent is sought, and the consent describes that activity and lists the records (if any) that will be released and to whom; and

<u>3.</u> The parent(s) or eligible student understands that the granting of consent is voluntary on the part of the parent(s) or eligible student and may be revoked any time.

If a parent [or eligible student] revokes consent, that revocation is not retroactive (i.e., it does not negate an action that has occurred after the consent was given and before the consent was revoked. []] Revocation ceases to be relevant after the activity for which consent was obtained was completed [$\frac{1}{2}$].

The meaning of the term "consent" is not the same as the meaning of the term "agree" or "agreement." "Agree" or "agreement" refers to an understanding between the parent [or eligible student] and the school about a particular matter and as required in this chapter. There is no requirement that an agreement be in writing, unless stated in this chapter. The school should document [their its] agreement.

<u>"Controlled substance" means a drug or other substance</u> identified under Schedules I, II, III, IV, or V [<u>in § 202(c)</u>] of the Controlled Substances Act, 21 USC § 812(c). [<u>(34 CFR</u> <u>300.530 (i)(1))</u>]

"Corrective action plan" means the school's plan of action to correct a finding of noncompliance [applicable to this chapter or other applicable regulations]. The plan must identify specific timelines and the person(s) responsible for implementation.

"Deaf-blindness" means simultaneous hearing and visual impairments, the combination of which causes such severe

communication and other developmental and educational needs that they cannot be accommodated in special education programs solely for children with deafness or children with blindness. [(34 CFR 300.8(c)(3))]

"Deafness" means a hearing impairment that is so severe that the child is impaired in processing linguistic information through hearing, with or without amplification, that adversely affects the child's educational performance. [(34-CFR 300.8(c)(3))]

"Department" means the Virginia Department of Education.

<u>"Developmental delay" means a disability affecting a child</u> age two by September 30 through six, inclusive: [(34 CFR 300.8(b)) and 34 CFR 300.306(b))]

1. Who (i) is experiencing developmental delays, as measured by appropriate diagnostic instruments and procedures, in one or more of the following areas: physical development, cognitive development, communication development, social or emotional development, or adaptive development or (ii) has an established physical or mental condition that has a high probability of resulting in developmental delay;

2. The delay is not primarily a result of cultural factors, environmental or economic disadvantage, or limited English proficiency; and

3. The presence of one or more documented characteristics of the delay has an adverse effect on educational performance and makes it necessary for the student to have specially designed instruction to access and make progress in the general educational activities for this age group.

"Disability category" means a listing of special education eligibility classifications for students served including: autism, deaf-blindness, developmental delay, emotional disability, hearing impairment (including deafness), intellectual disability, multiple disabilities, orthopedic impairment, other health impairment, specific learning disability, speech or language impairment, traumatic brain injury, and visual impairment (including blindness). [§ 22.1-213 of the Code of Virginia; 34 CFR 300.8(a)(1) and 34 CFR 300.8(a)(2)(i) and (ii)).

"Education records," [also known as scholastic records,] mean those records that are directly related to a student and maintained by the school or by a party acting for the school. Education records may be recorded in any manner including, but not limited to, handwriting, print, computer media, video or audiotape, film, microfilm, or microfiche. Education records include discipline and medical records. Education records include electronic exchanges between school personnel and parent(s) regarding matters associated with the child's educational program.

"Eligible student" means a student who has reached 18 years of age.

<u>"Emotional disability"</u> [<u>or "emotional disturbance"</u>] <u>means</u> <u>a condition exhibiting one or more of the following</u> characteristics over a long period of time and to a marked degree that adversely affects a child's educational performance: [(34 CFR 300.8(c)(4))]

1. An inability to learn that cannot be explained by intellectual, sensory, or health factors;

2. An inability to build or maintain satisfactory interpersonal relationships with peers and teachers;

3. Inappropriate types of behavior or feelings under normal circumstances;

<u>4. A general pervasive mood of unhappiness or depression;</u> <u>or</u>

5. A tendency to develop physical symptoms or fears associated with personal or school problems.

Emotional disability [or emotional disturbance] includes schizophrenia. The term does not apply to children who are socially maladjusted, unless it is determined that they have an [emotional disturbance or] emotional disability as defined [by the Regulations Governing Special Education Programs for Children with Disabilities in Virginia in this section].

[<u>"Funding agency</u>" means a community policy and management team under the Children's Services Act, Chapter 52 (§ 2.2-5200 et seq.) of Title 2.2 of the Code of Virginia; local school division; or local department of social services.]

<u>"Guaranty instrument" means a surety bond, irrevocable</u> letter of credit, or certificate of deposit.

"Hearing impairment" means an impairment in hearing in one or both ears, with or without amplification, whether permanent or fluctuating, that adversely affects a child's educational performance but that is not included under the definition of deafness in the Regulations Governing Special Education Programs for Children with Disabilities [in Virginia] (8VAC20-81). [(34 CFR 300.8(c)(5))

<u>"Illegal drug" means a controlled substance</u> [$\frac{1}{2}$ or a prescription drug not prescribed for the person] but does not include a controlled substance that is legally possessed or used under the supervision of a licensed [<u>health-care</u> health care] professional or that is legally possessed or used under any other authority under the Controlled Substances Act, 21 USC § 812(c), or under any other provision of federal law.

"Individualized Education Program" or "IEP" means a written statement for a child with a disability that is developed, reviewed, and revised at least annually in a team meeting in accordance with the Regulations Governing Special Education for Children with Disabilities in Virginia [(8VAC20-81)]. The IEP specifies the individual educational needs of the child and what special education and related services are necessary to meet the child's educational needs. [(34 CFR 300.22)]

<u>"Individualized Instruction Plan" or "IIP" means a written</u> statement [(plan)] for a child who is privately placed or for a child who has not been determined eligible for special education services that is developed, reviewed, and revised at

least annually in a team meeting that includes the parent [and student when appropriate]. The IIP specifies the student's academic level, course of study, individual educational needs, and the educational services the child will receive.

<u>"Intellectual disability" means the definition formerly</u> <u>known as "mental retardation" and means significantly</u> <u>subaverage general intellectual functioning, existing</u> <u>concurrently with deficits in adaptive behavior and</u> <u>manifested during the developmental period that adversely</u> <u>affects a child's educational performance.</u> [<u>34 CFR</u> <u>300.8(c)(6)</u>]

"Licensee," also known as the sponsor, means the person, partnership, corporation, or association to whom a license is issued and who is legally responsible for compliance with this chapter.

<u>"License to operate" or "license" means a document issued</u> by the [<u>State state</u>] <u>Superintendent of Public Instruction that</u> [<u>verifies authorizes</u>] <u>approval to operate a school for</u> <u>students with disabilities</u> [<u>and that indicates the status of the</u> <u>school regarding compliance with applicable regulations</u>].

[<u>"Licensing agency" means the Virginia Department of</u> <u>Education.</u>

"Mechanical restraint" means the use of any device or equipment to restrict a student's freedom of movement. This term does not include devices implemented by trained school personnel or utilized by a student that have been prescribed by an appropriate medical or related services professional and are used for the specific and approved purposes for which such devices were designed, such as:

1. Adaptive devices or mechanical supports used to achieve proper body position, balance, or alignment to allow greater freedom of mobility than would be possible without the use of such devices or mechanical supports;

2. Vehicle safety restraints when used as intended during the transport of a student in a moving vehicle;

3. Restraints for medical immobilization; or

<u>4. Orthopedically prescribed devices that permit a student</u> to participate in activities without risk of harm.]

"Multiple disabilities" mean simultaneous impairments (such as intellectual disability with blindness or intellectual disability with orthopedic impairment), the combination of which causes such severe educational needs that they cannot be accommodated in special education programs solely for one of the impairments. The term does not include deafblindness. [(34 CFR 300.8(c)(7))]

"Orthopedic impairment" means a severe orthopedic impairment that adversely affects a child's educational performance. The term includes impairments caused by congenital anomaly, impairments caused by disease (e.g., poliomyelitis, bone tuberculosis, etc.), and impairments from other causes (e.g., cerebral palsy, amputations, and fractures or burns that cause contractures). [(34 CFR 300.8(c)(8))] "Other health impairment" means having limited strength, vitality, or alertness, including a heightened alertness to environmental stimuli, that results in limited alertness with respect to the educational environment, that is due to chronic or acute health problems such as asthma, attention deficit disorder or attention deficit hyperactivity disorder, diabetes, epilepsy, a heart condition, hemophilia, lead poisoning, leukemia, nephritis, rheumatic fever, sickle cell anemia, and Tourette syndrome [, and] that adversely affects a child's educational performance. [(34-CFR-300.8(c)(9)]

"Paraprofessional," also known as paraeducator, means an appropriately trained employee who assists and is supervised by qualified professional staff in meeting the requirements of this chapter.

"Parent" means [(§ 22.1 213.1 of the Code of Virginia)]:

1. A person who is:

a. A biological or adoptive parent of a child;

b. A foster parent, even if the biological or adoptive parent's rights have not been terminated, but subject to subdivision [23] of this definition;

c. A guardian generally authorized to act as the child's parent or make educational decisions for the child (but not the Commonwealth if the child is a ward of the Commonwealth);

d. An individual acting in the place of a biological or adoptive parent (including grandparent, stepparent, or other relative) with whom the child lives, or an individual who is legally responsible for the child's welfare; or

e. If no party qualified under subdivisions 1 a through [<u>1</u>] <u>d of this definition can be identified, or those parties are unwilling to act as parent, a surrogate parent who has been appointed in accordance with [8VAC20-81-80<u>8VAC20-81-220].</u></u>

2. The biological or adoptive parent, when attempting to act as the parent pursuant to this section and when more than one party is qualified under subdivision 1 of this definition to act as a parent, must be presumed to be the parent for purposes of this section unless the biological or adoptive parent has had his residual parental rights and responsibilities terminated pursuant to § 16.1-277.01, 16.1-277.02, or 16.1-283 of the Code of Virginia or a comparable law in another state.

3. The local school division shall provide written notice to the biological or adoptive parents at their last known address that a foster parent is acting as the parent pursuant to this section, and the local school division is entitled to rely upon the actions of the foster parent pursuant to this section until such time that the biological or adoptive parent attempts to act as the parent.

4. If a judicial decree or order identifies a specific person or persons among subdivisions 1 a through [1] e of this definition to act as the "parent" of a child or to make educational decisions on behalf of a child, then such person

or persons shall be determined to be the "parent" for purposes of the special education identification, evaluation, and placement of a child and the provision of a free appropriate public education to a child.

[<u>"Pat down" means a thorough external body search of a clothed student.</u>]

<u>"Personally identifiable information" means information that</u> includes, but is not limited to:

1. The student's name, the child's parent, or other family member;

2. The address of the child;

3. A personal identifier, such as the child's social security number or student number; or

4. A list of personal characteristics that would make the student's identity easily traceable.

["Pharmacological restraints" means a drug or medication used on a student to control behavior or restrict freedom of movement that is not (i) prescribed by a licensed physician or other qualified health professional acting under the scope of the professional's authority for the standard treatment of a student's medical or psychiatric condition and (ii) administered as prescribed by the licensed physician or other qualified health professional acting under the scope of the professional's authority.]

"Physical restraint" means the use of approved physical interventions or "hands-on" holds by trained staff to prevent a student from moving his body to engage in a behavior that places him or others at risk of physical harm. Physical restraint does not include:

<u>1. Briefly holding a student in order to calm or comfort the student; or</u>

2. Holding a student's hand or arm to escort the student safely from one area to another. [(Board of Education's Guidelines for the Development of Policies and Procedures for Managing Student Behaviors in Emergency Situations)

"Placing agency" means the community policy and management team under the Children's Services Act, Chapter 52 (§ 2.2-5200 et seq.) of Title 2.2 of the Code of Virginia; the local school division; or the local department of social services.]

<u>"Privately placed student" means a student placed in a private school for students with disabilities by [his parent(s) the parent].</u>

<u>"Publicly placed student" means a student placed in a private</u> school for students with disabilities by a local school division [or, family assessment and planning team under the] [<u>Comprehensive</u> Children's] <u>Services Act</u> [<u>team</u>,] <u>or</u> [<u>by</u>] court order.

"Qualified personnel" or "qualified staff" means personnel who have met [Virginia Department of Education approved or recognized the state-approved or state-recognized] certification, licensing, [registration, or other comparable requirements that apply to the area in which the individual is providing special education or related services. In addition, the professional must meet other state agency requirements for such professional service and Virginia licensure requirements as designated by Virginia law or regulations or other comparable requirement applicable to a specific discipline].

["Regular basis" means more than twice a month.]

"Related services" means transportation and such developmental, corrective, and other supportive services as are required to assist a child with a disability to benefit from special education and includes speech-language pathology and audiology services; interpreting services; psychological services; physical and occupational therapy; recreation, including therapeutic recreation; early identification and assessment of disabilities in children; counseling services, including rehabilitation counseling; orientation and mobility services and medical services for diagnostic or evaluation purposes. Related services also [includes include] school health services and school nurse services; social work services in schools; and parent counseling and training. Related services do not include a medical device that is surgically implanted including cochlear implants, the optimization of device functioning (e.g., mapping), maintenance of the device, or the replacement of that device. The list of related services is not exhaustive and may include other developmental, corrective, or supportive services (such as artistic and cultural programs, and art, music and dance therapy, if they are required to assist a child with a disability to benefit from special education [)]. [(<u>\$ 22.2-213 of the</u> Code of Virginia; 34 CFR 300.34(a) and (b))

<u>"School" means a school for students with disabilities that</u> has a license to operate issued by the Superintendent of <u>Public Instruction.</u>

<u>"School for students with disabilities</u> $[\frac{1}{3}]$ " [<u>"school,"</u>] or <u>"schools" means a privately owned and operated preschool, school or educational organization, no matter how titled, maintained, or conducting classes for the purpose of offering instruction, for a consideration, profit or tuition, to persons determined to have autism, deaf-blindness, developmental delay, a hearing impairment including deafness, [intellectual disability,] multiple disabilities, orthopedic impairment, other health impairment, an emotional disturbance, [$\frac{a \text{ severe}}{disability_i}$] a specific learning disability, a speech or language impairment, a traumatic brain injury, or a visual impairment including blindness. [$\frac{(\$ 22.1 - 319)}{(\$ 22.1 - 319)}$]</u>

"Seclusion" means the confinement of a student alone in a room from which the student is physically prevented from leaving. [(Board of Education's Guidelines for the Development of Policies and Procedures for Managing Student Behaviors in Emergency Situations)

<u>"Section 504" means that section of the Rehabilitation Act</u> of 1973 (29 USC § 701 et seq.), as amended, which is

designed to eliminate discrimination on the basis of disability in any program or activity receiving federal financial assistance.]

"Serious incident" means:

1. Any accident or injury requiring medical attention by a licensed physician;

2. Any illness that requires hospitalization;

3. Any runaway; or

4. Any event that affects, or potentially may affect, the health, safety, or welfare of any student being served at the school or school-related activity.

<u>"Serious injury" means any injury resulting in bodily hurt,</u> damage, harm, or loss that requires medical attention by a licensed physician.

"Special education" means specially designed instruction to meet the unique needs of a child with a disability. [There is no cost to the parent(s) for special education for a child who is placed in a school for students with disabilities by a school division, the Department of Social Services, or court order. (§ 22.1 213 of the Code of Virginia; 34 CFR 300.39)

The term includes:

1. Speech-language pathology services or any other related service, if the service is considered special education rather than a related service under state standards;

2. Vocational education; and

3. Travel training.

<u>"Specially designed instruction" means adapting, as</u> appropriate [,] to the needs of an eligible child under this chapter, the content, methodology, or delivery of instruction to: [(34 CFR 300.39(b)(3))]

<u>1. Address the unique needs of the child that result from the child's disability; and</u>

2. Ensure access of the child to the general curriculum [$_{\overline{x}}$] so that the child can meet the educational standards that apply to all children within the jurisdiction of the local educational agency.

"Specific learning disability" means a disorder in one or more of the basic psychological processes involved in understanding or in using language, spoken or written, that may manifest itself in the imperfect ability to listen, think, speak, read, write, spell, or do mathematical calculations, including conditions such as perceptual disabilities, brain injury, minimal brain dysfunction, dyslexia, and developmental aphasia. Specific learning disability does not include learning problems that are primarily the result of (i) visual, hearing, or motor disabilities; (ii) intellectual disabilities; (iii) emotional disabilities; or (iv) environmental, cultural, or economic disadvantage. [(§ 22.1-213 of the Code of Virginia; 34 CFR 300.8(c)(10))]

Dyslexia is distinguished from other learning disabilities due to its weakness occurring at the phonological level. Dyslexia is a specific learning disability that is neurobiological in origin. It is characterized by difficulties with accurate [or and/or] fluent word recognition and by poor spelling and decoding abilities. These difficulties typically result from a deficit in the phonological component of language that is often unexpected in relation to other cognitive abilities and the provision of effective classroom instruction. Secondary consequences may include problems in reading comprehension and reduced reading experience that can impede growth of vocabulary and background knowledge.

"Speech or language impairment" means a communication disorder, such as stuttering, impaired articulation, expressive or receptive language impairment, or voice impairment, that adversely affects a child's educational performance. [(34 <u>CFR 300.8(c)(11))</u>]

"Standard precautions" mean [universal] precautions designed to prevent transmission of HIV, hepatitis B virus (HBV), and other bloodborne pathogens when providing first aid or health care. Standard [cautions precautions] apply to blood; all body fluids, secretions, and excretions except sweat, regardless of whether or not they contain blood; nonintact skin; and mucous membranes. The precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection when providing first aid or health care. Standard precautions include protective barriers such as gloves, gowns, aprons, masks, or protective eye wear that can reduce the risk of exposure with materials that may contain infectious microorganisms.

<u>"Standards of Learning" or "SOL" means Virginia's rigorous</u> academic standards established by the Board of Education.

"Strip search" means a visual inspection of the body of a student when that student's outer clothing or total clothing is removed, and there is an inspection of the removed clothing. Strip searches are conducted for the detection of contraband.

["Substantial compliance" means that while there may be noncompliance with one or more regulations that represent minimum risk, compliance clearly and obviously exists with most of the regulations as a whole.]

<u>"Superintendent" means the</u> [<u>State state</u>] <u>Superintendent of</u> <u>Public Instruction.</u>

<u>"Teacher of record" means the teacher who is responsible</u> for the delivery of instruction. The teacher of record shall hold a license issued by the [State Virginia] Board of Education.

"Time-out" means assisting a student to regain control by removing the student from his immediate environment to a different open location until the student is calm or the problem behavior has subsided. [(Board of Education's Guidelines for the Development of Policies and Procedures for Managing Student Behaviors in Emergency Situations)]

"Traumatic brain injury" means an acquired injury to the brain caused by an external physical force, resulting in total

or partial functional disability or psychosocial impairment, or both, that adversely affects a child's educational performance. Traumatic brain injury applies to open or closed head injuries resulting in impairments in one or more areas, such as cognition; language; memory; attention; reasoning; abstract thinking; judgment; [problem solving problem solving]; sensory, perceptual, and motor abilities; psychosocial behavior; physical functions; information processing; and speech. Traumatic brain injury does not apply to brain injuries that are congenital or degenerative or to brain injuries induced by birth trauma. [(34 CFR 300.8(c)(12))]

"Visual impairment including blindness" means an impairment in vision that, even with correction, adversely affects a child's educational performance. The term includes both partial sight and blindness. [(34 CFR 300.8(c)(13))]

"Volunteer" means any individual who of his own free will and without compensation provides goods or services to the school.

"Virtual learning" means the delivery of instruction through emerging technologies such as satellite, streaming video, or the Internet.

8VAC20-671-20. Exemptions.

<u>This chapter shall not apply to any of the following [at § 22.1-320 of the Code of Virginia</u>]:

1. Any school that is licensed or approved pursuant to other statutes of the Commonwealth;

2. Any public or private high school accredited or recognized by the Board of Education that has offered or may offer programs for students with disabilities covered in this chapter [$_{\bar{x}}$] if any tuition, fees, and charges made by the school are collected in accordance with the regulations prescribed by the governing body of such school;

3. Tutorial instruction given in a private home or elsewhere as supplemental to regular classes for students enrolled in any public or private school or in preparation of an individual for an examination for professional practice or higher education;

4. A program through which persons with disabilities are provided employment and training primarily in simple skills in a sheltered or protective environment; [or]

5. Any privately owned or operated preschool, or elementary, middle, or secondary school that operates primarily to provide educational services to students without disabilities, although the school may serve children with disabilities in a regular academic setting [: or

<u>6. Any private school for students with disabilities that</u> operates in or on the premises of an elementary, middle, or secondary public school in a regular school setting during a typical school day].

8VAC20-671-30. Licenses generally.

A. The Board of Education has established general requirements for a license to operate a private school for

students with disabilities and has authorized the Superintendent of Public Instruction to issue licenses. The following applies in accordance with § 22.1-323 of the Code of Virginia:

1. No person shall open, operate, or conduct any school for students with disabilities in this Commonwealth without a license to operate.

2. A license to operate shall be restricted to the disability categories specifically indicated on the license, which may include one or more of the disability categories in the definition of a school for students with disabilities in this chapter.

3. A license to operate may be issued for a period of up to three successive years.

4. The term of a school's license may be reduced at any time during the licensure period based on a change in the school's compliance with these requirements.

5. A license to operate shall be prominently displayed on the premises of the school in a place open for inspection by any interested person during the hours of operation.

6. A license to operate shall be restricted to the approved conditions as printed on the license. Such conditions include, but are not limited to, the maximum number of students that can be enrolled, the disability category or categories of students that can be served, [and the] age range and gender [, and grade levels].

<u>B. An individual seeking to operate a school for students</u> with disabilities shall file an application with the [licensing agency department].

[<u>C. The department may make exception to the</u> requirements of this chapter for good cause.]

8VAC20-671-40. Advertising.

<u>The following provisions consistent with</u> [<u>§ 22.1 323</u> <u>§ 22.1-325</u>] of the Code of Virginia regarding advertisement of a school shall apply:

<u>1. No school may use the seal of the Commonwealth in any</u> advertisement, publication, or document, including diplomas, certificates, and other awards.

2. The advertisement of a school shall be in a form and manner that is free from misrepresentation, deception, or fraud and shall conform to the following:

<u>a. The complete school name as listed on the license to</u> <u>operate shall be used in all publicity, publications, or</u> <u>promotions or for marketing purposes.</u>

b. Advertisement shall not expressly or by implication indicate by any means that the license to operate represents an endorsement by the Virginia Department of Education or the Board of Education.

c. No fraudulent or misleading statement shall be in print or nonprint about the school's admission policy, tuition and fees; programs and services; size and location; or any other information concerning the school. d. Endorsements, commendations, or recommendations by students, individuals, manufacturers, business establishments, or organizations are prohibited except with their written consent and without any offer of financial compensation.

e. The accrediting agency shall be named [$\frac{1}{5}$ using its official title] if accreditation is used [$\frac{1}{5}$] as part of a school's promotional materials.

3. Prospective applicants may advertise projected services and staff positions while in the application process but shall not misrepresent licensure status and shall not enroll students prior to receiving a license to operate from the Superintendent of Public Instruction.

8VAC20-671-50. Types of licenses.

The following shall apply consistent with [§ §§ 22.1-323,] 22.1-323.1 [, and 22.1-323.2] of the Code of Virginia:

<u>1. A conditional license [shall may] be issued [to a new school that demonstrates compliance with administrative and policy requirements but has not demonstrated compliance with all requirements of this chapter upon approval of an application to operate a school for students with disabilities not to exceed a period of six months].</u>

[a.] A conditional license may be renewed [for a period of six months when a new school demonstrates compliance with administrative and policy requirements but has not fully demonstrated substantial compliance with requirements of this chapter].

[<u>b. The issuance of a conditional license and any</u> renewals thereof shall be for no longer a period than six successive months.

<u>2. A provisional license may be issued to a school that has</u> <u>demonstrated an inability to maintain compliance with this</u> <u>chapter or other applicable regulations.</u>

a. A provisional license may be issued at any time.

b. A provisional license may be renewed.

<u>e. The issuance of a provisional license and any renewal</u> <u>thereof shall be for no longer a period than six successive</u> <u>months.</u>

<u>3. 2.</u>] <u>An annual license may be issued under the following conditions and may be extended for a period not to exceed [six 36] successive months:</u>

<u>a. A school</u> [<u>applies for renewal</u> provides notice for continued licensure] while holding a conditional or provisional license.

[<u>b.</u> When a school holds a provisional license and] substantially meets the requirements of this chapter;

[<u>b. The licensing agency determines that a major</u> <u>violation has occurred that impacts the overall operation</u> <u>of the school; or</u>]

c. [The When a] school makes significant changes in its operation.

 $[\underline{4.3.}]$ <u>A triennial license shall be issued when a school</u> $[\underline{\div}]$ <u>holds an annual or triennial license and substantially meets</u> the requirements of this chapter.]

[a. Applies for renewal while holding an annual or triennial license; and

b. Substantially meets or exceeds the requirements of this chapter and other applicable regulations.

5.4.] The term of a school's license may be [modified at any time during the licensure period based on a change in the school's reduced to provisional when the school has demonstrated an inability to achieve or maintain] compliance with this chapter [and or] other applicable regulations.

[a. A provisional license may be issued at any time.

b. A provisional license may be renewed.

<u>c.</u> The issuance of a provisional license and any renewal thereof shall be for no longer a period than six successive months.]

8VAC20-671-60. Change in condition.

A. A condition of a license may be modified during the term of the license with respect to: capacity of the school or classrooms; disability category or categories of students served; age range [of students]; [grade levels,] change in location; change in services; change in ownership; merger of schools; and enrollment of day student(s) in a residential setting.

B. A change in a condition shall not be implemented prior to approval by the [<u>licensing agency</u> department]. [<u>The</u> <u>licensing agency shall respond to the request and provide</u> approval or denial in 10 calendar days following the date the request was received.

<u>C. A change in a condition may not be approved during a provisional or conditional licensure period.</u>]

8VAC20-671-70. License to operate is nontransferable.

<u>A change of ownership occurs when control of a school changes from one owner to another. If there is a change in ownership, the following shall apply:</u>

<u>1. The licensee shall notify the [licensing agency</u> <u>department</u>] <u>at least 30 calendar days prior to the proposed</u> <u>change.</u>

2. The new owner shall submit an initial application for a license to operate to the [licensing agency department] within 30 calendar days following the effective date of the change in ownership.

3. The school may operate under the existing license for 60 calendar days from the effective date of the change in ownership at which time a conditional license may be issued.

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<u>8VAC20-671-80.</u> Penalty for noncompliance in obtaining <u>a license to operate.</u>

[<u>Failure to obtain a license to operate</u> Operating] <u>a school</u> for students with disabilities [without a license] shall result in the following penalties allowed in § 22.1-331 of the Code of Virginia:

1. Any person who opens, operates, or conducts a school without first obtaining a license to operate [may shall] be [found] guilty of a Class 2 misdemeanor.

2. Each day [such person who permits] the school [remains to be] open [and operate] without a license [to operate, the owner or board of directors] shall incur a separate offense.

3. The [<u>licensing agency</u> department] shall refer [<u>to the</u> Office of the Attorney General any alleged or known violation of this chapter. The Office of the Attorney General shall refer the matter any person who opens, operates, or conducts a school for students with disabilities without a license] to the [appropriate] Commonwealth's attorney [<u>of proper jurisdiction</u>].

<u>8VAC20-671-90.</u> [<u>Directory List</u>] of private schools for students with disabilities.

The [licensing agency department] shall maintain a [directory list] of schools holding valid licenses to operate that shall be available to the public [(§ 22.1 332 of the Code of Virginia)]. The [directory shall identify other applicable state licensing agencies over the school and list] may include additional information to inform the public about the school's operation.

8VAC20-671-100. Initial application.

<u>To obtain a license to operate a school for students with disabilities, an application shall be filed with the [Virginia]</u> Department of Education. A completed initial application shall include the following:

<u>1. Complete name</u> [<u>and with</u>] <u>physical</u> [<u>address and</u> <u>mailing addresses</u>] <u>of the school;</u>

2. Name and address of owners, controlling officials, and managing employees;

3. Evidence that the applicant has [conducted a needs assessment assessed the community's need for a new school]:

<u>4. Evidence of the applicant's compliance with the applicable regulations of the State Corporation</u> <u>Commission when the school is owned by a partnership or corporation;</u>

5. Narrative description of building and scale [drawing drawings] or copy of all floor plans including room use and dimensions;

6. Certificate of occupancy with educational use group or other report from the appropriate government agency or agencies indicating that the location meets applicable zoning, building code, use permit, business license, fire safety, and sanitation requirements;

7. Copy of the deed, lease, or other legal instrument authorizing the school to occupy such location;

8. Proposed working budget for the year showing projected revenue and expenses for the first year of operation and a balance sheet showing assets and liabilities; a three-year financial plan; and documentation of sufficient operating capital or line of credit to carry the school through the first year of operation;

9. Original signed surety bond, irrevocable letter of credit, or certificate of deposit to protect the contractual rights of parents and students;

<u>10. Schedule of tuition and other fees and the procedure for collecting and refunding tuition;</u>

11. Copies of all proposed advertisements;

12. Description of the education program to include disability category or categories to be served, enrollment capacity, [grade level or levels,] age range, gender, and course offerings;

13. Listing of instructional resources and equipment:

14. Description of related services;

15. School's policy manual;

16. Proposed staffing and organizational chart;

17. Job description for each position;

18. Parent/student handbook;

<u>19. Statement</u> [of regarding] <u>transportation services if the</u> <u>school provides transportation for students;</u>

20. Statement regarding provision of student lunches;

[<u>21. Description of the behavior management program;</u>] <u>and</u>

[<u>21.</u> 22.] <u>Any other information necessary to complete the application process.</u>

8VAC20-671-110. Applicant commitments.

Each application for a license to operate a school for students with disabilities shall contain the following commitments:

1. To conduct the school in accordance with all applicable regulations of the board;

2. To permit the board or department to inspect the school or classes being conducted therein at any time and to make available to the board or department, when requested to do so, all information pertaining to the activities of the school required for the administration of this chapter, including its financial condition;

<u>3. To advertise the school at all times in a form and manner</u> that is free from misrepresentation, deception, or fraud and to conform to provisions of the board governing such advertising; 4. To ensure that all representations made by an agent of the school are free from misrepresentation, deception, or fraud and to conform to provisions of the board governing such advertising;

5. To display the current license to operate prominently where it may be inspected by students, visitors, and the board or department; and

<u>6. To maintain all premises, equipment, and facilities of the school in an adequate, safe, and sanitary condition.</u>

8VAC20-671-120. Assessment of application.

<u>A. The</u> [<u>licensing agency</u> department] <u>shall evaluate each</u> application within 60 calendar days from the date received and advise the applicant in writing of approval or deficiencies.

<u>B. The applicant shall correct all deficiencies within 30 calendar days from the date of the written assessment of the application. The [licensing agency department] may grant an extension for a reasonable period of time.</u>

<u>C.</u> [<u>Any application that has not been approved within the allotted time period shall be denied and returned to the applicant. The applicant may reapply for a license 90 calendar days following the date of the returned application. The department shall conduct a review of the character, reputation, and status with other licensing agencies, and the responsibility of the applicant before issuing a license.]</u>

<u>D. The</u> [<u>licensing_agency_department</u>] <u>may_require_the</u> <u>applicant to</u> [<u>appear before a review committee for meet with</u> <u>department staff before</u>] <u>final approval of the application.</u>

8VAC20-671-130. On-site inspection.

Before a license can be issued [to an applicant], the [licensing agency department] shall conduct an on-site inspection or [equivalent virtual inspection review photographs or videos] of the school building and grounds to determine its suitability for the operation of a school for students with disabilities.

8VAC20-671-140. Renewal of licenses.

[<u>A. Sixty calendar days prior to the expiration of a license</u> to operate, the licensee shall submit to the licensing agency notification of intent for continued operation of the school.

<u>B.</u> A.] <u>The license of each school that continues to operate</u> as such shall be renewed on or before the anniversary date set by the [<u>licensing agency department</u>].

[<u>C.</u> B.] Each license that has not been renewed in accordance with this chapter shall expire [and a new license shall be obtained from the board before such school may continue to operate. A new application must be submitted to the licensing agency].

8VAC20-671-150. Monitoring.

The [licensing agency department] shall:

<u>1. Make at least one [announced or</u>] unannounced visit during the effective dates of the license to operate for the

purpose of monitoring the school's compliance with this chapter;

<u>2. Notify relevant local governments and placing and funding agencies of health and safety or human rights violations.</u>

3. [Notify the appropriate public agencies when a school's licensure status is lowered to provisional;

4.] Cooperate with other [state] licensing agencies [specifically, the Department of Social Services and the Department of Behavioral Health and Developmental Services,] in fulfilling licensing responsibilities [. The licensing agency shall notify relevant local governments and placing and funding agencies when a school's licensure status is lowered to provisional.; and

5. Re-examine findings of noncompliance in consultation with the school administrator when there is disagreement and amend any written report as appropriate in seven business days.]

8VAC20-671-160. Complaint resolution procedures.

A. A complaint may be filed with the [licensing agency department] by any individual or organization and shall address an action that occurred not more than one year prior to the date the complaint is received by the [licensing agency department].

B. A complaint must provide a statement of some disagreement with procedures or process regarding any matter relative to this chapter or other applicable regulations.

<u>C.</u> Upon receipt of a complaint, the [<u>licensing agency</u><u>department</u>] <u>shall initiate an investigation to determine</u> whether the school is in compliance with applicable laws and regulations in accordance with the following procedures:

<u>1. Within seven business days of the receipt of a complaint,</u> <u>the [licensing agency department] shall provide written</u> notification to each complainant and the private school.

a. The notification sent to the school shall include:

(1) A copy of the complaint;

(2) An offer of technical assistance in resolving the complaint;

(3) A statement that the school has the opportunity to propose a resolution of the complaint;

(4) A request that the school submit within 10 business days of receipt of the letter of notification either:

(a) Written documentation that the complaint has been resolved; or

(b) If the complaint was not resolved, a written response including all requested documentation.

<u>2. The</u> [<u>licensing agency department</u>] shall review the complaint and the school's response and determine the need for any further investigation or corrections.

<u>3. The</u> [<u>licensing agency</u> department] <u>shall notify</u> appropriate agencies of serious violations.

<u>4. During the course of the investigation, the [licensing agency department] shall:</u>

a. Conduct an investigation of the complaint that shall include a complete review of all relevant documentation and may include interviews with appropriate individuals and an independent on-site investigation, if necessary.

b. Consider all facts and issues presented and the applicable requirements specified in this chapter or other applicable regulations.

c. Make a determination of compliance or noncompliance on each issue in the complaint based upon the facts and applicable regulations and notify the parties in writing of the findings and the bases for such findings. The [<u>licensing agency</u> department] has 60 calendar days after the written complaint is received to carry out the investigation and to [<u>resolve the complaint</u> issue a letter of finding]. An extension of the 60 calendar day time limit may occur if exceptional circumstances exist with respect to a particular complaint.

d. Ensure that the final decision is effectively implemented, if needed, through technical assistance activities, negotiations, and corrective actions to achieve compliance.

e. Notify the parties in writing of any needed corrective actions and the specific steps that shall be taken by the school to bring it into compliance with applicable timelines.

[$\underline{E.}$ D.] Parties to the complaint procedures shall have the right to appeal the final decision to the [$\underline{\text{licensing-agency}}$ department] within 30 calendar days of the issuance of the decision.

[<u>F. E.</u>] When the school develops a plan of action to correct the violations, such plan shall include timelines to correct violations not to exceed 30 business days unless circumstances warrant otherwise. The plan of action shall include a description of all [proposed] changes [<u>contemplated</u>] and shall be subject to approval of the [<u>licensing agency</u> department].

[<u>G. F.</u>] If the school does not come into compliance within the period of time set forth in the notification, the [<u>licensing</u> <u>agency</u> department] may reduce or revoke the school's license to operate.

<u>8VAC20-671-170.</u> Denial, revocation, or suspension of <u>license.</u>

<u>A. The [superintendent board] may refuse to issue or renew</u> a license to operate or may revoke or suspend a license issued to any school pursuant to this chapter for the following causes [<u> \$ 22.1-329 of the Code of Virginia</u>]:

1. Violating any provision of this chapter or regulation of the board:

2. Furnishing false, misleading, or incomplete information to the board or department or failure to furnish information requested by the board or department;

3. Violating any commitment made in an application for a license;

4. Presenting either by the school or by any agent of the school to prospective students information relating to the school which is false, misleading, or fraudulent:

5. Failing to provide or maintain premises or equipment in a safe and sanitary condition as required by law;

6. Making any false promises through agents or by advertising or otherwise of a character likely to influence, persuade, or induce enrollments;

7. Paying a commission or valuable consideration to any person for any act of service performed in willful violation of this chapter;

8. Failing to maintain financial resources adequate for the satisfactory conduct of courses of instruction offered or to retain a sufficient or qualified instructional staff;

9. Demonstrating unworthiness or incompetency to conduct the school in a manner calculated to safeguard the interests of the public;

10. Failing within a reasonable time to provide information requested by the board or department as a result of a formal or informal complaint to or by the board or department that would indicate a violation of these requirements:

11. Attempting to use or employ any enrolled students in any commercial activity whereby the school receives any compensation whatsoever without reasonable remuneration to the student, except to the extent that employment of students in such activities is necessary or essential to their training and is permitted and authorized by the board; or

12. Engaging in or authorizing any other conduct, whether of the same or of a different character from that specified in this section, that constitutes fraudulent or dishonest dealings.

[<u>B.</u> The provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) shall be applicable to proceedings under this section.]

8VAC20-671-180. Summary or final order of suspension.

[<u>The provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) shall be applicable to proceedings under this section.</u>] In compliance with § 22.1-329 of the Code of Virginia, the following shall apply:

1. In addition to the authority for other disciplinary actions provided in this chapter, the Superintendent of Public Instruction may issue a summary order of suspension of a license of a residential or day school for students with disabilities in conjunction with any proceeding for revocation, denial, or other action when conditions or practices exist in the school that pose an immediate and substantial threat to the health, safety, and welfare of the students who are residing or attending the school and the Superintendent of Public Instruction believes the operation of the school should be suspended during the pendency of such proceeding.

2. The summary order of suspension shall take effect upon its issuance and shall be served on the licensee or its designee as soon as practicable thereafter by personal service and certified mail, return receipt requested, to the address of record of the licensee. The order shall state the time, date, and location of a hearing to determine whether the suspension is appropriate. Such hearing shall be held no later than three business days after the issuance of the summary order of suspension and shall be convened by the Superintendent of Public Instruction or designee.

3. After such hearing, the Superintendent of Public Instruction may issue a final order of summary suspension or may find that such summary suspension is not warranted by the facts and circumstances presented. A final order of summary suspension shall include notice that the licensee may appeal the Superintendent of Public Instruction's decision to the appropriate circuit court no later than 10 days following issuance of the order. The sole issue before the court shall be whether the Superintendent of Public Instruction had reasonable grounds to require the licensee to cease operations during the pendency of the concurrent revocation, denial, or other proceeding. The concurrent revocation, denial, or other proceeding shall not be affected by the outcome of any hearing on the appropriateness of the summary suspension.

4. The willful and material failure to comply with the summary order of suspension or final order of summary suspension shall be punishable as a Class 2 misdemeanor. The Superintendent of Public Instruction may require the cooperation of any other agency or subdivision of the Commonwealth in the relocation of students who are residents of a home or facility whose license has been summarily suspended pursuant to this section and in any other actions necessary to reduce the risk of further harm to students.

8VAC20-671-190. Timeline for correction of unsatisfactory conditions.

In compliance with § 22.1-330 of the Code of Virginia, the board or department:

1. May, upon its own motion, and shall, upon the verified complaint in writing of any person setting forth facts that [,] if proved [,] would constitute grounds for refusal, suspension, or revocation of a license, investigate the actions of any applicant for or any person or persons holding or claiming to hold a license to operate [a school].

2. Before refusing to renew, revoking, or suspending any license, may grant such period of time as it deems reasonable to correct any unsatisfactory condition.

8VAC20-671-200. Governing body.

<u>A. Each school shall use its complete name as [listed</u> printed] on the license to operate for all publicity, publications, promotions, or marketing purposes.

<u>B.</u> Any governing board, body, entity, or person to whom it delegates the legal responsibilities and duties of the licensee shall be clearly identified.

8VAC20-671-210. Responsibilities of the licensee.

The licensee shall:

1. Appoint an individual(s) to whom it delegates the authority and responsibility to assume the administrative direction of the school. The appointment shall be in writing.

2. Develop and implement a written decision-making plan that shall include provision for a staff person with the qualifications of the school administrator or education program director to be designated to assume the temporary responsibility for the operation of the school in the absence of the school administrator. The plan shall include a current organizational chart.

3. Ensure that staff positions and responsibilities meet the needs of the population served.

4. Develop a written statement of the objectives of the school including a description of the target population and the program offerings.

5. Develop and implement written policies and procedures to monitor and evaluate the effectiveness of the education program on a systematic and ongoing basis and implement improvements when the need is determined.

6. Ensure compliance with applicable child labor laws.

7. Develop a written policy prohibiting the consumption of tobacco products, [illegal] drugs, and alcohol or being under the influence of intoxicating or hallucinogenic agents while on campus and at school-sponsored [student] activities.

8. Require as a condition of employment that any applicant who accepts employment full-time or part-time, permanent or temporary, [including interns and] volunteers [to on a regular basis and will be alone with a student in the performance of his duties, or anyone who provides contractual services, including services of a student intern, on a regular basis and will be alone with a student in the performance of his duties shall] submit to fingerprinting and to provide personal descriptive information to be forwarded along with the applicant's fingerprints through [Virginia's the] Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding such applicant. [In addition, where the applicant has resided in another state within the last five years, the school shall as a condition of employment determine if there are any founded complaints of child abuse or neglect

in such state(s) pursuant to <u>\$</u> 22.1 296.3 and 22.1 296.4 of the Code of Virginia.

Anyone who is hired or is approved to provide volunteer services, contractual services, or services of a studentintern on a regular basis and will be alone with students cannot begin working with children until the criminal history background check has been received by the school.]

9. Require as a condition of employment that any applicant who accepts employment requiring direct contact with students, whether full-time or part-time, permanent or temporary, [including interns and] volunteers [on a regular basis and will be alone with a student in the performance of his duties; or anyone who provides contractual services, including services of a student intern on a regular basis and will be alone with a student in the performance of his duties, shall] provide written consent and necessary personal information for the school to obtain a search of the registry of founded complaints of child abuse and neglect maintained by the Department of Social Services [pursuant to § 63.2 1515 of the Code of Virginia]. [Where the applicant has resided in another state within the last five years, the school shall as a condition of employment, determine if there are any founded complaints of child abuse or neglect in such state(s) pursuant to §§ 22.1-296.3 and 22.1-296.4 of the Code of Virginia.

a. Anyone who has not submitted to a search of the registry of founded complaints of child abuse and neglect maintained by the Department of Social Services shall not be permitted to work alone with children.

<u>b.</u> The results of the search of the registry must be received prior to permitting an applicant to work alone with children.]

<u>10. Notify the [licensing agency department] within five</u> calendar days of any change in administration or newly appointed individual responsible for the day-to-day administration or operation of the school.

<u>11. Ensure that all staff members receive annual</u> professional development related to their job responsibilities.

12. Report to the [licensing agency department] within 10 business days lawsuits [, settlements, or criminal charges relating to the operation of the school against or settlements with the licensee relating to the health and safety or human rights of students and any criminal charges against any staff that may be related to the health and safety or human rights of students].

<u>13.</u> Develop and implement an accessible policy and procedures to handle [grievances school related complaints] from students, parents, and employees. [Schools are required to provide written notification of the

right to file a complaint with the department's private school licensure office.

<u>14. The school shall have a written policy and procedure that the school does not discriminate according to state and federal law.</u>]

8VAC20-671-220. Fiscal accountability.

A. The licensee shall prepare at the end of each fiscal year:

1. An operating statement to include a month-to-month accounting of revenue and expenses for the fiscal year just ended;

2. A working budget showing projected revenue and expenses for the next fiscal year that gives evidence of sufficient funds to operate; and

3. A balance sheet showing assets and liabilities for the fiscal year just ended.

<u>B.</u> There shall be a system of financial recordkeeping that shows a separation of the school's accounts from all other records.

<u>C.</u> There shall be written policies and procedures that address the day-to-day handling of the school's funds.

<u>D. The</u> [<u>licensing agency department</u>] reserves the right to call for one of these two types of statements:

1. An audited financial statement certified by an outside independent certified public accountant in accordance with standards established by the American Institute of Certified Public Accountants; or

2. A financial statement that has been reviewed by an outside independent certified public accountant in accordance with principles established for reviews by the American Institute of Certified Public Accountants.

8VAC20-671-230. Protection of contractual rights.

In compliance with § 22.1-324 of the Code of Virginia, provisions for the protection of contractual rights shall include the following:

1. With each application, the applicant shall submit and maintain a guaranty instrument payable to the Commonwealth of Virginia to protect the contractual rights of students and other contracting parties.

2. The guaranty instrument shall be based on the school's approved capacity. A [minimum] guaranty of \$10,000 for up to 25 students and \$5,000 for each additional 25 students shall apply.

3. In the event a guaranty instrument is terminated, the license to operate will terminate within 30 calendar days if a replacement bond or other instrument is not filed with the [licensing agency department].

4. If a school collects no advance tuition other than equal monthly installments or receives payment after services have been rendered, the school may apply to the [licensing agency department] for exemption from the guaranty requirements.

8VAC20-671-240. Insurance.

<u>A. The licensee shall maintain liability insurance covering</u> the premises and the school's operation.

B. The licensee shall maintain liability insurance on all vehicles used to transport students, including vehicles owned by staff. [The school shall obtain written consent from the parent to transport a student in a staff member's personal vehicle.]

<u>C. The members of the governing body and staff who are authorized to handle school or [students' student] funds shall be bonded [or indemnified against employee dishonesty].</u>

8VAC20-671-250. Fundraising.

[<u>A.</u>] Written consent of the [<u>parent(s) or legal guardian</u> and of a child age 14 or older parent] shall be obtained before [<u>participating</u> allowing a student to participate] in any school fundraising activity.

[<u>B. No student shall be forced to participate in any school fundraising activity.</u>]

<u>8VAC20-671-260. Relationship to the [licensing agency department].</u>

The licensee shall make information available to the [licensing agency department] upon the requested due date in order to make a timely determination of compliance with this chapter and other applicable regulations and statutes. The [licensing_agency_department] may alter the term of a license if the school fails to comply in a reasonable time period.

8VAC20-671-270. Personnel policies and procedures.

<u>A. The licensee shall have written personnel policies and procedures that include, but are not limited to, job qualifications, job descriptions, [staff] supervision, evaluation, [grievance dispute resolution], and termination.</u>

1. The licensee shall develop and implement written policies and procedures that persons appointed or designated to assume the responsibilities of each position possess the education, experience, [knowledge,] skills, and abilities specified in the job description.

<u>2. The licensee shall make written personnel policies and procedures accessible to each employee.</u>

<u>B. The licensee shall maintain a current organizational chart</u> of all full-time and part-time positions.

8VAC20-671-280. Job qualifications.

A person who assumes or is designated to assume the responsibilities of a position or any combination of positions described in this chapter shall meet the qualifications of the position, comply with all applicable regulations for each function, and demonstrate a working knowledge of the policies and procedures applicable to the position.

8VAC20-671-290. Job descriptions.

<u>A. There shall be a written job description for each position</u> that includes job title; duties and responsibilities; job title of the immediate supervisor; and minimum education, experience, [knowledge,] skills, and abilities required for entry-level performance of the job.

<u>B.</u> A copy of the job description shall be given to each person assigned to a position at the time of employment or assignment.

8VAC20-671-300. School administrators.

A. The licensee shall designate [<u>one or more individuals</u> an <u>individual(s)</u> who is a graduate of an accredited college or <u>university and is</u>] responsible for the administrative operation of the school [who serves as the instructional leader and is responsible for effective school management that promotes positive student achievement, and a safe and secure <u>environment in which to teach and learn</u>]. [This individual may also serve as the instructional leader.]

<u>B.</u> [<u>As the instructional leader, the The</u>] <u>school</u> <u>administrator</u> [<u>is responsible for ensuring that students are</u> <u>provided an opportunity to learn and</u>] <u>shall:</u>

1. Protect the academic instructional time from unnecessary interruptions [and disruptions and enable the professional teaching staff to spend the maximum time possible in the teaching/learning process by keeping to a minimum clerical responsibility and the time students are out of class];

2. Seek to maintain a safe and secure school environment;

<u>3. Involve the [school] staff [of the school] in identifying</u> [<u>the types of</u>] <u>staff development [needed needs] to</u> improve student achievement and ensure [<u>that the</u>] <u>staff</u> [<u>participate in those activities participation]:</u>

<u>4. Analyze classroom practices and methods for improvement of instruction;</u>

5. Ensure [that students' student] education records are maintained [and that criteria used in making placement and promotion decisions, as well as any instructional interventions used to improve the student's performance, are included in the record confidentially]; and

6. Monitor and evaluate the quality of instruction [₁ provide staff development, and provide support that is designed and provide supports as needed] to improve instruction.

C. The instructional leader shall hold a valid five-year renewable postgraduate professional license issued by the board with an endorsement in school administration and supervision or special education and have at least three years of experience working with students with disabilities.

<u>D.</u> The instructional leader or designee shall at all times be on the premises of the school while the school is in operation.

<u>E. All staff on duty must know who is responsible for the administration of the school at any given time.</u>

8VAC20-671-310. Teachers and staffing.

<u>A. Each teacher shall meet the requirements of the [Board of Education's]</u> Licensure Regulations for School Personnel (8VAC20-22).

[<u>1. Schools where students are instructed by content or grade level endorsed teachers shall have available appropriately endorsed special education teachers to case manage IEPs and to provide disability specific technical assistance and instruction.</u>

2. Schools offering only self-contained classroom instruction shall have teachers endorsed in either special education general curriculum or special education adapted curriculum depending on the functioning levels of the students.]

<u>B. Staffing shall be in accordance with the Regulations</u> <u>Governing Special Education Programs for Children with</u> <u>Disabilities in Virginia (8VAC20-81) in the following</u> <u>settings:</u>

1. A student with an Individualized Education Program (IEP) may be instructed with students without disabilities. as appropriate, and in accordance with the IEP.

2. A student with an IEP may receive services with children with the same disability or with children with different disabilities.

<u>C. Teacher personnel assignments shall be in accordance</u> with Regulations Governing Special Education Programs for Children with Disabilities in Virginia (8VAC20-81).

1. General education qualified personnel who are knowledgeable about the students and their special education may implement special services in collaboration with special education personnel.

2. Special education services include those services provided directly to the student and those provided indirectly.

<u>D. Teacher caseloads shall be assigned in accordance with</u> <u>the Regulations Governing Special Education Programs for</u> <u>Children with Disabilities in Virginia (8VAC20-81).</u>

1. If children with disabilities in a single building receive academic content area instruction from multiple special education teachers, the teachers' caseloads shall be determined by using a building average.

2. When special education personnel are assigned to provide services for students who do not have a disability under this chapter or are assigned to administrative duties, there shall be a reduction in the caseload specified in proportion to the percentage of school time on such assignment.

3. Special education personnel may be assigned to serve children who are not eligible for special education and related services as long as they hold appropriate licenses and endorsements for such assignments.

<u>E. Staffing for early childhood special education shall be in accordance with the Regulations Governing Special Education Programs for Children with Disabilities in Virginia (8VAC20-81).</u>

1. Children of preschool ages (two to five, inclusive) who are eligible for special education may receive early childhood special education.

2. Students receiving early childhood special education may receive services together with other preschool-aged children with the same or with different disabilities.

F. A school may offer for consideration of approval an alternative staffing plan in accordance with the department's procedures. The department may grant approval for alternative staffing levels [and teaching assignments] upon request from private schools for students with disabilities seeking to implement innovative programs that are not consistent with the staffing levels outlined in the Regulations Governing Special Education Programs for Children with Disabilities in Virginia (8VAC20-81).

8VAC20-671-320. Substitute teachers.

<u>A. No substitute teacher shall be used to fill a vacant</u> teaching position for more than 90 teaching days in such vacancy during one school year.

<u>B. Substitute teachers shall be at least 18 years of age, hold a</u> high school diploma or a [general educational diploma General Educational Development] (GED) [certificate], have two years of full-time postsecondary education or two years of [successful] work experience with children [with disabilities or equivalent, and attend orientation to the school's policies and procedures].

[<u>C. A substitute teacher employed to fill a teacher vacancy shall receive orientation to the school's policies and procedures.</u>]

8VAC20-671-330. Support staff.

<u>A. School support personnel, including contractual service</u> providers, shall meet the Board of Education's Licensure Regulations for School Personnel (8VAC20-22) or the requirements of another state or national accrediting agency.

B. Paraprofessionals and other ancillary staff shall be at least 18 years of age (21 years of age preferred), [at a minimum] hold a high school diploma or [a general educational diploma General Educational Development] (GED) [certificate], have two years of [full time successful] work experience with children or completed two years of coursework in a related field, [complete orientation conducted by the school administrator or designee regarding school policies and procedures and characteristics of students served, and work under the supervision of qualified staff or upon employment complete within 60 calendar days of hire training specific to the assigned student population and job duties as they relate to the academic and behavioral progress of students. Such training shall include individualized instruction and student behavior management, including

principles and strategies to reduce interfering behavior, build positive skills, and enhance communication of students with autism spectrum disorders].

<u>C. No support staff shall be used as replacement for teachers</u> or related service staff unless they meet the qualifications of the position.

<u>D.</u> Support staff who do not meet licensure or certification requirements shall not be given misleading work titles or titles that infer [that] they meet required credentials.

[<u>E. Paraprofessionals shall work under the supervision of qualified professional staff.</u>]

8VAC20-671-340. Staff supervision.

The licensee shall develop and implement written policies and procedures regarding the supervision of employees [, full-time and part-time,] and all other [individuals working with children, including volunteers and interns staff including volunteers and student interns working in the school building or on school grounds].

8VAC20-671-350. Staff development.

A. Within seven calendar days following [their staff's] begin date, each staff member responsible for working with students shall receive orientation of the school's philosophy, goals and objectives; duties and responsibilities of their position; and the school's policy and procedures for behavior intervention.

B. Within 14 calendar days following [their staff's] begin date [and before an individual is alone supervising students], all staff shall receive emergency preparedness and response training that shall include: alerting emergency personnel and sounding alarms; implementing evacuation procedures with particular attention to students with special needs; using, maintaining, and operating emergency equipment; accessing emergency information for students including medical information; and utilizing community support services.

C. Within 14 calendar days following [their staff's] begin date, [all] staff shall receive professional development on confidentiality; the school's administrative decision-making plan; and policies and procedures [, including prohibited actions,] that are applicable to their positions, duties, and responsibilities.

<u>D. Within 30 calendar days following [their staff's] begin</u> <u>date, [all] staff shall receive training on the school's policy</u> and procedures, including standard precautions, child abuse and neglect, [and] mandatory reporting [, maintaining appropriate professional relationships and interactions among staff and students, and suicide prevention].

[<u>E. Within 30 calendar days following their begin date, all</u> <u>staff responsible for medication administration shall have</u> <u>successfully completed an approved medication training</u> <u>program approved by the Board of Nursing or be licensed by</u> <u>the Commonwealth of Virginia to administer medications.</u> <u>Staff shall meet this requirement before administering any</u> <u>medication to students and shall receive annual retraining.</u> <u>F. E.</u>] <u>All staff shall receive annual professional</u> development and refresher [in on the school's policies and procedures on standard precautions;] emergency preparedness and response to include alerting emergency personnel and sounding alarms; implementing evacuation procedures with particular attention to students with special needs; [and] using, maintaining, and operating emergency equipment [: and accessing emergency information for students and staff including medical information and utilizing community supports].

[G. F.] All staff shall receive annual professional development and refresher on behavior supports, child abuse and neglect, [and] mandatory reporting [, maintaining appropriate professional relationships and interactions among staff and students, and suicide prevention].

[<u>H. Each full time staff person shall complete an additional</u> <u>15 hours of annual training applicable to his job duties</u> G. Each staff who works directly with students shall annually receive 15 hours of professional development related to <u>student progress and academic achievement that is applicable</u> to the population served and to their job duties].

8VAC20-671-360. Personnel records.

A. Separate up-to-date personnel records shall be maintained for each full-time and part-time employee, student intern, and volunteer for whom background investigations are required by Virginia statute. Content of personnel records of volunteers, student interns, and contractual service providers shall include, at a minimum, documentation of compliance with requirements of Virginia laws regarding child protective services and criminal history background investigations.

<u>B.</u> [<u>A record Records</u>] shall be maintained for each staff to include:

<u>1. A completed employment application or other</u> documentation providing the individual's name, address, and telephone number;

<u>2. Documentation of qualifications [, including</u> <u>educational background and professional licensure or</u> <u>certification</u>]:

3. Employment history;

4. Written references or notations of oral references;

5. Reports of required [health examinations tuberculosis certificate]:

6. Annual performance evaluations;

7. Date of employment for each position held and date of separation;

8. Documentation of compliance with requirements of Virginia laws regarding child protective services and criminal history background investigations;

<u>9.</u> [<u>Documentation of</u> Driving record verification from the] <u>Department of Motor Vehicles</u> [<u>checks</u>] and a current copy of the driver's license for [<u>all</u>] <u>staff</u> who transport students;

10. Documentation of all training required by this chapter and any other training or professional development received by individual staff; and

11. A current job description.

<u>C. All personnel records shall be maintained confidentially</u> and retained in their entirety for a minimum of three years after staff's separation from the school.

8VAC20-671-370. School facilities and safety.

<u>A. Each school shall be maintained in [a manner ensuring</u>] compliance with the Virginia Uniform Statewide Building Code (13VAC5-63). [Each school shall

<u>**1.** Maintain</u> B. Each school shall maintain] a physical plant that is accessible, barrier free, safe, and clean [$\frac{1}{2}$]

[<u>2. Provide 50 net square feet per occupant space for elassrooms and suitable</u> C. Each school shall provide safe and adequate instructional areas,] space for administrative staff, pupil personnel services, library and media services, and physical education [with consideration given to safety:. Schools established after the effective date of these regulations and classrooms added to existing buildings shall provide at least 50 square feet of classroom or instructional area per student excluding classroom fixtures.]

[<u>3. Provide</u> D. Each school shall provide] adequate, safe, and properly equipped classrooms [and instructional areas, and where appropriate], laboratories, play areas, and dining areas that meet the needs of students and instruction [; and.]

[<u>4. Provide</u> E. Each school shall provide] space for safe storage of items such as first aid equipment, medication, household supplies, school supplies, and equipment.

[B. F.] After the initial application, the school shall document annually that buildings and equipment are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51) and maintain records of regular safety, health, and fire inspections conducted and certified by local health and fire departments.

[<u>C.</u> G.] <u>Building plans and specifications for new construction, change in use of existing buildings, and any structural modifications or additions to existing buildings shall be submitted in advance to the [licensing agency department] for approval.</u>

[D. H.] <u>Animals allowed on the premises shall be tested</u>, inoculated, and licensed as required by law.

[<u>E. Smoking shall be prohibited at all times and in all</u> school buildings, on all school grounds, and during off campus school sponsored activities.

 $\underline{F. I.}$] Swimming pools shall be inspected annually by the state or local health authorities or by a swimming pool business.

[<u>G. J.</u>] <u>There shall be a written policy concerning</u> [<u>the</u> provision of] <u>safeguards for</u> [<u>aquatic related activities to</u> <u>include supervision by a certified lifeguard water-related</u>

activities and a provision that a certified lifeguard supervises all swimming activities].

[<u>H. K.</u>] <u>There shall be a written policy regarding</u> <u>safeguards</u> for school-sponsored activities including <u>adventure and wilderness activities.</u>

[<u>H. L.</u>] <u>There shall be</u> [<u>an electronic two way a</u>] <u>communication system available to staff at all times in the classroom and during school-sponsored activities.</u>

[<u>M. Schools shall have safeguards to be able to identify any visitor in the school building and on the premises during the school day.</u>]

8VAC20-671-380. Contingency plans.

<u>A. A school shall have contingency plans for [medical]</u> <u>emergencies that include staff certification in</u> <u>cardiopulmonary resuscitation (CPR), [abdominal thrust</u> <u>(Heimlich maneuver), and</u>] <u>emergency first aid [, and</u> <u>medication administration].</u>

<u>B. The school administration shall ensure that the school has:</u>

1. Written procedures to follow in emergencies such as fire, injury, illness, and violent or threatening behavior. Contingency plans should be developed with the assistance of state or local public safety authorities. Such plans shall be outlined in the student handbook and [discussed reviewed] with staff and students during the first week of each school year;

2. Space for the proper care of students who become ill; and

<u>3. A written procedure for responding to violent,</u> <u>disruptive, or illegal activities by students on school</u> <u>property or during a school-sponsored activity.</u>

<u>C. Each school shall [annually] have at least [three one]</u> tornado [drills every school year in order that students may be practiced in such drills drill, at least one earthquake drill, and at least two lockdown drills, one in September and one in January].

<u>D. The school shall have a written emergency preparedness</u> and response plan for all locations that addresses:

1. Documentation of contact with the local emergency coordinator to determine (i) local disaster risks, (ii) communitywide plans to address different disasters and emergency situations, and (iii) assistance, if any, that the local emergency management office will provide to the school in an emergency.

2. Analysis of the school's capabilities and potential hazards, including natural disasters, severe weather, fire, flooding, workplace violence [. intruder, hostage situation,] or terrorism, missing persons, riot, severe injuries, or other emergencies that would disrupt the normal course of service delivery.

3. Written emergency management policies outlining specific responsibilities for provision of administrative

direction and management of response activities; coordination of logistics during the emergency; communications; life safety of students, employees, contractors, student interns, volunteers, and visitors; property protection; community outreach; and recovery and restoration.

4. Written emergency response procedures for assessing the situation; protecting students, employees, contractors, student interns, volunteers, and visitors; [protecting] equipment and education records; and restoring services.

5. Emergency procedures, which shall address:

<u>a.</u> Communicating with employees, contractors, [volunteers, student interns,] and community responders;

b. Warning and notification of students;

c. Providing emergency access to secure areas and opening locked doors;

d. Conducting evacuations to emergency shelters or alternative sites and accounting for all students;

e. Relocating students and staff, if necessary;

f. Notifying family members and legal guardians;

g. Alerting emergency personnel and sounding alarms; and

h. Locating and shutting off utilities when necessary.

6. Supporting documents that would be needed in an emergency, including emergency call lists, building and site maps necessary to shut off utilities, designated escape routes, and list of major resources such as local emergency shelters.

7. Schedule for testing the implementation of the plan and conducting emergency preparedness drills.

8. Children who use wheelchairs, crutches, canes, or other mechanical devices for assistance in walking shall be provided with a planned, personalized means of effective egress for use in emergencies.

<u>E.</u> The school shall have emergency preparedness and response training for all employees, contractors, student interns, and volunteers that shall include responsibilities for:

1. Alerting emergency personnel and sounding alarms;

2. Implementing evacuation procedures [,] including evacuation of students with special needs (i.e., deaf, blind, nonambulatory);

<u>3. Using, maintaining, and operating emergency equipment:</u>

4. Accessing emergency information for students including medical information; and

5. Utilizing community support services.

<u>F. There shall be documented review of the emergency</u> preparedness plan annually and revisions made if necessary.

<u>G. Employees, contractors, student interns, and volunteers</u> shall be prepared to implement the emergency preparedness plan in the event of an emergency.

<u>H.</u> Floor plans showing primary and secondary means of egress shall be posted on each floor in locations where they can easily be seen by staff and students.

<u>I.</u> The procedures and responsibilities reflected in the emergency procedures shall be communicated to all students within seven days following admission or a substantive change in the procedures.

J. At least one [emergency] evacuation drill [(the simulation of the school's emergency procedures)] shall be conducted [each week during the first month of school and one each month thereafter] in each building occupied by students [at least once per week for the first 20 school days and then once a month for the rest of the school year and more often if necessary].

K. Evacuation drills shall include, at a minimum:

1. Sounding of emergency alarms;

2. Practice in evacuating buildings and buses or vans;

3. Practice in alerting emergency authorities;

4. Simulated use of emergency equipment; and

5. Practice in securing student emergency information.

L. A record shall be maintained for each evacuation drill and shall include the following:

<u>1. Buildings and buses or vans in which the drill was conducted:</u>

2. Date and time of drill;

3. Amount of time to evacuate the buildings;

4. Specific problems encountered;

5. Staff tasks completed including head count and practice in notifying emergency authorities; and

<u>6. The name of the staff members responsible for conducting and documenting the drill and preparing the record.</u>

<u>M. The record for each evacuation drill shall be retained for three years after the drill.</u>

<u>N. At least one staff member shall be assigned the</u> responsibility for ensuring that all requirements regarding the emergency preparedness and response plan and the evacuation drill program are met.

O. In the event of a disaster, fire, emergency, or any other condition that may jeopardize the health, safety, and welfare of students, the school shall notify the parent(s), the student's public school, placing agency, and [licensing agency department] as soon as possible, but no later than 24 hours after the incident occurs.

8VAC20-671-390. Weapons.

<u>The licensee shall develop written policies and procedures</u> governing prohibition of [the possession and use of firearms,

pellet guns, air guns, and other weapons on the school's premises and during school related activities unless the weapons are in the possession of licensed security personnel or law enforcement officers weapons on school property mandated in § 18.2-308.1 of the Code of Virginia. The staff and students shall be annually informed of the policies and procedures regarding the prohibition of weapons.]

8VAC20-671-400. [Strip searches Searches].

[A. Strip searches and body cavity searches are prohibited.

<u>B. A.</u>] <u>A school that does not conduct pat downs shall have a written policy prohibiting them.</u>

[<u>C. B.</u>] <u>A school that conducts pat downs shall develop and implement written policies and procedures that shall provide the following:</u>

1. Pat downs shall be limited to instances where they are necessary to prohibit contraband;

2. Pat downs shall be conducted by personnel of the same gender as the student being searched;

3. Pat downs shall be conducted only by personnel who are specifically authorized to conduct searches by the school's written policies and procedures; and

4. Pat downs shall be conducted in such a way as to protect the subject's dignity and in the presence of one or more witnesses.

8VAC20-671-410. Student application and admission.

A. The school's written admission policy shall include:

1. A description of the population to be served;

2. A description of the types of services offered;

3. Admission procedures;

4. Exclusion criteria that identify behaviors or conditions the school will not accept; and

5. A description of how educational services will be delivered.

<u>B.</u> [<u>A summary of each The</u>] <u>school's admissions policy,</u> <u>course offerings</u> [<u>at each grade level</u>], and behavioral <u>management program shall be made available to students,</u> <u>parents, and placing and licensing agencies.</u>

<u>C. Each school's admissions process shall be designed to</u> determine the suitability of enrolling a student. The school shall accept and serve only those students whose needs are compatible with the services provided by the school.

D. [The school shall provide written notification for a student's education records within five business days of the student's enrollment. Notification shall be made to the superintendent of the school division where the student last attended. The school shall request current information pertinent to the student's educational growth to include, but not limited to, the IEP, 504 Plan, or career development plan; plan of study; assessments; grades or transcript; discipline records; and health records Upon enrollment and at least annually, the school shall provide parents access to, or a copy

of upon request, the school's policies and procedures, including those governing the management of student behavior, the school's curriculum, and the school's promotion and retention policies].

E. [When the student's education records are not provided during the application process, the school with written parental consent shall make a request within five business days of enrollment to the student's last attended school or the division superintendent or designee.

<u>F.</u>] <u>An application for admission is not to be construed as a binding instrument on the part of the student or the school.</u>

[\underline{F} , \underline{G} .] A school may require the payment of a reasonable nonrefundable initial application fee to cover expenses in connection with processing a student's application provided [\underline{it} the school] retains a signed statement in which the parties acknowledge their understanding that the fee is nonrefundable. No other nonrefundable fees shall be allowed prior to enrollment.

[<u>G. H.</u>] <u>Any contract or enrollment agreement used by the school shall be in writing and clearly specify the following:</u>

1. Complete name and physical address of the school;

2. Itemized cost of the program to include tuition, [scholarships, and] all other charges [, and any scholarship amount applied to the cost of tuition]; and

3. The school's contingency, cancellation, and refund policies.

[<u>H. I.</u>] Any contract or enrollment agreement used by the school becomes a legally binding instrument upon the school's written acceptance [of the student].

[<u>I. Each school that serves privately placed students shall</u> offer access to a tuition insurance plan if the school financially obligates students for more than quarterly increments of annual tuition.]

8VAC20-671-420. Standard school year and school day.

A. Each school shall have a standard school year of at least 180 [instructional teaching] days [or a total of at least 990 teaching hours per year]. The standard school day for students in grades 1 through 12 shall average at least [5-1/2 instructional five and one-half teaching] hours [990 hours annual instructional time) or average 27 and one-half hours weekly], excluding breaks for meals and recess, and a minimum of three [instructional] hours [daily] for kindergarten.

B. [<u>All students in grades 1 through 12 shall maintain a full</u> <u>day schedule of classes (5 1/2 hours) unless otherwise stated</u> <u>in the child's Individualized Education Program (IEP),</u> <u>Individualized Instruction Plan (IIP), 504 Plan, or other</u> <u>documentation.</u> The private school shall initiate a team meeting to review the child's IEP, 504 Plan, or IIP when a student has a medical, mental, or physical condition that requires modification of the student's school schedule.]

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<u>C. Each school shall have policies and procedures that</u> address make-up days when the school is unable to meet the required instructional time.

<u>8VAC20-671-430.</u> [<u>School and community</u> <u>communications</u> Community relationships].

[<u>A. Each school shall promote communications and foster</u> mutual understanding with parents and the community and use information from parents, citizens, business, and industry in evaluating the educational program.

<u>B. At the beginning of each school year, the school shall</u> provide to parents or guardians information on the availability of and source for receiving the curriculum for their child's core subjects and a copy of the school's promotion and retention policies and access to the school's policies and procedures.

Each school shall facilitate cooperative relationships with neighbors, the school system, local law enforcement, local government officials, and the community at large.]

8VAC20-671-440. Philosophy, goals, and objectives.

<u>A. Each school shall have a current philosophy, goals, and objectives that serve as the basis for all policies and practices and shall be developed using the following criteria:</u>

1. The philosophy, goals, and objectives shall be developed with the advice of professional and lay people who represent the various populations served by the school and in consideration of the needs of the community and [shall] serve as a basis for an annual self-evaluation of the school.

2. [<u>The goals</u> Goals] and objectives shall [<u>(i)</u>] be written in plain language so as to be understandable to noneducators, including parents [<u>; (ii) to the extent</u> possible, be stated in measurable terms; and (iii) consist primarily of measurable objectives to raise student and school achievement in the core academic areas, to increase graduation rates, and to increase the quality of instruction through professional staff development and licensure].

<u>B. Copies of the school's philosophy, goals, and objectives</u> shall be available upon request.

8VAC20-671-450. Student achievement expectations.

<u>A.</u> [<u>A. process to identify and recommend</u> Schools shall <u>develop</u>] strategies to address the learning, behavior, [and] communication [<u>, or development of needs of</u>] individual students [who are having difficulty in the educational setting <u>shall be developed at each school</u> in collaboration with the parent].

B. Participation in the Virginia assessment program by students with disabilities shall be prescribed by provisions of their IEPs or 504 Plans. [All students with disabilities shall be assessed with appropriate accommodations and alternate assessments when required.]

<u>C. Each school that serves students who anticipate earning a diploma and graduating from a [public] Virginia high school</u>

must follow the requirements for graduation outlined in the Regulations Establishing Standards for Accrediting Public Schools in Virginia (8VAC20-131).

D. The school shall cooperate with the public school in the administration of SOL tests [to students with disabilities and students who need verified credits to graduate from a public high school in Virginia, and the administration of any other SOL tests].

<u>E.</u> The school shall use testing and evaluation materials that are not racially or culturally discriminatory and do take into consideration the student's disabling condition(s), racial background, and cultural background.

[<u>8VAC20-671-460.</u> 8VAC20-671-490.] <u>Program of instruction and learning objectives.</u>

A. Each school's instructional program shall reflect the written philosophy of the school. The methods, procedures, and practices shall reflect an understanding of and meet the applicable academic, vocational, therapeutic, recreational, and socialization needs of the students served.

B. The instructional program shall be designed to meet the needs of all students enrolled and shall educate students with age-appropriate peers [unless it can be shown that for a particular child with a disability, the alternative placement is appropriate and documented on the student's IEP, IIP, or 504 Plan].

<u>C. Services shall be delivered in accordance with the student's IEP, IIP, or 504 Plan.</u>

[<u>D. Children of preschool ages (two years to five years, inclusive) shall receive services determined by the child's IEP, IIP, or 504 Plan.</u>]

[<u>D. Each school serving students</u> E. Students] <u>14 years of age and older shall</u> [<u>provide be provided</u>] <u>opportunities</u> [for students] to gain knowledge and occupational readiness skills necessary for successful transition to [postsecondary education,] training, employment, and independent living, as appropriate.

[<u>E. Each school shall provide opportunities for students to</u> <u>gain knowledge and occupational readiness skills necessary</u> <u>for successful transition to postsecondary training, education,</u> <u>employment and independent living skills, as appropriate.</u>]

F. Each school shall provide a program of instruction that [supports the SOL clearly articulates learning outcomes] for the core subjects: English, mathematics, science, and history/social science. [Schools may use Virginia's Standards of Learning (SOL).]

<u>G. Each school shall require students to participate in a program of health and physical fitness during the regular school year unless the student is unable to participate due to a medical condition [or has met the credit requirement for graduation].</u>

<u>H. Each school shall provide students with opportunities to gain appreciation for art and music.</u>

<u>I. Each school shall provide an instructional program that</u> promotes the individual student's developmental growth and academic achievement at successive grade levels, as appropriate.

[J. The services provided by a private school shall be provided by personnel meeting the same licensure requirements as personnel providing services in the public school, outlined in Licensure Regulations for School Personnel (8VAC20-22).

<u>K. J.</u>] The school shall equitably serve the needs and interests of all students, taking into consideration age appropriateness, cultural norms, physical abilities, and cognitive abilities.

[<u>K. Each school shall implement evidence-based practices</u> to improve academic, behavior, and social outcomes for all <u>students.</u>]

[<u>8VAC20-671-470.</u> 8VAC20-671-460.] <u>Individualized</u> Education Program (IEP).

<u>A.</u> [When a child is presently receiving the services of a private school, a A] representative of the private school shall attend IEP meetings upon the request of the student's school division. If a representative is not able to attend, the school shall use other methods to ensure participation [by the private school] including individual or conference telephone calls.

B. [<u>After a child with a disability enters a private school,</u> <u>any Any</u>] meetings to review and revise the child's IEP may be initiated and conducted by the private school at the discretion of the student's school division.

<u>C. If the private school initiates and conducts these</u> meetings, the student's school division and the parent(s) shall:

1. Be involved in any decision affecting the child's IEP;

2. Agree to any proposed changes in the program before those changes are implemented; and

3. Be involved in any meetings that are held regarding reevaluation.

<u>D. A</u> [<u>parent(s)</u> parent] <u>does not include local or state</u> agencies or their agents, including local departments of social services, if the child is in the custody of such an agency.

<u>E.</u> When a child with a disability is placed by a local school division or [<u>a Comprehensive Services Act team family</u> assessment and planning team] in a private school, all rights and protections under state and federal regulations shall be extended to the child.

[<u>8VAC20-671-480.</u> 8VAC20-671-470.] Individualized Instruction Program (IIP).

<u>A. Students [without disabilities not determined eligible for</u> special education] and those placed by parents [for educational reasons] shall have an Individualized Instruction Program (IIP) developed within 30 [business] days of [admission enrollment] that describes strengths and needs of the student, current level of functioning, goals and objectives, [<u>timelines</u>,] <u>course of study</u>, and postsecondary goals for students 14 years of age and older.

B. Each school shall request with [written] consent of the [$\frac{\text{parent(s)}}{\text{parent}}$ parent] the student's education records from the last school attended [$\frac{1}{5}$] and information from other agencies as appropriate. This information should be used in developing the student's IIP.

<u>C. The IIP shall provide a beginning and ending date of services.</u>

D. The IIP shall be reviewed at least annually by a team that includes the [school administrator or teacher, other staff as appropriate, parent, and] student [and the parent as appropriate].

E. Student progress reports shall be provided to the parent [<u>or guardian</u>] at least quarterly.

[<u>8VAC20-671-490.</u> 8VAC20-671-480.] <u>504 Plans.</u>

Each school admitting students with 504 Plans shall implement the plan and cooperate with the school division in its annual review. [An individualized instruction plan (IIP) shall be developed for each student with a 504 plan.]

8VAC20-671-500. Instructional program for elementary school grades.

[<u>A. The elementary school grades shall provide each student a program of instruction that supports the SOL for English, mathematics, science, and history/social science. In addition, each school shall provide opportunities for students to gain an appreciation for art and music. Students shall be required to participate in a program of health and physical fitness during the regular school year.</u>

In addition to the applicable requirements under 8VAC20-671-490, the following shall apply:]

[<u>B. 1.</u>] <u>In kindergarten through grade 3, reading, writing, spelling, and mathematics shall be the focus of the instructional program.</u>

[<u>C. 2.</u>] To provide students with sufficient opportunity to learn, a minimum of 75% of the annual instructional time of 990 hours shall be given to instruction in the disciplines of English, mathematics, science, and history/social science. Students who are not successfully progressing in early reading proficiency or who are unable to read with comprehension the materials used for instruction shall receive additional [instructional time instruction] in reading.

<u>8VAC20-671-510.</u> Instructional program for middle school grades.

[<u>A. The middle school grades shall provide each student a</u> program of instruction that supports the SOL for English, mathematics, science, and history/social science. Each school shall provide opportunities for appreciation of art and music and an introduction to career and technical exploration and require students to participate in a program of health and physical fitness during the regular school year.

<u>B. English, mathematics, science, and history/social science</u> <u>shall be required.</u>

In addition to the applicable requirements under 8VAC20-671-490, the following shall apply:]

[<u>C. 1.</u>] To provide students a sufficient opportunity to learn, each student shall be provided 140 clock hours per year of instruction in each of the four disciplines of English, mathematics, science, and history/social science.

 $[\frac{D}{2}, 2, 2]$ <u>Each school shall ensure that students who are unable to read with comprehension the materials used for instruction receive additional instruction in reading.</u>

[<u>3. Each school shall provide students with opportunities</u> <u>for career and technical exploration.</u>]

<u>8VAC20-671-520.</u> Instructional program for secondary school grades.

[<u>A. The secondary school grades shall provide each student</u> <u>a program of instruction that supports the SOL in English,</u> <u>mathematics, science, and history/social science.</u>

In addition to the applicable requirements under 8VAC20-671-490, the following shall apply:]

[<u>B.</u>1.] To provide students a sufficient opportunity to learn, each student shall be provided 140 clock hours per year of instruction in each of the four disciplines [, English, mathematics, science, and history/social science].

[<u>C. Students in secondary education programs who plan to</u> <u>graduate with a standard or advanced diploma from a</u> <u>Virginia public high school should have the opportunity to</u> <u>complete credits in foreign languages, fine arts, and career</u> <u>and technical training.</u>

2. Each school shall provide a course of study that leads to graduation and postsecondary education, training, employment, and independent living, as appropriate.

<u>3. Each school shall provide instruction in economics and personal finance and occupational readiness.</u>

4. A curriculum that includes functional living skills training, including community-based instruction, shall be available for students as the need is determined by the IEP or IIP.]

[<u>D. 5.</u>] <u>Classroom driver education may count for 36 class</u> periods of health education. Students shall not be removed from classes other than health and physical education for the in-car phase of driver education.

 $[\underline{E. 6.}]$ Each school shall ensure that students who are unable to read with comprehension the materials used for instruction receive additional instruction in reading $[\underline{r.}]$

[<u>F. Guidance and counseling shall be provided for students</u> to ensure that a program of studies contributing to the student's academic achievement and meeting graduation requirements is being followed.

7. Staff shall provide guidance and counseling to assist students in meeting graduation requirements.]

8VAC20-671-530. Alternative education.

Schools may provide students, 16 years of age to 18 years of age [who choose to prepare for the Tests of General Educational Development (GED) certificate], an Individualized Student Alternative Education Plan (ISAEP) [<u>-a</u>] program [that includes career guidance counseling; mandatory enrollment in a GED preparation program; and career and technical education]. Implementation of the ISAEP [program] requires submission of an application and approval by the [Department of Education department].

8VAC20-671-540. Transition services.

A. Schools shall cooperate with the public schools to ensure that the transition plan for each student with a disability, beginning at 14 years of age (or younger), is implemented according to the child's IEP.

B. Schools shall provide evidence of transition services designed within an outcome-oriented process for all students, as appropriate, that promotes movement from the private school to a public school the child would normally attend; movement from school to post-school activities, including postsecondary education, vocational training, integrated employment (including supported employment), continuing and adult education, adult services, independent living, or community participation.

8VAC20-671-550. Extracurricular and other school activities, and recess.

A. School-sponsored extracurricular activities shall be under [<u>the</u>] direct supervision of [<u>the</u>] staff and [<u>shall-contribute</u> to the educational objectives of the school. Extracurricular <u>activities must be</u>] organized to avoid interrupting the instructional program.

<u>B.</u> [<u>School sponsored extracurricular CPR and first aid</u> certified staff shall accompany students on school-sponsored] activities [<u>shall have at least one person certified in CPR for</u> <u>every 10 students</u>].

<u>C. Schools that take students on [outdoor] adventure</u> activities [and offer programs such as canoeing, skiing, camping, and rock climbing] shall develop policies and procedures to ensure supervision, health and safety, and medical management.

8VAC20-671-560. Family life.

A. Schools may use the Standards of Learning for the family life education program or other education program, [which shall have the goals that is designed to promote parental involvement, foster positive self concepts, and provide mechanisms for coping with peer pressure and the stresses of modern living according to the student's developmental stage and has the goal] of reducing the incidence of pregnancy and sexually transmitted diseases and substance abuse.

<u>B. Schools offering family life shall obtain written consent</u> from the parent [<u>or guardian</u>] for the child's [<u>enrollment in</u> <u>the course</u> participation].

<u>8VAC20-671-570.</u> Student work-study or on-the-job training.

<u>A. Each school that places students on work-study, on-the-job training, or any other form of employment shall ensure compliance with the applicable laws governing the employment of children.</u>

[<u>B. Work assignments that are paid or unpaid shall be in</u> <u>accordance with the age, health, ability, and education</u> <u>program of the student.</u>]

[<u>C.</u> B.] Work assignments or employment [<u>outside the</u> <u>school</u>], including [<u>reasonable</u>] <u>rates of pay, shall be</u> approved by the school administrator with the [<u>knowledge</u> <u>and</u>] <u>consent of the parent [or legal guardian].</u>

8VAC20-671-580. Virtual learning.

A. [Schools are encouraged to pursue alternative means to deliver instruction to accommodate student needs through virtual learning. A school shall ensure that each virtual education course is provided by an institution accredited by a nationally recognized accrediting body or is authorized by a public school or school division. Virtual courses may only be offered through accredited providers as outlined in §§ 22.1-212.23 and 22.1-253.13:3 of the Code of Virginia.]

<u>B.</u> [<u>A school shall ensure that virtual learning courses meet</u> the following requirements:

1. The content, instruction, and assessment of each course is comparable in rigor and breadth to the course that is traditionally delivered;

2. The course content is appropriate for the school's grade levels and age range; and

<u>3. The virtual learning shall be supervised by a licensed</u> teacher or a person eligible to hold a Virginia teaching license. The individual shall be available to the student.

The virtual learning shall be proctored by a licensed teacher or appropriately trained paraprofessional who is supervised by a licensed teacher. The teacher or paraprofessional shall be available to the student.]

<u>8VAC20-671-590. Equipment, instructional materials, and library media.</u>

A. Each school shall provide [<u>a variety of current grade</u> <u>level</u> instructional] <u>materials and equipment</u> [<u>necessary</u>] to <u>support the instructional program, including</u> [<u>functional life</u> <u>skills programs</u> the goals and objectives established for <u>individual students</u>].

B. [Each school shall provide access to computers and library media necessary to meet research inquiry and reading requirements of the instructional program and general student interest. Students shall receive instruction on the use of classroom equipment as appropriate and demonstrate applicable safety competencies before being allowed to use such equipment.] [<u>C. Each student, as appropriate, shall be provided</u> <u>instruction on the use of instructional equipment and shall</u> <u>demonstrate understanding before access to laboratories.</u>

<u>D. Each school shall provide textbooks and instructional</u> materials that support Virginia's Standards of Learning.

<u>E. C.</u>] Each school shall establish written policy on the use of computers, including the use of the Internet and email.

8VAC20-671-600. School records.

Each school shall maintain up-to-date records to include [a listing of all enrolled students with directory information,] the school's academic calendar, class roster, class schedule, course descriptions, course curriculum, individual student schedules, student progress reports, and [student transcript or other] documentation of [each student's] grades [and credits earned].

8VAC20-671-610. Diplomas.

A. No school shall use the seal of Virginia in its diploma design.

<u>B. Each school that offers a diploma upon graduation shall</u> <u>have written</u> [<u>policy</u> policies] and procedures that address the following:

1. The requirements for a diploma shall be those in effect when the student enters the ninth grade for the first time.

<u>2. The requirements for a diploma shall be based upon</u> <u>completion of program requirements that demonstrate</u> <u>academic rigor.</u>

8VAC20-671-620. Student conduct.

[<u>A. Each school shall provide a schoolwide environment</u> that reinforces appropriate behaviors and assists students in becoming actively engaged in their own learning, academic, and behavioral success.]

[A. B.] Each school shall have written policies and procedures that address standards of student conduct and procedures for enforcement to include attendance, truancy, suspension, expulsion, alcohol, drugs, weapons, fighting, bullying, sexual and disability harassment, pornography, and other areas as appropriate.

[<u>B.</u><u>When a student is suspended, including in school</u> suspension, or expelled, the school shall notify the student's home school division within 24 hours. C. The parent shall be notified on the date on which the decision is made to suspend or expel a student because of a violation of a code of student conduct. When a publicly placed student is suspended or expelled, the student's home school division shall be notified within 24 hours.]

8VAC20-671-630. Behavior intervention.

<u>A. Each school shall develop and implement written policies</u> and procedures that emphasize positive behavior interventions [that focus on teaching and supporting students to practice methods to manage their own behavior]. B. Behavior techniques that are used or available for use shall be listed in the order of their relative degree of restrictiveness and specify the staff members who may authorize the use of each technique.

<u>C. Staff shall consider behavior management data in their annual review of the school's policies and procedures.</u>

D. When substantive revisions are made to policies and procedures governing management of student behavior, written information concerning the revisions shall be provided to students, parents, placing agencies, and the [licensing agency department] prior to implementation.

[<u>E.</u> The parent shall be provided access to the school's behavior management policy and procedures upon enrollment and at the beginning of each school year, and provided a written copy upon request.]

8VAC20-671-640. Time-out.

[<u>A. The school shall have written policy and procedures</u> <u>governing the conditions under which a student may use</u> <u>time out and the maximum period of time out not to exceed</u> <u>30 minutes per episode. The conditions and maximum period</u> <u>of time out shall be based on the student's chronological and</u> <u>developmental level. The school's policy and procedures shall</u> <u>include provisions that address the following:</u> Policies and procedures shall be written that govern the conditions under which a student may self-select or be placed in time-out and the maximum length of time a student may be in time-out. The conditions for time-out and length of time a student may be in time-out shall be based on the student's chronological and developmental levels. The school's policy and procedures <u>shall include:</u>]

<u>1. Each student is entitled to be completely free from any unnecessary use of time-out.</u>

2. [<u>The areas in which a student is placed A door to a</u> time-out room] shall not be locked nor [<u>the door</u>] secured in a manner that prevents the student from opening it.

3. A student in time-out shall be able to communicate with staff.

4. Staff shall check on the student [in the time out area] at least every 15 minutes and more often depending on the nature of the student's disability, condition, [and or] behavior.

5. [Procedures shall be implemented for documenting the The] use of time-out and staff checks on the student [shall be documented].

<u>6. Staff shall review procedures when a student</u> consistently chooses to stay in time-out beyond the determined time limit to determine that it has not become reinforcement.

8VAC20-671-650. Prohibitions.

[<u>A.</u>] <u>The following actions are prohibited:</u>

<u>1. Restraint and seclusion, except when it is necessary to</u> protect the student or others from personal harm, injury, or death and other less restrictive interventions were unsuccessful;

2. Prone "face down" restraints, mechanical restraints, [and] pharmacological restraints [, and any other restraint that restricts breathing or harms the child or interferes with the child's ability to communicate]:

3. Deprivation of drinking water or food;

<u>4. Limitation on contacts and visits [with from] the</u> <u>student's probation officer, [regulators, or social worker,]</u> <u>placing agency representative</u> [, or other service provider <u>as appropriate</u>];

5. Any action that is humiliating, degrading, or abusive;

6. Corporal punishment;

7. Deprivation of approved prescription medication or other necessary services [and treatment];

8. Denial of access to toilet facilities;

9. Application of aversive stimuli;

10. Strip and body cavity searches; and

<u>11.</u> Discipline, restraint, or implementation of behavior management plans by other students.

<u>8VAC20-671-660. Managing student behavior in</u> <u>emergency situations.</u>

[<u>A. Application of a formal behavior management program</u> designed to reduce or eliminate severely maladaptive, violent, or self injurious behavior contingent upon the exhibition of such behaviors is allowed only as part of an individually approved time specific plan that is consistent with sound therapeutic practice. Written consent of the student, parent or guardian, and the student's school division is required.

<u>**B**.</u> <u>A</u>.] <u>Each school shall have written policies and procedures [made available annually to students, parents, and placing agencies] that include, but are not limited to:</u>

<u>1. Methods for preventing student violence, self-injurious</u> behavior, and suicide, including de-escalation of potentially dangerous behavior occurring among groups of students or with an individual student.

<u>2. A [policy stating statement] that corporal punishment</u> and abusive techniques and interventions are not authorized, permitted, or condoned.

[<u>C. Each school shall develop and implement 3. A</u> statement that] behavior management techniques [are applied] in order of their [relative] degree of intrusiveness or restrictiveness and the conditions under which they may be used by trained [school] personnel.

[<u>D. While the use of restraint and seclusion is prohibited, a</u> school that finds it absolutely necessary can only do so under the following conditions:

<u>1.</u> B.] Physical restraint or seclusion is allowed only in an emergency situation [for a time period that and only when it] is necessary to [contain the behavior of the student so that the student no longer presents an immediate threat of causing

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physical injury to self or others or causing severe property damage protect the student or another person from imminent danger of serious physical harm after less intrusive interventions have been attempted and failed to manage that particular behavior and there is a substantial explanation for why other interventions were deemed inadequate or inappropriate].

[<u>1. The use of restraint or seclusion, particularly when</u> there is repeated use for an individual child, multiple uses within the same classroom, or multiple uses by the same individual, shall trigger a review and, if appropriate, a revision of behavioral strategies currently in place to address dangerous behavior. If positive behavioral strategies are not in place, staff shall develop them.

2. In cases where a student has a history of dangerous behavior for which restraint or seclusion was considered or used, a school shall have a plan developed in consultation with the parent for (i) teaching and supporting more appropriate behavior and (ii) determining positive methods to prevent behavioral escalations that have previously resulted in the use of restraint or seclusion.]

[<u>2.</u>3.] <u>Physical restraint or seclusion shall not be used</u> [<u>for disciplinary reasons</u>,] <u>as a punishment</u> [<u>, or</u>] retaliation, or for staff's convenience.

[<u>3. The school shall have written policies and procedures</u> governing use of physical restraint and seclusion incidents that shall include the following:

a. 4.] Each student is entitled to be completely free from any unnecessary use of physical restraint or seclusion. [Physical restraint and seclusion are allowed only in an emergency situation for a time period that is necessary to contain the behavior of the student so that the student no longer presents an immediate threat of causing physical injury to self or others or causing severe property damage.

<u>b. The school shall provide written notice of its behavior</u> <u>management program to students, parent(s), and placing</u> <u>agency at the time of the student's enrollment.</u>

<u>e. 5.</u>] <u>Staff shall</u> [<u>continuously</u>] <u>monitor the use of</u> [<u>physical</u>] <u>restraint and seclusion</u> [<u>through continuous</u> <u>face to face observation, not solely by and shall not rely</u> <u>on</u>] <u>an electronic surveillance device.</u>

[<u>d. Restraints</u> 6. Physical restraint] may only be implemented, monitored, [<u>and or</u>] discontinued by staff who have [<u>been trained in the proper and safe use of</u> restraint, including hands on techniques received proper training].

[e. Students must be supervised by staff members trained in behavior intervention.

f. Schools shall inform the parent and placing agency of each incident of physical restraint or seclusion on the day of the occurrence and make available to the licensing agency upon request. 7. The door to any room in which a student is secluded may be held shut only when a staff member is personally securing it. The door must immediately disengage when the staff member steps away from it. The room must meet specification including size and viewing panels that ensure the student's safety at all times including during a fire or other emergency.

8. Schools shall permit parents to inspect any area used during an emergency for the purpose of seclusion.

9. The parent shall be informed on the day of each incident of physical restraint or seclusion. The student's home school division and placing agency shall be informed as soon as possible but within 24 hours of the occurrence.]

[<u>e</u>. 10.] Each application of physical restraint or seclusion shall be fully documented in the student's record including date, time, staff involved, justification for the [physical] restraint or seclusion, [behavior antecedents,] less restrictive interventions that were unsuccessfully attempted prior to using physical restraint or seclusion, duration, description of method or methods of physical restraint techniques used, signature of the person completing the report and date, and reviewer's signature and date. [The written report shall be made available to the parent within two business days of the occurrence and opportunity given for the parent and student, as appropriate, to discuss the matter with school staff.

<u>11. Schools shall collect and annually report to the department the number of times restraint and seclusion</u> were used during the school year. The data shall be disaggregated by students and number of occurrences.]

8VAC20-671-670. Videotaping.

A. Schools shall have written policy and procedures regarding videotaping students while in school and any school-sponsored activity, including those used for staff training.

B. No student shall be videotaped without written consent of the parent and eligible student.

<u>C. Any videotaping of students shall be maintained</u> confidentially unless there is explicit written permission to release or disclose from the [parent(s) parent] and eligible student.

D. Buildings and grounds surveillance is not considered videotaping for the purpose of this chapter.

8VAC20-671-680. Referral for evaluation.

[A:] When a student [. including those placed by their parent(s) or from out of state.] is suspected of having a disability, the [private] school [shall may] make a referral to the division superintendent of the school division where the private school is located. Documentation of the referral notice shall be maintained in the student's record.

[B. The school shall cooperate with the school division on child find activities.]

8VAC20-671-690. Suspected child abuse and neglect.

<u>A. Written policies and procedures related to child abuse</u> and neglect shall comply with the requirements of § 63.2-1509 of the Code of Virginia and distributed to all staff members. Policies and procedures shall include:

1. Handling accusations against staff; and

2. [Promptly referring suspected cases Reporting immediately, but under no circumstance later than 24 hours after having a suspicion of a reportable offense] of child abuse and neglect to the [local] child protective services unit [of the local department of social services of the county or city wherein the abuse or neglect was believed to have occurred or to the Department of Social Services toll-free child abuse and neglect hotline and for cooperating with the unit during any investigation].

<u>B.</u> Any case of suspected child abuse or neglect occurring at the school or on a school-sponsored event or excursion shall be reported immediately to the student's parent [<u>. guardian, or</u> both if appropriate,] and the [placing and licensing agencies department]. For publically placed students, the home school division and the placing agency shall also be notified.

<u>C.</u> [<u>When a case of suspected</u> Suspected] <u>child abuse or</u> <u>neglect</u> [<u>is reported to child protective services</u>, <u>the school</u> <u>shall document</u>: <u>shall be immediately documented to include</u>] <u>the following</u>:

1. The date and time the suspected abuse or neglect occurred;

2. A description of the suspected abuse or neglect;

3. Action taken as a result of the suspected abuse or neglect;

4. The name of the person who made the report to child protective services; and

5. The name of the person to whom the report was made at the local child protective services unit.

[<u>D. Suspected child abuse shall be handled and reported as</u> <u>a serious incident.</u>]

8VAC20-671-700. Serious incident reports.

A. Any serious incident, accident, or injury to a student [$\frac{\Theta r}{\text{medication error}}$] that occurs at the school or a schoolsponsored activity shall be reported [to the parent] immediately, [but] no later than the end of the school day [$\frac{1}{2}$ to the parent, student's public school, placing agency, and licensing agency. A publically placed student's home school division and the placing agency shall be notified as soon as possible, but not later than 24 hours of the occurrence.]

B. The school shall document the following:

1. The date and time the incident occurred;

2. A brief description of the incident;

3. The action taken as a result of the incident;

4. The name of the person who completed the incident report; and

5. The date and name of the person who made the report to the proper authorities.

<u>C. The</u> [<u>licensing agency department</u>] <u>shall review</u> [<u>all</u>] <u>reports of serious incidents and investigate as appropriate</u> [<u>using the complaint resolution procedures of this chapter</u>].

8VAC20-671-710. Medication and health.

A. Each student shall have on file evidence of a comprehensive physical examination prescribed by the State Health Commissioner from a qualified licensed (i) physician, (ii) nurse practitioner, or (iii) physician assistant acting under the supervision of a licensed physician. The examination must contain, at a minimum, information required on the Commonwealth of Virginia School Entrance Health Form.

B. Each student shall have an up-to-date certificate of immunization [documenting the immunizations required by the Code of Virginia and State Board of Health's Regulations for the Immunization of School Children (12VAC5 110)].

<u>C. Any student or staff with a [disease or]</u> medical condition that is contagious or infectious shall [be excluded take leave] from school while in that condition unless attendance is approved by a qualified [bealthcare health care] provider. Conditions meeting this requirement must be provided in the parent/student handbook or other print materials.

D. A first aid kit shall be maintained and readily accessible for minor injuries and medical emergencies in each building used for instruction or other school activity.

E. All medications shall be accepted only in the original container with written permission signed and dated by the parent to administer to [his the] child. The use of all prescriptive medication must be authorized in writing by a licensed prescriber.

F. All medication and medical paraphernalia shall be [securely locked and properly labeled properly labeled and securely locked or stored in accordance with the Virginia School Health Guidelines].

[G. A program of medication administration shall be initiated for a student only when prescribed in writing by a person authorized by law to prescribe medication and written consent from the parent is obtained to administer.

H. G.] An individual medication administration record shall be maintained for each medication a student receives and shall include student name, date the medication is to begin, drug name, schedule for administration, strength, route, identification of the individual who administered the medication, and dates the medication was discontinued or changed.

[<u>H. H.</u>] <u>The provider shall develop and implement written</u> policies and procedures regarding:

<u>1. Managing medication errors to include the following:</u> <u>administering first aid; contacting the poison control</u> <u>center; notifying the prescribing physician; taking action as</u>

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directed; documenting the incident; reviewing medication errors and staff responses; and reporting errors to the parent and placing agency.

2. Handling adverse drug reactions;

3. Revising procedures as events may warrant;

4. Disposing of medication and medical supplies such as needles, syringes, lancets, etc.;

5. Storing of controlled substances;

6. Distributing medication off campus; and

7. [<u>Medication refusal to include who is responsible for</u> <u>documentation</u>, where it will be documented and action <u>taken by staff</u> Documenting medication refusal].

[J. I.] The telephone number of a regional poison control center and other emergency numbers shall be posted on or near the phone.

[K. J.]. Medication training.

1. All staff responsible for medication administration shall have successfully completed [a] medication training [, including refresher training, in a] program approved by the Board of Nursing or be licensed by the Commonwealth of Virginia to administer medication before they can administer medication.

<u>2. Training shall be provided to [all] staff in medication</u> procedures and effects and infection control measures, including the use of standard precautions.

3. [There shall be a ratio of one staff member to 10 students Staff] certified in first aid and CPR [and shall be] available at all times on the school grounds and during any school-sponsored activity.

4. Documentation of medication training must be maintained in personnel files.

5. Staff authorized to administer medication shall be informed of any known side effects of the medication and the symptoms of the effects.

[<u>L. K.</u>] <u>Monitoring the supply of medications.</u>

1. Upon receiving any medication, staff members handling medication shall count individual tablets and measure the level of liquid medicine in the presence of the parent(s) or another staff member and record the count on the medication log.

2. The medication log shall include the signature or initials of the staff member who counted the medication and the parent or staff who witnessed the occurrence. When initials are used, the medication administration record must contain the full name of the staff with corresponding initials for identification purposes.

<u>3. Students shall be prohibited from transporting medication [unless directed otherwise by the student's health care plan].</u>

8VAC20-671-720. School nutrition.

A. Schools with [internal] food service shall [serve to each student on a daily basis a daily ensure a] diet that (i) consists of nutritionally balanced meals, (ii) includes an adequate variety and quantity of food for the age of students, and (iii) meets [the] minimum requirements [and of] the [U.S.] Dietary Guidelines [for Americans, 2010, U.S. Department of Agriculture and U.S. Department of Health and Human Services, 7th Edition, December 2010].

[<u>B. Schools with internal food service shall ensure that all</u> <u>1. All</u>] <u>food safety and sanitation procedures</u> [<u>are shall</u> <u>be</u>] <u>followed in accordance with state and federal</u> <u>regulations.</u>

[<u>C. 2.</u>] <u>Records of menus for all meals served shall be kept on file for six months.</u>

[<u>D. Special diets shall be provided</u> 3. Provisions shall be made for special diets] when prescribed by a physician or requested by the student or parent because of the student's established religion.

[<u>E. B.</u>] In schools where students are required to bring their own lunch, provisions shall be made to ensure a meal for all students.

8VAC20-671-730. Transportation.

A. [Each school shall have on file evidence that any vehicles used for the purpose of transporting students to and from school and school related activities meet federal and state regulations, including: Transportation provided for or used by students shall comply with local, state, and federal laws relating to:]

1. Vehicle safety and maintenance;

2. Licensure of vehicles;

3. Licensure of drivers;

4. [<u>Vehicle liability insurance</u> Child passenger safety, including requiring children to wear appropriate seat belts or restraints for the vehicle in which they are being transported]:

5. [<u>Child passenger safety, including requiring students to</u> <u>wear seat belts or restraints</u> Vehicle liability insurance]; and

<u>6. Safety measures that take into consideration the age and disabling conditions of students.</u>

<u>B. All vehicles used to transport students to school activities</u> shall be equipped with first aid kits, a fire extinguisher, and two-way communication devices.

<u>C. Individual student emergency information including</u> <u>currently prescribed and over-the-counter medications,</u> <u>significant medical problems, and any allergies shall</u> <u>accompany students when they are being transported.</u>

<u>8VAC20-671-740.</u> [<u>Treatment services</u> (Reserved.)]

[Licensed providers of treatment services shall coordinate those services to allow students to receive the required hours

of instruction to the extent possible. When treatment services are not prescribed by a licensed mental health professional, the student shall receive the required number of hours of instruction.

8VAC20-671-750. Student discharge.

<u>A. Each school shall have policies and procedures that</u> <u>address conditions for which a student may be discharged</u> <u>from the school.</u>

<u>B. The school's criteria for discharge shall be made available</u> to prospective students, parents, and placing agencies before their enrollment.

<u>C. The student's education record shall be documented with</u> the date of discharge and reason for discharge.

<u>D. Students shall be discharged only to the parent or legally</u> <u>authorized representative.</u>

8VAC20-671-760. Maintenance of student records.

<u>A. The school shall have written policy and procedures for the management of all records, print and nonprint, regarding confidentiality, accessibility, security, [and] retention [, and disposition].</u>

<u>B. Student education records shall be maintained in</u> [<u>fireproof fire resistant</u>] <u>cabinets</u> [<u>and protected from</u> <u>unauthorized disclosure</u>].

<u>C. Each student's education record shall contain information</u> pertinent to the educational growth and development to include a completed enrollment sheet; a current IEP, 504 Plan, or IIP; student transcript; course of studies; and progress reports. Other information should include disciplinary records, health records, and achievement and test data.

D. [<u>A school shall obtain written</u> Written] consent from the child's parent [shall be obtained] before disclosure of information from a student's education record to unauthorized parties. Authorized parties shall be limited to school employees, including contracted employees, and representatives of [placing school divisions, accrediting agencies, and] state licensing agencies who need access to the student's records to carry out their work responsibilities.

<u>E.</u> [<u>A school may disclose information</u> Information may be disclosed] in an emergency to any person who needs that particular information for the purpose of preventing injury to a student or staff. The school shall not disclose any information that is not needed for this specific purpose. [<u>The school may disclose any records if they are properly subpoenaed</u>, if a court orders them to be produced, to the school's own legal counsel, or to anyone working on behalf of their legal counsel in providing representation to the school.]

F. The school shall permit a parent [or parents] to inspect and review any education records relating to [their the] child that are collected, maintained, or used by the school. The school shall comply with a request without unnecessary delay and before any meeting regarding an IEP or 504 Plan [or in no case more than 14 calendar days after the request has been made]. The right to inspect and review education records under this section includes:

1. The right to a response from the school to reasonable requests for explanations and interpretations of the records;

2. The right to request that the school provide copies of the records containing the information if failure to provide those copies would effectively prevent the parent from exercising the right to inspect and review the records:

3. The right to have a representative of the parent inspect and review the records; and

4. A school may presume that a parent has authority to inspect and review records relating to his child unless the school has been advised that the parent does not have the authority under applicable Virginia law governing such matters as guardianship, separation, and divorce.

<u>G. Each school shall keep a record of parties, except parents</u> and authorized employees of the school, obtaining access to education records collected or maintained, including the name of the party, the date of access, and the purpose of the access.

H. If any education record includes information on more than one child, the [parent(s) of those children have parent has] the right to inspect and review only the information relating to [their his] child or to be informed of the specific information requested.

I. Schools may charge a fee for copies of records that are made for a [parent(s) parent] under this chapter if the fee does not effectively prevent the [parent(s) parent] from exercising [their his] right to inspect and review those records. A school may not charge a fee to search for or to retrieve information under this section.

J. A [parent(s) parent] who believes that information in the education records collected, maintained, or used under this chapter is inaccurate or misleading or violates the privacy or other rights of the child may request the school that maintains the information to amend the information.

<u>1. The school shall decide whether to amend the information in accordance with the request within a reasonable period of time [of receipt of the request].</u>

2. If the school decides to refuse to amend the information in accordance with the request, it shall inform the [parent(s) parent] of the refusal and inform the parent of the right to place in the child's education records a statement commenting on the information or setting forth any reasons for disagreeing with the decision of the school.

3. Any explanation placed in the records of the child under this section must:

a. Be maintained by the school as part of the records of the child as long as the record or contested portion is maintained by the school; and

b. If the records of the child or the contested portion is disclosed by the school to any party, the explanation must also be disclosed to the party.

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K. [Records retention.

<u>1. Each school shall maintain all education records,</u> <u>including discipline and medical records for as long as the</u> <u>student continues enrollment at the school.</u>

2. When a student transfers to another school, the student's complete education record shall be transferred within five business days from the date of request and notification of the transfer to the parent, guardian, and placing agency.

3. When a student graduates or leaves school, the school shall offer all records to the eligible student or parent(s). The records of a publicly placed student who graduates or leaves school shall be transferred to the child's public school.

When a privately placed student graduates or leaves school, the student's education record shall be offered to the eligible student or parent. The records of a publically placed student who graduates or leaves school shall be transferred to the child's home school.

<u>L. Each school shall maintain a permanent record of attendance to include the following:</u>]

[a. 1.] Name and address of school;

[b. 2.] Name, address, and birth date of student;

[<u>3. Name and address of the home school division for</u> publically placed students;]

[c. 4.] Name and address of [the] parent [or parents];

[<u>d. 5.</u>] <u>Student ID</u> [<u>number</u>];

[e. 6.] Dates of attendance; [and]

[f. Verification of immunizations

g. Scholastic work completed; and

h. Academic transcript.

7. Academic transcript].

<u>8VAC20-671-770. Participation of students in human</u> research.

<u>A. No human research involving students shall be conducted</u> or authorized by any school unless in compliance with [the <u>Board of Education's regulation, 8VAC20-565, or other</u> applicable law, including §§ 32.1-162.16 through 32.1-162.20 of the Code of Virginia and] 45 CFR Part 46.

<u>B. No such research shall be conducted or authorized unless</u> the student and the student's legally authorized representative give their informed consent. Such informed consent shall be by a signed and witnessed informed consent form. Such form shall comply with § [<u>32.1 162</u> 32.1-162.18] of the Code of Virginia.

C. Any such research shall be approved and conducted under the review of a human research committee, which shall be established by the school conducting or authorizing the research. Any such committee shall comply with the provisions of § 32.1-162.19 of the Code of Virginia. The committee shall submit to the Governor, the General Assembly, and the Superintendent of Public Instruction or designee at least annually a report on the student projects reviewed and approved by the committee, which shall state significant deviations from the proposals as approved.

D. There shall be excluded from the operation of this chapter those categories of research in § 32.1-162.17 of the Code of Virginia that exempt research or student learning outcomes as conducted in educational settings involving regular or special education instructional strategies; the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods; or the use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that subjects cannot be identified, directly or through identifiers linked to the subjects.

<u>8VAC20-671-780.</u> Procedures for [permanent] <u>school</u> <u>closing.</u>

<u>A. A school that ceases operation shall provide written</u> notice as early as possible to all enrolled students, the parent(s), the student's public school, and licensing agencies.

<u>B. All advertisements of the school's operation shall cease</u> immediately, and the current license to operate shall be returned promptly to the [<u>licensing agency</u> department].

<u>C. If privately placed students are unable to complete the academic year due to the school's closing, the school's guaranty instrument shall be used for tuition reimbursement to the fullest extent allowable.</u>

D. All education records of privately placed students shall be provided to the parent or student who has reached 18 years of age and acknowledgement of such to the [licensing agency department].

E. All education records of publicly placed students shall be returned to the school division of the parent's residence and acknowledgement of such to the parent or student who has reached 18 years of age, and the [licensing agency department].

<u>NOTICE</u>: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

[FORMS (8VAC20-671)

<u>2015 -2016 Application to Operate a Private School for</u> <u>Students with Disabilities (rev. 7/15)</u>

School Entrance Health Form, MCH 213G (rev. 3/14)]

[DOCUMENTS INCORPORATED BY REFERENCE (8VAC20-671)

<u>Virginia School Health Guidelines - General Guidelines for</u> Administering Medication in School (pages 253-256), May

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<u>1999</u>, published by the Virginia Department of Health and printed by the Virginia Department of Education

Dietary Guidelines for Americans 2010, 7th Edition, December 2010, U.S. Department of Agriculture and U.S. Department of Health and Human Services, Washington, D.C.: U.S. Government Printing Office, www.dietary guidelines.gov]

VA.R. Doc. No. R11-2536; Filed July 2, 2015, 2:28 p.m.

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TITLE 9. ENVIRONMENT

STATE WATER CONTROL BOARD

Final Regulation

<u>REGISTRAR'S NOTICE</u>: The State Water Control Board 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 where no agency discretion is involved. The State Water Control Board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

<u>Title of Regulation:</u> 9VAC25-20. Fees for Permits and Certificates (amending 9VAC25-20-40, 9VAC25-20-50, 9VAC25-20-146, 9VAC25-20-147).

Statutory Authority: §§ 62.1-44.15 and 62.1-44.15:6 of the Code of Virginia.

Effective Date: October 1, 2015.

<u>Agency Contact:</u> William K. Norris, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4022, FAX (804) 698-4347, or email william.norris@deq.virginia.gov.

Summary:

The amendments (i) delete the fee exemption for the land application of materials classified as exceptional quality biosolids; (ii) add a fee of \$3.75 on each dry ton of exceptional quality biosolids cake sewage sludge that is land applied, beginning October 1, 2015; and (iii) clarify the distinction between Class B biosolids and exceptional quality biosolids for recordkeeping and reporting requirements. The amendments conform the regulation to changes in the Code of Virginia enacted by Item 361 of Chapter 665 of the 2015 Acts of Assembly.

9VAC25-20-40. Applicability.

A. This chapter applies to:

1. All applicants for issuance of a new permit, permit authorization or certificate, or reissuance of an existing permit, permit authorization or certificate, except as specifically exempt under 9VAC25-20-50 A. The fee due shall be as specified under 9VAC25-20-110 or 9VAC25-20-130.

2. All permit, permit authorization or certificate holders who request that an existing permit, permit authorization or certificate be modified, except as specifically exempt under 9VAC25-20-50 A 3 or 9VAC25-20-50 A 6. The fee due shall be as specified under 9VAC25-20-120.

3. All land appliers land applying biosolids on permitted sites in the Commonwealth of Virginia, except as specifically exempt under 9VAC25 20 50 C. The fee due shall be as specified under 9VAC25-20-146.

B. An applicant for a permit, permit authorization or certificate involving a permit that is to be revoked and reissued shall be considered an applicant for a new permit. The fee due shall be as specified under 9VAC25-20-110.

C. Permit maintenance fees apply to each Virginia Pollutant Discharge Elimination System (VPDES) permit holder and each Virginia Pollution Abatement (VPA) permit holder, except those specifically exempt under 9VAC25-20-50 B of this chapter. The fee due shall be as specified under 9VAC25-20-142.

D. Virginia Water Protection (VWP) Individual/Minimum Instream Flow permit fees apply to any permit for the construction of an intake on a stream or river, or to any permit for the construction of a new intake on an existing reservoir. The fee due shall be as specified under 9VAC25-20-110 or 9VAC25-20-120, as applicable.

E. VWP Individual/Reservoir permit fees apply to any permit for the construction of a new reservoir, or the expansion of an existing reservoir in which one of the purposes of the reservoir is for water supply. The fee due shall be as specified under 9VAC25-20-110 or 9VAC25-20-120, as applicable. VWP Individual/Reservoir permit fees do not apply to the construction of any impoundment, pond or lake in which water supply is not part of the project's purpose.

9VAC25-20-50. Exemptions.

A. No permit application fees will be assessed to:

1. An applicant for a permit, permit authorization, certificate or special exception pertaining to a farming operation engaged in production for market.

2. An applicant for a permit, permit authorization, or certificate pertaining to maintenance dredging for federal navigation channels or other U.S. Army Corps of Engineers-sponsored or Department of the Navy-sponsored dredging projects.

3. Permit holders who request minor modifications or minor amendments to permits, permit authorizations or certificates as defined in 9VAC25-20-10.

4. Permit, permit authorization or certificate holders whose permits, permit authorizations or certificates are modified or amended at the initiative of the board.

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5. VPDES permit holders or VPA permit holders for the regularly scheduled renewal of an individual permit for an existing facility, except VPDES and VPA permit holders whose permits expire on or before December 27, 2004.

6. An applicant for a permit, permit authorization, permit modification, or certificate pertaining solely to biosolids research.

B. No permit maintenance fees will be assessed to:

1. VPDES and VPA facilities operating under a general permit.

2. Permits pertaining to a farming operation engaged in production for market.

3. Virginia Water Protection (VWP), Surface Water Withdrawal (SWW), and Ground Water Withdrawal (GWW) permits, permit authorizations, certificates and special exceptions.

4. Permits pertaining solely to biosolids research.

C. No fee shall be imposed on the land application of materials classified as "exceptional quality biosolids" or the equivalent thereof, as defined by 9VAC25 32.

Part IV

Biosolids Fees and Reimbursable Costs

9VAC25-20-146. Established fees.

A. Land appliers shall remit the established fees to the department as specified in this regulation. The land appliers shall collect the required fees from the owners of the sewage treatment works and facilities that generate the <u>Class B</u> biosolids <u>and exceptional quality biosolids cake that are land applied</u>. Such works and facilities shall be approved sources of biosolids in accordance with this regulation <u>9VAC25-31 or 9VAC25-32</u>. Land application shall only include biosolids from approved sources as listed in the land application permit. The established fee shall be imposed on each dry ton of <u>Class B</u> biosolids <u>and exceptional quality biosolids cake</u> that is land applied in the Commonwealth of Virginia in accordance with 9VAC25-31 or 9VAC25-32.

B. The amount of the established fee and disbursement are as follows:

1. The fee shall be \$7.50 per dry ton of <u>Class B</u> biosolids land applied in the Commonwealth of Virginia.

2. The fee shall be \$3.75 per dry ton of exceptional quality biosolids land applied as a cake in the Commonwealth of Virginia.

2. <u>3.</u> Disbursement of the established fees collected by the department shall be made to reimburse or partially reimburse those counties, cities and towns with duly adopted local ordinances that submit documentation of reimbursable expenses acceptable to the department as provided for in this regulation.

3. 4. Disbursement of the established fees collected by the department shall be made to reimburse the Department of

Conservation and Recreation's costs for implementation of the biosolids application program.

9VAC25-20-147. Records and reports.

A. Records. Permittees shall maintain complete records of the land application activities and amounts of <u>Class B</u> biosolids <u>and exceptional quality biosolids cake</u> that they land apply in the Commonwealth of Virginia. Such records shall be maintained by the permittee for five years after the date of the activity in a form that is available for inspection by the department. Records of land application activities shall include at minimum:

1. Name of permittee, DEQ permit number, and dates of activity.

2. Identification of land application site, including the DEQ control number.

3. The source of biosolids, whether the biosolids are Class <u>B or exceptional quality cake</u>, and field area receiving those biosolids.

4. The amount of biosolids applied in dry tons, by class, and the method and calculations used to determine the reported value.

5. Name of responsible representative of permittee and a statement signed and dated by that representative indicating that the information submitted has been verified by that representative as correctly reported in accordance with this regulation.

B. Reports and notification. The permittee shall submit a monthly report by the 15th day of each month for land application activity that occurred in the previous calendar month, unless another date is specified in the permit in accordance with 9VAC25-32-80 I 4. The report shall include (i) the recorded information listed in subsection A of this section and (ii) a calculation of the total fee. The submitted report shall include a summary list of the total amount of Class B biosolids and exceptional quality biosolids cake applied and the calculated fee based on the land-applied Class B biosolids and exceptional quality biosolids cake for each county in which land application occurred. If no land application occurs under a permit during the calendar month, a report shall be submitted stating that no land application occurred.

VA.R. Doc. No. R15-4358; Filed July 1, 2015, 12:20 p.m.

Proposed Regulation

<u>REGISTRAR'S NOTICE</u>: The State Water Control Board is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 8 of the Code of Virginia, which exempts general permits issued by the State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), Chapter 24 (§ 62.1-242 et seq.) of Title 62.1, and Chapter 25 (§ 62.1-254 et seq.) of Title 62.1 if the board (i) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01; (ii)

following the passage of 30 days from the publication of the Notice of Intended Regulatory Action forms a technical advisory committee composed of relevant stakeholders, including potentially affected citizens groups, to assist in the development of the general permit; (iii) provides notice and receives oral and written comment as provided in § 2.2-4007.03; and (iv) conducts at least one public hearing on the proposed general permit.

<u>Title of Regulation:</u> 9VAC25-110. Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Domestic Sewage Discharges of Less Than or Equal to 1,000 Gallons Per Day (amending 9VAC25-110-10 through 9VAC25-110-80; adding 9VAC25-110-15).

Statutory Authority: § 62.1-44.15 of the Code of Virginia; § 402 of the Clean Water Act; 40 CFR Parts 122, 123, and 124.

Public Hearing Information:

August 25, 2015 - 3 p.m. - Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA

Public Comment Deadline: September 25, 2015.

<u>Agency Contact:</u> Allan Brockenbrough, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4147, FAX (804) 698-4032, or email allan.brockenbrough@deq.virginia.gov.

Announcement of Periodic Review and Small Business <u>Impact Review:</u> Pursuant to Executive Order 17 (2014) and § 2.2-4007.1 of the Code of Virginia, the agency is conducting a periodic review and small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Summary:

The proposed amendments reissue the existing Virginia Pollutant Discharge Elimination System general permit for domestic sewage discharges of less than or equal to 1,000 gallons per day (VAG40) that will expire on August 1, 2016. The general permit contains effluent limitations, permit conditions and monitoring requirements for domestic sewage discharges to surface waters from treatment works with a design discharge flow of less than or equal to 1,000 gallons per day on a monthly average. The permit requirements are designed to protect the quality of the waters receiving the treated wastewater discharges. Amendments are proposed to update and clarify definitions, effective dates, authorization to discharge, registration statement requirements, general permit limits pages, special conditions, and conditions applicable to all permits. The amendments include (i) adding a limit set for discharges to receiving waters subject to the Policy for the Potomac River Embayments (9VAC25-415); (ii) requiring owners of treatment works serving buildings or dwellings other than individual single family dwellings to submit the monitoring results to the Department of Environmental Quality on a Discharge Monitoring Report (DMR) after each monitoring period; and (iii) requiring owners of treatment works serving buildings or dwellings other than individual single family dwellings to maintain a log of all maintenance performed on the treatment works and submit the log to the department along with the facilities monitoring results.

9VAC25-110-10. Definitions.

The words and terms used in this chapter shall have the same meanings as given in the State Water Control Law, Chapter 3.1 (§ 62.1-44.2 et seq.) of Title 62.1 of the Code of Virginia and the VPDES Permit Regulation (9VAC25-31), unless the context clearly indicates otherwise, except that for the purposes of this chapter:

"7Q10" means the lowest flow averaged over a period of seven consecutive days that can be statistically expected to occur once every 10 elimatic years.

<u>"Board" or "State Water Control Board" means the Virginia</u> State Water Control Board.

"Climatic year" means a year beginning on April 1 and ending on March 31.

"Combined application" means the Virginia Department of Health Discharging System Application for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons per Day and State Water Control Board Virginia Pollutant Discharge Elimination System General Permit Registration Statement for Domestic Sewage Discharges Less Than or Equal to 1,000 Gallons per Day. This application combines the VDH Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings (12VAC5-640) requirements with the board's registration statement requirements.

<u>"Department" or</u> "DEQ" means the Virginia Department of Environmental Quality or the department.

"Domestic sewage" means the water-carried human wastes from residences, buildings, industrial establishments or other places.

<u>"Individual single family dwelling" means a residence</u> <u>housing one family or household or one that is designed for</u> <u>one family only.</u>

"Receiving water" means a creek, stream, river, lake, estuary, groundwater formation, or other body of water into which treated waste or untreated waste is discharged.

"Total maximum daily load" or "TMDL" means a calculation of the maximum amount of a pollutant that a

waterbody can receive and still meet water quality standards, and an allocation of that amount to the pollutant's sources. A TMDL includes wasteload allocations (WLAs) for point source discharges, and load allocations (LAs) for nonpoint sources or natural background or both, and must include a margin of safety (MOS) and account for seasonal variations.

"VDH" means the Virginia Department of Health.

<u>9VAC25-110-15. Applicability of incorporated references</u> based on the dates that they became effective.

Except as noted, when a regulation of the U.S. Environmental Protection Agency set forth in Title 40 of the Code of Federal Regulations (CFR) is referenced and incorporated herein, that regulation shall be as it exists and has been published as of July 1, 2014.

9VAC25-110-20. Purpose; delegation of authority; effective date of permit.

A. This general permit regulation governs domestic sewage discharges to surface waters from treatment works with a design discharge flow of less than or equal to 1,000 gallons per day on a monthly average.

B. The Director of the Department of Environmental Quality, or his designee, may perform any act of the board provided under this chapter, except as limited by § 62.1-44.14 of the Code of Virginia.

C. This general VPDES permit will become effective on August 2, 2011 2016, and it expires on August 1, 2016 2021. With respect to a particular facility dwelling, building, or site served, this general permit shall become effective upon the facility dwelling, building, or site served owner's compliance with the provisions of 9VAC25-110-60.

9VAC25-110-60. Authorization to discharge.

A. Any owner of a treatment works governed by this general permit is hereby authorized to discharge treated domestic sewage to surface waters of the Commonwealth of Virginia provided that:

1. The owner submits a registration statement, if required to do so, in accordance with 9VAC25-110-70, and that registration statement is accepted by the board. For an individual single family dwelling, the owner may submit a combined application in place of a registration statement;

2. The owner complies with the effluent limitations and other requirements of 9VAC25-110-80; and

3. The board has not notified the owner, in accordance with subsection B of this section, that the discharge is not eligible for coverage under this permit.

B. The board will notify an owner that the discharge is not eligible for coverage under this permit in the event of any of the following:

1. The owner is required to obtain an individual VPDES permit in accordance with 9VAC25-31-170 B 3 of the VPDES Permit Regulation;

2. The owner is proposing to discharge to surface waters specifically named in other board regulations that prohibit such discharges;

3. The owner is proposing to discharge to surface waters in an area where there are central sewage facilities reasonably available, as determined by the board;

4. The owner of any proposed treatment works or any treatment works that has not previously been issued a VPDES permit has applied to the Virginia Department of Health for an onsite sewage disposal system permit, and the Virginia Department of Health has determined that an onsite system is available to serve that parcel of land;

5. The discharge would violate the antidegradation policy stated in 9VAC25-260-30 of the Virginia Water Quality Standards; or

6. A TMDL (board adopted, EPA approved, or EPA imposed) contains an individual WLA for the facility, unless this general permit specifically addresses the TMDL pollutant of concern and the permit limits are at least as stringent as those required by the TMDL WLA The discharge is not consistent with the assumptions and requirements of an approved TMDL.

C. Compliance with this general permit constitutes compliance, for purposes of enforcement, with the federal Clean Water Act §§ 301, 302, 306, 307, 318, 403, and 405 (a) through (b), and the State Water Control Law, and applicable regulations under either, with the exceptions stated in 9VAC25-31-60 of the VPDES Permit Regulation. Approval for coverage under this general VPDES permit does not relieve any owner of the responsibility to comply with any other applicable federal, state or local statute, ordinance or regulation, including, for owners of sewage treatment works that serve individual single family dwellings, the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings (12VAC5-640) of the Virginia Department of Health adopted pursuant to §§ 32.1-12, 32.1-163, and 32.1-164 of the Code of Virginia and, for owners of sewage treatment works that serve nonsingle buildings or dwellings other than individual single family dwellings, the Sewage Collection and Treatment Regulations (9VAC25-790) adopted by the State Water Control Board pursuant to § 62.1-44.18 62.1-44.19 of the Code of Virginia.

D. Continuation of permit coverage.

1. Any owner that was authorized to discharge under the domestic sewage discharges general permit issued in 2006, 2011 and who is required to and submits a complete registration statement, or for an individual single family dwelling a combined application, on or before August 1, 2014 2016, is authorized to continue to discharge treated domestic sewage under the terms of the 2006 2011 general permit until such time as the board either:

a. Issues coverage to the owner under this general permit; or

b. Notifies the owner that <u>the discharge is not eligible for</u> coverage under this <u>general</u> permit is denied.

2. When the owner that was covered under the expiring or expired general permit has violated or is violating the conditions of that permit, the board may choose to do any or all of the following:

a. Initiate enforcement action based upon the <u>2011</u> general permit which has been continued;

b. Issue a notice of intent to deny coverage under the new reissued general permit. If the general permit coverage is denied, the owner would then be required to cease the activities discharges authorized by the administratively continued coverage under the terms of the 2011 general permit or be subject to enforcement action for operating without a permit;

c. Issue an individual permit with appropriate conditions; or

d. Take other actions authorized by the VPDES Permit Regulation (9VAC25-31).

9VAC25-110-70. Registration statement.

A. Deadlines for submitting registration statement. Any owner seeking coverage under this general permit, and who is required to submit a registration statement, shall submit a complete General general VPDES Permit Registration Statement permit registration statement in accordance with this chapter section, which shall serve as a notice of intent to be covered for coverage under the general General VPDES permit Permit for domestic sewage discharges Domestic Sewage Discharges of less than Less Than or equal Equal to 1,000 gallons per day Gallons per Day. For an individual single family dwelling, the owner may submit a combined application in place of the registration statement.

1. New facilities treatment works. Any owner proposing a new discharge shall submit a complete registration statement, or for an individual single family dwelling a combined application, to the department at least 60 days prior to the date planned for commencing operation of the treatment works.

2. Existing facilities treatment works.

a. Any owner of an existing treatment works covered by an individual VPDES permit who is proposing to be covered by this general permit shall notify the department and submit a complete registration statement, or for an individual single family dwelling a combined application, at least 240 days prior to the expiration date of the individual VPDES permit.

b. Any owner of a treatment works that was authorized to discharge under the general permit issued in 2006 2011, and who intends to continue coverage under this general permit, is automatically covered by this general permit and is not required to submit a registration statement, or for an individual single family dwelling a combined application, if:

(1) The ownership of the treatment works has not changed since the registration statement <u>or combined application</u> for coverage under the 2006 2011 general permit was submitted, or, if the ownership has changed, (i) a new registration statement <u>or combined application</u> or (ii) VPDES Change of Ownership form was submitted to the department <u>by the new owner</u> at the time of the title transfer;

(2) There has been no change in the design or operation, or both, of the treatment works since the registration statement <u>or combined application</u> for coverage under the $\frac{2006}{2011}$ general permit was submitted;

(3) For treatment works serving individual single family dwellings, the Virginia Department of Health <u>VDH</u> has no objection to the automatic permit coverage renewal for this treatment works based on system performance issues, enforcement issues, or other issues sufficient to the board. If the Virginia Department of Health <u>VDH</u> objects to the automatic renewal for this treatment works, the owner will be notified by the board in writing; and

(4) For treatment works serving nonsingle buildings or dwellings other than individual single family dwellings, the board has no objection to the automatic permit coverage renewal for this treatment works based on system performance issues, or enforcement issues, or other issues sufficient to the board. If the board objects to the automatic renewal for this treatment works, the owner will be notified by the board in writing.

<u>c.</u> Any owner that <u>of a treatment works that was authorized to discharge under the general permit issued in 2011 that does not qualify for automatic permit coverage renewal shall submit a complete registration statement, or for an individual single family dwelling a combined application, to the department on or before June 2, 2011 2016.</u>

3. Late notifications registration statements. Late registration Registration statements will be accepted by the board, or for individual single family dwellings combined applications, for existing treatment works covered under subdivision 2 b of this subsection will be accepted after August 1, 2016, but authorization to discharge will not be retroactive. Owners described in subdivision 2 b of this subsection that submit registration statements or combined applications after June 2, 2016, are authorized to discharge under the provisions of 9VAC25-110-60 D if a complete registration statement, or combined application, is submitted before August 2, 2016.

B. Registration statement. The registration statement shall contain the following information:

1. a. Indicate if the <u>facility building</u> served by the treatment works is <u>a an individual</u> single family dwelling. If the <u>facility building</u> is not <u>a an individual</u> single family dwelling, describe the <u>facility's</u> use <u>of the building or site</u> <u>served</u>.

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b. Name and street address of the facility building or site served by the treatment works.

2. <u>a.</u> Name, mailing address, email address (where available), and work and home telephone numbers number of the facility owner of the treatment works. For a dwelling, indicate Indicate if the owner is or will be the occupant of the dwelling or building served by the treatment works.

b. If the owner is not or will not be the occupant of the dwelling or building, provide an alternate contact name, mailing address, email address (where available), and telephone number of the dwelling or building, if available.

3. Name of the water body receiving the discharge. Indicate if the discharge point is on a stream that usually flows during dry weather.

4. The amount of discharge <u>from the treatment works</u>, in gallons per day, on a monthly average, and the design flow of the treatment works, in gallons per day.

5. A description of any pollutants, other than domestic sewage, to be discharged.

6. For a proposed treatment works, indicate if there are central sewage facilities available to serve the facility building or site.

7. If the <u>facility</u> <u>treatment works</u> currently has a VPDES permit, provide the permit number. Indicate if the <u>facility</u> <u>treatment works</u> has been built and begun discharging.

8. For the owner of any proposed treatment works or any treatment works that has not previously been issued a VPDES permit:

a. A 7.5 minute USGS U.S. Geological Survey (USGS) topographic map or equivalent (e.g., a computer generated map) that indicates the discharge point, the location of the property to be served by the treatment works, and the location of any wells, springs, other water bodies, and any residences within 1/2 mile downstream from the discharge point;

b. A site diagram of the existing or proposed sewage treatment works; to include the property boundaries, the location of the facility or dwelling to be , building, or site served, the individual sewage treatment units, the receiving water body, and the discharge line location; and

c. A copy of the notification from the Virginia Department of Health that an onsite sewage disposal system permit has been applied for and that the Virginia Department of Health has determined that there is no onsite system available to serve that parcel of land.

9. Maintenance contract Operation and maintenance.

a. For the owner of a treatment works serving an individual single family dwelling, indicate if a valid operation and maintenance contract has been obtained in

accordance with the requirements <u>are specified in VDH</u> regulations at 12VAC5-640-500, or if an variance to the maintenance contract requirement has been requested and granted by the Virginia Department of Health. Provide the name of the individual or company contracted to perform the treatment works maintenance and the expiration date of the current contract, if applicable. If the treatment works has not been constructed yet, provide the name after construction is complete and prior to starting the treatment plant operation.

Indicate if a monitoring contract has been obtained in accordance with the requirements in 12VAC5 640 490 F, or if the monitoring contract requirement has been waived by the Virginia Department of Health, or if the monitoring requirements are included as part of the maintenance contract. Provide the name of the individual or company contracted to perform the treatment works monitoring and the expiration date of the current contract, if applicable. If the treatment works has not been constructed yet, provide the name after construction is complete and prior to starting the treatment plant operation;

b. For the owner of a treatment works serving a nonsingle building or dwelling other than an individual single family dwelling, indicate if a valid maintenance contract has been obtained, or if an exception to the maintenance contract requirement has been requested and granted in accordance with subdivision 10 of this subsection. Provide the name of the individual or company contracted to perform the treatment works maintenance and the expiration date of the current contract, if applicable. If the treatment works has not been constructed yet, provide the name after the certificate to construct (CTC) is issued, and prior to requesting a certificate to operate (CTO). A valid maintenance contract shall provide for the following:

(1) Performance of all testing required in accordance with either 9VAC25 110 80 Part I A or Part I B, as appropriate, and periodic (at least annual) inspections of the treatment works. Note: The treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The owner or maintenance provider should not force a discharge in order to collect a sample;

(2) A written notification to the owner within 24 hours whenever the contract provider becomes aware that maintenance or repair of the owner's treatment works is necessary. The owner is responsible for prompt maintenance and repair of the treatment works including all costs associated with the maintenance or repair. Immediately upon receipt of notice that repair or maintenance is required, the owner shall begin emergency pump and haul of all sewage generated from

the facility or dwelling if full and complete repairs cannot be accomplished within 48 hours.

(3) A log of the following items shall be maintained by the contract provider for as long as the contract is in force:

(a) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts, and document and explain why no sample was taken or possible;

(b) Alarm activation incidents;

(c) Maintenance, corrective, or repair activities performed;

(d) Recommended repair or replacement items; and

(e) Copies of all reports prepared by the contract provider.

(4) An inspection shall be conducted by the contract provider within 48 hours after notification by the owner that a problem may be occurring; and

(5) The maintenance contract shall be kept in force during the entire permit term, and shall be valid for a minimum of 24 months of consecutive coverage.

10. The owner of a treatment works serving a nonsingle building or dwelling other than an individual single family dwelling may request an exception to the maintenance contract requirement by submitting an operation and maintenance plan to the board for review and approval. If an operation and maintenance plan has been approved by the board previously and remains current and complete, then it does not need to be resubmitted. In such cases, the owner shall provide the date of approval of the operation and maintenance plan. At a minimum, the operation and maintenance plan shall contain the following information:

a. An up to date operation and maintenance manual for the treatment works;

b. A log of all maintenance performed on the treatment works including, but not limited to, the following:

(1) The date and amount of disinfection chemicals added to the chlorinator.

(2) If dechlorination is used, the date and amount of any dechlorination chemicals that are added.

(3) The date and time of equipment failure(s) and the date and time the equipment was restored to service.

(4) The date and approximate volume of sludge removed.

(5) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts, and document and explain why no sample was taken or possible;

c. Dated receipts for chemicals purchased, equipment purchased, and maintenance performed; and

d. An effluent monitoring plan to conform with the requirements of 9VAC25-110 80 Part I A or Part I B, as appropriate, including all sample collection, preservation, and analysis procedures. Note: The treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The owner or maintenance provider should not force a discharge in order to collect a sample.

11. The following certification: "I hereby grant to duly authorized agents of the Department of Environmental Quality, upon presentation of credentials, permission to enter the property where the treatment works is located for the purpose of determining compliance with or the suitability of coverage under the General Permit. I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system or those persons directly responsible for gathering the information, the information submitted is to the best of my knowledge and belief true, accurate, and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment for knowing violations."

<u>C.</u> The registration statement shall be signed in accordance with the requirements of 9VAC25-31-110 <u>A of the VPDES</u> <u>Permit Regulation</u>.

D. The registration statement may be delivered to the department by either postal or electronic mail and shall be submitted to the DEQ regional office serving the area where the treatment works is located.

9VAC25-110-80. General permit.

Any owner whose registration statement is accepted by the board, or whose permit coverage is automatically renewed, shall comply with the requirements contained herein and be subject to all requirements of 9VAC25-31-170.

General Permit No.: VAG40 Effective Date: August 2, 2011 2016 Expiration Date: August 1, 2016 2021

GENERAL PERMIT FOR DOMESTIC SEWAGE DISCHARGES OF LESS THAN OR EQUAL TO 1,000 GALLONS PER DAY

AUTHORIZATION TO DISCHARGE UNDER THE VIRGINIA POLLUTANT DISCHARGE ELIMINATION SYSTEM AND THE VIRGINIA STATE WATER CONTROL LAW

In compliance with the provisions of the Clean Water Act (33 USC § 1251 et seq.), as amended, and pursuant to the State Water Control Law and regulations adopted pursuant thereto, owners of treatment works with domestic sewage

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discharges of a design flow of less than or equal to 1,000 gallons per day on a monthly average are authorized to discharge to surface waters within the boundaries of the Commonwealth of Virginia, except those waters specifically named in board regulations that prohibit such discharges.

The authorized discharge shall be in accordance with this cover page, Part I-Effluent Limitations, Monitoring Requirements and Special Conditions, and Part II-Conditions Applicable to All VPDES Permits, as set forth herein.

Part I

Effluent Limitations, Monitoring Requirements and Special Conditions

A. Effluent limitations and monitoring requirements receiving waters where the 7Q10 flows are less than 0.2 MGD.

1. During the period beginning with the permit's effective date and lasting until the permit's expiration date, the permittee is authorized to discharge from outfall number 001 to receiving waters where the 7Q10 flows are less than 0.2 MGD.

The discharge shall be limited and monitored by the permittee as specified below:

	DISCHARC	DISCHARGE LIMITATIONS		MONITORING REQUIREMENTS	
EFFLUENT CHARACTERISTICS	Instantaneous Minimum	Instantaneous Maximum	Frequency	Sample Type	
Flow (MGD) ⁽¹⁾	NA	NL	1/year	Estimate	
BOD ₅	NA	30 mg/l	1/year	Grab	
Total Suspended Solids	NA	30 mg/l	1/year	Grab	
Total Residual Chlorine ⁽²⁾					
After contact tank	1.0 mg/l	NA	1/year	Grab	
Final effluent	NA	0.016 mg/l ⁽⁶⁾	1/year	Grab	
E. coli ⁽³⁾	NA	235/100 235 CFU/100 ml	1/year	Grab	
enterococci ⁽⁴⁾	NA	104/100 104 <u>CFU/100</u> ml	1/year	Grab	
Fecal Coliform Bacteria ⁽⁵⁾	NA	200/100 200 CFU/100 ml	1/year	Grab	
pH (standard units)	6.0	9.0	1/year	Grab	
Dissolved Oxygen	5.0 mg/l ⁽⁶⁾	NA	1/year	Grab	

NL = No Limitation, monitoring required

NA = Not Applicable

⁽¹⁾The design flow of this treatment facility works is less than or equal to 1,000 gallons per day.

⁽²⁾Applies only when chlorine is used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations).

⁽³⁾Applies only when methods other than chlorine are used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the facility treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁴⁾Applies only when the discharge is into saltwater or the transition zone (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the facility treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁵⁾Applies only when the discharge is into shellfish waters (see 9VAC25-260-160 for the description of what are shellfish waters). When the <u>facility treatment works</u> is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

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⁽⁶⁾Does not apply when the receiving stream is an ephemeral stream. "Ephemeral streams" are drainage ways, ditches, hollows, or swales that contain only (i) flowing water during or immediately following periods of rainfall or (ii) water supplied by the discharger. These waterways would normally have no active aquatic community.

2. All monitoring data required by Part I A 1 shall be maintained on site in accordance with Part II B. Reporting of results to DEQ is not required; however, the monitoring Monitoring results for treatment works serving buildings or dwellings other than individual single family dwellings shall be made available to DEQ personnel upon request submitted to the department on a Discharge Monitoring Report (DMR) no later than the 10th of January following the monitoring period. The monitoring period is January 1 through December 31. A copy of the maintenance log required by Part I D 2 b (4) shall also be submitted with the DMR. Monitoring results for treatment works serving individual single family dwellings shall be are submitted to the Virginia Department of Health in accordance with 12VAC5-640.

3. The 30-day average percent removal for BOD_5 and total suspended solids shall not be less than 85%.

B. Effluent limitations and monitoring requirements—receiving waters where the 7Q10 flows are equal to or greater than 0.2 MGD.

1. During the period beginning with the permit's effective date and lasting until the permit's expiration date, the permittee is authorized to discharge from outfall number 001 to receiving waters where the 7Q10 flows are equal to or greater than 0.2 MGD.

	DISCHARGE	DISCHARGE LIMITATIONS		EQUIREMENTS
EFFLUENT CHARACTERISTICS	Instantaneous Minimum	Instantaneous Maximum	Frequency	Sample Type
Flow (MGD) ⁽¹⁾	NA	NL	1/year	Estimate
BOD ₅	NA	30 mg/l	1/year	Grab
Total Suspended Solids	NA	30 mg/l	1/year	Grab
Total Residual Chlorine ⁽²⁾				
After contact tank	<u>1.0 mg/l</u>	NA	<u>1/year</u>	<u>Grab</u>
Final effluent	1.0 mg/l <u>NA</u>	2.0 mg/l	1/year	Grab
E. coli ⁽³⁾	NA	235/100 235 <u>CFU/100</u> ml	1/year	Grab
enterococci ⁽⁴⁾	NA	104/100 <u>104</u> <u>CFU/100</u> ml	1/year	Grab
Fecal Coliform Bacteria ⁽⁵⁾	NA	200/100 200 CFU/100 ml	1/year	Grab
pH (standard units)	6.0	9.0	1/year	Grab

The discharge shall be limited and monitored by the permittee as specified below:

NL = No Limitation, monitoring required

NA = Not Applicable

⁽¹⁾The design flow of this treatment facility works is less than or equal to 1,000 gallons per day.

⁽²⁾Applies only when chlorine is used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations).

⁽³⁾Applies only when methods other than chlorine are used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the facility treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

⁽⁴⁾Applies only when the discharge is into saltwater or the transition zone (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the facility treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

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⁽⁵⁾Applies only when the discharge is into shellfish waters (see 9VAC25-260-160 for the description of what are shellfish waters). When the <u>facility treatment works</u> is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

2. All monitoring data required by Part I B 1 shall be maintained on site in accordance with Part II B. Reporting of results to DEQ is not required; however, the monitoring Monitoring results for treatment works serving buildings or dwellings other than individual single family dwellings shall be made available to DEQ personnel upon request submitted to the department on a Discharge Monitoring Report (DMR) no later than the 10th of January following the monitoring period. The monitoring period is January 1 through December 31. A copy of the maintenance log required by Part I D 2 b (4) shall also be submitted with the DMR. Monitoring results for treatment works serving individual single family dwellings shall be are submitted to the Virginia Department of Health in accordance with 12VAC5-640.

3. The 30-day average percent removal for BOD_5 and total suspended solids shall not be less than 85%.

C. <u>Effluent limitations and monitoring requirements</u>—discharges to receiving waters subject to the Policy for the Potomac River Embayments (9VAC25-415).

1. During the period beginning with the permit's effective date and lasting until the permit's expiration date, the permittee is authorized to discharge from outfall number 001 to receiving waters subject to the Policy for the Potomac River Embayments (9VAC25-415).

	DISCHARGE LIMITATIONS		MONITORING REQUIREMENTS	
EFFLUENT CHARACTERISTICS	<u>Instantaneous</u> <u>Minimum</u>	<u>Instantaneous</u> <u>Maximum</u>	Frequency	Sample Type
Flow (MGD) ⁽¹⁾	NA	<u>NL</u>	1/3 months	<u>Estimate</u>
pH (standard units)	<u>6.0</u>	<u>9.0</u>	1/3 months	<u>Grab</u>
<u>cBOD₅</u>	NA	<u>5 mg/l</u>	1/3 months	<u>Grab</u>
Total Suspended Solids	NA	<u>6.0 mg/l</u>	1/3 months	<u>Grab</u>
<u>Ammonia as N</u> (Apr 1 – Oct 31)	NA	<u>1.0 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
<u>Ammonia as N</u> (Nov 1 – Mar 31)	NA	<u>3.1 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>
Dissolved Oxygen	<u>6.0 mg/l</u>	<u>NA</u>	1/3 months	<u>Grab</u>
<u>E. coli⁽³⁾</u>	NA	235 CFU/100 ml	1/3 months	<u>Grab</u>
enterococci ⁽⁴⁾	NA	104 CFU/100 ml	1/3 months	<u>Grab</u>
Total Phosphorus	NA	<u>0.18 mg/l</u>	1/3 months	<u>Grab</u>
Total Residual Chlorine ⁽²⁾				
After contact tank	<u>1.0 mg/l</u>	<u>NA</u>	1/3 months	<u>Grab</u>
Final effluent	NA	<u>0.016 mg/l</u>	<u>1/3 months</u>	<u>Grab</u>

The discharge shall be limited and monitored by the permittee as specified below:

NL = No Limitation, monitoring required

<u>NA = Not Applicable</u>

⁽¹⁾The design flow of this treatment works is less than or equal to 1,000 gallons per day.

⁽²⁾Applies only when chlorine is used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations).

⁽³⁾Applies only when methods other than chlorine are used for disinfection and the discharge is into freshwater (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the treatment works is discharging, continuous

disinfection shall be provided in order to maintain this effluent limit.

⁽⁴⁾Applies only when the discharge is into saltwater or the transition zone (see 9VAC25-260-140 C for the classes of waters and boundary designations). When the treatment works is discharging, continuous disinfection shall be provided in order to maintain this effluent limit.

2. All monitoring data required by Part I C 1 shall be maintained on site in accordance with Part II B. Monitoring results shall be submitted to the department on a Discharge Monitoring Report (DMR) no later than the 10th day of the month following the monitoring period. The quarterly monitoring periods shall be January through March, April through June, July through September, and October through December. A copy of the maintenance log required by Part I D 2 b (4) shall also be submitted with the DMR. Monitoring results for treatment works serving individual single family dwellings shall also be submitted to the Virginia Department of Health in accordance with 12VAC5-640.

<u>3. The 30-day average percent removal for BOD₅ and total</u> suspended solids shall not be less than 85%.

D. Special conditions.

1. There shall be no discharge of floating solids or visible foam in other than trace amounts.

2. Maintenance contract Operation and maintenance.

a. Treatment works serving individual single family dwellings. The Operation and maintenance requirements for treatment works serving individual single family dwellings are specified in the Virginia Department of Health regulations at 12VAC5-640-500 require maintenance contracts for treatment works serving individual single family dwellings.

(1) For existing treatment works, the permittee shall keep a maintenance contract in force during the permit term, unless the permittee has been granted a variance from the maintenance contract requirement by the Virginia Department of Health. A copy of the maintenance contract, if applicable, shall be kept at the site of the treatment works and shall be made available to DEQ or to the Virginia Department of Health for examination upon request. The permittee is also responsible for ensuring that the local health department has a current copy of a valid maintenance agreement in accordance with 12VAC5-640-500 B.

(2) For proposed treatment works, the permittee shall submit a copy of a valid maintenance contract to both DEQ and the Virginia Department of Health prior to operation of the treatment works unless the permittee has been granted a variance from the maintenance contract requirement by the Virginia Department of Health. The maintenance contract shall be kept in force during the permit term. A copy of the maintenance contract, if applicable, shall be kept at the site of treatment works, and made available to DEQ or the Virginia Department of Health for examination upon request. The permittee is also responsible for ensuring that the local health department has a current copy of a valid maintenance agreement in accordance with 12VAC5 640 500 B.

(3) At a minimum, the maintenance contract shall provide for the following:

(a) Performance of all testing required in either Part I A or Part I B of this permit, as appropriate, and in the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings, 12VAC5 640-490 B, unless the owner maintains a separate monitoring contract in accordance with 12VAC5 640 490 F. Note: The treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The owner or maintenance provider should not force a discharge in order to collect a sample;

(b) A written notification to the owner within 24 hours whenever the contract provider becomes aware that maintenance or repair of the owner's treatment works is necessary. The owner is responsible for prompt maintenance and repair of the treatment works including all costs associated with the maintenance or repair. Immediately upon receipt of notice that repair or maintenance is required, the owner shall begin emergency pump and haul of all sewage generated in the dwelling if full and complete repairs cannot be accomplished within 48 hours; and

(c) The maintenance contract shall be valid for a minimum of 24 months of consecutive coverage.

b. Treatment works serving nonsingle <u>buildings</u> or <u>dwellings</u> other than individual single family dwellings.

(1) For existing treatment works, the permittee shall keep a maintenance contract in force during the permit term, unless an exception to the maintenance contract requirement has been requested and granted in accordance with Part I $\subseteq \underline{D}$ 3. A copy of the maintenance contract, if applicable, shall be kept at the site of the treatment works and made available to DEQ for examination upon request.

(2) For proposed treatment works, the permittee shall submit a copy of certification that the permittee has a valid maintenance contract to DEQ prior to operation of the treatment works, unless an exception to the maintenance contract requirement has been requested and granted in accordance with Part I C D 3. The A maintenance contract shall be kept in force during the permit term. A copy of the maintenance contract shall be kept at the site of the treatment works, and shall be made available to DEQ for examination upon request.

(3) At a minimum, the maintenance contract shall provide for the following:

(a) Performance of all testing required in accordance with either Part I A, Part I B, or Part I B C, as appropriate, and periodic (at least annual) inspections of the treatment works. Note: The Discharges from the treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility) treatment works). The owner or maintenance provider should not force a discharge in order to collect a sample;

(b) A written notification to the owner within 24 hours whenever the contract provider becomes aware that maintenance or repair of the owner's treatment works is necessary. The owner is responsible for prompt maintenance and repair of the treatment works including all costs associated with the maintenance or repair. Immediately upon receipt of notice that repair or maintenance is required, the owner shall begin emergency pump and haul of all sewage generated from the facility building or dwelling or otherwise ensure that no discharge occurs if full and complete repairs cannot be accomplished within 48 hours;

(c) A log of the following items shall be maintained <u>at</u> <u>the treatment works</u> by the contract provider:

(i) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts, and document and explain why no sample was taken or possible;

(ii) Alarm activation incidents;

(iii) Maintenance, corrective, or repair activities performed;

(iv) Recommended repair or replacement items; and

(v) Copies of all reports prepared by the contract provider; and

(d) An inspection shall be conducted by the contract provider within 48 hours after notification by the owner that a problem may be occurring; and.

(e) The maintenance contract shall be valid for a minimum of 24 months of consecutive coverage.

(4) The permittee shall keep a log of all maintenance performed on the treatment works including, but not limited to, the following:

(a) The date and amount of disinfection chemicals added to the chlorinator.

(b) If dechlorination is used, the date and amount of any dechlorination chemicals that are added.

(c) The date and time of equipment failure and the date and time the equipment was restored to service.

(d) The date and approximate volume of sludge removed.

(e) Dated receipts for chemicals purchased, equipment purchased, and maintenance performed.

3. Operation and maintenance plan. The owner of any treatment works serving a nonsingle building or dwelling other than an individual single family dwelling may request an exception to the maintenance contract requirement by submitting an operation and maintenance plan to the board for review and approval. At a minimum, the operation and maintenance plan shall contain the following information:

a. An up-to-date operation and maintenance manual for the treatment works;

b. A log of all maintenance performed on the treatment works including, but not limited to, the following:

(1) The date and amount of disinfection chemicals added to the chlorinator (if applicable).

(2) If dechlorination is used, the date and amount of any dechlorination chemicals that are added.

(3) The date and time of equipment <u>failure(s)</u> <u>failure</u> and the date and time the equipment was restored to service.

(4) The date and approximate volume of sludge removed.

(5) Results of all tests and sampling. Note: If sampling is attempted, but no sample was taken or possible, the log shall show all sampling attempts, and document and explain why no sample was taken or possible;

c. Dated receipts for chemicals purchased, equipment purchased, and maintenance performed; and

d. An effluent monitoring plan to conform with the requirements of Part I A<u>, Part I B</u>, or Part I <u>B</u> <u>C</u>, as appropriate, including all sample collection, preservation, and analysis procedures. Note: The Discharges from the treatment works should be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility) treatment works). The owner or maintenance provider should not force a discharge in order to collect a sample.

Should the permittee fail to implement the approved operation and maintenance plan, or if there are violations of effluent limitations, the board reserves the right to require the permittee to obtain a maintenance contract.

4. Compliance recordkeeping under Part I A, Part I B, and Part I $\frac{B}{C}$.

a. The quantification levels (QL) shall be less than or equal to the following concentrations:

Effluent Parameter	Quantification Level
BOD ₅	2 .0 mg/l
<u>cBOD</u> ₅	<u>2 mg/l</u>
<u>Ammonia as N</u>	<u>0.20 mg/l</u>
Total Phosphorus	<u>0.10 mg/l</u>

TSS	1.0 mg/l
Chlorine	0.10 mg/l

The QL is defined as the lowest concentration used to calibrate a measurement system in accordance with the procedures published for the test method.

b. Recording results. Any concentration data below the QL used in the analysis shall be recorded as "<QL" if it is less than the QL in subdivision <u>4</u> a <u>of this subsection</u>. Otherwise the numerical value shall be recorded.

c. Monitoring results shall be recorded using the same number of significant digits as listed in the permit. Regardless of the rounding convention used by the permittee (e.g., 5 always rounding up or to the nearest even number), the permittee shall use the convention consistently, and shall ensure that consulting laboratories employed by the permittee use the same convention.

5. The discharges authorized by this permit shall be controlled as necessary to meet water quality standards.

Part II Conditions Applicable to all <u>All</u> VPDES Permits

A. Monitoring.

1. Samples and measurements taken as required by this permit shall be representative of the monitored activity.

2. Monitoring shall be conducted according to procedures approved under 40 CFR Part 136 or alternative methods approved by the U.S. Environmental Protection Agency, unless other procedures have been specified in this permit.

3. The permittee shall periodically calibrate and perform maintenance procedures on all monitoring and analytical instrumentation at intervals that will ensure accuracy of measurements.

4. Samples taken as required by this permit shall be analyzed in accordance with 1VAC30-45 (Certification for Noncommercial Environmental Laboratories) or 1VAC30-46 (Accreditation for Commercial Environmental Laboratories).

B. Records.

1. Records of monitoring information shall include:

a. The date, exact place, and time of sampling or measurements;

b. The individual(s) who performed the sampling or measurements;

c. The date(s) and time(s) analyses were performed;

d. The individual(s) who performed the analyses;

e. The analytical techniques or methods used; and

f. The results of such analyses.

2. Except for records of monitoring information required by this permit related to the permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years, the permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the registration statement for this permit, for a period of at least three years from the date of the sample, measurement, report or request for coverage. This period of retention shall be extended automatically during the course of any unresolved litigation regarding the regulated activity or regarding control standards applicable to the permittee, or as requested by the board.

C. Reporting monitoring results. Monitoring results under this permit are not required to be submitted to the department. However, should the board request that the permittee submit monitoring results, the following subsections would apply.

1. The permittee shall submit the results of the monitoring required by this permit not later than the 10th day of the month after monitoring takes place, unless another reporting schedule is specified elsewhere in this permit. Monitoring results shall be submitted to the department's regional office.

2. Monitoring results shall be reported on a Discharge Monitoring Report (DMR) or on forms provided, approved or specified by the department.

3. If the permittee monitors any pollutant specifically addressed by this permit more frequently than required by this permit using test procedures approved under 40 CFR Part 136 or using other test procedures approved by the U.S. Environmental Protection Agency or using procedures specified in this permit, the results of this monitoring shall be included in the calculation and reporting of the data submitted on the DMR or reporting form specified by the department.

4. Calculations for all limitations that require averaging of measurements shall utilize an arithmetic mean unless otherwise specified in this permit.

D. Duty to provide information. The permittee shall furnish to the department, within a reasonable time, any information that the board may request to determine whether cause exists for modifying, revoking and reissuing, or terminating <u>coverage under</u> this permit or to determine compliance with this permit. The board may require the permittee to furnish, upon request, such plans, specifications, and other pertinent information as may be necessary to determine the effect of the wastes from his the discharge on the quality of state waters, or such other information as may be necessary to accomplish the purposes of the State Water Control Law. The permittee shall also furnish to the department, upon request, copies of records required to be kept by this permit.

E. Compliance schedule reports. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of

this permit shall be submitted no later than 14 days following each schedule date.

F. Unauthorized discharges. Except in compliance with this permit, or another permit issued by the board, it shall be unlawful for any person to:

1. Discharge into state waters sewage, industrial wastes, other wastes, or any noxious or deleterious substances; or

2. Otherwise alter the physical, chemical or biological properties of such state waters and make them detrimental to the public health, to animal or aquatic life, to the use of such waters for domestic or industrial consumption, for recreation, or for other uses.

G. Reports of unauthorized discharges. Any permittee who discharges or causes or allows a discharge of sewage, industrial waste, other wastes or any noxious or deleterious substance into or upon state waters in violation of Part II F, or who discharges or causes or allows a discharge that may reasonably be expected to enter state waters in violation of Part II F, shall notify the department of the discharge immediately upon discovery of the discharge, but in no case later than 24 hours after said discovery. A written report of the unauthorized discharge shall be submitted to the department within five days of discovery of the discharge. The written report shall contain:

1. A description of the nature and location of the discharge;

2. The cause of the discharge;

3. The date on which the discharge occurred;

4. The length of time that the discharge continued;

5. The volume of the discharge;

6. If the discharge is continuing, how long it is expected to continue;

7. If the discharge is continuing, what the expected total volume of the discharge will be; and

8. Any steps planned or taken to reduce, eliminate and prevent a recurrence of the present discharge or any future discharges not authorized by this permit.

Discharges reportable to the department under the immediate reporting requirements of other regulations are exempted from this requirement.

H. Reports of unusual or extraordinary discharges. If any unusual or extraordinary discharge including a bypass or upset should occur from a treatment works and the discharge enters or could be expected to enter state waters, the permittee shall promptly notify, in no case later than 24 hours, the department by telephone after the discovery of the discharge. This notification shall provide all available details of the incident, including any adverse <u>affects effects</u> on aquatic life and the known number of fish killed. The permittee shall reduce the report to writing and shall submit it to the department within five days of discovery of the discharge in accordance with Part II I 2. Unusual and extraordinary discharges include, but are not limited to, any discharge resulting from:

1. Unusual spillage of materials resulting directly or indirectly from processing operations;

2. Breakdown of processing or accessory equipment;

3. Failure or taking out of service some or all of the treatment works; and

4. Flooding or other acts of nature.

I. Reports of noncompliance. The permittee shall report any noncompliance that may adversely affect state waters or may endanger public health.

1. An oral report shall be provided within 24 hours from the time the permittee becomes aware of the circumstances. The following shall be included as information that shall be reported within 24 hours under this paragraph:

a. Any unanticipated bypass; and

b. Any upset that causes a discharge to surface waters.

2. A written report shall be submitted within five days and shall contain:

a. A description of the noncompliance and its cause;

b. The period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and

c. Steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance.

The board may waive the written report on a case-by-case basis for reports of noncompliance under Part II I if the oral report has been received within 24 hours and no adverse impact on state waters has been reported.

3. The permittee shall report all instances of noncompliance not reported under Part II I 1 or 2, in writing, at the time the next monitoring reports are submitted. The reports shall contain the information listed in Part II I 2.

NOTE: The immediate (within 24 hours) reports required in Parts II G, H, and I may be made to the department's regional office. Reports may be made by telephone or by fax, FAX, or online at http://www.deq.virginia.gov/Programs/Pollution <u>ResponsePreparedness/MakingaReport.aspx</u>. For reports outside normal working hours, leave a message <u>may be left</u> and this shall fulfill the immediate reporting requirement. For emergencies, the Virginia Department of Emergency Management maintains a 24-hour telephone service at 1-800-468-8892.

J. Notice of planned changes.

1. The permittee shall give notice to the department as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when: a. The permittee plans alteration or addition to any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced:

(1) After promulgation of standards of performance under Section § 306 of the Clean Water Act (33 USC § 1251 et seq.) that are applicable to such source; or

(2) After proposal of standards of performance in accordance with Section § of the Clean Water Act that are applicable to such source, but only if the standards are promulgated in accordance with Section § 306 within 120 days of their proposal;

b. The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants that are subject neither to effluent limitations nor to notification requirements specified elsewhere in this permit; or

c. The alteration or addition results in a significant change in the permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or <u>of</u> disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan.

2. The permittee shall give advance notice to the department of any planned changes in the permitted facility or activity that may result in noncompliance with permit requirements.

K. Signatory requirements.

1. Registration statement. All registration statements shall be signed as follows:

a. For a corporation: by a responsible corporate officer. For the purpose of this section, a responsible corporate officer means: (i) a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy-making or decision-making functions for the corporation, or (ii) the manager of one or more manufacturing, production, or operating facilities, provided the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiating and directing other comprehensive measures to assure long term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or other actions taken to gather complete and accurate application information for permit registration requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures;

b. For a partnership or sole proprietorship: by a general partner or the proprietor, respectively; or

c. For a municipality, state, federal, or other public agency: by either a principal executive officer or ranking elected official. For purposes of this section, a principal executive officer of a public agency includes: (i) the chief executive officer of the agency or (ii) a senior executive officer having responsibility for the overall operations of a principal geographic unit of the agency.

2. Reports, etc. All reports required by permits, and other information requested by the board shall be signed by a person described in Part II K 1 or by a duly authorized representative of that person. A person is a duly authorized representative only if:

a. The authorization is made in writing by a person described in Part II K 1;

b. The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity such as the position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company. A duly authorized representative may thus be either a named individual or any individual occupying a named position; and

c. The written authorization is submitted to the department.

3. Changes to authorization. If an authorization under Part II K 2 is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of Part II K 2 shall be submitted to the department prior to or together with any reports, or information to be signed by an authorized representative.

4. Certification. Any person signing a document under Part II K 1 or 2 shall make the following certification:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

L. Duty to comply. The permittee shall comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the State Water Control Law and the Clean Water Act, except that noncompliance with certain

provisions of this permit may constitute a violation of the State Water Control Law but not the Clean Water Act. Permit noncompliance is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or denial of a permit <u>coverage</u> renewal application.

The permittee shall comply with effluent standards or prohibitions established under Section § 307(a) of the Clean Water Act for toxic pollutants and with standards for sewage sludge use or disposal established under Section § 405(d) of the Clean Water Act within the time provided in the regulations that establish these standards or prohibitions or standards for sewage sludge use or disposal, even if this permit has not yet been modified to incorporate the requirement.

M. Duty to reapply.

1. If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, and the permittee does not qualify for automatic permit coverage renewal, the permittee shall submit a new registration statement, or for an individual single family dwelling a combined application, at least 60 days before the expiration date of the existing permit, unless permission for a later date has been granted by the board. The board shall not grant permission for registration statements or combined applications to be submitted later than the expiration date of the existing permit.

2. A permittee qualifies for automatic permit coverage renewal and is not required to submit a registration statement, or for an individual single family dwelling a combined application, if:

a. The ownership of the treatment works has not changed since this general permit went into effect on August 2, 2011 2016, or, if the ownership has changed, (i) a new registration statement or for an individual single family dwelling a combined application or (ii) a VPDES Change of Ownership form was submitted to the department by the new owner at the time of the title transfer;

b. There has been no change in the design or operation, or both, of the treatment works since this general permit went into effect on August 2, $\frac{2011}{2016}$;

c. For treatment works serving individual single family dwellings, the Virginia Department of Health does not object to the automatic permit coverage renewal for this treatment works based on system performance issues, enforcement issues, or other issues sufficient to the board. If the Virginia Department of Health objects to the automatic renewal for this treatment works, the permittee will be notified by the board in writing; and

d. For treatment works serving nonsingle <u>buildings or</u> <u>dwellings other than single</u> family dwellings, the board has no objection to the automatic permit coverage renewal for this treatment works based on system performance issues, or enforcement issues, or other issues sufficient to the board. If the board objects to the automatic renewal for this treatment works, the permittee will be notified by the board in writing.

<u>3.</u> Any permittee that does not qualify for automatic permit coverage renewal shall submit a new registration statement, or for an individual single family dwelling a combined application, in accordance with Part II M 1.

N. Effect of a permit. This permit does not convey any property rights in either real or personal property or any exclusive privileges, nor does it authorize any injury to private property or invasion of personal rights, or any infringement of federal, state or local law or regulations.

O. State law. Nothing in this permit shall be construed to preclude the institution of any legal action under, or relieve the permittee from any responsibilities, liabilities, or penalties established pursuant to, any other state law or regulation or under authority preserved by Section § 510 of the Clean Water Act. Except as provided in permit conditions on "bypassing" (Part II U), and "upset" (Part II V) nothing in this permit shall be construed to relieve the permittee from civil and criminal penalties for noncompliance.

P. Oil and hazardous substance liability. Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties to which the permittee is or may be subject under §§ 62.1-44.34:14 through 62.1-44.34:23 of the State Water Control Law.

Q. Proper operation and maintenance. The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) that are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also include effective plant performance, adequate funding, adequate staffing, and adequate laboratory and process controls, including appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems that are installed by the permittee only when the operation is necessary to achieve compliance with the conditions of this permit.

R. Disposal of solids or sludges. Solids, sludges or other pollutants removed in the course of treatment or management of pollutants shall be disposed of in a manner so as to prevent any pollutant from such materials from entering state waters.

S. Duty to mitigate. The permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit that has a reasonable likelihood of adversely affecting human health or the environment.

T. Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

U. Bypass.

1. "Bypass" means the intentional diversion of waste streams from any portion of a treatment facility. The permittee may allow any bypass to occur that does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to ensure efficient operation. These bypasses are not subject to the provisions of Parts II U 2 and 3.

2. Notice.

a. Anticipated bypass. If the permittee knows in advance of the need for a bypass, prior notice shall be submitted, if possible, at least 10 days before the date of the bypass.

b. Unanticipated bypass. The permittee shall submit notice of an unanticipated bypass as required in Part II I.

3. Prohibition of bypass.

a. Bypass is prohibited, and the board may take enforcement action against a permittee for bypass, unless:

(1) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(2) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass that occurred during normal periods of equipment downtime or preventive maintenance; and

(3) The permittee submitted notices as required under Part II U 2.

b. The board may approve an anticipated bypass after considering its adverse effects if the board determines that it will meet the three conditions listed above in Part II U 3 a.

V. Upset.

1. An upset, defined in 9VAC25-31-10, constitutes an affirmative defense to an action brought for noncompliance with technology-based permit effluent limitations if the requirements of Part II V 2 are met. A determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is not a final administrative action subject to judicial review.

2. A permittee who wishes to establish the affirmative defense of upset shall demonstrate through properly signed, contemporaneous operating logs, or other relevant evidence that:

a. An upset occurred and that the permittee can identify the cause(s) of the upset;

b. The permitted facility was at the time being properly operated;

c. The permittee submitted notice of the upset as required in Part II I; and

d. The permittee complied with any remedial measures required under Part II S.

3. In any enforcement proceeding the permittee seeking to establish the occurrence of an upset has the burden of proof.

W. Inspection and entry. The permittee shall allow the director, or an authorized representative, upon presentation of credentials and other documents as may be required by law, to:

1. Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

3. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

4. Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act and the State Water Control Law, any substances or parameters at any location.

For purposes of this section, the time for inspection shall be deemed reasonable during regular business hours, and whenever the facility is discharging. Nothing contained herein shall make an inspection unreasonable during an emergency.

X. Permit actions. Permits may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, termination, or notification of planned changes or anticipated noncompliance does not stay any permit condition.

Y. Transfer of permits. 1. Permits are not transferable to any person except after notice to the department. Except as provided in Part II Y 2, a permit may be transferred by the permittee to a new owner or operator only if the permit has been modified or revoked and reissued, or a minor modification made, to identify the new permittee and incorporate such other requirements as may be necessary under the State Water Control Law and the Clean Water Act. 2. As an alternative to transfers under Part II Y 1, Coverage under this permit may be automatically transferred to a new permittee if:

a. <u>1.</u> The current permittee notifies the department within 30 days of the transfer of the title to the facility or property, <u>unless permission for a later date has been granted by the board;</u>

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b. <u>2</u>. The notice includes a written agreement between the existing and new permittees containing a specific date for transfer of permit responsibility, coverage, and liability between them; and

e. 3. The board does not notify the existing permittee and the proposed new permittee of its intent to modify or revoke and reissue deny the new permittee coverage under the permit. If this notice is not received, the transfer is effective on the date specified in the agreement mentioned in Part II Y 2 b.

Z. Severability. The provisions of this permit are severable, and if any provision of this permit or the application of any provision of this permit to any circumstance is held invalid, the application of such provision to other circumstances, and the remainder of this permit, shall not be affected thereby.

<u>NOTICE</u>: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (9VAC25-110)

VPDES Change of Ownership Agreement Form (eff. 7/10)-

Combined Application - Virginia Department of Health Discharging System Application for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons per Day and State Water Control Board Virginia Pollutant Discharge Elimination System General Permit Registration Statement for Domestic Sewage Discharges Less Than or Equal to 1,000 Gallons per Day (eff. 9/11)

VA.R. Doc. No. R15-4177; Filed July 1, 2015, 1:55 p.m.

Final Regulation

<u>REGISTRAR'S NOTICE</u>: The State Water Control Board 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 where no agency discretion is involved. The State Water Control Board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

<u>Title of Regulation:</u> 9VAC25-830. Chesapeake Bay Preservation Area Designation and Management Regulations (amending 9VAC25-830-40, 9VAC25-830-80).

Statutory Authority: §§ 62.1-15:69 and 62.1-15:72 of the Code of Virginia.

Effective Date: August 26, 2015.

<u>Agency Contact:</u> William K. Norris, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4022, FAX (804) 698-4347, or email william.norris@deq.virginia.gov.

<u>Summary:</u>

To conform the regulation to changes in the Code of Virginia enacted by Chapter 674 of the 2015 Acts of Assembly, the amendments define a daylighted stream and add an exemption for a locality's designation of a Resource Protection Area adjacent to a daylighted stream.

9VAC25-830-40. Definitions.

The following words and terms used in this chapter have the following meanings, unless the context clearly indicates otherwise. In addition, some terms not defined herein are defined in § 62.1-44.15:68 of the Act.

"Act" means the Chesapeake Bay Preservation Act, Article 2.5 (§ 62.1-44.15:67 et seq.) of Chapter 3.1 of Title 62.1 of the Code of Virginia.

"Best management practice" means a practice, or combination of practices, that is determined by a state or designated area-wide planning agency to be the most effective, practicable means of preventing or reducing the amount of pollution generated by nonpoint sources to a level compatible with water quality goals.

"Board" means the State Water Control Board.

"Buffer area" means an area of natural or established vegetation managed to protect other components of a Resource Protection Area and state waters from significant degradation due to land disturbances.

"Chesapeake Bay Preservation Area" means any land designated by a local government pursuant to Part III (9VAC25-830-70 et seq.) of this chapter and § 62.1-44.15:74 of the Act. A Chesapeake Bay Preservation Area shall consist of a Resource Protection Area and a Resource Management Area.

"Daylighted stream" means a stream that had been previously diverted into an underground drainage system and has been redirected into an aboveground channel using natural channel design concepts as defined in § 62.1-44.15:51 of the Code of Virginia, and where the adjacent lands would meet the criteria for being designated as a Resource Protection Area (RPA) as defined by the board under this chapter.

"Department" means the Department of Environmental Quality.

"Development" means the construction or substantial alteration of residential, commercial, industrial, institutional, recreation, transportation or utility facilities or structures.

"Director" means the Director of the Department of Environmental Quality.

"Erosion and Sediment Control Law" means Article 2.4 (§ 62.1-44.15:51 et seq.) of Chapter 3.1 of Title 62.1 of the Code of Virginia.

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"Floodplain" means all lands that would be inundated by flood water as a result of a storm event of a 100-year return interval.

"Highly erodible soils" means soils (excluding vegetation) with an erodibility index (EI) from sheet and rill erosion equal to or greater than eight. The erodibility index for any soil is defined as the product of the formula RKLS/T, where K is the soil susceptibility to water erosion in the surface layer; R is the rainfall and runoff; LS is the combined effects of slope length and steepness; and T is the soil loss tolerance.

"Highly permeable soils" means soils with a given potential to transmit water through the soil profile. Highly permeable soils are identified as any soil having a permeability equal to or greater than six inches of water movement per hour in any part of the soil profile to a depth of 72 inches (permeability groups "rapid" and "very rapid") as found in the "National Soil Survey Handbook" of November 1996 in the "Field Office Technical Guide" of the U.S. Department of Agriculture Natural Resources Conservation Service.

"Impervious cover" means a surface composed of any material that significantly impedes or prevents natural infiltration of water into the soil. Impervious surfaces include, but are not limited to, roofs, buildings, streets, parking areas, and any concrete, asphalt or compacted gravel surface.

"Infill" means utilization of vacant land in previously developed areas.

"Intensely Developed Areas" means those areas designated by the local government pursuant to 9VAC25-830-100.

"Local governments" means counties, cities and towns. This chapter applies to local governments in Tidewater Virginia, as defined in § 62.1-44.15:68 of the Act, but the provisions of this chapter may be used by other local governments.

"Local program" means the measures by which a local government complies with the Act and this chapter.

"Local program adoption date" means the date a local government meets the requirements of subdivisions 1 and 2 of 9VAC25-830-60.

"Nontidal wetlands" means those wetlands other than tidal wetlands that are inundated or saturated by surface or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions, as defined by the U.S. Environmental Protection Agency pursuant to § 404 of the federal Clean Water Act in 33 CFR 328.3b.

"Plan of development" means any process for site plan review in local zoning and land development regulations designed to ensure compliance with § 62.1-44.15:74 of the Act and this chapter, prior to issuance of a building permit.

"Public road" means a publicly owned road designed and constructed in accordance with water quality protection criteria at least as stringent as requirements applicable to the Virginia Department of Transportation, including regulations promulgated pursuant to (i) the Erosion and Sediment Control Law and (ii) the Virginia Stormwater Management Act. This definition includes those roads where the Virginia Department of Transportation exercises direct supervision over the design or construction activities, or both, and cases where secondary roads are constructed or maintained, or both, by a local government in accordance with the standards of that local government.

"Redevelopment" means the process of developing land that is or has been previously developed.

"Resource Management Area" means that component of the Chesapeake Bay Preservation Area that is not classified as the Resource Protection Area.

"Resource Protection Area" means that component of the Chesapeake Bay Preservation Area comprised of lands adjacent to water bodies with perennial flow that have an intrinsic water quality value due to the ecological and biological processes they perform or are sensitive to impacts which may result in significant degradation to the quality of state waters.

"Silvicultural activities" means forest management activities, including but not limited to the harvesting of timber, the construction of roads and trails for forest management purposes, and the preparation of property for reforestation that are conducted in accordance with the silvicultural best management practices developed and enforced by the State Forester pursuant to § 10.1-1105 of the Code of Virginia and are located on property defined as real estate devoted to forest use under § 58.1-3230 of the Code of Virginia.

"Substantial alteration" means expansion or modification of a building or development that would result in a disturbance of land exceeding an area of 2,500 square feet in the Resource Management Area only.

"Tidal shore" or "shore" means land contiguous to a tidal body of water between the mean low water level and the mean high water level.

"Tidal wetlands" means vegetated and nonvegetated wetlands as defined in § 28.2-1300 of the Code of Virginia.

"Tidewater Virginia" means those jurisdictions named in § 62.1-44.15:68 of the Act.

"Use" means an activity on the land other than development including, but not limited to, agriculture, horticulture and silviculture.

"Virginia Stormwater Management Act" means Article 2.3 (§ 62.1-44.15:24 et seq.) of Chapter 3.1 of Title 62.1 of the Code of Virginia.

"Water-dependent facility" means a development of land that cannot exist outside of the Resource Protection Area and must be located on the shoreline by reason of the intrinsic nature of its operation. These facilities include, but are not limited to (i) ports; (ii) the intake and outfall structures of power plants, water treatment plants, sewage treatment plants

and storm sewers; (iii) marinas and other boat docking structures; (iv) beaches and other public water-oriented recreation areas; and (v) fisheries or other marine resources facilities.

9VAC25-830-80. Resource Protection Areas.

A. At a minimum, Resource Protection Areas shall consist of lands adjacent to water bodies with perennial flow that have an intrinsic water quality value due to the ecological and biological processes they perform or are sensitive to impacts which may cause significant degradation to the quality of state waters. In their natural condition, these lands provide for the removal, reduction or assimilation of sediments, nutrients and potentially harmful or toxic substances in runoff entering the bay and its tributaries, and minimize the adverse effects of human activities on state waters and aquatic resources.

B. The Resource Protection Area shall include:

1. Tidal wetlands;

2. Nontidal wetlands connected by surface flow and contiguous to tidal wetlands or water bodies with perennial flow;

3. Tidal shores; and

4. Such other lands considered by the local government to meet the provisions of subsection A of this section and to be necessary to protect the quality of state waters; and.

5. A buffer area not less than 100 feet in width located adjacent to and landward of the components listed in subdivisions 1 through 4 above of this subsection, and along both sides of any water body with perennial flow. The full buffer area shall be designated as the landward component of the Resource Protection Area notwithstanding the presence of permitted uses, encroachments, and permitted vegetation clearing in compliance with Part IV (9VAC25-830-120 et seq.) of this chapter.

C. Designation of the components listed in subdivisions 1-4 <u>through 4</u> of subsection B of this section shall not be subject to modification unless based on reliable, site-specific information as provided for in 9VAC25-830-110 and subdivision 6 of 9VAC25-830-140.

D. For the purpose of generally determining whether water bodies have perennial flow, local governments may use one of the following methods as long as the methodology is adopted into the local program and applied consistently: (i) designation of water bodies depicted as perennial on the most recent U.S. Geological Survey 7-1/2 minute topographic quadrangle map (scale 1:24,000) or (ii) use of a scientifically valid system of in-field indicators of perennial flow. However, site-specific determinations shall be made or confirmed by the local government pursuant to 9VAC25-830-110.

E. A locality is not required to designate a Resource Protection Area adjacent to a daylighted stream. However, a locality that elects not to designate a Resource Protection Area adjacent to a daylighted stream shall use a water quality assessment as identified in subdivision 6 of 9VAC25-830-140 to ensure that proposed development on properties adjacent to the daylighted stream do not result in the degradation of the stream. The objective of this assessment is to ensure that practices on properties adjacent to daylighted streams are effective in retarding runoff, preventing erosion, and filtering nonpoint source pollution.

VA.R. Doc. No. R15-4357; Filed July 1, 2015, 12:17 p.m.

Final Regulation

<u>REGISTRAR'S NOTICE</u>: The State Water Control Board 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 where no agency discretion is involved. The State Water Control Board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

<u>Title of Regulation:</u> 9VAC25-840. Erosion and Sediment Control Regulations (amending 9VAC25-840-40).

Statutory Authority: § 62.1-44.15:52 of the Code of Virginia.

Effective Date: August 26, 2015.

<u>Agency Contact:</u> William K. Norris, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4022, FAX (804) 698-4347, or email william.norris@deq.virginia.gov.

Summary:

To conform to Chapter 497 of the 2015 Acts of Assembly, the amendment exempts routine maintenance projects from the flow rate capacity and velocity requirements of the Virginia Erosion and Sediment Control Law (Article 2.4 of Chapter 3.1 of Title 62.1 of the Code of Virginia).

9VAC25-840-40. Minimum standards.

A VESCP must be consistent with the following criteria, techniques and methods:

1. Permanent or temporary soil stabilization shall be applied to denuded areas within seven days after final grade is reached on any portion of the site. Temporary soil stabilization shall be applied within seven days to denuded areas that may not be at final grade but will remain dormant for longer than 14 days. Permanent stabilization shall be applied to areas that are to be left dormant for more than one year.

2. During construction of the project, soil stock piles and borrow areas shall be stabilized or protected with sediment trapping measures. The applicant is responsible for the temporary protection and permanent stabilization of all soil stockpiles on site as well as borrow areas and soil intentionally transported from the project site.

3. A permanent vegetative cover shall be established on denuded areas not otherwise permanently stabilized.

Permanent vegetation shall not be considered established until a ground cover is achieved that is uniform, mature enough to survive and will inhibit erosion.

4. Sediment basins and traps, perimeter dikes, sediment barriers and other measures intended to trap sediment shall be constructed as a first step in any land-disturbing activity and shall be made functional before upslope land disturbance takes place.

5. Stabilization measures shall be applied to earthen structures such as dams, dikes and diversions immediately after installation.

6. Sediment traps and sediment basins shall be designed and constructed based upon the total drainage area to be served by the trap or basin.

a. The minimum storage capacity of a sediment trap shall be 134 cubic yards per acre of drainage area and the trap shall only control drainage areas less than three acres.

b. Surface runoff from disturbed areas that is comprised of flow from drainage areas greater than or equal to three acres shall be controlled by a sediment basin. The minimum storage capacity of a sediment basin shall be 134 cubic yards per acre of drainage area. The outfall system shall, at a minimum, maintain the structural integrity of the basin during a 25-year storm of 24-hour duration. Runoff coefficients used in runoff calculations shall correspond to a bare earth condition or those conditions expected to exist while the sediment basin is utilized.

7. Cut and fill slopes shall be designed and constructed in a manner that will minimize erosion. Slopes that are found to be eroding excessively within one year of permanent stabilization shall be provided with additional slope stabilizing measures until the problem is corrected.

8. Concentrated runoff shall not flow down cut or fill slopes unless contained within an adequate temporary or permanent channel, flume or slope drain structure.

9. Whenever water seeps from a slope face, adequate drainage or other protection shall be provided.

10. All storm sewer inlets that are made operable during construction shall be protected so that sediment-laden water cannot enter the conveyance system without first being filtered or otherwise treated to remove sediment.

11. Before newly constructed stormwater conveyance channels or pipes are made operational, adequate outlet protection and any required temporary or permanent channel lining shall be installed in both the conveyance channel and receiving channel.

12. When work in a live watercourse is performed, precautions shall be taken to minimize encroachment, control sediment transport and stabilize the work area to the greatest extent possible during construction. Nonerodible material shall be used for the construction of

causeways and cofferdams. Earthen fill may be used for these structures if armored by nonerodible cover materials.

13. When a live watercourse must be crossed by construction vehicles more than twice in any six-month period, a temporary vehicular stream crossing constructed of nonerodible material shall be provided.

14. All applicable federal, state and local requirements pertaining to working in or crossing live watercourses shall be met.

15. The bed and banks of a watercourse shall be stabilized immediately after work in the watercourse is completed.

16. Underground utility lines shall be installed in accordance with the following standards in addition to other applicable criteria:

a. No more than 500 linear feet of trench may be opened at one time.

b. Excavated material shall be placed on the uphill side of trenches.

c. Effluent from dewatering operations shall be filtered or passed through an approved sediment trapping device, or both, and discharged in a manner that does not adversely affect flowing streams or off-site property.

d. Material used for backfilling trenches shall be properly compacted in order to minimize erosion and promote stabilization.

e. Restabilization shall be accomplished in accordance with this chapter.

f. Applicable safety requirements shall be complied with.

17. Where construction vehicle access routes intersect paved or public roads, provisions shall be made to minimize the transport of sediment by vehicular tracking onto the paved surface. Where sediment is transported onto a paved or public road surface, the road surface shall be cleaned thoroughly at the end of each day. Sediment shall be removed from the roads by shoveling or sweeping and transported to a sediment control disposal area. Street washing shall be allowed only after sediment is removed in this manner. This provision shall apply to individual development lots as well as to larger land-disturbing activities.

18. All temporary erosion and sediment control measures shall be removed within 30 days after final site stabilization or after the temporary measures are no longer needed, unless otherwise authorized by the VESCP authority. Trapped sediment and the disturbed soil areas resulting from the disposition of temporary measures shall be permanently stabilized to prevent further erosion and sedimentation.

19. Properties and waterways downstream from development sites shall be protected from sediment deposition, erosion and damage due to increases in volume, velocity and peak flow rate of stormwater runoff for the

stated frequency storm of 24-hour duration in accordance with the following standards and criteria. Stream restoration and relocation projects that incorporate natural channel design concepts are not man-made channels and shall be exempt from any flow rate capacity and velocity requirements for natural or man-made channels:

a. Concentrated stormwater runoff leaving a development site shall be discharged directly into an adequate natural or man-made receiving channel, pipe or storm sewer system. For those sites where runoff is discharged into a pipe or pipe system, downstream stability analyses at the outfall of the pipe or pipe system shall be performed.

b. Adequacy of all channels and pipes shall be verified in the following manner:

(1) The applicant shall demonstrate that the total drainage area to the point of analysis within the channel is one hundred times greater than the contributing drainage area of the project in question; or

(2) (a) Natural channels shall be analyzed by the use of a two-year storm to verify that stormwater will not overtop channel banks nor cause erosion of channel bed or banks.

(b) All previously constructed man-made channels shall be analyzed by the use of a ten year <u>10-year</u> storm to verify that stormwater will not overtop its banks and by the use of a two-year storm to demonstrate that stormwater will not cause erosion of channel bed or banks; and

(c) Pipes and storm sewer systems shall be analyzed by the use of a ten year <u>10-year</u> storm to verify that stormwater will be contained within the pipe or system.

c. If existing natural receiving channels or previously constructed man-made channels or pipes are not adequate, the applicant shall:

(1) Improve the channels to a condition where a ten year <u>10-year</u> storm will not overtop the banks and a two-year storm will not cause erosion to the channel, the bed, or the banks; or

(2) Improve the pipe or pipe system to a condition where the ten year <u>10-year</u> storm is contained within the appurtenances;

(3) Develop a site design that will not cause the predevelopment peak runoff rate from a two-year storm to increase when runoff outfalls into a natural channel or will not cause the pre-development peak runoff rate from a ten year <u>10-year</u> storm to increase when runoff outfalls into a man-made channel; or

(4) Provide a combination of channel improvement, stormwater detention or other measures which is satisfactory to the VESCP authority to prevent downstream erosion.

d. The applicant shall provide evidence of permission to make the improvements.

e. All hydrologic analyses shall be based on the existing watershed characteristics and the ultimate development condition of the subject project.

f. If the applicant chooses an option that includes stormwater detention, he shall obtain approval from the VESCP of a plan for maintenance of the detention facilities. The plan shall set forth the maintenance requirements of the facility and the person responsible for performing the maintenance.

g. Outfall from a detention facility shall be discharged to a receiving channel, and energy dissipators shall be placed at the outfall of all detention facilities as necessary to provide a stabilized transition from the facility to the receiving channel.

h. All on-site channels must be verified to be adequate.

i. Increased volumes of sheet flows that may cause erosion or sedimentation on adjacent property shall be diverted to a stable outlet, adequate channel, pipe or pipe system, or to a detention facility.

j. In applying these stormwater management criteria, individual lots or parcels in a residential, commercial or industrial development shall not be considered to be separate development projects. Instead, the development, as a whole, shall be considered to be a single development project. Hydrologic parameters that reflect the ultimate development condition shall be used in all engineering calculations.

k. All measures used to protect properties and waterways shall be employed in a manner which minimizes impacts on the physical, chemical and biological integrity of rivers, streams and other waters of the state.

1. Any plan approved prior to July 1, 2014, that provides for stormwater management that addresses any flow rate capacity and velocity requirements for natural or manmade channels shall satisfy the flow rate capacity and velocity requirements for natural or man-made channels if the practices are designed to (i) detain the water quality volume and to release it over 48 hours; (ii) detain and release over a 24-hour period the expected rainfall resulting from the one year, 24-hour storm; and (iii) reduce the allowable peak flow rate resulting from the 1.5, 2, and 10-year, 24-hour storms to a level that is less than or equal to the peak flow rate from the site assuming it was in a good forested condition, achieved through multiplication of the forested peak flow rate by a reduction factor that is equal to the runoff volume from the site when it was in a good forested condition divided by the runoff volume from the site in its proposed condition, and shall be exempt from any flow rate capacity and velocity requirements for natural or manmade channels as defined in any regulations promulgated pursuant to § 62.1-44.15:54 or 62.1-44.15:65 of the Act.

m. For plans approved on and after July 1, 2014, the flow rate capacity and velocity requirements of § 62.1-44.15:52 A of the Act and this subsection shall be satisfied by compliance with water quantity requirements in the Stormwater Management Act (§ 62.1-44.15:24 et seq. of the Code of Virginia) and attendant regulations, unless such land-disturbing activities are in accordance with 9VAC25-870-48 of the Virginia Stormwater Management Program (VSMP) Regulations Regulation or are exempt pursuant to subdivision C 7 of § 62.1-44.15:34 of the Act.

n. Compliance with the water quantity minimum standards set out in 9VAC25-870-66 of the Virginia Stormwater Management Program (VSMP) Regulations Regulation shall be deemed to satisfy the requirements of this subdivision 19 of this subsection.

VA.R. Doc. No. R15-4356; Filed July 1, 2015, 12:13 p.m.

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TITLE 12. HEALTH

STATE BOARD OF HEALTH

Final 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 12VAC5-12VAC5-481-1591, 481-1581, 12VAC5-481-1601, 12VAC5-481-1611, 12VAC5-481-1621, 12VAC5-481-1631, 12VAC5-481-1641, 12VAC5-481-1651, 12VAC5-481-1653, 12VAC5-481-1657; 12VAC5-481-1655, 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.

Effective Date: August 27, 2015.

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

Summary:

The 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.

<u>Summary of Public Comments and Agency's Response:</u> 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

12VAC5-481-10. Definitions.

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

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

"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 onetime measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

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

"Acute" means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

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"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 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 airpurifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

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

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

"Analytical $\frac{x}{x}$ ray $\frac{x}{x}$ equipment" means equipment used for $\frac{x}{x}$ ray $\frac{x}{x}$ 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 <u>(APF)</u>" <u>or "APF"</u> 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.

<u>"Articulated joint" means a joint between two separate</u> 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 $\frac{x}{ray} \frac{x}{x-ray}$ system or subsystem. The term includes the owner of an $\frac{x}{ray} \frac{x-ray}{x-ray}$ system or his [or her] employee or agent who assembles components into an $\frac{x}{ray} \frac{x-ray}{x-ray}$

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 $\frac{X}{x}$ ray $\frac{x}{x}$ 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) <u>or "Bq"</u> means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

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

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

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

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

"Board" means the State Board of Health.

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

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

"Byproduct material" means:

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

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

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

b. Any material that:

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

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

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

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

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

"C-arm X ray system <u>fluoroscope</u>" means an X ray <u>x-ray</u> system in which the image receptor and X ray <u>x-ray</u> 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 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 $\frac{x}{x-ray} \frac{x-ray}{x-ray}$ system" means an existing uncertified $\frac{x}{x-ray} \frac{x-ray}{x-ray}$ 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 $\frac{X}{X}$ 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)" <u>or "C"</u> means the ratio of the standard deviation to the mean value of a <u>set population</u> of observations. It is estimated using the following equation:

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

where:

s = Standard deviation of the observed values;

 $\left[\underline{X} \ \underline{X} \right] =$ 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" $(H_{T,50})$ 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 ($H_{E,50} = \Sigma (w_T H_{T,50})$).

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of $\frac{1}{x-ray}$ 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:

$$CTDI = 1/nT \int_{-T_T}^{+T_T} D(z) dz$$

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.

"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:

 $\left[\frac{\mu_{\rm w}}{\mu_{\rm x}}\right]$ = Linear attenuation coefficient of the material of interest;

 $\left[\frac{\mu_{x}}{CTN_{x}}\right] = \text{Linear attenuation coefficient of water;}$ $\overline{CTN}_{x} = \text{of the material of interest;}$ $\overline{\text{CTN}}_{W} = \text{of water.}$

"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 $\frac{X}{X}$ ray $\frac{x-ray}{ray}$ 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").

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"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, beamlimiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT <u>Number</u>" <u>number</u>" means the number used to represent the <u>X ray x-ray</u> attenuation associated with each elemental area of the CT image.

$$\overline{\text{CTN}} = \frac{k(\mu_{\bullet} - \mu_{\bullet})}{\mu_{\bullet}}$$

where:

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

 μ_{x} = Linear attenuation coefficient of the material of interest;

 $\mu_{\mathbf{w}}$ = 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 " $H_{d,d}$ " 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 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,

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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 Xrays 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 and] a disposable escape-only self-contained breathing apparatus (SCBA).

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

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"Disposal site" means that portion of a land disposal facility that is used for disposal of waste. It consists of disposal units and a buffer zone.

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

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

"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 ($H_E = \Sigma w_T H_T$).

"Elemental area" means the smallest area within a tomogram for which the $\frac{X}{X}$ -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").

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"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 $\frac{x - xy}{x - xy}$ 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 operatorapplied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

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

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

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

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

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

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

"General purpose radiographic X ray <u>x-ray</u> system" means any radiographic X ray <u>x-ray</u> 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.

<u>"Hand-held radiographic unit" means x-ray equipment that</u> 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 [AB] 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 $\frac{X}{x}$ -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 $\frac{X}{x}$ -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>U.S.</u> 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 $\frac{x}{x}$ -ray pattern into a corresponding light image of higher intensity.

"Image receptor" means any device, such as a fluorescent screen $\Theta \mathbf{r}_{\mathbf{x}}$ radiographic film, <u>x-ray image intensifier tube</u>, <u>solid-state detector</u>, or <u>gaseous detector</u> that transforms incident X ray <u>x-ray</u> 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 <u>device</u>.

"Image receptor support <u>device</u>" means, for mammographic systems, that part of the system designed to support the image receptor during <u>mammography mammographic examination</u> 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 <u>DAC hours</u>]. (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.

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"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 <u>smallest</u> sphere through which the <u>useful</u> beam axis passes <u>while the gantry moves</u> through its full range of motions <u>when the equipment moves</u> through a full range of rotations about its common center.

"kBq" means kilabecquerels.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus K=dEtr/dm, in units of J/kg, where the special name for the units of kerma is gray (Gy). When the materials is air, the quantity is referred to as "air kerma."

"Kilovolt-(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").

"kWs" means kilowatt second.

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

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

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

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

"Leakage radiation" means radiation emanating from the diagnostic source assembly 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 milliampere 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 $\frac{x}{x}$ 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 <u>percent</u> of the load line potential. It is calculated using the following equation <u>as follows</u>:

Percent line-voltage regulation = $100 (V_n - V_l)/V_l$ where:

 $V_n =$ No-load line potential; and

 V_1 = Load line potential.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Local components" mean part of an analytical $\frac{X - ray}{X - ray}$ system and include areas that are struck by $\frac{X - rays}{X - rays}$ 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 [material]" means radioactive material with limited specific activity that is nonfissile or is excepted under 12VAC5-481-2970 C, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

1. LSA-I

a. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclide that are not intended to be processed for the use of these radionuclides;

b. Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

c. Radioactive material, for which the A_2 value is unlimited; or

d. Other radioactive material in which the activity is distributed throughout and the estimated average specific

activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 12VAC5-481-3720.

2. LSA-II

a. Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or

b. Other material in which the activity is distributed throughout, and the average specific activity does not exceed 1.0 E-04 A_2/g for solids and gases, and 1.0 E-05 A_2/g for liquids.

3. LSA-III

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77) in which:

a. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (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 E-03 $A_{2}/g.$

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

"Lung class" (See "Class").

"mA" means milliampere.

"mAs" means milliampere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this section.

"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

<u>f.</u> 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;

<u>b</u> [<u>,</u>] <u>Involving the wrong treatment site; or</u>

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 <u>x-ray</u> equipment" (See "X-ray equipment").

"Mode of operation" means, for fluoroscopy systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or

optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"Monitor unit (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 <u>x-ray</u> system that obtains X ray <u>x-ray</u> transmission data simultaneously during a single scan to produce more than one tomogram.

"NARM" means any naturally occurring or acceleratorproduced radioactive material. It does not include byproduct, source, or special nuclear material.

"National Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 12VAC5-481-3780. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold 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.

 $\mu_{\mathbf{W}}$ = 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 $\frac{X \text{ ray } x \text{ -ray}}{X \text{ ray } \text{ transmission data are collected.}}$

<u>"Non-image-intensified fluoroscopy" means fluoroscopy</u> 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 $\frac{x}{x}$ ray $\frac{x}{x}$ 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 <u>542</u> <u>542A</u>" 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 $\frac{X-ray}{X-ray}$ 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.

"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 $\frac{x-ray}{x-ray}$ 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 wetsource-storage irradiators and underwater irradiators.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by this state to prescribe drugs in the practice of medicine.

"Picture element" means an elemental area of a tomogram.

"PID" (See "Position indicating device").

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Portable X-ray x-ray equipment" (See "X-ray equipment").

"Position indicating device" means a device on dental $\frac{x}{x-ray}$ equipment used to indicate the beam position and to

establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an $\frac{x - ray}{x - ray}$ beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

[<u>"Positive emission tomography</u>] (PET) [<u>Positron emission</u> tomography] radionuclide production facility" <u>or "PET"</u> means a facility operating a cyclotron or [<u>other particle</u>] accelerator for the purpose of producing [<u>PET</u>] radionuclides [<u>that decay by positron emission</u>].

"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 <u>x-rays</u>. 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 $\frac{x}{xay}$ 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 radiationattenuating 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) <u>or "Q"</u> means the modifying factor, that is referenced in 12VAC5-481-240, that is used to derive dose equivalent from absorbed dose.

"Quantitative fit test <u>(QNFT)</u>" <u>or "QNFT"</u> 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 <u>x-rays</u>, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose" (See "Dose").

"Radiation field" (See "Useful beam").

"Radiation head" means the structure from which the useful beam emerges.

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Radiation safety officer (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 $\frac{X-ray}{x-ray}$ 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 $\frac{x - ray}{x - ray}$ 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 $\frac{x - ray}{x - ray}$ 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;

<u>3. A teletherapy x-ray [or electron] dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or</u>

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>U.S.</u> Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the

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extraction of uranium and other valuable constituents of the ores and (ii) other waste (that the <u>U.S.</u> 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 <u>x</u>ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray 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 $\frac{x}{x}$ 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 DOT 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) <u>or "Sv"</u> 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 $\frac{x}{x}$ ray $\frac{x}{x}$ system that obtains $\frac{x}{x}$ ray $\frac{x}{x}$ 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 $\frac{x-ray}{x-ray}$ 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)" <u>or "SSD"</u> 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 \S] 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:

175(gramscontainedU-235)	50 (grams U- 233) +	50 (grams P
350	200	200

"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 $\frac{1}{x-ray}$ 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 <u>X-ray</u> 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.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the wellbore or adjacent formation.

"Supplied-air respirator-(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 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm² (1 E-05 μ Ci/cm²) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1.0 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm² (0.1 μ Ci/cm²) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm² (0.1 μ Ci/cm²) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 400 becquerel per cm² (1 E-02 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm² (1 E-03 μ Ci/cm²) for all other alpha emitters;

b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μ Ci/cm²) for all other alpha emitters; and

c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μ Ci/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μ Ci/cm²) for all other alpha emitters.

"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.

<u>"Tabletop, stationary" means a tabletop that, when</u> 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 <u>x-ray</u> 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 $\frac{kV}{kilovolts}$ (kV) and quantity of charge in mAs milliampere-seconds (mAs);

2. For field emission equipment rated for pulsed operation, peak tube potential in $\frac{kV}{kilovolts}$ (kV), and number of X-ray x-ray pulses;

3. For CT X-ray systems equipment designed for pulsed operation, peak tube potential in $\frac{kV}{kilovolts}$ ($\frac{kV}{k}$), 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 milliampere-seconds (mAs);

4. For CT X-ray systems equipment not designed for pulsed operation, peak tube potential in $\frac{kV}{kilovolts}$ ($\frac{kV}{k}$), and either tube current in Ma milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in mAs milliampere-seconds (mAs) and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in $\frac{kV}{kilovolts (kV)}$, and either tube current in $\frac{Ma}{milliamperes}$ (mA) and exposure time in seconds, or the product of tube current and exposure time in $\frac{mAs}{milliampere-seconds}$ (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 [$\frac{XRF}{x-ray}$ fluorescense] use is performed and where licensed material may be stored other than those location(s) of use authorized on the license.

"Tenth-value layer <u>(TVL)</u>" <u>or "TVL"</u> 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 <u>x-ray</u> 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 <u>x-ray</u> 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 $\frac{X - ray}{x - ray}$ attenuation properties are imaged in a tomogram.

"Total effective dose equivalent" (TEDE) <u>or "TEDE"</u> 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 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 A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of 12VAC5-481-3770 or may be determined by procedures described in Table A-1 of 12VAC5-481-3770.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

"Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or 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 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Uranium-natural, depleted, enriched"

1. "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.

2. "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Useful beam" means the radiation emanating from that passes through the tube housing port or the radiation head and passing through and the aperture of the beam limiting beamlimiting 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 beamlimiting device which has capacity for stepless adjustment of the $\frac{x-ray}{x-ray}$ 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 $\frac{x}{x}$ ray $\frac{x}{x}$ 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, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Weighting factor [$(w_T)^{"}$ " or " w_T " for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors		
Organ or Tissue	WT	
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 $\frac{X - ray}{X - ray}$ system, subsystem, or component thereof. Types of $\frac{X - ray}{X - ray}$ 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 <u>x-ray</u> equipment" means X ray <u>x-ray</u> equipment designed to be hand-carried.

3. "Stationary X-ray <u>x-ray</u> equipment" means $\frac{x-ray}{x-ray}$ 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 including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate <u>AKR</u> 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 <u>x-rays</u>. It includes minimally an X-ray <u>x-ray</u> high-voltage generator, an X-ray <u>x-ray</u>

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 $\frac{x}{x}$ 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 $\frac{12VAC5}{481-1591}$ 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 $\frac{x}{x}$ ray $\frac{x}{x}$, mammographic or therapeutic $\frac{x}{x}$ ray $\frac{x}{x}$ 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 <u>x-ray</u> (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 $\frac{X-ray}{x-ray}$ 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 $\frac{X-ray}{x-ray}$ 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 $\frac{X}{X}$ ray <u>x-ray</u>, 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 $\frac{X - ray}{x - ray}$ 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 $\frac{X - ray}{x - ray}$ and teletherapy machines. The person must have adequate knowledge, training, and experience to calibrate a therapeutic $\frac{X - ray}{x - ray}$ 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 [<u>or therapeutic</u> medical 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 A; 12VAC5-481-3420 P; [12VAC5-481-3420 Q,] 12VAC5-481-3430 T; [12VAC5-481-3420 Q;] 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, b, 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 <u>x-ray</u> 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 $\frac{X}{X} - \frac{x}{xy}$ or teletherapy facilities and at least one therapeutic $\frac{X}{X} - \frac{x}{xy}$ 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 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

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

(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 Xray 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:

⁽¹⁾ Collimation

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;

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
	Bitewing Speed Film
50 kVp	575 mR
55 kVp	500 mR
60 kVp	440 mR
65 kVp	4 00 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

c. 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;

e. 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);

1. 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.

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
°C	°F	Time (Minutes)
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	4 2
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:

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(1) Films shall be developed in accordance with the timetemperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum
<u>°</u> €	°E	Immersion Time ^a
		(Seconds)
35.5	96	19
35	95	20
34.5	94	21
3 4	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

* 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. 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 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.

<u>12VAC5-481-1591</u> 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:

<u>a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;</u>

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;

<u>d. Source to image receptor distance to be used (except for dental intraoral radiography);</u>

e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

<u>f.</u> 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 [. However, when distances provide sufficient protection from scatter radiation, or for low dose rate devices such as bone densitometry equipment, no protective devices may be necessary]; 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 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 [. Caregivers who stay in the room to assist with imaging of patients shall be positioned and instructed to keep the protective apron between themselves and the patient]:

d. No individual shall be used routinely to hold image receptors 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.

<u>9. Procedures and auxiliary equipment designed to</u> 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 radiographic [(exclude fluoroscopic)] 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. that is], 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:

<u>a.</u> 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. that is], type and number of views;

<u>d.</u> Description of the population to be examined in the screening program, [<u>i.e.</u> that is], 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;

<u>f.</u> An evaluation by a qualified medical physicist of the xray 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;

<u>h.</u> 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:

<u>k.</u> The name and address of the practitioner licensed in the state who will interpret the radiograph;

1. 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 [, or was enrolled within the past three months,] in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, [and or] 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.

<u>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:</u>

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			
<u>Thermometer Reading</u> (Degrees)		<u>Minimum</u> <u>Developing Time</u> (<u>Minutes)</u>	
<u>°C</u>	°F		
<u>26.7</u>	<u>80</u>	<u>2</u>	
<u>26.1</u>	<u>79</u>	<u>2</u>	
<u>25.6</u>	<u>78</u>	<u>2-1/2</u>	
<u>25.0</u>	<u>77</u>	<u>2-1/2</u>	
<u>24.4</u>	<u>76</u>	<u>3</u>	
<u>23.9</u>	<u>75</u>	<u>3</u>	
<u>23.3</u>	<u>74</u>	<u>3-1/2</u>	
<u>22.8</u>	<u>73</u>	<u>3-1/2</u>	
22.2	<u>72</u>	<u>4</u>	
<u>21.7</u>	<u>71</u>	<u>4</u>	
<u>21.1</u>	<u>70</u>	<u>4-1/2</u>	
<u>20.6</u>	<u>69</u>	<u>4-1/2</u>	
<u>20.0</u>	<u>68</u>	<u>5</u>	
<u>19.4</u>	<u>67</u>	<u>5-1/2</u>	
<u>18.9</u>	<u>66</u>	<u>5-1/2</u>	
<u>18.3</u>	<u>65</u>	<u>6</u>	
<u>17.8</u>	<u>64</u>	<u>6-1/2</u>	
<u>17.2</u>	<u>63</u>	<u>7</u>	
<u>16.7</u>	<u>62</u>	<u>8</u>	
<u>16.1</u>	<u>61</u>	<u>8-1/2</u>	
<u>15.6</u>	<u>60</u>	<u>9-1/2</u>	

(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		<u>Minimum Immersion</u> <u>Time*</u>
<u>°C</u>	°F	<u>Seconds</u>
<u>35.5</u>	<u>96</u>	<u>19</u>
<u>35</u>	<u>95</u>	<u>20</u>
<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>

*Immersion time only, no crossover time included.

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.

<u>C. The registrant shall submit to the agency a copy of all</u> 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.

<u>E. Violations identified as "serious" must be corrected</u> within 30 days. Certification of the unit will not be issued until the violation is corrected. Violations identified as "nonserious" 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 μ C/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 μ C/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 Xray 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

		Half Value Layer In mm Aluminum	
Design Operating Range (kVp)	Measured Potential (kVp)	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	<u>2.1</u>	2.1
	80	2.3	2.3
	90	2.5	<u>2.5</u>
	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 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.

<u>12VAC5-481-1601. General requirements for all</u> <u>diagnostic x-ray systems.</u>

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 xray 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

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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	
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X-Ray Tube Voltage (kilovolt peak)				
Design Operating	Measured Operating	Minimum HVL (mm in Aluminum)		
<u>Range</u>	Potential	Specified Dental Systems ¹	<u>I-Other X-Ray</u> <u>Systems²</u>	<u>II-Other X-Ray</u> <u>Systems³</u>
Below 51	$\frac{30}{40}$ <u>50</u>	<u>1.5</u> <u>1.5</u> <u>1.5</u>	0.3 0.4 0.5	$\begin{array}{r} \underline{0.3}\\ \underline{0.4}\\ \underline{0.5} \end{array}$
<u>51 to 70</u>	$\frac{51}{60}$ $\overline{70}$	<u>1.5</u> <u>1.5</u> <u>1.5</u>	$\frac{1.2}{1.3}$ $\frac{1.5}{1.5}$	$\frac{1.3}{1.5}$ $\frac{1.8}{1.8}$
<u>Above 70</u>	$ \begin{array}{r} \frac{71}{80} \\ \underline{90} \\ \underline{100} \\ \underline{110} \\ \underline{120} \\ \underline{130} \\ \underline{140} \\ \underline{150} \end{array} $	$ \begin{array}{r} \underline{2.1} \\ \underline{2.3} \\ \underline{2.5} \\ \underline{2.7} \\ \underline{3.0} \\ \underline{3.2} \\ \underline{3.5} \\ \underline{3.5} \\ \underline{3.8} \\ \underline{4.1} \\ \end{array} $	$ \begin{array}{r} $	$ \begin{array}{r} $
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</u> <u>Aluminum</u> Equivalent (mm)
Front panel(s) of cassette holders (total of all)	<u>1.2</u>
Film panel(s) of film changer (total of all)	<u>1.2</u>
Cradle	<u>2.3</u>
<u>Tabletop, stationary, without</u> <u>articulated joints</u>	<u>1.2</u>
Tabletop, movable, without articulated joints (including stationary subtop)	<u>1.7</u>
Tabletop, with radiolucent panel having one articulated joint	<u>1.7</u>
Tabletop, with radiolucent panel having two or more articulated joints	<u>2.3</u>
Tabletop, cantilevered	<u>2.3</u>
Tabletop, radiation therapy simulator	<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.

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;

(c) 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 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 setion1;

(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 %v(508)%E2%vC/kg (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 mC/kg (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 ontime 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 Xray 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.

<u>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.</u>

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 3.34×10^{-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 beamlimiting 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.

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.

<u>E. Air kerma rates. For fluoroscopic equipment, the following requirements apply:</u>

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.

<u>d. In a C-arm type of fluoroscope having an SID less than</u> 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.

<u>4. Exemptions. Fluoroscopic radiation therapy simulation</u> systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

F. Reserved.

<u>G. Indication of potential and current. During fluoroscopy</u> and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential 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.

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(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.

<u>K.</u> 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.

<u>3. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.</u>

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:

<u>a. Is at least 120 centimeters from the center of the useful</u> <u>beam; or</u>

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.

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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.

<u>P.</u> 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 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. c. 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 Xray 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, beamlimiting 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 kWs 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_i) of exposure to the indicated timer setting, in units of C kg⁻¹s⁻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 kg⁻¹s⁻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 panographic 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 $\frac{v(508)}{E2\%}vC/kg$ (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_i) of exposure to the indicated milliampere seconds product $(C \text{ kg}^{+} \text{ mAs}^{+} \text{ (or mR/mAs)})$ 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 milliampere 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.

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:

<u>a. Indication shall be made on the control panel when this</u> <u>mode of operation is selected;</u>

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 milliampere-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 (kWs) per exposure or the product of xray 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.

<u>B. Reproducibility. The following requirements shall apply</u> when the equipment is operated on an adequate power supply as specified by the manufacturer:

<u>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.</u>

2. Measuring compliance. Determination of compliance shall be based on [$\frac{10}{10}$ four] 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

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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 milliampere-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:

 $|X1 - X2| \le 0.10(X1 + X2)$

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 currentexposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-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:

 $|X1 - X2| \le 0.10(X1 + X2)$

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 [$\frac{10}{10}$ four] 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 spotfilm 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.

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

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the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

<u>F. Field limitation on radiographic x-ray equipment other</u> 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 xray beam such that:

a. If the minimum [source to skin source-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.

Radiographic systems designed only for a. 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.

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 align] the x-ray field such that the xray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

<u>a.</u> 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, beamlimiting 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.

<u>G. Positive beam limitation (PBL). The requirements of this</u> subsection shall apply to radiographic systems that contain <u>PBL.</u>

<u>1. Field size. When a PBL system is provided, it shall prevent x-ray production when:</u>

<u>a. Either the length or width of the x-ray field in the</u> plane of the image receptor differs from the corresponding image receptor dimension by more than 3.0% of the SID; or

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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;

<u>d.</u> 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.

<u>H. Field limitation and alignment for spot-film devices. The following requirements shall apply to spot-film devices,</u>

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 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.

<u>L. Radiation from capacitor energy storage equipment.</u> <u>Radiation emitted from the x-ray tube shall not exceed:</u>

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.

<u>M. Primary protective barrier for mammography x-ray systems.</u>

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 beamlimiting 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 xray systems that are:

(1) Used continuously for greater than one week in the same location, [i.e. that is], 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.

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 milliampere 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 currentexposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliampere 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_{\perp} 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.

<u>12VAC5-481-1631.</u> 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 [<u>i.e.</u> that is], a room or suite, shall meet the requirements of subdivision 2 a 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.

<u>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.</u>

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.

e. 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.

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 twoway 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 eylinders 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.

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 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.

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 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.

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.

<u>a. The CT x-ray control and gantry shall provide visual</u> <u>indication whenever x-rays are produced and, if</u> <u>applicable, whether the shutter is open or closed.</u>

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.

<u>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.</u>

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.

<u>d.</u> 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.

<u>1. Aural communication. Provision shall be made for two-</u> 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

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(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.

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, sourceto 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 bv 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 %v(508)%E2%vC/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:

a. Conduct equipment performance monitoring functions;

b. Analyze the monitoring results to determine if there are problems requiring correction;

c. 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

d. Maintain records for a minimum of two years documenting that actions required under subdivisions 1 a through c of this subsection have been completed.

2. Quality assurance program review. At intervals not to exceed 12 months, the registrant shall:

a. 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

b. 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.

a. 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 middensity (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.

I. 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; of 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. 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.

<u>A. Only x-ray systems, pursuant to the Mammography</u> <u>Quality Standards Reauthorization Act of 1998</u> [(Public Law (Pub.L.] 105-248) and 21 CFR Part 900, shall be used for screening and diagnostic mammography.</u>

<u>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.</u>

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.

<u>F. Agency inspectors may conduct unannounced inspections</u> <u>during normal business hours.</u>

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

D. Additional state requirements.

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.

<u>B.</u> 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.

<u>C. Operators of a bone densitometry system shall meet one of the following:</u>

<u>1. Be certified by the American Registry of Radiologic</u> <u>Technologists (ARRT);</u>

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;

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 subdivision] 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.

<u>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.</u>

<u>F. Bone densitometry on human patients shall be conducted only:</u>

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.

<u>All registrants of diagnostic x-ray imaging equipment may</u> <u>be required by the agency to establish and maintain a quality</u> assurance program consisting of quality control assessments.

12VAC5-481-2110. Area requirements.

A. Radiation Levels. The local components of an analytical $\frac{X \cdot ray}{x \cdot ray}$ 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 $\frac{X \cdot ray}{x \cdot ray}$ 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 [by or under the supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with this chapter];

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 xray 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 July 1, 2015, 10:50 a.m.

EXECUTIVE ORDER NUMBER 45 (2015)

Extension of the Governor's Climate Change and Resiliency Update Commission

Importance of the Issue

The National Oceanic and Atmospheric Administration has identified some Virginia coastal areas as among the most vulnerable to sea level rise in the nation, and the U.S. Navy Task Force Climate Change has identified Naval Station Norfolk as one of its most endangered installations. The Chesapeake Bay is particularly susceptible to damage caused by climate change. While Virginia has taken certain steps to mitigate the effects of climate change, it is imperative that the Commonwealth redouble its efforts in the face of this looming problem.

In 2008, Governor Kaine established the Governor's Commission on Climate Change to address these concerns. The Commission's final report outlined the impact that changing weather conditions have on Virginia's built environment, natural systems, and the health of its citizens. Among the findings was the decline or disappearance of key species of the Chesapeake Bay, increased damage from more frequent and severe storms, and the spread of vector born diseases like West Nile virus. The report also made over 150 recommendations to help Virginia adapt to the consequences of climate change, as well as reduce Virginia's contributions to the problem.

Extension of the Commission

On July 1, 2014, I convened the Governor's Climate Change and Resiliency Update Commission ("Commission") to review, update, and prioritize the recommendations of the 2008 Climate Change Action Plan. This updated report will work to identify sources of revenue to fund the implementation of these recommendations. Pursuant to § 2.2-135(C) of the Code of Virginia, I hereby reissue Executive Order Nineteen (2014) as Executive Order Forty-Five (2015), and extend the Commission's work for an additional year.

Composition of the Commission

The Governor's Climate Change and Resiliency Update Commission membership will remain as currently constituted.

The Governor may appoint any other member(s) deemed necessary to carry out the assigned functions of the Commission and the members shall serve at his pleasure.

Staff support for the Commission will be provided by the Offices of the Secretary of Natural Resources, the Secretary of Public Safety and Homeland Security, the Secretary of Transportation, the Secretary of Commerce and Trade, the Department of Environmental Quality, the Department of Mines, Minerals and Energy, the Office of the Governor, and other agencies as may be designated by the Governor. The

estimated direct cost of the Commission is \$5,000. All executive branch agencies shall cooperate fully with the Commission and provide any assistance necessary, upon request of the Commission or its staff.

Duties of the Commission

The Commission is charged with conducting an assessment of the recommendations from the 2008 Climate Change Action Plan. Specifically, the Commission will:

- Determine which recommendations from the original report were implemented;
- Update and prioritize the recommendations; and,
- Identify sources of funding to support the implementation of the recommendations.

The Commission shall submit a report with its updated recommendations by September 30, 2015.

Effective Date of the Order

This Executive Order shall be effective upon its signing and, pursuant to §§ 2.2-134 and 2.2-135 of the Code of Virginia, shall remain in force and effect for a year or until superseded or rescinded.

Given under my hand and under the Seal of the Commonwealth of Virginia, this 1st day of July, 2015.

/s/ Terence R. McAuliffe Governor

GENERAL NOTICES/ERRATA

DEPARTMENT OF ENVIRONMENTAL QUALITY

Rocky Forge Small Wind Energy Project

The Department of Environmental Quality has received a Notice of Intent from Rocky Forge Wind, LLC (Rocky Forge), an affiliate of Apex Clean Energy Holdings, LLC. Rocky Forge intends to submit the necessary document for a permit by rule (PBR) for a small renewable energy project (wind) in Botetourt County, Virginia, pursuant to the Small Renewable Energy Projects (Wind) Permit By Rule regulation (9VAC15-40).

Rocky Forge is studying the feasibility of constructing and operating the Rocky Forge Wind Project (Project), which would be located on a remote tract of private property in northern Botetourt County. The Project site is ideal for a wind project due to the strong wind resource and existing onsite transmission line. The Project is likely to consist of 15 to 25 modern wind turbines, depending upon the turbine model selected, with a total project capacity not to exceed 80 MW. Rocky Forge is committed to responsibly developing the Project and complying with local, state, and federal permit standards to ensure the Project is a long-term benefit for both Botetourt County and the Commonwealth of Virginia.

Contact Information: Mary E. Major, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804)698-4510, or email mary.major@deq.virginia.gov.

STATE BOARD OF HEALTH

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Health is conducting a periodic review and small business impact review of **12VAC5-66**, **Regulations Governing Durable Do Not Resuscitate Orders**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins July 27, 2015, and ends August 17, 2015.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Michael Berg, Regulation and Compliance Manager, Virginia Department of Health, Office of Emergency Medical Services, 1001 Technology Park Drive, Glen Allen, VA 23059, telephone (804) 888-9131, FAX (804)371-3108, or email michael.berg@vdh.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

BOARD OF JUVENILE JUSTICE

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board of Juvenile Justice conducted a small business impact review of **6VAC35-11, Public Participation Guidelines** and determined that this regulation should be retained in its current form. The Board of Juvenile Justice is publishing its report of findings dated June 25, 2015, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

This regulation has no impact on small business.

1. Section 2.2-4007.02 of the Code of Virginia requires each agency subject to the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) to develop, adopt, and use public participation guidelines for soliciting the input of interested parties in the formation and development of the agency's regulations.

2. No comments or complaints have been received regarding this regulation.

3. The regulation is not complex and clearly outlines the requirements for notice and the timelines for public comment.

4. The regulation duplicates the requirements of the Virginia Administrative Process Act. The regulation does not conflict with federal or state law or regulation.

5. The regulation was last reviewed in September of 2008. As part of the review process, the department assessed whether changes or clarifications were needed. The conclusion was reached that no revisions to the regulation were necessary and maintaining this regulation is in keeping with the requirements of the Administrative Process Act.

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Contact Information: Janet Van Cuyk, Manager, Legislative and Research Unit, Department of Juvenile Justice, P.O. Box 1110, Richmond, VA 23218-1110, telephone (804) 588-3879, FAX (804) 371-6490, or email janet.vancuyk@djj.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board of Juvenile Justice conducted a small business impact review of **6VAC35-190**, **Regulations Governing Juvenile Work and Educational Release Programs** and determined that this regulation should be retained in its current form. The Board of Juvenile Justice is publishing its report of findings dated June 25, 2015, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

This regulation is intended to have a positive impact on juveniles, communities, and small businesses. Allowing juveniles to work in communities during their commitment is intended to benefit the juvenile and the community by facilitating the juvenile's successful reintegration into society. The regulation does not place any undue burden on businesses. The only regulatory requirement related to businesses is the requirement that all federal and state laws and regulations including but not limited to those related to employment and child labor be followed. All other requirements of the regulation are requirements for juveniles and department staff.

1. The regulation is still necessary. Section 66-25.1:3 of the Code of Virginia authorizes the board to promulgate regulations governing the form and review process of agreements entered into by the director or his designee with a public or private entity for the operation of work programs for juveniles committed to the department. Additionally, the board is required to establish rules and regulations for work release programs established by the director.

2. No comments or complaints have been received regarding this regulation.

3. The regulation is not complex and clearly outlines the eligibility criteria and the requirements for procedures to ensure adequate supervision is provided to juveniles participating in work and education release programs.

4. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation.

5. The regulation was last reviewed in September of 2008. As part of the review process, the department assessed whether any changes or clarifications were needed. The conclusion was reached that no revisions to the regulation were necessary at this time. Maintaining this regulation is important because it provides clear, concise, and consistent requirements for work and education release programs for department staff and committed juveniles. Contact Information: Janet Van Cuyk, Manager, Legislative and Research Unit, Department of Juvenile Justice, P.O. Box 1110, Richmond, VA 23218-1110, telephone (804) 588-3879, FAX (804) 371-6490, or email janet.vancuyk@djj.virginia.gov.

VIRGINIA LOTTERY

Director's Orders

The following Director's Orders of the Virginia Lottery were filed with the Virginia Registrar of Regulations on June 16, 2015. The orders may be viewed at the Virginia Lottery, 900 East Main Street, Richmond, VA, or at the office of the Registrar of Regulations, 201 North 9th Street, 2nd Floor, Richmond, VA.

Director's Order Number Seventy (15)

Virginia's Instant Game Lottery 1570 "Spades" Final Rules for Game Operation (effective June 22, 2015)

Director's Order Number Seventy-One (15)

Virginia's Instant Game Lottery 1569 "Triple Your Luck" Final Rules for Game Operation (effective June 22, 2015)

Director's Order Number Seventy-Four (15)

"Raise the Bar Retailer Incentive Promotion" Virginia Lottery Retailer Incentive Program Requirements (This Director's Order becomes effective on July 14, 2015, and shall remain in full force and effect until ninety (90) days after the conclusion of the incentive program, unless otherwise extended by the Director)

Director's Order Number Seventy-Five (15)

Virginia Lottery's Redskins Champions Club Promotion Final Rules for Operation (This Director's Order becomes effective on Tuesday, August 4, 2015, and shall remain in full force and effect unless amended or rescinded by further Director's Order)

Director's Order Number Ninety-Five (15)

"Retailer Recruitment Incentive Promotion" Virginia Lottery Retailer Incentive Program Requirements (This Director's Order becomes effective on July 1, 2015, and shall remain in full force and effect until ninety (90) days after the conclusion of the Incentive Program, unless otherwise extended by the Director)

Director's Order Number Ninety-Seven (15)

Virginia Lottery's "Premium Registration Coupon" Final Rules for Operation (This Director's Order becomes effective nunc pro tunc to Tuesday, June 15, 2015, and shall remain in full force and effect unless amended or rescinded by further Director's Order) Director's Order Number Ninety-Eight (15)

Virginia Lottery's "Social Media Sweepstakes/Contest Promotion" Final Rules for Operation (This Director's Order becomes effective on July 1, 2015, and shall remain in full force and effect effective through December 31, 2015, unless amended or rescinded by further Director's Order)

DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL REGULATION

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Professional and Occupational Regulation is conducting a periodic review and small business impact review of **18VAC120-11**, **Public Participation Guidelines**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins July 27, 2015, and ends August 17, 2015.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Mark N. Courtney, Senior Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8500, FAX (804) 527-4403, or email mark.courtney@dpor.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

STATE WATER CONTROL BOARD

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the State Water Control Board conducted a small business impact review of **9VAC25-220**, **Surface Water Management Area Regulation** and determined that this regulation should be retained in its current form. The State Water Control Board is publishing its report of findings dated June 17, 2015, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

This regulation continues to be needed. It establishes requirements for the use of surface water in surface water management areas, including reporting requirements from those withdrawing surface water and when a permit is or is not required. Surface water withdrawals need to be regulated to prevent negative impacts from occurring due to the over withdrawal of surface water. No comments were received during the public comment period.

The regulation is written to clearly describe the requirements within surface water management areas. The regulations in 9VAC25-220-70 B exclude certain scenarios from being required to obtain a permit. One of these exclusions is not requiring a permit for a surface water withdrawal of less than 300,000 gallons in any single month. Depending on the type of small business, this provision may exempt small businesses from being required to obtain a permit, while a larger business competing with the small business may be required to obtain a permit. This would provide the small businesses with some regulatory relief since their withdrawal would have a smaller impact on the environment.

This regulation is a state-only regulation and there is no equivalent federal regulation. This regulation is part of a series of regulations utilized by the State Water Control Board to protect water in the Commonwealth. The Surface Water Management Area Regulation is closely related to the Virginia Water Protection Permit Program Regulation (9VAC25-210) since both regulate impacts to surface waters. The Surface Water Management Area Regulation however specifically addresses surface water withdrawals regulated under the Surface Water Management Act of 1989. The Water Withdrawal Reporting regulation (9VAC25-200) requires withdrawers of surface water (and groundwater) to report monthly and annual withdrawals of water. Collectively the regulations adopted by the State Water Control Board protect state waters including surface waters, and regulating withdrawals of surface water within surface water management areas plays a role in protecting surface waters from impacts caused from the withdrawals.

The regulation was last amended in 2013 in response to Chapter 348 of the 2013 Acts of Assembly. Prior to that, the regulation was amended in 2000 in response to an act of the 1999 General Assembly. In recent years technology has improved the monitoring of surface water levels and flows, and more accurate information concerning surface water availability has been available to assist with making decisions concerning the use of surface water. This is important since both groundwater and surface water withdrawals are used to

meet water supply demands and the supply of groundwater available is decreasing, which will potentially impact demand for surface water withdrawals.

The department has determined that the regulation should be retained. The department plans to recommend making minor revisions to the regulation to the State Water Control Board in the near future. These changes will update the citations in the regulation.

Contact Information: Melissa Porterfield, Office of Regulatory Affairs, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

Total Maximum Daily Loads for the Lower Chickahominy River and its Tributaries in New Kent, Charles City, and James City Counties

The Department of Environmental Quality (DEQ) seeks written and oral comments from interested persons on the development of total maximum daily loads (TMDLs) for the Lower Chickahominy River and its tributaries in New Kent, Charles City, and James City Counties. These streams are listed on the § 303(d) TMDL Priority List and Report as impaired due to violations of the state's water quality standards for bacteria for recreation use.

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the State Water Control Law (§ 62.1-44.2 et seq. of the Code of Virginia) require the DEQ to develop TMDLs for pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL Priority List and Report.

Waterbodies identified for TMDL development include the following:

Stream	Impairment	Location	
Beaverdam Creek and XAH-Beaverdam Creek, UT	D	New Kent County	
Diascund Creek		New Kent and James City Counties	
Mill Creek	Recreation use (bacteria)	James City County	
Barrows Creek		Charles City County	
Chickahominy River		Charles City, James City, New Kent Counties	
Gordon Creek		James City County	

The first public meeting on the development of the TMDL to address the recreation impairment for these segments will be held on Tuesday, July 28, 2015, at 10:30 a.m. at the Heritage Public Library located at 6215 D Chesapeake Circle, New Kent, VA 23124.

The public comment period begins July 29, 2015, and ends August 27, 2015.

An advisory committee to assist in development of this TMDL will be established. Persons interested in assisting should notify the DEQ contact person listed below by the end of the comment period and provide name, address, phone number, email address, and the organization being represented, if any. Notification of the composition of the panel will be sent to all applicants.

A component of a TMDL is the wasteload allocation (WLA); therefore, this notice is provided pursuant to § 2.2-4006 A 14 of the Administrative Process Act for any future adoption of the TMDL WLAs. Information on the development of the TMDLs for the impairments is available upon request. Questions, information requests, and written comments should be addressed to Margaret Smigo, 4949 Cox Road, Glen Allen, VA 23060, telephone (804) 527-5124, or email margaret.smigo@deq.virginia.gov. Please note all written comments should include the name, address, and telephone number of the person submitting the comments.

Total Maximum Daily Loads for North Fork Catoctin Creek in Loudoun County

The Department of Environmental Quality (DEQ) seeks written and oral comments from interested persons on the draft stressor identification analysis in support of the development of total maximum daily loads (TMDLs) for North Fork Catoctin Creek in Loudoun County. Two segments of the stream are listed on the Draft 2014 § 303(d) TMDL Priority List and Report as impaired due to violations of the state's water quality standards for the aquatic life use due to poor health of the benthic macroinvertebrate communities.

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the State Water Control Law require DEQ to develop TMDLs for pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL Priority List and Report.

Stream Name	Location	Length (miles)	Upstream Limit	Downstream Limit
North Fork Catoctin Creek	Loudoun County	4.42	Unnamed tributary, located ~0.15 mile downstream of Route 287	Catoctin Creek
North Fork Catoctin Creek	Loudoun County	2.54	Unnamed tributary, located ~0.75 mile upstream of Route 719	Impoundment (Godfrey Pond)

The first public meeting will focus on the results of the draft stressor identification analysis, which identifies the stressors

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to the benthic communities in the North Fork Catoctin Creek watershed. The meeting will be held on Monday, August 3, 2015, 6 p.m., Purcellville Library, Robey Meeting Room, 220 East Main Street, Purcellville, VA 20132.

In case of inclement weather, the alternate meeting date is Monday, August 10, 2015, 6 p.m., Purcellville Library, Robey Meeting Room, 220 East Main Street, Purcellville, VA 20132.

The public comment period begins August 3, 2015, and ends September 2, 2015.

An advisory committee to assist in development of this TMDL was convened on May 20, 2015. A component of a TMDL is the wasteload allocations (WLAs); therefore, this notice is provided pursuant to § 2.2-4006 A 14 of the Administrative Process Act for any future adoption of the TMDL's associated WLAs.

Information on the development of the TMDLs for the impairments is available upon request. Questions or information requests should be addressed to the DEQ contact person listed below. Please note, all written comments should include the name, address, and telephone number of the person submitting the comments and should be sent to Jennifer Carlson, Department of Environmental Quality, 13901 Crown Court, Woodbridge, VA 22193, telephone (703) 583-3859, or email jennifer.carlson@deq.virginia.gov.

Notice of Final Public Meeting for the Development of a TMDL Implementation Plan for Upper Rapidan River Watersheds: Garth Run, Rippin Run, Blue Run, Marsh Run, Beautiful Run, Poplar Run, Unnamed Tributaries to the Rapidan River, and the Rapidan River in Madison, Greene, Orange, and Albemarle Counties

The Virginia Department of Environmental Quality (DEQ) will host a public meeting on a water quality study for Garth Run, Rippin Run, Blue Run, Marsh Run, Beautiful Run, Poplar Run, unnamed tributaries to the Rapidan River, and the Rapidan River on August 13, 2015.

The meeting will start at 6 p.m. and will be held at James Madison's Montpelier in Lewis Hall, located at 13384 Laundry Road, Montpelier Station, VA 22957. The purpose of the meeting is to present the draft Upper Rapidan Implementation Plan to interested local community members and government staff.

The waters listed for this study were identified in Virginia's Water Quality Assessment Integrated Report as impaired for not supporting the E.coli bacteria criteria for recreational uses. The impairments are based on water quality monitoring data reports of sufficient exceedences of Virginia's water quality standard for bacteria. A draft implementation plan (IP) has been developed by DEQ in order to identify measurable goals for restoring water quality. The draft IP also includes corrective actions needed and their associated costs, benefits, and environmental impacts. Please see the link below for information presented during the first public meeting and working group meetings: http://www.deq.virginia.gov/Programs/Water/WaterQualityIn formationTMDLs/TMDL/TMDLImplementation/TMDLImpl ementationProgress.aspx

The implementation plan has been under development for the last six months and has included a series of local meetings and input from local citizens and government agencies. A copy of the draft can be found at the link listed above the day after the public meeting.

The public comment period on materials presented at this meeting begins August 13, 2015, through September 14, 2015. For additional information or to submit comments, contact May Sligh, Department of Environmental Quality, Northern Regional Office, 13901 Crown Court, Woodbridge, VA 22193, telephone (804) 450-3802, or email may.sligh@deq.virginia.gov.

Additional information is also available on the DEQ website at www.deq.virginia.gov/tmdl

Notice of 30-day Public Comment Period on the Draft List of Impaired Waters Prioritized for TMDL or TMDL Alternative Development for 2016-2022

The Department of Environmental Quality (DEQ) seeks written or electronic comments from interested persons on the draft list of impaired waters prioritized for total maximum daily load (TMDL) or TMDL alternative development throughout 2016-2022. The public comment period begins July 27, 2015, and ends August 26, 2015. Please note that all written comments should include the name, address, and telephone number of the person submitting the comments. DEQ will hold a public meeting to address and discuss the draft list of impaired waters prioritized for TMDL or TMDL alternative development if there is sufficient interest from the public. For more information or to submit written or electronic comments, please contact Will Isenberg, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4228, or email william.isenberg@deq.virginia.gov.

DEQ is implementing the national § 303(d) Vision, which facilitates the prioritization of impaired waters for TMDL or TMDL alternative development throughout 2016-2022. While the national § 303(d) Vision involves prioritizing impaired waters for TMDL or TMDL alternative development, DEQ took this opportunity to also prioritize impaired waters that require a stressor analysis report or a natural conditions report. TMDLs or TMDL alternatives are reports that outline necessary reductions in pollutant or pollution loads in order to restore water quality. In some cases, stressor analyses must be conducted prior to any restoration plan development due to the uncertain causes of water quality impairment. These

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reports analyze water quality data to determine what the most probable stressors are that contribute to the impaired status of the water. In other cases where either a stressor analysis or a watershed characteristic suggests that the impaired status of the water is due more to natural conditions than human activity, a natural conditions report is conducted.

Before finalizing the list of prioritized impaired waters, DEQ is seeking comments from the public on this draft list of priorities. DEQ will hold a public meeting to address and discuss the draft priorities list if there is sufficient interest from the public. Once all of the comments have been addressed following the 30-day public comment period, DEQ will finalize the 2016-2022 priorities list and post it on DEQ TMDL program webpage. The final list will also be published in the 2016, 2018, and 2020 biennial § 305(b)/303(d) Integrated Reports, where it will be available for additional public comment under the comment period for the entire Integrated Report.

External links to priorities information

1. Description of the Process for Prioritizing Impaired Waters

- 2. Maps of Draft Two Year Targets (2016-2017)
- 3. List of Draft Two Year Targets (2016-2017)
- 4. Map of Draft 2016-2022 Priority Waters and Watersheds
- 5. Summary of Draft 2016-2022 Priorities
- 6. Draft List of 2016-2022 Priority Waters by City/County

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, General Assembly Building, 201 North 9th Street, 2nd Floor, Richmond, VA 23219; *Telephone:* Voice (804) 786-3591; *Email:* varegs@dls.virginia.gov.

Meeting Notices: Section 2.2-3707 C of the Code of Virginia requires state agencies to post meeting notices on their websites and on the Commonwealth Calendar at http://www.virginia.gov/connect/commonwealth-calendar.

Cumulative Table of Virginia Administrative Code Sections Adopted, Amended, or Repealed: A table listing regulation sections that have been amended, added, or repealed in the *Virginia Register of Regulations* since the regulations were originally published or last supplemented in the print version of the Virginia Administrative Code is available at

http://register.dls.virginia.gov/documents/cumultab.pdf.

Filing Material for Publication in the Virginia Register of Regulations: Agencies use the Regulation Information System (RIS) to file regulations and related items for publication in the *Virginia Register of Regulations*. The Registrar's office works closely with the Department of Planning and Budget (DPB) to coordinate the system with the Virginia Regulatory Town Hall. RIS and Town Hall complement and enhance one another by sharing pertinent regulatory information.