

**State Board of Health – Nominating Committee
Agenda
June 5, 2014 – 8:30 a.m.
Perimeter Center – Hearing Room 3
9960 Mayland Drive
Richmond, Virginia 23233**

Welcome and Introductions	Eric Deaton, Chair
Discussion	Nominating Committee Members
Adjourn	

**State of Board of Health
Agenda
June 5, 2014 – 9:00 a.m.
Perimeter Center – Boardroom 2
9960 Mayland Drive
Richmond, Virginia 23233**

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Dr. Steven Escobar
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of March 20, 2014 Minutes	Mr. Edwards
Commissioner’s Report	Marissa J. Levine, MD, MPH, FAAFP State Health Commissioner
Nominating Committee Report	Eric Deaton
Election of Officers and Executive Committee Members	Mr. Edwards
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Break	
Public Comment Period	

Action Items

State Emergency Medical Services Plan
(§ 32.1-111.3 of the Code of Virginia) Gary Brown, Director
Office of Emergency

Regulatory Action Items

Virginia Emergency Medical Services Regulations
12VAC5-31 Mr. Brown
(Fast track amendments)

Virginia Radiation Protection Regulations
12VAC5-481 Steve Harrison, Director
(Final amendments) Office of Radiological Health

Working Lunch

Regulatory Action Items

Guidelines for General Assembly Nursing
Scholarships Adrienne McFadden, MD, JD, Director
12VAC5-510 Office of Minority Health and Health Equity
(Final amendments)

Regulations for Disease Reporting and Control
12VAC5-90 Laurie Forlano, DO, MPH, Acting Director
(Final amendments) Office of Epidemiology

Rabies Regulations
12VAC5-105 Dr. Forlano
(Final regulations)

Sewage Handling and Disposal Regulations
12VAC5-610 Allen Knapp, Director
(Proposed amendments) Office of Environmental Health Services

Sanitary Regulations for Marinas and Boat Moorings
12VAC5-570 Mr. Knapp
(Final amendments)

Regulations Governing Application Fees for
Construction Permits for Onsite Sewage
Disposal Systems and Private Wells Mr. Knapp
12VAC5-620
(Final amendments)

Alternative Discharging Sewage Treatment
Regulations for Individual Single Family Dwellings Mr. Knapp
12VAC5-640
(Final amendments)

Regulations for the Repacking of Crab Meat
12VAC5-165
(Final amendments)

Mr. Knapp

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA
Department of Health

Marissa J. Levine, MD, MPH, FAAFP
State Health Commissioner

Gary R. Brown
Director

P. Scott Winston
Assistant Director

Office of Emergency Medical Services

**1041 Technology Park Drive
Glen Allen, VA 23059-4500**

1-800-523-6019 (VA only)
804-888-7507
FAX: 804-371-3108

April 24, 2014

Bruce W. Edwards, MPA, NRP
Chair Virginia State Board of Health
109 Governor Street
Richmond, Virginia 23219

Dear Chairman Edwards:

As stated in §32.1-111.3 of the Code of Virginia, the Board of Health shall develop a comprehensive, coordinated, statewide emergency medical services plan. The Board of Health must review, update and publish the plan triennially, making such revisions as may be necessary to improve the effectiveness and efficiency of the Commonwealth's emergency care system. The objectives of the plan shall include, but not be limited to, the 19 objectives outlined in § 32.1-111.3.

The VDH Office of EMS (OEMS), in coordination with the Executive Committee of the State EMS Advisory Board, the Legislation and Planning Committee and the chairs of all standing committees of the State EMS Advisory Board submitted planning templates created by the OEMS. Each template pertains to a specific aspect of the EMS system, which that committee oversees. Much of the information included in each planning template, as well as information in many EMS review reports, namely those prepared by the Joint Legislative Audit and Review Commission and the Institute of Medicine report was included in the draft version of this plan.

Attached to this document is the current version of the Strategic and Operational State EMS Plan. It is comprised of four core strategies, with each core strategy including several key strategic initiatives. The State EMS Advisory Board unanimously approved this plan at its February 7, 2014 meeting. Please note there is a glossary of acronyms included toward the end of the document.

As the Code of Virginia mandates, this plan must be reviewed, updated and published by the State Board of Health. The OEMS appreciates the opportunity to present this document to the Board of Health and greatly values its input, as well as the input of any other stakeholder or interested party. Any questions related to this document can be forwarded to Tim Perkins, EMS systems planner at 804-888-9136 or tim.perkins@vdh.virginia.gov.

Sincerely,

A handwritten signature in black ink that reads "Gary R. Brown".

Gary R. Brown, Director
Office of Emergency Medical Services
Virginia Department of Health

Virginia's State EMS Plan

Reviewing the State EMS Plan

What is the State EMS Plan?

- Three year strategic and operational plan.
- Designed to utilize core strategies and strategic initiatives to outline and address the needs of the EMS System over a three year span.
- Goal is to make improvements to EMS System in Virginia.
- Build on the past efforts made in previous versions of State EMS Plan.

Why was the State EMS Plan created?

- §32.1-111.3 of the *Code of Virginia* requires the development of a comprehensive, coordinated, statewide emergency medical services plan by the Virginia Department of Health's Office of EMS (OEMS).
- Support delivery of EMS care in Virginia.
- Support existing and new initiatives designed to improve all aspects of the EMS system in Virginia.

How was the State EMS Plan created?

- In the fall of 2009, the Office of EMS, in conjunction with the EMS Advisory Board and its 13 committees, reviewed the existing plan to determine the needs of the EMS system. State EMS Plan is divided into four core strategies:
 - Develop Partnerships
 - Create Tools and Resources
 - Develop Infrastructure
 - Assure Quality and Evaluation

State EMS Plan Creation – 2009

- OEMS staff gathered and evaluated information submitted by committees, and integrated that information into the draft plan.
- State EMS Plan presented to EMS Advisory Board in May of 2010, approved in August of 2010.
- State EMS Plan posted to OEMS website for public comment from June 1 to July 16, 2010.
- State EMS Plan presented to State Board of Health for approval in October 2010, approved in March 2011.

Highlights of State EMS Plan

- Use of technology and social media to provide accurate and timely information.
- Creation of EMS Agency and Provider Portal.
- Creation, maintenance, and expansion of Virginia Pre-hospital Information Bridge (VPHIB).
- Transition to new EMS education standards.

Why is a revision to the State EMS Plan necessary?

- Required by the Code of Virginia to be revised triennially.
- Current plan is three years old.
- Many of the strategic initiatives and action steps have been met, or significant progress has been made.
- EMS is a dynamic field, and plan must also remain dynamic to address the needs of a changing system.

What happens to the current plan?

- Unfinished initiatives carry over to new version of plan.

Virginia's State EMS Plan

- Summary information provided as requested.
- Lessons learned help shape the new version of plan.

How will the new State EMS Plan be created?

- OEMS staff held planning retreat in September 2012.
- Input was gathered from EMS Advisory Board committees between February 2013 - May 2013.
- Revised plan presented to EMS Advisory Board for review in August 2013.
- Public comment period – September 1 – October 15, 2013.
- Unanimous approval of the revised plan by EMS Advisory Board – November 6, 2013.
- Presented to State Board of Health for approval – June 2014.

For more information:

<http://www.vdh.state.va.us/OEMS/EMSPlan/index.htm>

**VIRGINIA STATEWIDE
EMERGENCY MEDICAL SERVICES
PLAN**

2013 - 2016



STATEWIDE EMERGENCY MEDICAL SERVICES PLAN
Table of Contents

<u>Content</u>	<u>Pages</u>
Introduction	3
Virginia EMS System Information, OEMS Mission and Vision Statements	4
Core Strategy 1 – Develop Partnerships	
Strategic Initiative 1.1 – Promote collaborative approaches	5
Strategic Initiative 1.2 – Coordinate responses to emergencies both natural and man-made	6
Core Strategy 2 – Create Tools and Resources	
Strategic Initiative 2.1 – Sponsor EMS related research and education	7
Strategic Initiative 2.2 – Supply quality education and certification of EMS personnel	9
Core Strategy 3 – Develop Infrastructure	
Strategic Initiative 3.1 – EMS regulations, protocols, policies and standards	10
Strategic Initiative 3.2 – Focus recruitment and retention efforts	11
Strategic Initiative 3.3 – Upgrade technology and communication systems	12
Strategic Initiative 3.4 – Stable support for EMS funding	12
Strategic Initiative 3.5 – Enhance regional and local EMS efficiencies	13
Core Strategy 4 – Assure Quality and Evaluation	
Strategic Initiative 4.1 – Assess compliance with EMS performance-based standards	14
Strategic Initiative 4.2 – Assess and enhance quality of education for EMS providers	15
Strategic Initiative 4.3 – Pursue new initiatives that support EMS.	15
Appendices	
A. Glossary of Terms and Acronyms	16
B. Resources	19

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

INTRODUCTION

As stated in §32.1-111.3 of the Code of Virginia, the Board of Health shall develop a comprehensive, coordinated, statewide emergency medical care system in the Commonwealth and prepare a Statewide Emergency Medical Services (EMS) Plan, which shall incorporate, but not be limited to, the plans prepared by the Regional Emergency Medical Services Councils. The Board of Health must review, update and publish the plan triennially, making such revisions as may be necessary to improve the effectiveness and efficiency of the Commonwealth's emergency care system. The objectives of the plan shall include, but not be limited to the 19 objectives outlined in §32.1-111.3.

Recent changes have been made to the development of this plan due to review reports, namely the Joint Legislative Audit and Review Commission report "Review of Emergency Medical Services in Virginia" and the Institute of Medicine report, "EMS at the Crossroads." The recommendations made in these documents have assisted in moving the planning process forward.

As the Code of Virginia mandates, this plan must be reviewed, updated and published triennially by the Board of Health. The Virginia Department of Health (VDH) Office of Emergency Medical Services (OEMS) appreciates the opportunity to present this document to the Board of Health, and values its input, as well as the input of any other stakeholder or interested party. Additionally, the OEMS is prepared to report on the progress of the plan to the Board of Health or other interested parties upon request, through the OEMS Annual Reports and Service Area Plans as required by VDH and the Code of Virginia.

This operational plan identifies the specific initiatives required throughout 2013 – 2016. Each objective and action step is intended to accomplish those items most critical to the Statewide EMS Plan in the given fiscal year. The plan is designed to improve priority areas of performance and initiate new programs. Therefore, much of the routine, but important, work of the OEMS staff is not included in the plan.

No later than three months prior to the end of a particular fiscal year, the OEMS staff will evaluate progress on the plan and begin the process of creating the operational plan for the next fiscal year.

In most cases, "accountability" should be the name of a person, division, or entity that has the lead responsibility for the implementation of the objective or action step. The plan will be reviewed quarterly, and only those objectives and items relevant to the time frame will be a part of the review. Any changes in the objective or action steps should be noted in writing on the form at that time.

Definitions of acronyms included in the plan can be found on **Page 17**.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

What is the Emergency Medical Services System in Virginia?

The Virginia Emergency Medical Services (EMS) system is very large and complex. It involves a wide variety of EMS agencies and personnel, including volunteer and career providers functioning in volunteer rescue squads, municipal fire departments, commercial ambulance services, hospitals, and a number of other settings to enable the EMS community to provide the highest quality emergency medical care possible to those in need. Every person living in or traveling through the state is a potential recipient of emergency medical care.

The Virginia Department of Health, Office of Emergency Medical Services (OEMS) is responsible for development of an efficient and effective statewide EMS system. The EMS System in Virginia is designed to respond to all situations where emergency medical care is necessary. This is accomplished through a coordinated system of over 35,000 trained, prepared and certified providers, nearly 4,500 permitted EMS vehicles, and over 680 licensed EMS agencies, to provide ground and air emergency medical care to all citizens of the Commonwealth of Virginia.

Virginia Office of Emergency Medical Services Mission Statement

To reduce death and disability resulting from sudden or serious injury and illness in the Commonwealth through planning and development of a comprehensive, coordinated statewide EMS system; and provision of other technical assistance and support to enable the EMS community to provide the highest quality emergency medical care possible to those in need.

Virginia Office of Emergency Medical Services Vision Statement

To establish a unified, comprehensive and effective EMS system for the Commonwealth of Virginia that provides for the health and safety of its citizens and visitors.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 1.1- Promote collaborative approaches			
	Objectives	Accountability	Action Steps
Core Strategy 1: Develop Partnerships	1.1.1 Use technology to provide accurate and timely communication within the Virginia EMS System.	OEMS, Regional EMS Councils	1.1.1.1 Track and report on amount, and general content of material, posted to OEMS and Regional EMS Council websites and social media on a monthly and quarterly basis.
	1.1.2 Promote collaborative activities between local government, EMS agencies, hospitals, and increase recruitment and retention of certified EMS providers.	OEMS, System stakeholders	1.1.2.1. Determine amount of new EMS providers recruited via recruitment and retention programs and activities. 1.1.2.2. Continue to schedule “Keeping The Best!” programs. 1.1.2.3. Maintain informational items regarding benefits and incentives for local governments to provide to volunteer fire and EMS providers. 1.1.2.4. Educate and familiarize local government officials on the importance in taking a greater role in EMS planning and coordination.
	1.1.3 Provide a platform for clear, accurate and concise information sharing and improved interagency communications between the Office of EMS, state agencies and EMS system stakeholders in Virginia.	OEMS, State Agencies (VDEM, OCP, VSP, VDFP), Regional EMS Councils, System Stakeholders.	1.1.3.1. Encourage agencies and providers to visit OEMS web page regularly, subscribe to OEMS email list, and social media. 1.1.3.2. Encourage providers to utilize OEMS Provider Portal.
	1.1.4 Identify resources and/or opportunities to work collaboratively with other state agencies, organizations, and associations to improve processes and patient outcomes.	OEMS	1.1.4.1. Attend meetings of, and exchange knowledge with the National Association of State EMS Officials. 1.1.4.2. Encourage appropriate state agencies and organizations to participate in meetings and activities hosted or sponsored by OEMS. 1.1.4.3. Collaborate among AMS entities to ensure systems enhancements.
	1.1.5 Promote data sharing projects which benefit internal and external projects.	OEMS	1.1.5.1. Further data sharing efforts with the highway safety community. 1.1.5.2 Establish data use agreements with bordering states to share EMS data on a regional level utilizing the national EMS database. 1.1.5.3 Provide a means for VDH bio-surveillance programs to utilize VPHIB data.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 1.2 – Coordinate responses to emergencies both natural and man-made			
	Objectives	Accountability	Action Steps
Core Strategy 1: Develop Partnerships	1.2.1 Support, coordinate and maintain deployable emergency response resources.	OEMS, VDEM	1.2.1.1. Create recruiting and selection process for resource management team. 1.2.1.2 Work to recruit single resource components to the HMERT system.
	1.2.2 Increase knowledge of Emergency Operations capabilities with Emergency Managers, leaders and supervisors on a local, regional and state level.	OEMS	1.2.2.1. Continue to promote Emergency Operations resources, training courses and abilities to localities across the Commonwealth.
	1.2.3 Assist EMS agencies to prepare and respond to natural and man-made emergencies by incorporating strategies to develop emergency response plans that address the four phases of an emergency: preparedness, mitigation, response and recovery, and to exercise the plan.	OEMS, VDEM	1.2.3.1. Create and promote planning templates aimed at EMS agencies, specifically related to COOP, Emergency Preparedness and response concerns (MCI, Surge Planning, etc.)

FINAL DRAFT

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 2.1 - Sponsor EMS related research and education

Objectives	Accountability	Action Steps
<p>2.1.1 Sponsor research and other projects that contribute to high quality EMS and improve patient outcomes utilizing data collected by the EMS registries.</p>	<p>OEMS</p>	<p>2.1.1.1. Revive “Trends in Trauma and Emergency Medicine” as a web based product.</p> <ul style="list-style-type: none"> • Begin with statewide summaries from VSTR and VPHIB for 2007 – 2011 by end of CY 2013. • Add Regional EMS Council level summaries by end of FY 2014. <p>2.1.1.2. Expand “Trends in Trauma and Emergency Medicine” to include:</p> <ul style="list-style-type: none"> • Measures based on combined VSTR and VPHIB data to be available to the public by the November State EMS Advisory Board meeting and annually beginning in CY 2014. <p>2.1.1.3. Develop VSTR and VPHIB research dataset to be available for entities upon request and that have obtained an institutional review board approval by the end of 2015.</p>
<p>2.1.2 Determine quality of EMS service and conduct analysis of trauma triage effectiveness.</p>	<p>OEMS, Designated Trauma Centers, TSOMC, Regional EMS Councils</p>	<p>2.1.2.1. Trauma Performance Improvement Committee and/or EMS staff will provide quarterly reports to the regional trauma committees through their representative on the TSOMC that identify over and under triage events. The statewide version of this quarterly report shall be included in the quarterly report and posted on the OEMS website.</p> <p>2.1.2.2. Develop and implement OEMS component of VDH DW by end of CY 2014.</p> <ul style="list-style-type: none"> • Use DW to integrate VPHIB and VSTR data by the end of 2015. • Use DW to access and integrate VHI and Vital Statistics data OEMS databases. • Provide agency-wide access to EMS data to be used in other public health efforts. <p>2.1.2.3. Use the DW to support bio-surveillance projects being performed within the VDH.</p>
<p>2.1.3 Establish scholarships for EMS provider education and EMS specific research.</p>	<p>OEMS, FARC, Regional EMS Councils. Other</p>	<p>2.1.3.1. Establish scholarship program for EMS education.</p>

**Core Strategy 2:
Create Tools and Resources**

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

		EMS Stakeholders	2.1.3.2. Establish funding program for EMS research.
2.1.4	Evaluate the impact of an aging workforce on service provision around the state.	OEMS, Workforce Development Committee, VAGEMSA, VAVRS	2.1.4.1. Assess demographic and profile characteristics of EMS providers in Virginia through EMS Provider Portal. 2.1.4.2. Utilize EMS database to evaluate information related to impact of aging workforce on provision of EMS service.

FINAL DRAFT

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 2.2 - Supply quality education and certification of EMS personnel			
	Objectives	Accountability	Action Steps
Core Strategy 2: Create Tools and Resources	2.2.1 Ensure adequate, accessible and quality EMS provider training and continuing education exists in Virginia.	OEMS, TCC, Regional EMS Councils	2.2.1.1. Widely publicize the availability of training and ensure adequate, accessible and quality EMS provider training and continuing education through course offerings held across the state. 2.2.1.2. Review student disposition on a biannual basis; identifying areas of concern for TCC input and possible corrective action. 2.2.1.3 Provide continued support for an annual multidisciplinary EMS Symposium (i.e. Virginia EMS Symposium) as a primary statewide EMS system continuing education event.
	2.2.2 Enhance competency-based EMS training programs.	OEMS, TCC, MDC	2.2.2.1. Compare and contrast traditional versus competency-based programs. 2.2.2.2 Identify and document aspects from competency-based programs that directors feel enhance their programs as compared to the traditional approach.
	2.2.3 Develop, implement and promote leadership and management standards for EMS agency leaders.	OEMS, Workforce Development Committee	2.2.3.1. Development of EMS Officer standards based on duties of "Attendant in Charge" position, supervisor and director. 2.2.3.2. On an annual basis, test efficacy of standards through pilot program.
	2.2.4 Align all initial EMS education programs to that of other allied health professions to promote professionalism in EMS.	OEMS, TCC, MDC, Board of Health Professions	2.2.4.1. Proactively promote AEMT.
	2.2.5 Increase the amount and quality of pediatric training and educational resources for EMS providers, and emergency department staff in Virginia.	OEMS, EMSC Committee, VHHA	2.2.5.1. Purchase and distribute pediatric training equipment for EMS agencies. 2.2.5.2. Sponsor pediatric training related instructor courses. 2.2.5.3. Provide support for speakers and topics at the annual Virginia EMS Symposium.
	2.2.6 Provide an increased number of training opportunities for EMS personnel in emergency operations methods and activities.	OEMS, VDEM	2.2.6.1. Create a yearly training calendar for OEMS-sponsored Emergency Operations training offerings. 2.2.6.2. Review and update MCI management modules.
	2.2.7. Assure an adequate amount and quality of geriatric training and educational resources for EMS providers, emergency department staff and primary care providers in Virginia.	OEMS, TCC, MDC	2.2.7.1. Sponsor geriatric training related instructor courses. 2.2.7.2. Provide support for speakers and topics at the annual Virginia EMS Symposium.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 3.1 - EMS Regulations, protocols, policies and standards

Objectives	Accountability	Action Steps
3.1.1 Review and assess state and federal legislation related to the EMS system.	OEMS, Rules and Regulations Committee, Legislation and Planning Committee	3.1.1.1. Legislation review, determination of impact of legislation on Virginia EMS system. 3.1.1.2. Gather legislative news and interest items from NASEMSO and EMS Advocates.
3.1.2 Establish standards for the utilization of AMS.	OEMS, State Medevac Committee, MDC	3.1.2.1. Development of AMS guidelines for proper resource utilization.
3.1.3 Establish statewide air/ground safety Standards.	OEMS, State Medevac Committee	3.1.3.1. Identify and adopt universal safety standards. 3.1.3.2. Maintain weather turn down system. 3.1.3.3. Establish standard safety protocols and training based on protocols. 3.1.3.4. Standardize air/ground safety standards. 3.1.3.5. Standardize LZ procedures. 3.1.3.6. Develop process for consistent use of air-to-air communication.
3.1.4 Develop criteria for a voluntary Virginia Standards of Excellence recognition program for EMS agencies.	OEMS, WDC	3.1.4.1. Approval of first stage of voluntary accreditation standards by State EMS Advisory Board. 3.1.4.2. Implement and market program to interested agencies. 3.1.4.3. Evaluate efficacy of program based on feedback of EMS agency officials and technical assistance teams.
3.1.5 Maintain and enhance the Trauma Center designation process.	OEMS, TSOMC, EMSC	3.1.5.1. Revise the trauma designation criteria to include burn criteria, pediatric criteria, nursing education requirements and infrastructure needs. 3.1.5.2. Conduct an analysis to determine the benefits of adding Level IV designation to our trauma care system.
3.1.6 Maintain and enhance the Regional EMS Council designation process.	OEMS	3.1.6.1. Evaluate pros/cons of initial designation process. 3.1.6.2. Incorporate input of applicants and evaluators into next round of designations. 3.1.6.3. Conduct re-designation of councils on staggered basis in 2013 and 2014.
3.1.7 Establish standardized methods and procedures for the inspection and licensing and/or permitting of all EMS agencies and vehicles, including equipment and supply requirements.	OEMS, Transportation Committee	3.1.7.1. Development of standard inspection checklist, to include all aspects of agency and EMS vehicle inspection.
3.1.8 Through a consensus process, develop a recommendation for evidence-based patient care guidelines and formulary.	OEMS, State EMS Medical Director, MDC, Patient Care Guidelines Ad-hoc Workgroup, Drug Formulary Ad-hoc Workgroup, BoP	3.1.8.1. Resource document being developed to assist regional Medical Directors, agency medical director and agency personnel as patient care guidelines and protocols are produced.

Core Strategy 3: Develop Infrastructure

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 3.2 - Focus recruitment and retention efforts			
<i>Objectives</i>	<i>Accountability</i>	<i>Action Steps</i>	
Core Strategy 3: Develop Infrastructure	3.2.1 Develop, implement and promote a comprehensive recruitment and retention campaign for EMS personnel and physicians, supporting the needs of the EMS system.	OEMS, State EMS Medical Director, MDC, Workforce Development Committee, FARC, Regional EMS Councils	3.2.1.1. Continue to support “Virginia EMS Jobs” website. 3.2.1.2. Develop and implement voluntary “Standards of Excellence” for EMS agencies. 3.2.1.3. Maintain Leadership & Management track at the Virginia EMS Symposium and recommend topics and presenters. 3.2.1.4. Continue to promote and support special RSAF applications related to recruitment and retention of EMS providers. 3.2.1.5. Review and promote the OMD Workshop curriculum. 3.2.1.6. Promote and develop an ongoing relationship with EMS fellowship programs.
	3.2.2 Support and expand the Virginia Recruitment and Retention Network.	OEMS, WDC	3.2.2.1. Continue to support information and education for distribution. 3.2.2.2. Seek new avenues for EMS recruitment outreach. 3.2.2.3. Recommend strategies to expand existing programs and distribute to EMS stakeholders.
	3.2.3 Develop, implement and promote the EMS Officer Standards program.	OEMS, WDC	3.2.3.1. Provide Virginia’s EMS agencies with the highest quality of leadership. 3.2.3.2. Develop and/or review leadership criteria and qualifications for managing an EMS agency. 3.2.3.3. Develop model job descriptions for EMS officers.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 3.3 – Upgrade technology and communication systems

Strategic Initiative 3.3 – Upgrade technology and communication systems			
Objectives		Accountability	Action Steps
Core Strategy 3: Develop Infrastructure	3.3.1 Assist with, and promote, the compliance of all emergency medical radio systems with state and federal regulations for narrow banding and interoperability.	OEMS, Communications Committee	3.3.1.1. Continue to ensure that all emergency medical radio systems meet FCC mandated narrow banding regulation. 3.3.1.2. Prior to 2015, ensure that all emergency medical radio systems meet state interoperability requirements.
	3.3.2 Promote Emergency Medical Dispatch standards and accreditation among 911 PSAPs in Virginia.	OEMS, Communications Committee	3.3.2.1. Support concept of accredited PSAPs, operating with EMD standards, and assist agencies in achieving accreditation, and/or adopting EMD as standard operating procedure.
	3.3.3 Provide technical assistance on wireless communication products available for use in the emergency medical community.	OEMS, Communications Committee	3.3.3.1. Continue to stay informed and up-to-date on new products and technologies, and serve as information conduit to communications entities.

Strategic Initiative 3.4 – Stable support for EMS funding

Strategic Initiative 3.4 – Stable support for EMS funding			
Objectives		Accountability	Action Steps
Core Strategy 3: Develop Infrastructure	3.4.1 Standardize EMS grant review and grading process by graders at regional and state level.	OEMS, FARC	3.4.1.1. Revise RSAF grant review sheet developed by FARC and OEMS staff, and continue to evaluate for efficacy. 3.4.1.2. Solicit concerns/comments of regional EMS councils/stakeholders regarding the grant process.
	3.4.2 Explore feasibility of creating EMS consortium for purchase of EMS equipment and supplies.	OEMS, FARC, Transportation Committee	3.4.2.2. Collaborate with DGS in developing resource guide and distribute to grant applicants.
	3.4.3 Develop uniform pricing schedule for state funded items.	OEMS, FARC	3.4.3.1. Determine items that can be standardized. 3.4.3.2. Distribute schedule to grant applicants.
	3.4.4 Develop standard specifications for state grant funded equipment awarded to eligible nonprofit EMS agencies.	OEMS, FARC, VDH Office of Purchasing and General Services	3.4.4.1. Develop and maintain list of eligible equipment and vehicles that agencies are eligible to purchase using state grant funds. 3.4.4.2. Utilize standard equipment and vehicle lists for future grant applications and cycles.
	3.4.5 Assist EMS agencies to identify grant programs and funding sources for EMS equipment, training and supplies.	OEMS, FARC	3.4.5.1. Continue to promote RSAF program through Regional EMS Councils. 3.4.5.2. Identify grant opportunities that EMS agencies may be eligible for and distribute information to the EMS system.
	3.4.6 Integrate state grant funding programs with other related grant funding programs.	OEMS, FARC	3.4.6.1. Continue to seek federal grant funds for items intended to improve the statewide EMS system.
	3.4.7 Develop guidance documents to assist EMS agencies account for the use of state grant funds and develop internal audit processes.	OEMS, FARC	3.4.7.1. Work with contracted audit firms and Office of Internal Audit to create reference documents to assist agencies to account for grant funds and ensure sound auditing practices.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 3.5 – Enhance regional and local EMS efficiencies			
Objectives		Accountability	Action Steps
Core Strategy 3: Develop Infrastructure	3.5.1 Standardize performance and outcomes based service contracts with designated Regional EMS Councils and other qualified entities.	OEMS, Regional EMS Councils	3.5.1.1. Maintain annual service contracts with Regional EMS Councils. 3.5.1.2. Provide standard contracts, plan templates and other reference documents to Regional EMS Councils in each fiscal year. 3.5.1.3. Provide input on contract deliverables to Regional EMS Councils on a quarterly basis.
	3.5.2 Improve regulation and oversight of AMS statewide.	OEMS, State Medevac Committee, Rules & Regulations Committee, MDC	3.5.2.1. Revise/implement state AMS regulations. More clearly define licensure requirements for AMS agencies. 3.5.2.2. Establish response areas for AMS agencies. 3.5.2.3. Develop criteria for ongoing AMS performance improvement program.
	3.5.3 Educate local government officials and communities about the value of a high quality EMS system to promote development in economically depressed communities and the importance of assuming a greater responsibility in the planning, development, implementation, and evaluation of its Emergency Medical Services system.	OEMS, Workforce Development Committee, OMHHE	3.5.3.1. Give presentations at VACO and VML meetings to educate local government officials about EMS. 3.5.3.2. Contribute EMS related articles and news items to monthly and quarterly publications of VACO and VML.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 4.1 – Assess compliance with EMS performance-based standards

Core Strategy 4: Assure Quality and Evaluation	Objectives	Accountability	Action Steps
	4.1.1 Maintain statewide data-driven performance improvement process.	OEMS, MDC	4.1.1.1. Utilize epidemiology-trained OEMS staff to conduct risk adjusted data analysis of patients in collaboration with our stakeholders. 4.1.1.2. Develop an EMS performance improvement program.
	4.1.2 Maintain statewide prehospital and inter-hospital trauma triage plan.	OEMS, TSO&MC, State EMS Medical Director, MDC	4.1.2.1. Maintain statewide trauma triage plan to support regional plan development and maintenance by regional trauma committees. 4.1.2.2. Supply state level data to assist with monitoring individual regional performance compared to state and national benchmarks.
	4.1.3 Maintain statewide prehospital and inter-hospital stroke triage plan.	OEMS, State Stroke Task Force, MDC	4.1.3.1. Actively participate on the Virginia Heart Attack Coalition, and develop and maintain a Statewide Stroke Triage Plan. 4.1.3.2 If available, provide funds for the development of regional stroke triage plans to ensure implementation is performed based on local resources.
	4.1.4 Review and evaluate data collection and submission efforts.	OEMS, MDC	4.1.4.1. Develop standard reports within VPHIB that will allow individual EMS agencies to view the quality of data being submitted. 4.1.4.2. OEMS will provide quality “dashboards” where education can improve data quality and update validity rules within the application when education alone cannot correct poor data. 4.1.4.3. Provide quarterly compliance reports to the OEMS, Division of Regulation and Compliance and Executive Management.
	4.1.5 Review functional adequacy and design features of EMS vehicles utilized in Virginia and recommend changes to improve EMS provider safety, unit efficiency and quality of patient care.	OEMS, Rules & Regulations Committee, Transportation Committee	4.1.5.1. Evaluation of national/international documents and information related to vehicle and provider safety, with potential incorporation into EMS regulation and inspection procedure.
	4.1.6 Measure EMS system compliance utilizing national EMSC performance measures.	OEMS, EMSC Committee	4.1.6.1. Assist in assessing the pediatric emergency care readiness of Virginia emergency departments.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Strategic Initiative 4.2 – Assess and enhance quality of education for EMS providers			
	Objectives	Accountability	Action Steps
Core Strategy 4: Assure Quality and Evaluation	4.2.1 Update the certification process to assure certification examinations continue to be valid, psychometrically sound and legally defensible.	OEMS, TCC	4.2.1.1. Review and revision of psychomotor examination by TCC as needed. 4.2.1.2. Review statistical data and make recommendations for the EC recertification exam.
	4.2.2 Assure adequate and appropriate education of EMS students.	OEMS, TCC, AEMS	4.2.2.1. Review state statistics for certification rates and assist in determining avenues to improve outcomes and implement new processes. 4.2.2.2. Improve instructor compliance with student registration process.
	4.2.3 Explore substitution of practical examination with successful completion of a recognized competency based training program conducted by accredited training sites and using computer-based technology for written examinations.	OEMS, TCC	4.2.3.1. Explore possibility of administering a summative practical exam in lieu of state practical exam at the completion of EMS educational programs.

Strategic Initiative 4.3 – Pursue new initiatives that support EMS			
	Objectives	Accountability	Action Steps
Core Strategy 4: Assure Quality and Evaluation	4.3.1 Engage the EMS system in unintentional injury, illness and violence prevention efforts.	OEMS, Health & Safety Committee, VDH – Division of Injury and Violence Prevention	4.3.1.1. Participate in intentional and unintentional injury and illness prevention initiatives, and facilitate involvement for EMS agencies and providers.
	4.3.2 Develop, implement and promote programs that emphasize safety, wellness and the physical health of fire and EMS personnel.	OEMS, Health & Safety Committee, State EMS Medical Director	4.3.2.1. Maintain OEMS staff support at quarterly meetings of the Health and Safety Committee of the State EMS Advisory Board. 4.3.2.2. Maintain Health and Safety track at the Virginia EMS Symposium, and recommend topics and presenters. 4.3.2.3. Maintain Governor’s EMS Award category for contribution to the EMS system related to the health and safety of EMS providers.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Appendix A

Glossary of Terms

SWOT Analysis: An assessment of the internal strengths and weaknesses of the organization and the organization's external opportunities and threats.

Core Strategy: A main thrust or action that will move the organization towards accomplishing your vision and mission.

Strategic Initiative: An action that will address areas needing improvement or set forth new initiatives under the core strategy. This is the planning part of the strategy that when combined with the vision, the mission and core strategies complete the strategic effort.

Operational Plan: This is the plan that implements the strategic intent of the organization on an annual basis.

Objective: A specific, realistic and measurable statement under a strategic initiative.

Action Step: A specific action required to carry out an objective.

Template: A guide and/or format that assists the user in accomplishing a task efficiently in a uniform and consistent manner.

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Appendix A (Continued)

Glossary of Commonly Used Acronyms

AEMER	Alliance for Emergency Medical Education and Research
AEMS	Atlantic EMS Council (PA, WV, NJ, DE, MD, VA, DC, NC, SC)
AEMT	Advanced Emergency Medical Technician certification level
AHA	American Heart Association
AMS	Air Medical Services
BoP	Board of Pharmacy
CAH	Critical Access Hospital
COOP	Continuity Of Operations Plan
DGS	Department of General Services
DHS	Department of Homeland Security
DW	VDH Data Warehouse
EC	EMS Education Coordinator
EMD	Emergency Medical Dispatch
EMSC	EMS For Children
FARC	Financial Assistance and Review Committee (committee of state EMS Advisory Board)
FCC	Federal Communications Commission
HMERT	Health and Medical Emergency Response Team
LZ	Landing Zone
MCI	Mass Casualty Incident
MDC	Medical Direction Committee (committee of State EMS Advisory Board)
NAEMSO	National Association of State EMS Officials
OCP	Office of Commonwealth Preparedness
OEMS	Office of Emergency Medical Services
OMD	Operational Medical Director
OMHHE	Office of Minority Health and Health Equity
PSAP	Public Service Answering Point
RSAP	Rescue Squad Assistance Fund
TCC	Training and Certification Committee (committee of State EMS Advisory Board)
TSOMC	Trauma System Oversight and Management Committee (committee of State EMS Advisory Board)
VACO	Virginia Association of Counties
VAGEMSA	Virginia Association of Governmental EMS Administrators
VAVRS	Virginia Association of Volunteer Rescue Squads
VDEM	Virginia Department of Emergency Management
VDFP	Virginia Department of Fire Programs
VDH	Virginia Department of Health
VHAC	Virginia Heart Attack Coalition

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

VHHA	Virginia Hospital and Healthcare Association
VHI	Virginia Health Information
VML	Virginia Municipal League
VPHIB	Virginia Pre Hospital Information Bridge
VSP	Virginia State Police
VSTR	Virginia State Trauma Registry
WDC	EMS Workforce Development Committee (committee of State EMS Advisory Board)

FINAL DRAFT

STATEWIDE EMERGENCY MEDICAL SERVICES PLAN

Appendix B

Resources

In the development of this plan, the following resources were used in addition to meetings and interviews with the director and assistant director of OEMS.

- Code of Virginia: § 32.1-111.3. Statewide emergency medical care system. Requires a comprehensive, coordinated EMS system in the Commonwealth and identifies specific objectives that must be addressed.
- EMS Agenda for the Future: A document created by the National Highway Traffic and Safety Administration (NHTSA) that outlines a vision and objectives for the future of EMS. August 1996.
- OEMS 5-Year Plan: July 1, 2010-June 30, 2013.
- Service Area Strategic Plan State Office of Emergency Medical Services (601 402 04) which describes the statutory authority and expectations for OEMS and identifies the growing EMS needs of the citizens and visitors of Virginia.
- Service Area Strategic Plan Financial Assistance for Nonprofit Emergency Medical Services Organizations and Localities (601 402 03) This service area includes Virginia Rescue Squads Assistance Fund grants program, Financial Assistance to Localities to support Nonprofit Emergency Medical Service (EMS) agencies, and funding provided to support Virginia Association of Volunteer Rescue Squads (VAVRS).
- State Emergency Medical Services Systems: A Model: National Association of State EMS Officials – July 2008.
- EMS at the Crossroads: Institute of Medicine - 2006.
- Agency Planning Handbook: A Guide for Strategic Planning and Service Area Planning Linking to Performance-Based Budgeting: Department of Planning and Budget 2006-2008 Biennium, May 1, 2005.
- Joint Legislative Audit and Review Commission (JLARC) Report – House Document 37, Review of Emergency Medical Services in Virginia. 2004.
- EMS Advisory Board Committee Planning Templates – Developed May-August 2009.
- Regional EMS Council Process Action Team (PAT) Retreat Report - November 2008.



COMMONWEALTH of VIRGINIA
Department of Health

March 19, 2014

Mr. Bruce Edwards, Chair
Virginia State Board of Health
109 Governor Street
Richmond, VA 23219

Dear Chairman Edwards:

Section 32.1-111.12. of the Code of Virginia establishes the Virginia Rescue Squads Assistance Fund (RSAF) program for the purpose of providing financial assistance to rescue squads and other emergency medical services organizations in the Commonwealth, of providing the requisite training for emergency medical service personnel, and of purchasing equipment needed by such rescue squads and organizations. The Code also requires that regulations governing the RSAF program be developed and in accordance with regulations of the Board, the Commissioner shall disburse and expend the moneys in the Virginia Rescue Squads Assistance Fund. No moneys shall be disbursed directly to any rescue squad or other emergency medical services organization unless such squad or organization operates on a nonprofit basis exclusively for the benefit of the general public.

Section 32.1-111.12:01. of the Code of Virginia establishes a Financial Assistance and Review Committee (FARC) for the purposes of administering the Virginia Rescue Squads Assistance Fund as provided in § 32.1-111.12. The Committee shall be composed of six members who shall be representatives of the regions encompassed by the emergency medical services councils and appointed by the State Emergency Medical Services Advisory Board.

The Code further defines that the Financial Assistance and Review Committee shall:

1. Administer the Rescue Squads Assistance Fund in accordance with the rules and regulations of the State Board of Health as shall be established for the Fund;
2. Review the Rescue Squads Assistance Fund grant applications from eligible emergency medical services agencies and make recommendations on the funding of such grant applications to the Commissioner of Health; and
3. Report biannually, after each funding cycle, the number of grant applications received, the total costs of grant applications funded, the number of grant applications denied funding, the total costs of grant applications denied funding, and the nature of the denied requests and the reasons for denying funding, to the State Emergency Medical Services Advisory Board and the Commissioner.

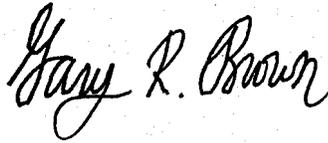
Mr. Bruce Edwards, Chair
March 19, 2014
Page Two

The Office of Emergency Medical Services (OEMS) has worked with the FARC, the State EMS Advisory Board and other stakeholder groups and identified certain technical changes necessary to create an easier understanding of the regulations by better defining the purpose, process and approval for certain grant applications. OEMS has developed the TH-04 Fast Track form to the Virginia Regulatory Town Hall for the purpose of amending the Virginia EMS Regulations pertaining to the Financial Assistance for Emergency Medical Services with technical changes that do not affect the purpose or scope of the regulatory section.

Attached to this document is the TH-04 form and a copy of the regulatory text.

As the Code of Virginia mandates, this regulatory action must be reviewed and approved by the State Board of Health. OEMS appreciates the opportunity to present this document to the Board, and values any input that the Board provides, as well as the input of any other stakeholder, or interested party.

Respectfully submitted,



Gary R. Brown, Director
Office of Emergency Medical Services
Virginia Department of Health



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Fast Track Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-31
Regulation title	Virginia Emergency Medical Services Regulations
Action title	Amend the <i>Virginia EMS Regulations</i> pertaining to Financial Assistance for Emergency Medical Services.
Date this document prepared	April 23, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

The proposed amendments make certain technical changes in order to improve the clarity of the regulations by better defining the purpose, eligibility criteria and approval process for certain grant applications. These proposed amendments do not affect the purpose of the regulations.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

FARC – Financial Assistance and Review Committee

RSAF – Rescue Squad Assistance Fund

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The State Board of Health approved the fast track amendments to the Virginia Emergency Medical Services Regulations on behalf of the Board of Health on June 5, 2014

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

§ 32.1-111.4. Regulations; emergency medical services personnel and vehicles; response times; enforcement provisions; civil penalties.

A. The State Board of Health shall prescribe by regulation:

1. Requirements for record keeping, supplies, operating procedures and other agency operations;
2. Requirements for the sanitation and maintenance of emergency medical services vehicles and their medical supplies and equipment;
3. Procedures, including the requirements for forms, to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § [54.1-2987.1](#);
4. Requirements for the composition, administration, duties and responsibilities of the State Emergency Medical Services Advisory Board;
5. Requirements, developed in consultation with the Emergency Medical Services Advisory Board, governing the training, certification, and recertification of emergency medical services personnel;
6. Requirements for written notification to the State Emergency Medical Services Advisory Board, the State Office of Emergency Medical Services, and the Financial Assistance and Review Committee of the Board's action, and the reasons therefor, on requests and recommendations of the Advisory Board, the State Office of Emergency Medical Services or the Committee, no later than five workdays after reaching its decision, specifying whether the Board has approved, denied, or not acted on such requests and recommendations;
7. Authorization procedures, developed in consultation with the Emergency Medical Services Advisory Board, which allow the possession and administration of epinephrine or a medically accepted equivalent for emergency cases of anaphylactic shock by certain levels of certified emergency medical services personnel as authorized by § [54.1-3408](#) and authorization procedures that allow the possession and

administration of oxygen with the authority of the local medical director and a licensed emergency medical services agency;

8. A uniform definition of "response time" and requirements, developed in consultation with the Emergency Medical Services Advisory Board, for each agency to measure response times starting from the time a call for emergency medical care is received until (i) the time an appropriate emergency medical response unit is responding and (ii) the appropriate emergency medical response unit arrives on the scene, and requirements for agencies to collect and report such data to the Director of the Office of Emergency Medical Services who shall compile such information and make it available to the public, upon request; and

9. Enforcement provisions, including, but not limited to, civil penalties that the Commissioner may assess against any agency or other entity found to be in violation of any of the provisions of this article or any regulation promulgated under this article. All amounts paid as civil penalties for violations of this article or regulations promulgated pursuant thereto shall be paid into the state treasury and shall be deposited in the emergency medical services special fund established pursuant to § [46.2-694](#), to be used only for emergency medical services purposes.

B. The Board shall classify agencies and emergency medical services vehicles by type of service rendered and shall specify the medical equipment, the supplies, the vehicle specifications and the personnel required for each classification.

C. In formulating its regulations, the Board shall consider the current Minimal Equipment List for Ambulances adopted by the Committee on Trauma of the American College of Surgeons.

§ 32.1-111.5. Certification and recertification of emergency medical services providers; appeals process.

A. The Board shall prescribe by regulation the qualifications required for certification of emergency medical services providers, including those qualifications necessary for authorization to follow Do Not Resuscitate Orders pursuant to § [54.1-2987.1](#). Such regulations shall include criteria for determining whether an applicant's relevant practical experience and didactic and clinical components of education and training completed during his service as a member of any branch of the armed forces of the United States may be accepted by the Commissioner as evidence of satisfaction of the requirements for certification.

B. Each person desiring certification as an emergency medical services provider shall apply to the Commissioner upon a form prescribed by the Board. Upon receipt of such application, the Commissioner shall cause the applicant to be examined or otherwise determined to be qualified for certification. When determining whether an applicant is qualified for certification, the Commissioner shall consider and may accept relevant practical experience and didactic and clinical components of education and training completed by an applicant during his service as a member of any branch of the armed forces of the United States as evidence of satisfaction of the requirements for certification. If the Commissioner determines that the applicant meets the requirements for certification as an emergency medical services provider, he shall issue a certificate to the applicant. An emergency medical services provider certificate so issued shall be valid for a period required by law or prescribed by the Board. Any certificate so issued may be suspended at any time that the Commissioner determines that the holder no longer meets the qualifications prescribed for such emergency medical services provider. The Commissioner may temporarily suspend any certificate without notice, pending a hearing or informal fact-finding conference, if the Commissioner finds that there is a substantial danger to public health or safety. When the Commissioner has temporarily suspended a certificate pending a hearing, the Commissioner shall seek an expedited hearing in accordance with the Administrative Process Act (§ [2.2-4000](#) et seq.).

C. The Board shall prescribe by regulation procedures and the qualifications required for the recertification of emergency medical services providers.

D. The Commissioner may issue a temporary certificate when he finds that it is in the public interest. A temporary certificate shall be valid for a period not exceeding 90 days.

E. The State Board of Health shall require each person who, on or after July 1, 2013, applies to be a volunteer with or employee of an emergency medical services agency to submit fingerprints and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation, for the purpose of obtaining his criminal history record information. The Central Criminal Records Exchange shall forward the results of the state and national records search to the Commissioner or his designee, who shall be a governmental entity. If an applicant is denied employment or service as a volunteer because of information appearing on his criminal history record and the applicant disputes the information upon which the denial was based, the Central Criminal Records Exchange shall, upon written request, furnish to the applicant the procedures for obtaining a copy of the criminal history record from the Federal Bureau of Investigation.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The proposed amendments are essential to protect the health, safety and welfare of the citizens because the technical changes clarify the regulations by better defining the purpose, eligibility criteria and approval process for certain grant applications. There are no substantive content changes being proposed. The changes have been reviewed by the Financial Assistance Review Committee and approved by the Rules and Regulations Committee of the EMS Advisory Board.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The technical changes have been vetted through the standing committees of the EMS Advisory Board and are technical in nature only. There is no anticipated opposition to these changes as presented.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the “Detail of changes” section.) Please be sure to define any acronyms.

The changes proposed are technical in nature and intended to clarify existing language in the regulations without making any substantive changes. There is no new terminology or requirements to this section of the EMS Regulations. Recommended changes include moving certain language to a more appropriate section of the regulations, improve the flow, understanding and readability of the regulations, and better define the purpose, and approval process for the grant application.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1. The primary advantage to the public is information is easier to read and makes it easier to understand the grant process. There are no disadvantages to the public.
2. The primary advantage to the agency and the Commonwealth is a clearer, more understandable flow of the EMS Regulations for the reviewer.
3. There are no are known disadvantages to the agency or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements that exceed any applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is disproportionately affected by this recommended change.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will

accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods to accomplish the objectives of the applicable laws. There are no known adverse impacts on small business.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	All eligible licensed EMS agencies and non-profit entities who participate in EMS activities.
Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million.	All eligible EMS agencies (approximately 600), nonprofit entities who participate in EMS activities (approximately 500) and local governments who provide EMS services (approximately 100).
Benefits expected as a result of this regulatory proposal.	A better understanding of regulatory requirements with wording changes that do not affect content.
Projected cost to the state to implement and enforce this regulatory proposal.	There are no projected costs to the state as these are technical changes only.
Projected cost to localities to implement and enforce this regulatory proposal.	None.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	None.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no readily identified alternatives.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory action has no impact on the institution of the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
------------------------	--	---------------------	--

<p>12VAC5-31-2810. The Financial Assistance and Review Committee (FARC).</p>		<p>B. Geographical representation. 2. The eligible designated regional EMS council shall nominate one to three candidates to fill a vacancy on the FARC. The EMS Advisory Board shall make appointments from the nominations submitted by the designated regional EMS council. Consideration for filling vacancies shall include length of nonrepresentation on FARC in an effort to provide reasonable geographic distribution.</p>	<p>2. The eligible designated regional EMS council shall nominate one to three three candidates to fill a vacancy on the FARC. The EMS Advisory Board shall make appointments from the nominations submitted by the designated regional EMS council. Consideration for filling vacancies shall include length of nonrepresentation on FARC in an effort to provide reasonable geographic distribution.</p> <p>Rationale: The intent is to be consistent with similar nomination processes for other appointed positions. This creates an opportunity for a broader pool of potential nominates and an objective selection process.</p>
<p>12VAC5-31-2830. Award of RSAF General Grants.</p>		<p>A. The requirements of this section shall apply to the disbursement of funds. B. A nonprofit licensed EMS agency or other Virginia emergency medical service organization operating on a nonprofit basis exclusively for the benefit of the general public pursuant to § 32.1-111.12 of the Code of Virginia is eligible for an RSAF General Grant. An applicant must be in compliance with these regulations. C. Programs, services, and equipment funded by the RSAF must comply with the plans, policies, procedures, and guidelines adopted by the State EMS Advisory Board. Awards are based upon one or more of the following criteria: 1. Establishment of a new EMS agency, program, or service where needed to improve emergency medical services offered in an area; 2. Expansion or improvement of an existing EMS agency, program, or</p>	<p>A. The requirements of this section shall apply to the disbursement of funds. B. A nonprofit licensed EMS agency or other Virginia emergency medical service organization operating on a nonprofit basis exclusively for the benefit of the general public pursuant to § 32.1-111.12 of the Code of Virginia is eligible for an RSAF General Grant. <u>C.</u> An applicant must be in compliance with these regulations. C-D. Programs, services, and equipment funded by the RSAF must comply with the plans, policies, procedures, and guidelines adopted by the State EMS Advisory Board. Awards are based upon one or more of the following criteria: 1. Establishment of a new EMS agency, program, or service where needed to improve emergency medical services offered in an area; 2. Expansion or improvement of an existing EMS agency, program, or service; 3. Replacement of equipment or procurement of new equipment. EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased; or 4. Establishment, expansion or improvement of EMS training programs.</p>

<p>12VAC5-31-2840. Grant award cycle.</p>	<p>12VAC5-31-2840. <u>General Grant grant award cycle.</u></p>	<p>service; 3. Replacement of equipment or procurement of new equipment. EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased; or 4. Establishment, expansion or improvement of EMS training programs.</p> <p>C. Dates of award shall be July 1 and January 1 of each year. D. Other dates in the award process shall be established by the Office of EMS.</p>	<p>Rationale: Technical grammar correction, The stricken language was moved to section 2920 "Use of Funds".</p> <p><u>C. Applications shall be made to the Office of EMS on an approved application form.</u></p> <p>C. D. Dates of award shall be July 1 and January 1 of each year. D. E. Other dates in the award process shall be established by the Office of EMS.</p> <p>Rationale: This section is specific for the General grant award. This provides clarification on type of form required and adds consistency in application.</p>
<p>12VAC5-31-2850. Emergency awards.</p>		<p>D. Award of funds shall be based upon the demonstrated needs arising from a natural or man-made disaster as defined in § 44-146.16 of the Code of Virginia. E. Award of funds shall be based upon incidents or circumstances involving the loss or potential loss of critical equipment or services.</p>	<p>D. Award of funds shall be based upon the demonstrated needs arising from a natural or man-made disaster as defined in § 44-146.16 of the Code of Virginia. E. Award of funds shall be based upon incidents or circumstances involving the loss or potential loss of critical equipment or services <u>emergency medical services as defined in these Regulations.</u></p> <p>Rationale: The Code section identified already defines "emergency". The scope is limited to those items within that of EMS.</p>
<p>12VAC5-31-2860. EMS System Initiative Awards.</p>		<p>EMS System Initiative Awards are based on priorities and needs identified by the Advisory Board in concert with the office to meet EMS system objectives as stipulated in § 32.1-111.3 of the Code of Virginia.</p>	<p>EMS System Initiative Awards are based on priorities and needs identified by the Advisory Board in concert with the office to meet EMS system objectives as stipulated in § 32.1-111.3 of the Code of Virginia. 2. Applications must be made to the Office of EMS on an approved application form. <u>EMS System Initiative Award applications</u></p>

<p>12VAC5-31-2880. Application for award.</p>		<p>1. The Office of EMS or FARC, in consultation with EMS Advisory Board, may implement EMS System Initiative Awards at any time. Examples of such awards would include medically advanced equipment with broad application (automated external defibrillation) and information technology to enhance communications and data (computers).</p> <p>2. Applications must be made to the Office of EMS on an approved application form.</p> <p>4. EMS System Initiative Awards shall be based upon the demonstrated needs from the following criteria:</p> <ul style="list-style-type: none"> a. Establishment of a new EMS agency, program, or service where needed to improve emergency medical services offered in an area; b. Expansion or improvement of an existing EMS agency, program, or service; c. Replacement of equipment or procurement of new equipment. EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased; <p>B. The Office of EMS will review applications for compliance with the EMS regulations and RSAF policies and procedures. The FARC reviews and grades applications and makes recommendations on funding.</p>	<p><u>must be on the Office of EMS approved application form, using approved pricing, application eligibility, award criteria and approved priorities.</u></p> <p>4. EMS System Initiative Awards shall be based upon the demonstrated needs from the following criteria:</p> <ul style="list-style-type: none"> a. Establishment of a new EMS agency, program, or service where needed to improve emergency medical services offered in an area; b. Expansion or improvement of an existing EMS agency, program, or service; c. Replacement of equipment or procurement of new equipment. EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased; d. Establishment, expansion or improvement of EMS training programs. <p>Rationale: This provides clarification on the type of form required to apply for a grant and adds consistency in to the application process.</p> <p>B. The Office of EMS will review applications for compliance with the EMS regulations and RSAF policies and procedures. The FARC reviews and grades applications and makes recommendations on <u>general grant</u> funding.</p> <p>Rationale: This defines the category of grants to be reviewed by the FARC.</p>
--	--	--	--

<p>12VAC5-31-2900. Awards.</p> <p>12VAC5-31-2920. Use of funds.</p> <p>12VAC5-31-2930. Ownership.</p>		<p>B. Grantees will be notified of their award by mail.</p> <p>E. Funds must not be used for expenditures or commitments made before the date of the grant award or after the conclusion of the grant period.</p> <p>F. Funds will not be approved or disbursed for:</p> <ol style="list-style-type: none"> 1. Leased equipment or vehicle; 2. Equipment or vehicles secured by a lien; 3. Guarantees or warranties; 4. Used equipment or vehicles without prior approval; or 5. Fire suppression apparatus or law-enforcement equipment. <p>The title for all equipment, including EMS vehicles, shall be in the name of the organization to which the award has been made or in the name of the local jurisdiction or government entity in which the organization is located. This requirement shall apply to the ownership of equipment purchased in whole or in part with the use of these funds.</p>	<p>B. Grantees will be notified of their award by mail.</p> <p>Rationale: Allows for use of technology to provide more timely notification and reduction of paperwork in accordance with Executive Order 82 (2009).</p> <p><u>E. EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased.</u></p> <p>E <u>F</u>. Funds must not be used for expenditures or commitments made before the date of the grant award or after the conclusion of the grant period.</p> <p>F <u>G</u>. Funds will not be approved or disbursed for:</p> <ol style="list-style-type: none"> 1. Leased equipment or vehicle; 2. Equipment or vehicles secured by a lien; 3. Guarantees or warranties; 4. Used equipment or vehicles without prior approval; or 5. Fire suppression apparatus or law-enforcement equipment. <p>Rationale: Statement added to this section as criteria for the use of funds and to clarify considerations for award determinations.</p> <p>The title for all <u>All</u> equipment, including EMS vehicles, shall be in the name of the organization to which the award has been made or in the name of the local jurisdiction or government entity in which the organization is located. This requirement shall apply to the ownership of equipment purchased in whole or in part with the use of these funds.</p> <p><u>A copy of the title for all EMS vehicles must be provided to the Office of EMS.</u></p> <p>Rationale: This clarifies a title is needed only for automotive equipment.</p>
--	--	--	--

DEPARTMENT OF HEALTH
Amend Financial Assistance for Emergency Medical Services

Part VIII
Financial Assistance For Emergency Medical Services

12VAC5-31-2810. The Financial Assistance and Review Committee (FARC).

A. Financial Assistance and Review Committee appointments.

1. Appointments shall be made for terms of three years or the unexpired portions thereof in a manner to preserve, insofar as possible, the representation of the emergency medical services councils. No member may serve more than two successive terms. The chairman shall be elected from the membership of the FARC for a term of one year and shall be eligible for reelection.
2. The EMS Advisory Board may revoke appointment for failure to adhere to the standards set forth in these regulations, and the State and Local Government Conflict of Interests Act (§ 2.2-3100 et seq. of the Code of Virginia).
3. Members serving on the FARC on January 1, 2008, shall complete their current terms of office.
4. Midterm vacancies shall be filled by nominations submitted from affected designated regional EMS council.

B. Geographical representation.

1. Designated regional EMS councils shall be eligible to submit nominations to the EMS Advisory Board for representation on the FARC.
2. The eligible designated regional EMS council shall nominate ~~one to three~~ candidates to fill a vacancy on the FARC. The EMS Advisory Board shall make appointments from the nominations submitted by the designated regional EMS council. ~~Consideration for filling vacancies shall include length of nonrepresentation on FARC in an effort to provide reasonable geographic distribution.~~
3. A designated regional EMS council whose representative has completed two successive terms on FARC shall not be eligible to submit a nomination for one full term (three years).

C. Meetings and attendance.

1. The FARC shall meet at least four times annually at the call of the chairman or the commissioner.
2. Attendance at FARC Grant Review meetings is mandatory for all members.
3. A quorum for a meeting of the FARC shall consist of not fewer than four members.

12VAC5-31-2830. Award of RSAF General Grants.

A. The requirements of this section shall apply to the disbursement of funds.

B. A nonprofit licensed EMS agency or other Virginia emergency medical service organization operating on a nonprofit basis exclusively for the benefit of the general public pursuant to § 32.1-111.12 of the Code of Virginia is eligible for an RSAF General Grant.

C. An applicant must be in compliance with these regulations.

CD. Programs, services, and equipment funded by the RSAF must comply with the plans, policies, procedures, and guidelines adopted by the State EMS Advisory Board. Awards are based upon one or more of the following criteria:

1. Establishment of a new EMS agency, program, or service where needed to improve emergency medical services offered in an area;
2. Expansion or improvement of an existing EMS agency, program, or service;
3. Replacement of equipment or procurement of new equipment. ~~EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased;~~ or
4. Establishment, expansion or improvement of EMS training programs.

12VAC5-31-2840. General Grant award cycle.

A. The grant period shall be for a period of 12 months from the date of award and there shall be two review cycles per year;

B. Deadline for submission of applications shall be March 15 and September 15 of each year. Applications must be received in the Office of EMS by 5 p.m. of the date of the deadline. In the event the deadline falls on a Saturday, Sunday, state or federal holiday, the application must be received by 5 p.m. in the Office of EMS the next business day.

C. Applications shall be made to the Office of EMS on an approved application form.

D. Dates of award shall be July 1 and January 1 of each year.

E. Other dates in the award process shall be established by the Office of EMS.

12VAC5-31-2850. Emergency awards.

A. The commissioner empowers the Office of EMS the ability to implement Emergency Grant Awards. The Office of EMS will advise the EMS Advisory Board and FARC of emergency grants awarded and the purpose(s) of disbursement of these funds.

B. Applications shall be made to the Office of EMS on an approved application form at any time.

C. The Emergency Grant Award will be made or rejected by the Office of EMS within 10 business days after receiving an application on an approved form.

D. Award of funds shall be based upon ~~the demonstrated needs~~ need arising from a natural or man-made disaster as defined in § 44-146.16 of the Code of Virginia.

E. Award of funds shall be based upon incidents or circumstances involving the loss or potential loss of ~~critical equipment or services~~ emergency medical services as defined in these Regulations.

12VAC5-31-2860. EMS System Initiative Awards.

EMS System Initiative Awards are based on priorities and needs identified by the EMS Advisory Board in concert with the office to meet EMS system objectives as stipulated in § 32.1-111.3 of the Code of Virginia.

1. The Office of EMS or FARC, in consultation with EMS Advisory Board, may implement EMS System Initiative Awards at any time. Examples of such awards would include medically advanced equipment with broad application (automated external defibrillation) and information technology to enhance communications and data (computers).

~~2. Applications must be made to the Office of EMS on an approved application form.~~ EMS System Initiative Award applications must be submitted on the Office of EMS approved form, using approved pricing, application eligibility award criteria and approved priorities.

3. The EMS System Initiative Award will be made or rejected by the Office of EMS within 30 business days after receiving an application on an approved form.

4. EMS System Initiative Awards shall be based upon the demonstrated needs from the following criteria:

- a. Establishment of a new EMS agency, program, or service where needed to improve emergency medical services offered in an area;
- b. Expansion or improvement of an existing EMS agency, program, or service;
- c. Replacement of equipment or procurement of new equipment. ~~EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased; or~~
- d. Establishment, expansion or improvement of EMS training programs.

12VAC5-31-2880. Application for award.

A. Applications must be made to the Office of EMS.

B. The Office of EMS will review applications for compliance with the EMS regulations and RSAF policies and procedures. The FARC reviews and grades applications and makes recommendations on general grant funding.

12VAC5-31-2900. Awards.

A. The Office of EMS shall make awards as approved by the commissioner.

B. Grantees will be notified of their award ~~by mail~~.

C. Funds may be disbursed to the grantee at any time within the grant period. Agreement to the award and any attached conditions shall be secured prior to any disbursements.

12VAC5-31-2920. Use of funds.

A. Awards will be made in accordance with § 32.1-111.12 of the Code of Virginia.

B. Funds must be used only for the specific items, service, or programs for which they were awarded. This includes any conditions placed upon a grant award.

C. The grantee is required to sign an agreement form attesting that the award funds will be used as granted and meets all conditions placed upon the award.

D. Sale, trade, transfer, or disposal, within five years of vehicles or items specified by the Office of EMS in the notice of award purchased in whole or in part with the use of state moneys requires prior approval by the Office of EMS.

E. EMS vehicles purchased with funding from the RSAF shall meet the current state and/or federal standards for the type of vehicle purchased.

~~E~~F. Funds must not be used for expenditures or commitments made before the date of the grant award or after the conclusion of the grant period.

~~F~~G. Funds will not be approved or disbursed for:

1. Leased equipment or vehicle;
2. Equipment or vehicles secured by a lien;
3. Guarantees or warranties;
4. Used equipment or vehicles without prior approval; or
5. Fire suppression apparatus or law-enforcement equipment.

12VAC5-31-2930. Ownership.

~~The title for all~~ All equipment, including EMS vehicles, shall be in the name of the organization to which the award has been made or in the name of the local jurisdiction or government entity in which the organization is located. This requirement shall apply to the ownership of equipment purchased in whole or in part with the use of these funds.

A copy of the title for all EMS vehicles must be provided to the Office of EMS.

MEMORANDUM

DATE: March 11, 2014

TO: Board of Health

FROM: Steven A. Harrison, Director
Office of Radiological Health

SUBJECT: **Request for Action by the State Board of Health to Amend Regulations titled “Virginia Radiation Protection Regulations, 12 VAC5-481” - Approval of Final Regulation.**

The Virginia Department of Health (VDH) intends to amend the existing *Virginia Radiation Protection Regulations* (12 VAC 5-481) in order to adopt the latest version of the *Suggested State Regulations Part F Diagnostic X-rays and Imaging Systems in the Healing Arts and Part X Medical Therapy* published in 2009 by the Conference of Radiation Control Program Directors. This request to publish Final Regulations is being presented to the Board of Health for approval at its meeting on June 5, 2014.

Purpose of Regulations

The purpose of the x-ray program is to protect the public from unnecessary radiation due to faulty x-ray equipment or substandard radiographic practices. The purpose of registering facilities that use x-ray machines is to have an accurate database of who is using these machines and to track the inspection record of the machines. The purpose of machine inspections is to assure compliance with equipment standards. VDH registers approximately 20,000 X-ray machines, and inspects X-ray machines whenever a private inspector is not available, or upon request of a registrant.

Upcoming Steps

Executive Branch approval will be solicited, the TH03 “Final Regulation” and associated documentation will be published on Regulatory Town Hall and the 30-day final adoption period will begin. Unless it is suspended or greater than 25 individuals request an additional public comment period, the regulation change will become effective.



Final Regulation Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-481
Regulation title	Virginia Radiation Protection Regulations
Action title	Update to the Diagnostic X-ray Therapy, Analytical & Radiation Machine Regs.
Date this document prepared	February 3, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Virginia Department of Health (VDH), Office of Radiological Health (ORH) proposes to amend 12VAC5-481, Radiation Protection Regulations, to adopt the 2009 Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs) to reflect new X-ray modalities in the medical field, reinsert definitions that were deleted in 2006 and update the regulations to meet Virginia Register Form, Style, and Procedure Manual guidance.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

On June 5, 2014 the Board of Health voted to adopt the proposed regulatory changes to 12VAC5-481.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

These regulations are authorized by the Code of Virginia Sections 32.1-229 et seq.

Section 32.1-229 authorizes the Board of Health to require the licensure and inspection of radioactive materials facilities, and mandates inspections of mammography facilities.

Section 32.1-229.1 requires the Board of Health to promulgate regulations for the registration, inspection, and certification of X-ray machines; and set the criteria for Private Inspectors.

Refer to the following web sites for viewing the statutory authority cited in Section 32.1-229 and Section 32.1-229.1 of the Code of Virginia:

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229> and

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1>

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

During the 2006 revision of the Virginia Radiation Protection Regulations, and in order for Virginia to become an Agreement State, some definitions were deleted in order to comply with the Nuclear Regulatory Commission's rules (10 CFR). Some of these definitions, however, were used by the X-ray program. This amendment will reinsert these definitions into 12VAC5-481 and update their verbiage such that they would apply specifically to X-ray registrants.

The Conference of Radiation Control Program Directors (CRCPD) publishes Suggested State Regulations (SSR) upon which individual Agreement States base their regulations. The X-ray regulations were based upon the SSRs in 2006. The sections in Part VI were repealed and new sections were inserted that now include the 2009 revised CRCPD SSRs.

This amendment is essential to protect the health, safety and welfare of our citizens by ensuring that Virginia's regulations conform to the most recent SSRs as endorsed by the Nuclear Regulatory Commission and the thirty-seven (37) Agreement State Radiation Control Programs.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The CRCPD SSRs were updated in 2009 to reflect current practices and devices used in the X-ray field. Virginia’s X-ray regulations were last updated to conform to the CRCPD SSRs in 2006. 12VAC5-481 needs to be amended to reflect and conform to the current practices and to include regulations that govern all devices used in the X-ray field.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.*

1. The advantage of the proposed regulation is that businesses regulated by both federal agencies and VDH will operate under identical standards which will eliminate some confusion, particularly with respect to occupational worker standards and X-ray machine performance standards. Another advantage for healthcare professionals and patients is that regulations governing the application of radiation will meet nationally recognized performance standards, which will promote quality of care. This amendment will include definitions that were removed in 2006 that pertain to the X-ray program.

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

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

There are no disadvantages to the agency in promulgating the proposed regulation

3. None

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Several changes, all non-substantive, have been made since the publication of the proposed regulations. These changes are enumerated in the table below:

Section number	Requirement at proposed stage	What has changed	Rationale for change
12 VAC5-481-10 Definitions	“Positive emission tomography (PET) radionuclide production facility” or “PET” means a facility operating a cyclotron or accelerator for the purpose of	“Positron Emission Tomography radionuclide production facility” or “PET” means a facility operating a cyclotron or [other particle] accelerator for the purpose of producing radionuclides that decay by	Cleaner language

	producing PET radionuclides.	positron emission.	
12 VAC5-481-10 Definitions	“Reportable event” means the administration of either: 3. A teletherapy x-ray dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or	“Reportable event” means the administration of either: 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	Cleaner language
12VAC5-481-340 – Private Inspector qualifications	B. 1.a.(1) Therapeutic radiological physics	B.1.a.(1) Therapeutic radiological physics or therapeutic medical physics;	Designation changed by the American Board of Radiology in 2012.
12VAC5-481-1591 A.5	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 .25 mm lead equivalent materials; and	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 .25 mm lead equivalent materials. 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	Protective aprons may not be necessary if dose rate is low or distance provides the necessary reduction in radiation exposure.
12VAC5-481-1591 A.8	c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 5 of this subsection.	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/or instructed to keep the protective apron between them and the patient;	Care givers do not require the same level of training as facility staff. It is highly unlikely that a caregiver that occasionally helps hold a patient would receive more than 100 mrem/year.
12VAC5-481-1591.A.9.c.	c. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.	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.	Need to specify radiographic equipment and not fluoroscopic equipment used in pain management centers.
12VAC5-481-	14. Operator list. The registrant shall maintain a list of x-ray operators	14. Operator list. The registrant shall maintain a list of x-ray operators for each facility.	Need to allow individuals waiting to test for their registry

1591 A.14	for each facility. Operators must be licensed by the Department of Health Professions where x-ray are used within the scope of practice or be certified by the ARRT, or be an individual enrolled in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, and if a dental assistance, comply with the Board of dentistry/s radiation certification requirements in 18VAC60-20-195.	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 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, or if a dental assistant, comply with the Board of Dentistry’s radiation certification requirements in 18 VAC60-20-195.	exam.
12VAC5-481-1621 B Reproducibility	2. Measuring compliance. Determination of compliance shall be based on 10 consecutive measurements taken within a time period of one hour.	2. Measuring compliance. Determination of compliance shall be based on four consecutive measurements taken within a time period of one hour.	Four exposures are sufficient to determine reproducibility. With 10 exposures, one would overwork the unit.
12VAC5-481-1621 C Linearity	3. Measuring compliance. Determination of compliance shall be based on 10 exposures made within one hour, at each of the two settings.	3. Measuring compliance. Determination of compliance shall be based on four exposures made within one hour, at each of the two settings.	Four exposures are sufficient to determine linearity. With 10 exposures, one would overwork the unit.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
James Nunn, Medical Physicist for Lewis gale Hospital - Pulaski	12VAC5-481-10 Definitions concerning “Reportable event” Item 1. For a diagnostic x-ray exposure. Wanted to consider adding a dose threshold consistent with The Joint Commission’s Sentinel Event Policy for diagnostic radiation overexposure.	Keep clear, concise and consistent with CRCPD SSRs. Do not refer to another policy used by Joint Commission. Change not recommended.
	12VAC5-481-10 Definitions concerning “Reportable event” Item	Keep consistent with CRCPD SSRs. Other states adopted this format. Change not

	4. A brachytherapy dose. Believes the rule may be burdensome on some institutions.	recommended.
Lee Anthony, Jr., Medical Physicist for Physics Associates – Roanoke and Harold Prussia, Medical Physicist from Riverside Hospitals	12VAC5-481-1591E concerning “non-serious” violations becoming “serious” if not corrected with the next inspection cycle.	Repeated non-serious violations that remain uncorrected are a concern to the Office of Radiological Health. Unless the registrant is required to repair the “non-serious” violation within a set time period, they will not fix, repair, or replace it. Change not recommended.
Harold Prussia, Medical Physicist from Riverside Hospitals	12VAC5-481-1655 Bone densitometry. D.2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure. Wants this section deleted.	Keep consistent with CRCPD SSRs. Other states adopted this format. Change not recommended.
	12VAC5-481-1641. Computed tomography equipment. D.2.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 physicists, and , 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. Believes inspection after a major change is burdensome before patient use.	Keep consistent with CRCPD SSRs. Other states adopted this format. Change not recommended. After discussing this with the Medical Physicist, does not believe this is an issue. Change not recommended.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
10		Definitions	Adding 21 definitions to conform to the 2009 SSRs, deleting 14 definitions and amending 114 definitions to meet Virginia Registrar standards;

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
290		Registration of radiation machine facilities	Revising the regulation reference;
340		Private inspector qualifications	Revising the word “x-ray” and amending the language for disqualifying individuals;
350		Assembler or transfer obligations	Update regulation to include FDA standard;
1580		Purpose and scope	Repealed;
	1581		Create a new purpose and scope section;
1590		General and administrative requirements	Repealed;
	1591		Create a new general and administrative requirements section which includes the 2009 CRCPD SSR update;
1600		General requirements for all diagnostic X-ray systems	Repealed;
	1601		Create a new general requirements for all diagnostic X-ray systems section which includes the 2009 CRCPD SSR update;
1610		Fluoroscopic X-ray systems	Repealed;
	1611		Create a new fluoroscopic equipment section which includes the 2009 CRCPD SSR update;
1620		Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems	Repealed;
	1621		Create a new radiographic section which includes the 2009 CRCPD SSR update;
1630		Intraoral dental radiographic systems	Repealed;
	1631		Create a new intraoral dental radiographic section which includes the 2009 CRCPD SSR update;
1640		Computed tomography X-ray systems	Repealed;
	1641		Create a new computed tomography equipment section which includes the 2009 CRCPD SSR update;

Current Section Number	Proposed New Section Number, If Applicable	Current Requirement	Proposed Change, Rationale, and Consequences
1650		Mammography	Repealed;
	1651		Create a new mammography requirements section which includes the 2009 CRCPD SSR update;
	1653	Hand-held radiography unit	Create a new hand-held radiography unit section which includes the 2009 CRCPD SSR update;
	1655	Bone densitometry	Create a new bone densitometry section which includes the 2009 CRCPD SSR update;
	1657	Quality assurance program	Create a new quality assurance program section which includes the 2009 CRCPD SSR update;
2110		Area requirements	Change the survey requirement from 12 months to 5 years; and
3410		Quality management program	Include the reporting requirement for a reportable event.

Project 2412 - Proposed

**DEPARTMENT OF HEALTH
CH 0481 Radiation Protection Regulations-Diagnostic X-ray/Therapeutic Radiation
Machine 2009 Update**

Part I
General Provisions

12VAC5-481-10. Definitions.

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

"A₁" means the maximum activity of special form radioactive material permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770.

"A₂" means the maximum activity of radioactive material, other than special form radioactive material, LSA, and SCO material, permitted in a Type A package. This value is listed in Table 1 of 12VAC5-481-3770.

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

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

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

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

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

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

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

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

"Acute" means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

~~"Added filtration" means any filtration that is in addition to the inherent filtration.~~

"Address of use" means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

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

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

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

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

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

1. In excess of the derived air concentrations (DACs) specified in 12VAC5-481-3690; or
2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC-hours.

~~"Air kerma (K)" or "K" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of D_e by D_m , where D_e is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass D_m . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy) kerma in air (see definition of "kerma").~~

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

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

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

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

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

"Analytical ~~X-ray~~ x-ray system" means a group of components utilizing ~~x-rays~~ or gamma-rays to determine the elemental composition or to examine the microstructure of materials.

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

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

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

"ANSI" means the American National Standards Institute.

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

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

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

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

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

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

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

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

"Authorized medical physicist" means an individual who:

1. Meets the requirements in 12VAC5-481-1760 and 12VAC5-481-1790; or
2. Is identified as an authorized medical physicist or teletherapy physicist on:
 - a. A specific medical use license issued by the NRC or another agreement state;
 - b. A medical use permit issued by an NRC master material licensee;
 - c. A permit issued by an NRC or another agreement state broad scope medical use licensee; or
 - d. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

1. Meets the requirements in 12VAC5-481-1770 and 12VAC5-481-1790;
2. Is identified as an authorized nuclear pharmacist on:
 - a. A specific license issued by the NRC or another agreement state that authorizes medical use or the practice of nuclear pharmacy;
 - b. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
 - d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;
3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
4. Is designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-440 I 2.

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

1. Meets the requirements in 12VAC5-481-1790 and any of the following:
 - a. 12VAC5-481-1910;
 - b. 12VAC5-481-1940;
 - c. 12VAC5-481-1980;
 - d. 12VAC5-481-1990;
 - e. 12VAC5-481-2000;
 - f. 12VAC5-481-2010;
 - g. 12VAC5-481-2030;
 - h. 12VAC5-481-2040; or
2. Is identified as an authorized user on:
 - a. A specific license issued by the NRC or another agreement state that authorizes medical use;
 - b. A permit issued by an NRC master material licensee that authorizes medical use;
 - c. A permit issued by an NRC or another agreement state broad scope medical use licensee that authorizes medical use; or
 - d. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use.

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

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

"Barrier" (See "Protective barrier").

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

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the ~~X-ray~~ x-ray field.

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

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

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

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

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

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

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement,

in-vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Board" means the State Board of Health.

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

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

"Byproduct material" means:

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;
2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these 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~~ fluoroscope" means an ~~X-ray~~ x-ray system in which the image receptor and ~~X-ray~~ x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

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

"Cabinet ~~X-ray~~ x-ray system" means an ~~X-ray~~ x-ray system with the ~~X-ray~~ x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet ~~X-ray~~ x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all ~~X-ray~~ x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An ~~X-ray~~ x-ray tube used within a shielded part of a building, or ~~X-ray~~ x-ray equipment

that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet ~~X-ray~~ x-ray system.

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

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

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

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

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

~~"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.~~

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

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

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

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

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

~~"Certified system" means any X-ray system which has one or more certified component(s).~~

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

"CFR" means Code of Federal Regulations.

~~"Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.~~

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

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

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

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons

to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

"cm" means centimeters.

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

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where:

s = Standard deviation of the observed values;

[~~x~~ \bar{X}] = Mean value of observations in sample;

x_i = i_{th} observation in sample;

n = Number of observations in sample.

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

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

"Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

"Committed dose equivalent" (~~$H_{T,50}$~~) 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 ($H_{E,50} = \sum (w_T H_{T,50})$).

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

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

$$CTDI = 1/nT \int_{-7T}^{+7T} D(z) dz$$

where:

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

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

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

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

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

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

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

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

"Constraint (~~dose constraint~~)" or "dose constraint" means a value above which specified licensee actions are required.

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

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

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water;

\overline{CTN}_x = of the material of interest;

\overline{CTN}_w = of water.

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

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

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

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

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

"Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;
2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and
3. For transport by any aircraft.

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

"Cradle" means either:

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

2. A device:

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

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

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

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

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

"CS" (See "Contrast scale").

"CT" (See "Computed tomography").

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

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

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

"CTN" (See "CT number").

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

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

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

"Curie" means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7E+10 disintegrations or transformations per second (dps or tps).

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

~~"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.~~

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

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

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

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

"Deep dose equivalent" ($H_{d,1}$ or " $H_{d,1}$ ") which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm²).

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

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

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

"Derived air concentration" (~~DAC~~) or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in 12VAC5-481-3690.

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

"Detector" (See "Radiation detector").

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

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

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

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

~~"Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image.~~

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

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

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

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

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"Disposal site" means that portion of a land disposal facility that is used for disposal of waste. It consists of disposal units and a buffer zone.

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

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

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

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

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

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

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

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

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

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

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

"Effective dose equivalent—(~~H_E~~)" or "H_E" means the sum of the products of the dose equivalent (H_T) to each organ or tissue and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

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

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

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

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

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

~~"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. "Fissile material" means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

1. Fissile Class I: A package that may be transported in unlimited numbers and in any arrangement, and that requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.
2. Fissile Class II: A package that may be transported together with other packages in any arrangement but, for criticality control, in numbers that do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

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

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

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

"Fluoroscopic imaging assembly" means a subsystem in which ~~X-ray~~ x-ray photons produce a ~~visible image~~ set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the ~~image receptor(s) such as the image intensifier and spot film device~~ receptors, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

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

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

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

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

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

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

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

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

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

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

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

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

"Half-value layer-~~(HVL)~~" or "HVL" means the thickness of a specified material that attenuates ~~X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point~~ the beam of radiation to an extent that the AKR is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

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

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

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

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

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

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

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

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

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

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

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

~~"HVL" (See "Half value layer").~~

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

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

"Image receptor" means any device, such as a fluorescent screen ~~or~~, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident ~~X-ray~~ x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

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

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

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

"Individual" means any human being.

"Individual monitoring" means the assessment of:

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

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

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

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

"Inhalation class" (See "Class").

~~"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.~~

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

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

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

"Instrument traceability" (for ionizing radiation measurements) means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a program that requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

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

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

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

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

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

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

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

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

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

"kBq" means kilobecquerels.

"Kerma" or "K" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all charged particles liberated by uncharged particles in a mass dm of materials; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the units of kerma is gray (Gy). When the materials is air, the quantity is referred to as "air kerma."

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

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

"kV" means kilovolts.

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

"kW" means kilowatt second.

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

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

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

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

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

1. The useful beam; and
2. Radiation produced when the exposure switch or timer is not activated.

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

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, ~~i.e., 10 milliamperere seconds~~ (10 mAs), or the minimum obtainable from the unit, whichever is larger;
2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of ~~X-ray~~ x-ray pulses in an hour for operation at the maximum-rated peak tube potential; or

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

"Lens dose equivalent-(LDE)" or "LDE" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm²).

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

"Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the agency.

"Licensee" means any person who is licensed by the agency in accordance with these regulations and the Act.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"Limits" (See "Dose limits").

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percentage percent of the load line potential. ~~It is calculated using the following equation as follows:~~

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where:

V_n = No-load line potential; and

V_l = Load line potential.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Local components" mean part of an analytical ~~X-ray~~ x-ray system and include areas that are struck by ~~X-rays~~ x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by Part XIV (12VAC5-481-3140 et seq.) of this chapter.

"Logging supervisor" means the individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of this chapter and the conditions of the license.

"Logging tool" means a device used subsurface to perform well-logging.

"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Lost or missing licensed material" means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Lot tolerance percent defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

"Low specific activity (~~LSA~~) material" or "LSA" means radioactive material with limited specific activity that is nonfissile or is excepted under 12VAC5-481-2970 C, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material

may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

1. LSA-I

- a. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclide that are not intended to be processed for the use of these radionuclides;
- b. Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;
- c. Radioactive material, for which the A_2 value is unlimited; or
- d. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 12VAC5-481-3720.

2. LSA-II

- a. Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L); or
- b. Other material in which the activity is distributed throughout, and the average specific activity does not exceed $1.0 \text{ E-04 } A_2/\text{g}$ for solids and gases, and $1.0 \text{ E-05 } A_2/\text{g}$ for liquids.

3. LSA-III

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77) in which:

- a. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (for example: concrete, bitumen, or ceramic);
- b. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed $0.1 A_2$; and
- c. The estimated average specific activity of the solid does not exceed $2.0 \text{ E-03 } A_2/\text{g}$.

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

"Lung class" (See "Class").

"mA" means milliamperere.

"mAs" means milliamperere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this section.

~~"Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.~~

"Management" means the chief executive officer or that individual's designee.

"MBq" means megabecquerels.

"Medical event" means an event that meets the criteria in 12VAC5-481-2080.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"~~Megavolt (MV) (mega electron volt (MeV))~~" or "MV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

"Member of the public" means an individual except when that individual is receiving an occupational dose.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Minor" means an individual less than 18 years of age.

"Misadministration" means either:

1. An x-ray teletherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong mode of treatment;

c. Involving the wrong treatment site;

d. Where the calculated total administered dose differs from the total prescribed dose by more than 10% when the treatment consists of three or fewer fractions;

e. Where the calculated weekly administered dose differs from the weekly prescribed dose by 30%; or

f. Where the calculated total administered dose differs from the total prescribed dose by more than 20%; or

2. An x-ray brachytherapy radiation dose:

a. Involving the wrong patient;

b. Involving the wrong treatment site; or

c. Where the calculated administered dose differs from the prescribed dose by more than 20%.

"mm" means millimeters.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"~~Mobile X-ray~~ x-ray equipment" (See "X-ray equipment").

"Mode of operation" means, for fluoroscopy systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

"~~Monitor unit (MU)~~" or "MU" (See "Dose monitor unit").

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these

measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms. For Part XI (12VAC5-481-2330 et seq.) of this chapter, it means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

"Multiple tomogram system" means a computed tomography ~~X-ray~~ x-ray system that obtains ~~X-ray~~ x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

"National Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 12VAC5-481-3780. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes, which is essentially 100 weight percent thorium-232.

"Natural uranium" (See "Uranium – natural, depleted, enriched").

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Negative pressure respirator ~~(tight fitting)~~ or "tight fitting"" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \otimes \overline{CS} \otimes s}{\mu_w}$$

where:

\overline{CS} = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which ~~X-ray~~ x-ray transmission data are collected.

"Non-image-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

"NORM" means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

"Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant (or licensee), and data recording procedures, which are related to radiation safety.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
2. For ~~X-ray~~ x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"NRC Forms 540, 540A, 541, 541A, 542, and ~~542~~ 542A" means official NRC forms referenced in this chapter. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Nuclear Regulatory Commission (~~NRC~~)" or "NRC" means the NRC or its duly authorized representatives.

"Nuclear waste" means a quantity of source, byproduct or special nuclear material (the definition of nuclear waste in this part is used in the same way as in 49 CFR 173.403) required to be in NRC-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, from voluntary participation in medical research programs, or as a member of the public.

"Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

"Offshore waters" means that area of land and water, beyond the Commonwealth of Virginia's jurisdiction, on or above the U.S. Outer Continental Shelf.

"Open-beam configuration" means an analytical ~~X-ray~~ x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Package" means the packaging together with its radioactive contents as presented for transport.

1. Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

2. Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

3. Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in²) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of these regulations. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

"Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

"Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

"Particle accelerator" (See "Accelerator").

"Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

"PBL" (See "Positive beam limitation").

"Peak tube potential" means the maximum value of the potential difference across the ~~X-ray~~ x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, department of the Commonwealth other than the Department of Health, political subdivision of the Commonwealth, any other state or political subdivision or

department thereof, and any legal successor, representative, agent, or department of the foregoing, but not including federal government agencies.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required. In radiography it means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Personnel monitoring equipment" (See "Individual monitoring devices").

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Physical description" means the items called for on NRC Form 541 to describe a low-level radioactive waste.

"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by this state to prescribe drugs in the practice of medicine.

"Picture element" means an elemental area of a tomogram.

"PID" (See "Position indicating device").

"Pigtail" (See "Source assembly").

"Pill" (See "Sealed source").

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Portable ~~X-ray~~ x-ray equipment" (See "X-ray equipment").

"Position indicating device" means a device on dental ~~X-ray~~ x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an ~~X-ray~~ x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

" [~~Positive emission tomography (PET)~~ Positron Emission Tomography] radionuclide production facility" or "PET" means a facility operating a cyclotron or [other particle] accelerator for the purpose of producing [PET] radionuclides [that decay by positron emission] .

"Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Powered air-purifying respirator-~~(PAPR)~~" or "PAPR" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung ~~X-rays~~ x-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb. 1991) and ICRU Report 35,

"Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

"Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or
2. For teletherapy, the total dose and dose per fraction as documented in the written directive; or
3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

"Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the ~~X-ray~~ x-ray tube or a radioactive source located in the radiation source housing.

"Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and that will terminate irradiation when a preselected number of dose monitor units have been delivered.

"Primary protective barrier" (~~See "Protective barrier"~~) means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection barriers.

"Principal activities," as used in this chapter, means activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Private inspector" means an individual who meets the requirements set forth in 12VAC5-481-340 and who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Product" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, something produced, made, manufactured, refined, or benefited.

"Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

"Projection sheath" (See "Guide tube").

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

"Protective apron" means an apron made of radiation-attenuating or absorbing materials used to reduce exposure to radiation.

~~"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:~~

- ~~1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam;~~

2. ~~"Secondary protective barrier" means the material that attenuates stray radiation.~~

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 12VAC5-481-1870, or from voluntary participation in medical research programs.

"Pulsed mode" means operation of the x-ray system such that the x-ray tube is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or that can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Qualitative fit test ~~(QLFT)~~" or "QLFT" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quality factor" ~~(Q)~~ or "Q" means the modifying factor, that is referenced in 12VAC5-481-240, that is used to derive dose equivalent from absorbed dose.

"Quantitative fit test ~~(QNFT)~~" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, ~~X-rays~~ x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose" (See "Dose").

"Radiation field" (See "Useful beam").

"Radiation head" means the structure from which the useful beam emerges.

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Radiation safety officer ~~(RSO)~~" or "RSO" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

"Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of 12VAC5-481-1310.

"Radiation safety officer for medical" means an individual who meets the requirements of 12VAC5-481-1750 and 12VAC5-481-1790 or is identified as an RSO on: a medical use license issued by the agency, NRC or another agreement state, or a medical use permit issued by an NRC masters material licensee.

"Radiation therapy physicist" means an individual qualified in accordance with 12VAC5-481-340.

"Radiation therapy simulation system" means a radiographic or fluoroscopic ~~X-ray~~ x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay" (See "Bioassay").

"Radiograph" means an image receptor on which the image is created directly or indirectly by an ~~X-ray~~ x-ray pattern and results in a permanent record.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the agency's regulations and the conditions of the license or registration.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 12VAC5-481-1320.

"Radiographer instructor" means any radiographer who has been authorized by the agency to provide on-the-job training to radiographer trainees in accordance with Part V (12VAC5-481-1170 et seq.) of this chapter.

"Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

~~"Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.~~

"Radiographic operations" means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

"Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee.

"Radiography" (See "Industrial radiography") means:

1. For radioactive materials: See "Industrial radiography."
2. For x-ray: A technique for generating and recording an x-ray pattern for the purpose of providing the user with an image after termination of the exposure.

"Rating" means the operating limits as specified by the component manufacturer.

"Reasonably maximally exposed individual" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

"Recording" means producing a ~~permanent~~ retrievable form of an image resulting from ~~X-ray~~ x-ray photons.

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Registrant" means any person who is registered with the agency and is legally obligated to register with the agency pursuant to these regulations and the Act.

"Registration" means registration with the agency in accordance with the regulations adopted by the agency.

"Regulations of the United States Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

"Reportable event" means the administration of either:

1. A diagnostic x-ray exposure where an actual or suspected acute or long-term functional damage to an organ or a physiological system has occurred. Exempt from this reporting requirement is any event when any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed;
2. A procedure where the patient or operator is injured as a result of a mechanical injury;
3. A teletherapy x-ray [or electron] dose where the calculated weekly administered dose differs from the weekly prescribed dose by 15% or more; or
4. A brachytherapy x-ray dose where the calculated administered dose differs from the prescribed dose by 10% or more.

"Research and development" means (i) theoretical analysis, exploration, or experimentation; or (ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstrative purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and

development does not include the internal or external administration of radiation or radioactive material to human beings.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Residual radioactive material" means (i) waste (that the U.S. Secretary of Energy determines to be radioactive) in the form of tailings resulting from the processing of ores for the extraction of uranium and other valuable constituents of the ores and (ii) other waste (that the U.S. Secretary of Energy determines to be radioactive) at a processing site that relates to such processing, including any residual stock of unprocessed ores or low-grade materials. This term is used only with respect to materials at sites subject to remediation under Title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part IV (12VAC5-481-600 et seq.) of this chapter.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Respiratory protective device" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "Exposure" and 12VAC5-481-240).

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Scan" means the complete process of collecting ~~X-ray~~ x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT ~~X-ray~~ x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of ~~X-ray~~ x-ray transmission data accumulation for a single scan.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered

primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

"Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of any radioactive material.

~~"Sealed Source and Device Registry (SSD)" means the national registry that contains the registration certificates, maintained by the NRC, that summarize the radiation safety information for sealed sources and devices, and describes the licensing and use conditions approved for the product.~~

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

~~"Secondary protective barrier" (See "Protective barrier").~~

"Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

"Self-contained breathing apparatus ~~(SCBA)~~ or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shallow dose equivalent ~~(H_s)~~," or "H_s" which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²).

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 12VAC5-481-640.

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means NRC Form 540 and, if required, NRC Form 540A, which includes the information required by ~~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)~~ or "Sv" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

~~"Simulator (radiation therapy simulation system)"~~ or "radiation therapy simulation system" means any ~~X-ray~~ x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Single tomogram system" means a CT ~~X-ray~~ x-ray system that obtains ~~X-ray~~ x-ray transmission data during a scan to produce a single tomogram.

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Source" means the focal spot of the ~~X-ray~~ x-ray tube.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
2. Ores that contain by weight one-twentieth of 1.0% (0.05%) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Source-skin distance (~~SSD~~)" or "SSD" means the distance ~~between~~ from the source and ~~the skin entrance plane of the patient~~ to the center of the entrant x-ray field in the plane tangent to the patient's skin surface.

"Source traceability" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology, or by a laboratory that participates in a continuing measurement quality assurance program with National Institute of Standards and Technology or other equivalent national or international program.

"Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than five millimeters (0.2 in.); and
3. It satisfies the test requirements specified by the NRC. A special form encapsulation designed in accordance with the NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material the NRC, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175(\text{grams contained U-235})}{350} + \frac{50(\text{grams U-233})}{200} + \frac{50(\text{grams Pu})}{200} = 1$$

"Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the ~~X-ray~~ x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stability" means structural stability.

"State inspector" means an employee of the Virginia Department of Health designated to perform those duties or functions assigned the Radiological Health Program.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Stationary ~~X-ray~~ x-ray equipment" (See "X-ray equipment").

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

"Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

"Storage container" means a device in which sealed sources or radiation machines are secured and stored.

"Stray radiation" means the sum of leakage and scattered radiation.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

"Supplied-air respirator ~~(SAR) or,~~ "airline respirator," or "SAR" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Surface contaminated object" (~~SCO~~) or "SCO" means a solid object that is not itself classed as radioactive material, but that has radioactive material distributed on any of its surfaces. An SCO must be in one of two groups with surface activity not exceeding the following limits:

1. SCO-I: A solid object on which:
 - a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed four becquerel per cm² (1 E-04 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerel per cm² (1 E-05 μCi/cm²) for all other alpha emitters;
 - b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1.0 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 becquerel per cm² (0.1 μCi/cm²) for all other alpha emitters; and
 - c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 4 E+04 becquerel per cm² (1 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E+03 Becquerel per cm² (0.1 μCi/cm²) for all other alpha emitters.
2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:
 - a. The nonfixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 400 becquerel per cm² (1 E-02 μCi/cm²) for beta and gamma and low toxicity alpha emitters or 40 becquerel per cm² (1 E-03 μCi/cm²) for all other alpha emitters;
 - b. The fixed contamination on the accessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/cm²) for all other alpha emitters; and
 - c. The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm², or the area of the surface if less than 300 cm², does not exceed 8 E+05 becquerel per cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E+04 becquerel per cm² (2 μCi/cm²) for all other alpha emitters.

"Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

"Tabletop, stationary" means a tabletop that, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

"Target" means that part of an ~~X-ray~~ x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

"Technologically Enhanced Naturally Occurring Radioactive Material—(~~TENORM~~)" or "TENORM" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, naturally occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the AEA and NRC regulations.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in ~~kV~~ kilovolts (kV) and quantity of charge in ~~mAs~~ milliampere-seconds (mAs);
2. For field emission equipment rated for pulsed operation, peak tube potential in ~~kV~~ kilovolts (kV), and number of ~~X-ray~~ x-ray pulses;
3. For CT ~~X-ray systems~~ equipment designed for pulsed operation, peak tube potential in ~~kV~~ kilovolts (kV), scan time in seconds, and either tube current in ~~Ma~~ milliamperes (mA), ~~X-ray~~ x-ray pulse width in seconds, and the number of ~~X-ray~~ x-ray pulses per scan, or the product of tube current, ~~X-ray~~ x-ray pulse width, and the number of ~~X-ray~~ x-ray pulses in ~~mAs~~ milliampere-seconds (mAs);
4. For CT ~~X-ray systems~~ equipment not designed for pulsed operation, peak tube potential in ~~kV~~ kilovolts (kV), and either tube current in ~~Ma~~ milliamperes (mA) and scan time in seconds, or the product of tube current and exposure time in ~~mAs~~ 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 ~~kV~~ kilovolts (kV), and either tube current in ~~Ma~~ milliamperes (mA) and exposure time in seconds, or the product of tube current and exposure time in ~~mAs~~ 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 XRF use is performed and where licensed material may be stored other than those location(s) of use authorized on the license.

"Tenth-value layer ~~(TVL)~~" or "TVL" means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

~~"Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.~~

"Test" means the process of verifying compliance with an applicable regulation.

"Therapeutic radiation machine" means ~~X-ray~~ x-ray or electron-producing equipment designed and used for external beam radiation therapy.

"These regulations" mean all parts of these regulations.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

"Tomogram" means the depiction of the ~~X-ray~~ x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose ~~X-ray~~ x-ray attenuation properties are imaged in a tomogram.

"Total effective dose equivalent" (~~TEDE~~) or "TEDE" means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" (~~TODE~~) or "TODE" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 12VAC5-481-1040.

"Traceable to a National Standard" (See "Instrument traceability" or "Source traceability").

"Transfer" means, as used in Part XVI (12VAC5-481-3460 et seq.) of this chapter, the physical relocation of NORM containing materials not directly associated with commercial distribution within a business's operation or between general or specific licensees. This term does not include a change in legal title to NORM containing materials that does not involve physical movement of those materials.

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the United States Department of Transportation.

"Transport index-~~(TI)~~" or "TI" means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)).

"Treatment site" means the correct anatomical description of the area intended to receive a radiation dose, as described in a written directive.

"Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

"Tube" means an ~~X-ray~~ x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed 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 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Uranium—natural, depleted, enriched"

1. "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes, which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238.
2. "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.
3. "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Useful beam" means the radiation ~~emanating from that passes through~~ the tube housing port ~~or the radiation head and passing through~~ and the aperture of the ~~beam-limiting beam-limiting~~ device when the exposure controls are in a mode to cause the system to produce radiation switch or timer is activated.

"User seal check (~~fit check~~) or "fit check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the ~~X-ray~~ x-ray field size at a given SID.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

"Virtual source" means a point from which radiation appears to originate.

"Visible area" means that portion of the input surface of the image receptor over which incident ~~X-ray~~ x-ray photons are producing a visible image.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

"Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subdivisions 2, 3, and 4 of the definition of byproduct material.

"Waste collector" means an entity, operating under a specific license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

"Waste generator" means an entity, operating under a license, who (i) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (ii) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

"Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

"Waste processor" means an entity, operating under a specific license, whose principal purpose is to process, 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)" for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^{a/}
Whole Body	1.00 ^{b/}

^{a/}0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

^{b/}For the purpose of weighting the external whole body dose for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

"Well-bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools that may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Wireline" means a cable containing one or more electrical conductors that is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service that is performed in the well-bore using devices on a wireline.

"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant but does not include the licensee or registrant.

"Working level (~~WL~~)" or "WL" means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of $1.3E+5$ MeV of potential alpha particle energy. The short-lived radon daughters of radon-222 are polonium-218, lead-214, bismuth-214, and polonium-214; and those of radon-220 are polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" (~~WLM~~) or "WLM" means an exposure to one working level for 170 hours. Two thousand working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in subdivision 6 below, containing the following information:

1. For any administration of quantities greater than 1.11 megabecquerels (30 mCi) of sodium iodide I-125 or I-131: the radionuclide, and dosage; or
2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; or
3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or
4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or
5. For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or
6. For all other brachytherapy,
 - a. Prior to implantation: the radionuclide, number of sources, and source strengths; and
 - b. After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

"X-ray control" means a device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The ~~X-ray~~ x-ray exposure control may include such associated equipment as timers and back-up timers.

"X-ray equipment" means an ~~X-ray~~ x-ray system, subsystem, or component thereof. Types of ~~X-ray~~ x-ray equipment are as follows:

1. "Mobile ~~X-ray~~ x-ray equipment" means ~~X-ray~~ x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
2. "Portable ~~X-ray~~ x-ray equipment" means ~~X-ray~~ x-ray equipment designed to be hand-carried.
3. "Stationary ~~X-ray~~ x-ray equipment" means ~~X-ray~~ x-ray equipment that is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the ~~exposure rate~~ AKR is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the ~~X-ray~~ x-ray control to the tube operating potential. The device may also

include means for transforming alternating current to direct current, filament transformers for the ~~X-ray~~ x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of ~~X-rays~~ x-rays. It includes minimally an ~~X-ray~~ x-ray high-voltage generator, an ~~X-ray~~ x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, ~~image intensifier~~ fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube that is designed for the conversion of electrical energy into ~~X-ray~~ x-ray energy.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year. If a licensee or registrant changes in a year, the licensee or registrant shall assure that no day is omitted or duplicated in consecutive years.

12VAC5-481-290. Registration of radiation machine facilities.

Each person having a radiation machine facility shall:

1. Apply for registration of such facility with the agency within 30 days following installation of equipment. Application for registration shall be completed on forms furnished by the agency and shall contain all the information required by the form and accompanying instructions. Registrations filed with the agency prior to September 20, 2006, shall remain in effect until a renewal notice is issued by the agency pursuant to 12VAC5-481-310.
2. Designate on the application form an individual to be responsible for radiation protection;
3. Submit to the agency as part of any application for registration or renewal of registration one copy of each radiation survey or calibration report for which records are required to be maintained pursuant to ~~42VAC5-481-1590~~ 12VAC5-481-1591 A 12 c. Records submitted once need not be submitted again for renewal of registration.
4. Have an initial inspection by a private or state inspector no later than 30 days after the registration of the equipment. Subsequent inspections shall be made periodically in accordance with other parts of these regulations or whenever the equipment is moved to a new location. The agency shall furnish a list of private inspectors.

12VAC5-481-340. Private inspector qualifications.

Any person desiring designation as a private inspector for diagnostic ~~X-ray~~ x-ray, mammographic or therapeutic ~~X-ray~~ x-ray and teletherapy machines must be qualified by training and experience to perform inspections or calibrations according to the following criteria and must submit to the agency a statement on the appropriate form certifying his specific qualifications. In order to maintain designation as a private inspector, the individual must maintain satisfactory performance of work performed in that capacity. The agency shall disqualify ~~individuals~~ any individual from this designation ~~for just cause provided that a show-cause hearing has been held and the agency~~ if the agency has determined that the individual has demonstrated unsatisfactory performance as a private inspector. The individual may request an informal hearing.

A. Private inspector, diagnostic ~~X-ray~~ x-ray (except mammography). The person must have adequate knowledge, training and experience to measure ionizing radiation, evaluate safety

techniques, and advise regarding radiation protection needs to assure compliance with Virginia Rules and Regulations for Ionizing Radiation as evidenced by all of the following:

1. Initial qualifications: evidenced by one or more of the following:
 - a. Certification by one of the following: American Board of Radiology either in diagnostic or radiological physics, American Board of Health Physics in comprehensive practice, or the American Board of Medical Physics in diagnostic imaging physics.
 - b. Bachelor's degree in one of the physical sciences or engineering and three years of full-time experience in radiation safety including at least one year in diagnostic ~~X-ray~~ x-ray safety. Advanced degrees in related areas may be substituted for experience on an equal time basis, except that no substitution shall be allowed for the required one year of experience in diagnostic ~~X-ray~~ x-ray safety.
 - c. Those individuals listed as private inspectors immediately prior to September 20, 2006, shall be considered grandfathered.
2. Continuing qualifications:
 - a. Continuing education. Private inspectors must participate in continuing education programs relating to diagnostic ~~X-ray~~ x-ray, either by teaching or completing at least 15 continuing education units (CMEs) every three years.
 - b. Continuing experience. The private inspector must have inspected at least 10 diagnostic ~~X-ray~~ x-ray machines within the preceding 12 months.
3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform the inspections without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications, as follows:
 - a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to five continuing education units during the preceding 12 months.
 - b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of a sufficient number of facilities and machines under the direct supervision of a private inspector who meets the qualifications of this section to bring the number to the required level.

B. Private inspector, therapeutic ~~X-ray~~ x-ray and teletherapy machines. The person must have adequate knowledge, training, and experience to calibrate a therapeutic ~~X-ray~~ x-ray machine or teletherapy machine, perform inspections and to establish procedures for (and review the results of) spot-check measurements as evidenced by all of the following:

1. Initial qualifications: evidenced by one or more of the following:
 - a. Be certified by the American Board of Radiology in:
 - (1) Therapeutic radiological physics [or therapeutic 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; 12VAC5-481-3430 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~~ x-ray and teletherapy machines, either by teaching or completing at least 15 continuing education units (CEUs) every three years.

b. ~~Continuing experience~~: The private inspector must have inspected at least one therapeutic ~~X-ray~~ x-ray or teletherapy facilities and at least one therapeutic ~~X-ray~~ x-ray or teletherapy machine within the preceding 12 months.

3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform an inspection without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications, as follows:

a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to five continuing education units during the preceding 12 months.

b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of a sufficient number of facilities and machines under the direct supervision of a private inspector who meets the qualifications of this section to bring the number to the required level.

C. Private inspector, mammography. The person must have adequate knowledge, training, and experience to inspect mammography ~~X-ray~~ x-ray machines and facilities. All mammography private inspector conducting inspections of mammography facilities and providing oversight of the facility quality assurance program must meet one of the following tracks, either through the initial master's degree of higher route or the alternative initial bachelor's degree route:

1. Initial qualifications:

Master Route:

a. Be certified by the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) in:

(1) Diagnostic radiological physics;

(2) Radiological physics; or

(3) Diagnostic imaging physics;

b. A master's degree or higher in a physical science with at least 20 semester hours or equivalent of graduate or undergraduate physics; and

c. Twenty contact hours of mammography facility training; and

d. The experience of conducting inspections of at least one mammography facility and a total of at least 10 mammography units.

Bachelor Route (must have been qualified before April 28, 1999):

a. A bachelor's degree in a physical science with at least 10 semester hours or equivalent of college level physics;

- b. Forty contact hours of documented specialized training in conducting inspections of mammography facilities; and
 - c. The experience of conducting inspections of at least one mammography facility and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.
2. Continuing qualifications.
- a. ~~Continuing education.~~ At all times after the third anniversary of completion of the initial requirements of this section, the private inspector shall have taught or completed at least 15 continuing education units in mammography during the preceding three years.
 - b. ~~Continuing experience.~~ At all times after the first anniversary of the completion of the initial requirements of this section, the private inspector shall have inspected at least two mammography facilities and six machines in 24 months.
 - c. Before a private inspector may begin independently performing mammographic examinations using a new modality, that is, a modality other than one for which the physicist received training to qualify under this section, the inspector must receive at least eight hours of training in inspecting units with the new modality.
3. Reestablishing qualifications. Private inspectors who fail to maintain the required continuing qualifications of this section may not perform the mammography inspections without the supervision of a qualified private inspector. Before independently inspecting another facility, private inspectors must reestablish their qualifications as follows:
- a. Private inspectors who fail to meet the continuing educational requirements of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.
 - b. Private inspectors who fail to meet the continuing experience requirement of this section shall complete a satisfactory inspection of three mammography facilities under the direct supervision of a private inspector who meets the qualifications of this section.

12VAC5-481-350. Assembler or transfer obligation.

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines or upon significant service or modification thereof of any radiation machine (such as tube inserts, generators, or collimators) in this state shall notify the agency within 15 days of:

- 1. The name and address of persons who have received these machines;
- 2. The manufacturer, model, and serial number of each radiation machine transferred; however, in the case of diagnostic x-ray systems that contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with the requirements of the Food and Drug Administration's Federal Diagnostic X-ray Standard (21 CFR 1020.30(d)) shall be submitted and shall suffice in lieu of any other report by the assembler; and
- 3. The date of transfer of each radiation machine.

B. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

Part VI

Use Of Diagnostic X-Rays In The Healing Arts

12VAC5-481-1580. Purpose and scope. (Repealed.)

~~This part establishes requirements, for which a registrant is responsible, for use of diagnostic X-ray equipment by, or under the supervision of, an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine.~~

~~The provisions of this part are in addition to, and not in substitution for, other applicable provisions of Parts I (12VAC5-481-10 et seq.); II (12VAC5-481-260 et seq.); IV (12VAC5-481-600 et seq.); and X (12VAC5-481-2250 et seq.) of this chapter. Some registrants may also be subject to the requirements of Parts IX (12VAC5-481-2140 et seq.) and XV (12VAC5-481-3380 et seq.) of this chapter.~~

12VAC5-481-1581. Purpose and scope.

This part establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with Virginia law to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to and not in substitution for other applicable provisions of this chapter.

12VAC5-481-1590. General and administrative requirements. (Repealed.)

~~A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the X-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the X-ray system(s).~~

- ~~1. An X-ray system that does not meet the provisions of these regulations shall not be operated for diagnostic purposes.~~
- ~~2. Individuals who will be operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. The agency may use interview, observation and/or testing to determine compliance. The following are areas in which the agency considers it important that an individual have expertise for the competent operation of X-ray equipment:
 - ~~a. Familiarization with equipment
 - ~~(1) Identification of controls~~
 - ~~(2) Function of each control~~
 - ~~(3) How to use a technique chart~~~~
 - ~~b. Radiation protection
 - ~~(1) Collimation~~
 - ~~(2) Filtration~~
 - ~~(3) Gonad shielding and other patient protection devices, if used~~
 - ~~(4) Restriction of X-ray tube radiation to the image receptor~~
 - ~~(5) Personnel protection~~
 - ~~(6) Grids~~~~
 - ~~c. Image processing
 - ~~(1) Film speed as related to patient exposure~~
 - ~~(2) Image processing parameters~~
 - ~~(3) Quality assurance program~~~~
 - ~~d. Emergency procedures—termination of exposure in event of automatic timing device failure~~
 - ~~e. Proper use of personnel dosimetry, if required~~
 - ~~f. Understanding units of radiation~~~~
- ~~3. A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel that specifies, for all examinations performed with that system, the following information:
 - ~~a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;~~~~

- ~~b. Reserved;~~
 - ~~c. Reserved;~~
 - ~~d. Source to image receptor distance to be used (except for dental intra-oral radiography);~~
 - ~~e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and~~
 - ~~f. For mammography, indication of kVp/target/filter combination.~~
- ~~4. The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures. A copy of the written safety procedures shall be posted near each X-ray machine.~~
- ~~5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:~~
- ~~a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;~~
 - ~~b. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;~~
 - ~~c. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers, or protective aprons of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.~~
- ~~6. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.~~
- ~~7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:~~
- ~~a. Exposure of an individual for training, demonstration, or other nonhealing arts purposes; and~~
 - ~~b. Exposure of an individual for the purpose of healing arts screening except as authorized by subdivision A 11 of this section.~~
- ~~8. When a patient or film must be provided with auxiliary support during a radiation exposure:~~
- ~~a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by subdivision A 4 of this section, shall list individual projections where holding devices cannot be utilized;~~
 - ~~b. Written safety procedures, as required by subdivision A 4 of this section, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;~~
 - ~~c. The human holder shall be instructed in personal radiation safety and protected as required by subdivision A 5 of this section;~~

- d. ~~No individual shall be used routinely to hold film or patients;~~
 - e. ~~In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and~~
 - f. ~~Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.~~
 - g. ~~When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected by appropriate shielding devices, such as protective glove and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The radiation exposure of and individual used for this purpose shall be monitored and recorded. These records of radiation exposure must be maintained indefinitely for inspection by the agency.~~
9. ~~Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.~~
- a. ~~The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.~~
 - b. ~~The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality and, where applicable, shall not exceed the following standards:~~

EXPOSURE LIMITS FOR SELECTED PROJECTIONS

~~Using a method acceptable to the agency, the exposure measurement shall be determined in the center of the X-ray field at the location of the entrance skin of a standard patient, except for dental intraoral X-ray machines in which case the measurement shall be determined at the conetip. The technique factors selected shall be those used for routine radiography for an average size adult patient at that facility for that X-ray machine. At least one projection must be tested for each X-ray machine unless none of the projections listed are used. If an X-ray machine is used in both the manual and phototimed modes, then only the manual mode shall be tested. If the machine is used only in the phototimed mode, then this test is not required. An average size adult, for purposes of these regulations, is defined as a 5'8", 164 lb. adult male meeting the following anthropometric guidelines for the radiographic examination projection specified: PA Chest—Thorax—23 cm thickness; AP Abdomen and AP Lumbar Spine—Abdomen—23 cm thickness.~~

~~The exposure shall not exceed the following maximum exposure limits for the projections below:~~

Projection	Maximum Exposure
PA Chest	50 mR
AP Lumbar Spine	1400 mR
AP Abdomen	1100 mR
Dental Bitewing Using D Speed Film	

50 kVp	575 mR
55 kVp	500 mR
60 kVp	440 mR
65 kVp	400 mR
70 kVp	350 mR
75 kVp	260 mR
80 kVp	230 mR
85 kVp	200 mR
90 kVp	180 mR
95 kVp	160 mR
100 kVp	140 mR
Using E-Speed Film	
50 kVp	320 mR
55 kVp	270 mR
60 kVp	230 mR
65 kVp	200 mR
70 kVp	170 mR
75 kVp	140 mR
80 kVp	120 mR
85 kVp	105 mR
90 kVp	90 mR
95 kVp	80 mR
100 kVp	70 mR

- 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;~~
 - ~~c. A detailed description of the X-ray examinations proposed in the screening program;~~
 - ~~d. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;~~
 - ~~e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations;~~
 - ~~f. An evaluation by a private inspector of the X-ray system(s) to be used in the screening program. The evaluation by the private inspector shall show that such system(s) do satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed;~~
 - ~~g. A description of the diagnostic X-ray quality control program;~~
 - ~~h. A copy of the technique chart for the X-ray examination procedures to be used;~~
 - ~~i. The qualifications of each individual who will be operating the X-ray system(s);~~
 - ~~j. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;~~
 - ~~k. The name and address of the individual who will interpret the radiograph(s);~~
 - ~~l. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;~~
 - ~~m. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations;~~
 - ~~n. An indication of the frequency of screening and the duration of the entire screening program.~~
- ~~12. Information and maintenance record and associated information. The registrant shall maintain the following information for each X-ray system for inspection by the agency:~~
- ~~a. Model and serial numbers of all major components, and user's manuals for those components;~~
 - ~~b. Tube rating charts and cooling curves;~~
 - ~~c. Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s); and~~
 - ~~d. A copy of all correspondence with this agency regarding that X-ray system.~~
- ~~13. X-ray utilization log. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the~~

examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

14. The registrant shall maintain a list of X-ray machine operators for each facility. The following information will be maintained on the list:

The name of the X-ray machine operator. Operators must be licensed by the Department of Health Professions where X-rays are used within the scope of practice or be certified by the ARRT, or an individual enrolled in an accredited program for radiologic technology and under the supervision of a licensed or certified radiological technologist, and if a dental assistant, comply with the Board of Dentistry's radiation certification requirements in 18VAC60-20-195.

B. X-ray film processing facilities and practices:

1. Each installation using a radiographic X-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film:

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart that must be posted in the darkroom:

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	22
25.0	77	22
24.4	76	3
23.9	75	3
23.3	74	32
22.8	73	32
22.2	72	4
21.7	71	4
21.1	70	42
20.6	69	42
20.0	68	5
19.4	67	52

18.9	66	52
18.3	65	6
17.8	64	62
17.2	63	7
16.7	62	8
16.1	61	82
15.6	60	92

~~(3) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.~~

~~b. Automatic processors and other closed processing systems:~~

~~(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:~~

Developer Temperature		Minimum Immersion Time ^a (Seconds)
°C	°F	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

~~^a Immersion time only, no crossover time included.~~

~~(2) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.~~

~~c. Processing deviations from the requirements of subdivision 1 of this subsection shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).~~

~~2. Other requirements:~~

~~a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall~~

~~incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.~~

~~b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.~~

~~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.~~

12VAC5-481-1591 General and administrative requirements

A. Radiation safety requirements. The registrant shall be responsible for directing the operation of the x-ray system under his administrative control. The registrant or the registrant's agent shall assure that the requirements of this chapter are met in the operation of the x-ray system or systems.

1. An x-ray system that does not meet the provisions of this chapter shall not be operated for diagnostic purposes.

2. Individuals who will be operating the x-ray systems shall meet the qualifications of this part to conduct the practice of radiologic technology.

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel that specifies, for all examinations performed with that system, the following information:

a. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

b. Type and size of the image receptor to be used;

c. Type and size of the image receptor combination to be used, if any;

- d. Source to image receptor distance to be used (except for dental intraoral radiography);
 - e. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and
 - f. For mammography, indication of kVp/target/filter combination.
4. The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.
5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
- a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;
 - b. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material [. 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/or instructed to keep the protective apron between them 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.
- 9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
 - a. The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.
 - b. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 - c. Portable or mobile 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., tube side facing the right direction, and grid centered to the central ray; and
 - (2) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.
- 10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 12VAC5-481-640, 12VAC5-481-700, and 12VAC5-481-710.
- 11. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:
 - a. Name and address of the applicant and, where applicable, the names and addresses of agents within this state;
 - b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;
 - c. A description of the x-ray examinations proposed in the screening program, i.e., type and number of views;
 - d. Description of the population to be examined in the screening program, i.e., age range, sex, physical condition, and other appropriate information;
 - e. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;
 - f. An evaluation by a qualified medical physicist of the x-ray system or systems to be used in the screening program. The evaluation shall include the following:
 - (1) Documentation that such systems satisfy all requirements of this chapter; and

- (2) Measurement of patient exposures from the x-ray examinations to be performed;
- g. A description of the diagnostic x-ray quality control program;
- h. A copy of the technique chart for the x-ray examination procedures to be used;
- i. The qualifications of each individual who will be operating the x-ray system or systems;
- j. The qualifications of the individual who will be supervising the operators of the x-ray system or systems. The extent of supervision and the method of work performance evaluation shall be specified;
- k. The name and address of the practitioner licensed in the state who will interpret the radiograph;
- l. Procedures to be used in advising the individuals screened and their practitioners of the healing arts or health care providers of the results of the screening procedure and any further medical needs indicated;
- m. Procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;
- n. Frequency of screening of individuals; and
- o. The duration of the screening program.

12. The registrant shall maintain the following information and maintenance record for each x-ray system for inspection by the agency:

- a. Model and serial numbers of all major components, and user's manuals for those components;
- b. Tube rating charts and cooling curves;
- c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system or systems; and
- d. A copy of all correspondence with the agency regarding that x-ray system.

13. Except for veterinary facilities, each facility shall maintain an x-ray utilization log containing the patient's name, the type of examination, and the date the examination was performed.

14. The registrant shall maintain a list of x-ray operators for each facility. Operators must be licensed by the Department of Health Professions where x-rays are used within the scope of practice or be certified by the American Registry of Radiological Technologists (ARRT), or be an individual enrolled [, 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.

1. Each installation using a radiographic x-ray system and analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film.

(1) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(2) The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the following time-temperature chart:

<u>Time-Temperature Chart</u>

<u>Thermometer Reading (Degrees)</u>		<u>Minimum Developing Time (Minutes)</u>
<u>°C</u>	<u>°F</u>	
<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>
<u>22.2</u>	<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:

<u>Developer Temperature</u>		<u>Minimum Immersion Time*</u>
<u>°C</u>	<u>°F</u>	<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.

C. The registrant shall submit to the agency a copy of all surveys, calibrations, and inspections performed by a private inspector within 30 days of completion of the survey, calibration, or inspection.

D. The private inspector shall provide the inspection report to the registrant within 14 days of the completion of the inspection. A summary or recommendation shall be included with this report. The inspector shall notify the registrant of any noncompliances that need corrective action.

E. Violations identified as "serious" must be corrected within 30 days. Certification of the unit will not be issued until the violation is corrected. Violations identified as "non-serious" shall be corrected before the next inspection cycle. Uncorrected "non-serious" violations will become "serious" and require immediate correction.

12VAC5-481-1600. General requirements for all diagnostic X-ray systems. (Repealed.)

In addition to other requirements of this part, all diagnostic X-ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 $\mu\text{C}/\text{kg}$ (100 milliroentgens) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 $\mu\text{C}/\text{kg}$ (2 milliroentgens) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

5. Beam quality.

a. Half-value layer.

(1) The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential that is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (kVp)	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		Dental Intra-Oral Manufactured Before Aug. 1, 1974, and on or After Dec. 1, 1980	All Other Diagnostic X-ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5

51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

~~(2) For capacitor energy storage equipment, compliance with the requirements of subdivision 5 a of this section shall be determined with the system fully charged and a setting of 10 mAs for each exposure.~~

~~(3) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.~~

~~b. Filtration controls. For X-ray systems that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by subdivision 5 a of this section is in the useful beam for the given kVp that has been selected.~~

~~6. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly that has been selected.~~

~~7. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.~~

~~8. Technique indicators:~~

~~a. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.~~

~~b. The requirement of subdivision 8 a of this section may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.~~

~~9. Maintaining compliance. Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the federal X-ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.~~

~~10. Locks. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.~~

11. Mechanical timers. The use of a mechanical timer is prohibited.

12VAC5-481-1601. General requirements for all diagnostic x-ray systems.

In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

2. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (100 milliroentgen (mR) exposure) in one hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

3. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (two milliroentgens exposure) in one hour at five cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

4. Beam quality half-value layer (HVL).

a. The HVL of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1 (i) under the heading "Specified Dental Systems" for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; (ii) under the heading "I-Other X-Ray Systems" for any dental x-ray system designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and (iii) under the heading "II-Other X-Ray Systems" for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 1, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector that will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 1

<u>X-Ray Tube Voltage (kilovolt peak)</u>				
<u>Design Operating Range</u>	<u>Measured Operating Potential</u>	<u>Minimum HVL (mm in Aluminum)</u>		
		<u>Specified Dental Systems¹</u>	<u>I-Other X- Ray Systems²</u>	<u>II-Other X- Ray Systems³</u>

<u>Below 51</u>	<u>30</u>	<u>1.5</u>	<u>0.3</u>	<u>0.3</u>
	<u>40</u>	<u>1.5</u>	<u>0.4</u>	<u>0.4</u>
	<u>50</u>	<u>1.5</u>	<u>0.5</u>	<u>0.5</u>
<u>51 to 70</u>	<u>51</u>	<u>1.5</u>	<u>1.2</u>	<u>1.3</u>
	<u>60</u>	<u>1.5</u>	<u>1.3</u>	<u>1.5</u>
	<u>70</u>	<u>1.5</u>	<u>1.5</u>	<u>1.8</u>
<u>Above 70</u>	<u>71</u>	<u>2.1</u>	<u>2.1</u>	<u>2.5</u>
	<u>80</u>	<u>2.3</u>	<u>2.3</u>	<u>2.9</u>
	<u>90</u>	<u>2.5</u>	<u>2.5</u>	<u>3.2</u>
	<u>100</u>	<u>2.7</u>	<u>2.7</u>	<u>3.6</u>
	<u>110</u>	<u>3.0</u>	<u>3.0</u>	<u>3.9</u>
	<u>120</u>	<u>3.2</u>	<u>3.2</u>	<u>4.3</u>
	<u>130</u>	<u>3.5</u>	<u>3.5</u>	<u>4.7</u>
	<u>140</u>	<u>3.8</u>	<u>3.8</u>	<u>5.0</u>
<u>150</u>	<u>4.1</u>	<u>4.1</u>	<u>5.4</u>	

¹ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

² Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

³ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

b. Optional filtration. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube or tubes with a continuous output of one kilowatt or more and an anode heat storage capacity of one million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions in Table 1. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

c. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

5. Aluminum equivalent of material between patient and image receptor. Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table 2, which are used between the patient and the image receptor, shall not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in Table 1 for the potential. This requirement applies to front panel or panels of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE 2

<u>Item</u>	<u>Maximum Aluminum Equivalent (mm)</u>
<u>Front panel(s) of cassette holders (total of all)</u>	<u>1.2</u>
<u>Film panel(s) of film changer (total of all)</u>	<u>1.2</u>
<u>Cradle</u>	<u>2.3</u>
<u>Tabletop, stationary, without articulated joints</u>	<u>1.2</u>
<u>Tabletop, movable, without articulated joints (including stationary subtop)</u>	<u>1.7</u>
<u>Tabletop, with radiolucent panel having one articulated joint</u>	<u>1.7</u>
<u>Tabletop, with radiolucent panel having two or more articulated joints</u>	<u>2.3</u>
<u>Tabletop, cantilevered</u>	<u>2.3</u>
<u>Tabletop, radiation therapy simulator</u>	<u>5.0</u>

6. Battery charge indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

7. Modification of certified diagnostic x-ray components and systems.

a. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this part.

b. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or a component to comply with the applicable requirements of this part. The owner who causes such modification need not submit the reports required by this part, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with this part.

8. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

9. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

10. Technique indicators.

a. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set prior to the exposure shall be indicated.

b. The requirement of subdivision 10 a of this subsection may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

11. Maintaining compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

12. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

13. Mechanical timers. The use of mechanical timers is prohibited.

12VAC5-481-1610. Fluoroscopic X-ray systems. (Repealed.)

All fluoroscopic X-ray systems used shall be image intensified and meet the following requirements:

~~1. Limitation of useful beam.~~

~~a. Primary barrier.~~

~~(1) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.~~

~~(2) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.~~

~~b. Fluoroscopic beam limitation.~~

~~(1) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.~~

~~(2) For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.~~

~~(3) For uncertified fluoroscopic systems without a spot film device, the requirements of subdivision b (1) of this section apply.~~

~~(4) Other requirements for fluoroscopic beam limitation:~~

~~(a) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;~~

~~(b) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;~~

~~(c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;~~

~~(d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;~~

~~(e) For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field that pass through the center of the visible area of the image receptor.~~

~~c. Spot-film beam limitation. Spot-film devices shall meet the following requirements:~~

~~(1) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;~~

~~(2) Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3.0% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4.0% of the SID;~~

~~(3) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;~~

~~(4) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2.0% of the SID; and~~

~~(5) On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.~~

~~d. Override. If a means exists to override any of the automatic X-ray field size adjustments required in subdivisions 1 b and c of this section that means:~~

~~(1) Shall be designed for use only in the event of system failure;~~

~~(2) Shall incorporate a signal visible at the fluoroscopist's position that will indicate whenever the automatic field size adjustment is overridden; and~~

~~(3) Shall be clearly and durably labeled as follows:~~

~~FOR X-RAY FIELD LIMITATION SYSTEM FAILURE~~

~~2. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.~~

~~3. Exposure rate limits.~~

~~a. Entrance exposure rate allowable limits.~~

~~(1) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:~~

~~(a) During recording of fluoroscopic images; or~~

~~(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5.2 mC/kg-min (20 R/min) at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~(2) Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:~~

~~(a) During recording of fluoroscopic images; or~~

~~(b) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~(3) Compliance with the requirements of subdivision 3 of this section shall be determined as follows:~~

~~(a) If the source is below the X-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;~~

~~(b) If the source is above the X-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;~~

~~(c) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;~~

~~(d) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.~~

~~b. Periodic measurement of entrance exposure rate shall be performed by a private inspector for both typical and maximum values as follows:~~

~~(1) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate;~~

~~(2) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 12VAC5-481-1590 A 12 c. The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;~~

~~(3) Conditions of periodic measurement of typical entrance exposure rate are as follows:~~

~~(a) The measurement shall be made under the conditions that satisfy the requirements of subdivision 3 a (3) of this section;~~

~~(b) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;~~

~~(c) The X-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of subdivision 3 b (3) (b) of this section.~~

- ~~(4) Conditions of periodic measurement of maximum entrance exposure rate are as follows:~~
- ~~(a) The measurement shall be made under the conditions that satisfy the requirements of subdivision 3 a (3) of this section;~~
 - ~~(b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;~~
 - ~~(c) The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.~~
4. ~~Barrier transmitted radiation rate limits.~~
- ~~a. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 mR/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 on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.~~
 - ~~b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.~~
8. ~~Control of scattered radiation.~~

~~a. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.~~

~~b. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:~~

~~(1) Is at least 120 centimeters from the center of the useful beam; or~~

~~(2) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12VAC5-481-1590 A 5.~~

~~c. The agency may grant exemptions to subdivision 8 b of this section where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption. The following is a suggested list of fluoroscopic procedures where such exemptions will be automatically granted: angiograms, arthrograms, biliary drainage procedures, fluoroscopic biopsy procedures, myelograms, percutaneous cholangiograms, percutaneous nephrostomies, sinograms or fistulograms, t-tube cholangiograms, interventional cardiac catheterization, and interventional special procedures.~~

~~9. Spot film exposure reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of 12VAC5-481-1620-D when operating in the spot film mode.~~

~~10. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of subdivision 3 of this section. In addition, these systems shall be exempt from:~~

~~a. The requirements of subdivisions 1 and 4 of this section provided such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and~~

~~b. The requirements of subdivision 7 of this section if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.~~

~~11. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic X-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.~~

12VAC5-481-1611. Fluoroscopic equipment.

A. The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

B. Primary protective barrier.

1. Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed $3.34 \times 10^{-3}\%$ of the entrance AKR, at a

distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation.

2. Measuring compliance. The AKR shall be measured in accordance with subsection E of this section. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

C. Field limitation.

1. Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with subdivisions 4 and 5 of this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Further means for limitation. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of subdivisions 4 and 5 of this subsection. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or capability of a visible area of greater than 300 square cm, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five cm by five cm. This paragraph does not apply to non-image-intensified fluoroscopy.

3. Non-image-intensified fluoroscopy. The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

4. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

a. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

(2) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

b. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

(1) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80% of the area of the x-ray field overlaps the visible area of the image receptor; or

(2) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm.

5. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies:

a. Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0% of the SID. The sum of the excess length and the excess width shall be no greater than 4.0% of the SID.

b. The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

"For X-Ray Field Limitation System Failure"

D. Activation of tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure or exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

E. Air kerma rates. For fluoroscopic equipment, the following requirements apply:

1. Fluoroscopic equipment manufactured before May 19, 1995.

a. Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

b. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

c. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 1 e of this subsection.

d. Equipment may be modified in accordance with this part to comply with subdivision 2 of this subsection. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

e. Exceptions:

(1) During recording of fluoroscopic images; or

(2) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of any of the rates specified in subdivisions 1 a, b, and c of this subsection at the measurement point specified in subdivision 3 of this subsection, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

2. Fluoroscopic equipment manufactured on or after May 19, 1995.

a. Equipment shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Provision or manual selection of technique factors may be provided.

b. Equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection, except as specified in subdivision 2 c of this subsection.

c. Exceptions:

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from the fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(2) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image or images after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(3) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in subdivision 3 of this subsection. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

3. Measuring compliance. Compliance with this subsection shall be determined as follows:

a. If the source is below the x-ray table, the AKR shall be measured at one cm above the tabletop or cradle.

b. If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c. In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

d. In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

e. In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

4. Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

F. Reserved.

G. Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

H. Source-skin distance.

1. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subsection, provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this subsection, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

I. Fluoroscopic irradiation time, display, and signal.

1. Fluoroscopic equipment manufactured before June 10, 2006.

a. Equipment shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of this subdivision. When the equipment is modified, it shall bear a label indicating the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)"

b. As an alternative to the requirements of this subsection, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

2. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

a. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements apply:

(1) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds.

(2) The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.

(3) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

b. A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

J. Mobile and portable fluoroscopes. In addition to the other requirements of this subsection, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

K. Display of last-image-hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

3. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

L. Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

1. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

2. The cumulative air kerma in units of mGy shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

3. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

4. The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

a. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in subdivision E 3 a or E 3 e of this section.

b. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

5. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than $\pm 35\%$ over the range of six mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three seconds.

M. Control of scattered radiation.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 centimeters from the center of the useful beam; or

b. The radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 12VAC5-481-1591 A 5.

3. The agency may grant exemptions to subdivision 2 of this subsection where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

N. Operator qualifications. The facility shall ensure that only a licensed practitioner of the healing arts or a radiologic technologist or equivalent be allowed to operate fluoroscopic x-ray systems.

O. Equipment operation.

1. All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. The operation of fluoroscopic x-ray systems by radiologic technologists or equivalent shall be performed under the direct supervision of a licensed practitioner of the healing arts.

3. Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or radiologic technologist as specified in subsection N of this section.

4. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

5. Facilities shall maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

P. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all fluoroscopic x-ray systems by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1620. Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems. (Repealed.)

A. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 12VAC5-481-1620 H-2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

1. General purpose stationary and mobile X-ray systems, including veterinary systems (other than portable) installed after September 20, 2006.

a. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

b. A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2.0% of the 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 X-ray field with the center of the image receptor to within 2.0% of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.~~

~~c. Subdivisions 4 a and b of this subsection may be met with a system that meets the requirements for a general purpose X-ray system as specified in subdivision 1 of this subsection or, when alignment means are also provided, may be met with either:~~

~~(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or~~

~~(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.~~

~~B. Radiation exposure control.~~

~~1. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.~~

~~2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.~~

~~3. Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."~~

~~a. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:~~

~~(1) Exposure of two seconds or less; or~~

~~(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.~~

~~b. Automatic exposure controls. When an automatic exposure control is provided:~~

~~(1) Indication shall be made on the control panel when this mode of operation is selected;~~

~~(2) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;~~

~~(3) The minimum exposure time for all equipment other than that specified in subdivision 3 b (2) of this subsection shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five mAs, whichever is greater;~~

~~(4) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kW-s per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and~~

~~(5) A visible signal shall indicate when an exposure has been terminated at the limits required by subdivision 3 b (4) of this subsection, and manual resetting shall be required before further automatically timed exposures can be made.~~

~~4. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of $C\text{ kg}^{-1}\text{s}^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:~~

$$\frac{X_1 - X_2}{X_1 + X_2} \leq 0.1$$

~~where X_1 and X_2 are the average $C\text{ kg}^{-1}\text{s}^{-1}$ (mR/s) values.~~

~~5. Exposure control location. The X-ray exposure control shall be so placed that the operator can view the patient while making any exposure.~~

~~6. Operator protection, except veterinary systems, bone densitometers, and other self-contained machines whose design was approved by the FDA.~~

~~a. Stationary systems. Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted behind a protected barrier so that the operator can remain behind that protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, dental panoramic and podiatry X-ray systems may, as an alternative, be provided with means to allow the operator to be at least nine feet from the tube housing assembly during exposures.~~

~~b. Mobile and portable systems. Mobile and portable X-ray systems that are:~~

~~(1) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 6 a of this subsection;~~

~~(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.~~

~~7. Operator protection for veterinary systems. All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.~~

~~C. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.~~

~~D. Reproducibility for Exposure and Time. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.10. This requirement applies to clinically used techniques.~~

~~E. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not~~

activated shall not exceed a rate of 0.5 $\mu\text{C}/\text{kg}$ (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 milliamperere-seconds product ($\text{C kg}^{-1}\text{mAs}^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

2. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of $\text{C kg}^{-1}\text{mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

H. Additional requirements. Diagnostic X-ray systems shall be required to comply with the following additional requirements.

1. Beam limitation for stationary and mobile general purpose X-ray systems.

a. There shall be provided a means of stepless adjustment of the size of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

b. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 120 lux or 10 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

2. Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

a. PBL shall prevent the production of X-rays when:

~~(1) Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by subdivision 2 c of this subsection, from the corresponding image receptor dimensions by more than 3.0% of the SID; or~~

~~(2) The sum of the length and width differences as stated in subdivision 2 a (1) of this subsection without regard to sign exceeds 4.0% of the SID;~~

~~b. Compliance with subdivision 2 a of this subsection shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor;~~

~~c. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters;~~

~~d. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in subdivision 2 a of this subsection, then any change of image receptor size or SID must cause the automatic return.~~

~~3. Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of subdivisions A 1 or H 2 of this section.~~

~~I. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be hand held during exposures unless the system is specifically designed to be handheld.~~

~~J. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all X-ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers and X-ray machines used in the practice of podiatry or dentistry shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.~~

12VAC5-481-1621. Radiographic equipment.

A. Control and indication of technique factors.

1. Visual indication. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

2. Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

a. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. Automatic exposure controls. When an automatic exposure control is provided:

a. Indication shall be made on the control panel when this mode of operation is selected;

b. When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver five milliamperere-seconds (mAs), whichever is greater;

c. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (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 when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

d. A visible signal shall indicate when an exposure has been terminated at the limits described in subdivision 3 c of this subsection, and manual resetting shall be required before further automatically timed exposures can be made.

4. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits given by the manufacturer. In the absence of manufacturer's limits, the deviation shall not exceed 10% of the indicated value for kVp and time.

B. Reproducibility. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

1. Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.10.

2. Measuring compliance. Determination of compliance shall be based on [~~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 minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

C. Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated.

1. Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$$\underline{|X_1 - X_2| \leq 0.10(X_1 + X_2)}$$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

2. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$$|X_1 - X_2| \leq 0.10(X_1 + X_2)$$

where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

3. Measuring compliance. Determination of compliance shall be based on [4four] exposures, made within one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ± 1 of the mean value for all measurements at these technique factors.

D. Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

1. Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm.

2. Visual definition.

a. Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2.0% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

b. When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 10 foot-candles at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

c. The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2 , where I_1 is the illuminance three mm from the edge of the light field toward the center of the field, and I_2 is the illuminance three mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one mm.

E. Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in subsection D of this section:

1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2.0% of the SID and to indicate the SID to within 2.0%;

2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in centimeters or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane

of the image receptor that correspond to those indicated by the beam-limiting device to within 2.0% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

F. Field limitation on radiographic x-ray equipment other than general purpose radiographic systems.

1. Equipment for use with intraoral image receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

a. If the minimum source-to-skin distance (SSD) is 18 cm or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven cm; and

b. If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six cm.

For dental intraoral uses, an open ended shielded positioning device shall be used.

2. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of image receptor to within 2.0% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

3. Systems designed for mammography.

a. Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

b. Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2.0% of the SID. This requirement can be met with a system that performs as prescribed in subdivisions 4 a, b, and c of this subsection. For systems that allow changes in SID, the SID indication specified in subdivisions 4 b and c of this subsection shall be the maximum SID for which the beam-limiting device or aperture is designed.

c. Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

4. Other x-ray systems. Radiographic systems not specifically covered in subsections D, E, and H of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2.0% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2.0% of the SID, or means shall be provided to both size and [alignment 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. These requirements may be met with:

a. A system that performs in accordance with subsections D and E of this section; or when alignment means are also provided, may be met with either;

b. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

c. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

G. Positive beam limitation (PBL). The requirements of this subsection shall apply to radiographic systems that contain PBL.

1. Field size. When a PBL system is provided, it shall prevent x-ray production when:

a. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3.0% of the SID; or

b. The sum of the length and width differences stated in subdivision 1 a of this subsection without regard to sign exceeds 4.0% of the SID.

c. The beam-limiting device is at an SID for which PBL is not designed for sizing.

2. Conditions for PBL. When provided, the PBL system shall function as described in subdivision 1 of this subsection whenever all the following conditions are met:

a. The image receptor is inserted into a permanently mounted cassette holder;

b. The image receptor length and width are less than 50 cm;

c. The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ± 3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

d. The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees; and

e. Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance. Compliance with the requirements of subdivision 1 of this subsection shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of subdivision 2 of this subsection are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

4. Operator initiated undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than five cm. Return to PBL function as described in subdivision 1 of this subsection shall occur automatically upon any change of image receptor size or SID.

5. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

"For X-Ray Field Limitation System Failure"

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

H. Field limitation and alignment for spot-film devices. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3.0% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4.0% of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2.0% of the SID.

4. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

a. For spot-film devices used on fixed-SID fluoroscopic systems that are not required to and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

b. For spot-film devices used on fluoroscopic systems that have a variable SID or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five cm by five cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

"For X-ray Field Limitation System Failure"

I. Source-skin distance.

1. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

- a. 18 cm if operable above 50 kVp; or
- b. 10 cm if not operable above 50 kVp.

2. Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 cm.

J. Beam-on indicators. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

K. Reserved.

L. Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube shall not exceed:

1. An air kerma of 0.26 microGy (0.03 mR exposure) in one minute at five cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm: and

2. An air kerma of 0.88 mGy (100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in one hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

M. Primary protective barrier for mammography x-ray systems.

1. For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

2. For mammographic x-ray systems manufactured on or after September 30, 1999:

- a. At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.
- b. The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in subdivision 2 a of this subdivision.
- c. The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (0.1 mR exposure) for each activation of the tube.

3. Compliance with the requirements of subdivisions 1 and 2 c of this subsection for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring

instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

N. Reserved.

O. Beam limitation, except mammographic systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of subsection G of this section have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

P. Radiation exposure control.

1. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Operator protection, except veterinary systems.

a. Stationary systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator may remain in that protected area during the entire exposure. For dental intraoral systems installed prior to September 20, 2006, if the x-ray control is not permanently mounted behind a protected barrier, then dosimetry is required by all operators of the system.

b. Mobile and portable systems. Mobile and portable x-ray systems that are:

(1) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 3 a of this subsection;

(2) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

4. Operator protection for veterinary systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during exposures.

Q. Tube stands for portable x-ray systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

R. Surveys. Radiation safety and equipment performance surveys shall be performed annually on all x-ray machines covered by this section in order to assure compliance with the regulations, except that bone densitometers, hand-held units, and x-ray machines other than head CT or cone beam units used in the practice of podiatry, dentistry, or veterinary medicine shall be surveyed every three years. The surveys shall be performed by or under the direct supervision of a private or state inspector who is physically present at the facility during the inspection.

12VAC5-481-1630. Intraoral dental radiographic systems. (Repealed.)

~~In addition to the provisions of 12VAC5-481-1590 and 12VAC5-481-1600, the requirements of 12VAC5-481-1630 apply to X-ray equipment and associated facilities used for dental~~

radiography. Requirements for extraoral dental radiographic systems are covered in 12VAC5-481-1620. Only systems meeting the requirements of this section shall be used.

A. Source-to-skin distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:

1. 18 centimeters if operable above 50 kVp; or
2. 10 centimeters if operable at 50 kVp only.

B. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.

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 $C \cdot kg^{-1} \cdot s^{-1}$ (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:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

5. Exposure control location and operator protection.

- a. After September 20, 2006, stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted behind a protected barrier, so that the operator can remain behind that protected barrier during the entire exposure. Where it is impractical to stand behind a protected barrier, the X-ray exposure shall be permanently mounted at least 2.7 meters (9 feet) from the tube housing assembly while making exposures. If an X-ray machine was installed prior to September 20, 2006, and if the X-ray exposure control is not permanently mounted behind a protected barrier, so that the operator can remain behind that protected barrier during the entire exposure, then dosimetry shall be required by all operators of the X-ray system.

b. Mobile and portable X-ray systems that are:

- (1) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 5 of this subsection;

~~(2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly while making exposures.~~

~~D. Reproducibility for Exposure and Time. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures and times shall be no greater than 0.10, for any specific combination of selected technique factors.~~

~~E. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40% to 100% of the maximum rated.~~

~~1. Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of $C\text{ kg}^{-4}\text{ mAs}^{-4}$ (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:~~

$$\del X_1 - X_2 < 0.10 (X_1 + X_2)$$

~~where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.~~

~~2. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of $C\text{ kg}^{-4}\text{ mAs}^{-4}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:~~

$$\del X_1 - X_2 < 0.10 (X_1 + X_2)$$

~~where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.~~

~~3. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.~~

~~F. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10% of the indicated value for kVp and 10% for time.~~

~~G. kVp limitations. Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.~~

~~H. Administrative controls.~~

~~1. Patient and film holding devices shall be used when the techniques permit.~~

~~2. The tube housing and the PID shall not be hand held during an exposure.~~

~~3. The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subsection B of this section.~~

~~4. Dental fluoroscopy without image intensification shall not be used.~~

~~I. Radiation safety and equipment performance surveys shall be performed every three years on all dental X-ray systems by or under the direct supervision of a private or state~~

inspector who is physically present at the facility during the inspection in order to assure compliance with these regulations.

12VAC5-481-1631. Intraoral dental radiographic equipment.

In addition to the applicable provisions of 12VAC5-481-1591, 12VAC5-481-1601, and 12VAC5-481-1621, the requirements of this section apply to x-ray equipment and associated facilities used for dental intraoral radiography. Requirements for extraoral dental radiographic systems are in 12VAC5-481-1621.

1. Radiation exposure control. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Exposure control location and operator protection.

a. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

b. Mobile and portable x-ray systems that are:

(1) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subdivision 1 of this section.

(2) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

3. kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4. Administrative controls.

a. Patient and film holding devices shall be used when the techniques permit.

b. The tube housing and the PID for a permanently mounted intraoral dental system shall not be hand-held during an exposure.

c. Dental fluoroscopy without image intensification shall not be used.

12VAC5-481-1640. Computed tomography X-ray systems. (Repealed.)

~~A. Reserved.~~

~~B. Requirements for equipment.~~

~~1. Termination of exposure.~~

~~a. Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.~~

~~b. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by subdivision 1 a of this subsection.~~

~~c. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.~~

~~2. Tomographic plane indication and alignment.~~

~~a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.~~

- ~~b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.~~
 - ~~c. If a device using a light source is used to satisfy the requirements of subdivisions 2 a or b of this subsection, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.~~
- ~~3. Beam-on and shutter status indicators and control switches.~~
 - ~~a. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.~~
 - ~~b. Each emergency button or switch shall be clearly labeled as to its function.~~
- ~~4. Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.~~
- ~~5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subdivision 3 of 12VAC5-481-1600.~~
- ~~6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.~~
- ~~7. Additional requirements applicable to CT X-ray Systems containing a gantry manufactured after September 3, 1985.~~
 - ~~a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.~~
 - ~~b. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.~~
 - ~~c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.~~
 - ~~d. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.~~
- ~~C. Facility design requirements.~~
 - ~~1. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.~~
 - ~~2. Viewing systems.~~
 - ~~a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.~~
 - ~~b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.~~

~~D. Surveys, calibrations, spot checks, and operating procedures:~~

~~1. Surveys.~~

~~a. All CT X-ray systems installed after September 20, 2006, and those systems not previously surveyed shall have a survey made by, or under the direct supervision of a private inspector who is physically present at the facility during the inspection. In addition, such surveys shall be done at least annually or after any change in the facility or equipment that might cause a significant increase in radiation hazard, whichever occurs first.~~

~~b. The registrant shall obtain a written report of the survey from the private inspector, and a copy of the report shall be sent to the agency within 60 days of the date of the survey.~~

~~2. Radiation calibrations.~~

~~a. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a private inspector who is physically present at the facility during such calibration.~~

~~b. The calibration of a CT X-ray system shall be performed at intervals specified by a private inspector and after any change or replacement of components that, in the opinion of the private inspector, could cause a change in the radiation output.~~

~~c. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.~~

~~d. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:~~

~~(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;~~

~~(2) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;~~

~~(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;~~

~~(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.~~

~~e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.~~

~~f. Calibration shall meet the following requirements:~~

~~(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal~~

~~tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;~~

~~(2) The CTDI along the two axes specified in subdivision 2 d (2) of this subsection shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;~~

~~(3) The spot checks specified in subdivision 3 of this subsection shall be made.~~

~~g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.~~

~~3. Spot checks.~~

~~a. The spot check procedures shall be in writing and shall have been developed by a private inspector.~~

~~b. The spot check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.~~

~~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.~~

~~e. If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the private inspector, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the private inspector.~~

12VAC5-481-1641. Computed tomography equipment.

A. Reserved.

B. Requirements for equipment.

1. Termination of exposure.

a. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices that monitor equipment function.

b. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by subdivision 1 a of this subsection.

c. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

2. Tomographic plane indication and alignment.

a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

c. If a device using a light source is used to satisfy the requirements of subdivision 2 a or b of this subsection, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and shutter status indicators and control switches.

a. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT conditions of operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

5. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subdivision 3 of 12VAC5-481-1601.

6. Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985.

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five mm.

b. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment shall not exceed one millimeter with any mass from 0 to 100 kg resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

C. Facility design requirements.

1. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing systems.

a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

D. Surveys, calibrations, spot checks, and operating procedures.

1. Surveys.

a. All CT x-ray systems installed after September 19, 2006, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

b. The registrant shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the agency upon request.

2. Radiation calibrations.

a. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified medical physicist who is physically present at the facility during such calibration.

b. The calibration of a CT x-ray system shall be performed (i) after initial installation and before use on human patients, (ii) annually or at intervals specified by a qualified medical physicist, and (iii) after any change or replacement of components that in the opinion of the qualified medical physicist could cause a change in the radiation output.

c. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

d. CT dosimetry phantom shall be used in determining the radiation output of a CT x-ray system. Such phantom shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic cm. The phantom shall be at least 14 cm in length and shall have diameters of 32.0 cm for testing CT x-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(2) CT dosimetry phantom shall provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(2) The CTDI along the two axes specified in subdivision 2 d (2) of this subsection shall be measured. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and

(3) The spot checks specified in subdivision 3 of this subsection shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

3. Spot checks.

a. The spot-check procedures shall be in writing and shall have been developed by a qualified medical physicist.

b. The spot-check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of (i) providing an indication of contrast scale, noise, nominal tomographic section thickness, and the resolution capability of the system for low and high contrast objects; and (ii) measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by subdivision 2 of this subsection and at time intervals and under system conditions specified by a qualified medical physicist.

d. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom or phantoms using the same processing mode and CT conditions of

operation as are used to perform calibrations required by subdivision 2 of this subsection.

e. The results of each spot check shall be maintained for two years.

4. Operating procedures.

a. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

b. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(2) Instructions on the use of the CT dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination.

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: $((\text{measured kVp})/100)$ and $((\text{measured kVp})/100 + 0.1)$ millimeters aluminum for molybdenum targets;~~

~~(2) At least the value of $((\text{measured kVp})/100)$ millimeters aluminum for rhodium alloy targets.~~

~~b. For xeroradiography, the HVL of the useful beam with the compression device in place shall be at least 1.0 and not greater than 1.6 mm aluminum, measured at 49 kVp with a tungsten target tube.~~

~~5. Resolution. The combination of focal spot size, source-to-image receptor distance and magnification shall result in a resolution of at least 12 line pairs per millimeter (cycles/mm) measured when a resolution pattern is positioned 4.2 cm above all breast supports and when the resolution pattern is either perpendicular to or parallel with the chest wall edge of the image receptor support. The measurement shall be made with the kVp in the range of 25-30 and the mA shall be the highest available for the focal spot size selected. The resolution shall be at least 11 line pairs when a high-contrast~~

~~resolution bar test pattern is orientated with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line pairs/mm when the bars are parallel to that axis. The bar pattern must be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within one cm of the chest wall edge of the image receptor. When more than one target material is provided, the measurement must be made using the appropriate focal spot for each target material.~~

~~6. Compression.~~

~~a. The X-ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least three minutes.~~

~~b. The chest wall edge of the compression paddle shall extend beyond the chest wall edge of the image receptor by no more than 2.0% of the Source-to-Image Receptor Distance with the compression paddle placed 4.2 cm above the breast support device. With the compression paddle in this position, the chest wall edge of the compression paddle shall not be visible in the acquired image.~~

~~7. System capabilities. A mammographic X-ray system utilizing screen-film image receptors shall have:~~

~~a. The capability of using anti-scatter grids that are:~~

~~(1) Integral to the X-ray system;~~

~~(2) Available for all image receptor sizes used;~~

~~b. The capability of automatic exposure control, for systems installed after September 20, 2006; and~~

~~c. The capability of displaying post-exposure mAs after an exposure made using an automatic exposure control device, for systems installed after September 20, 2006.~~

~~8. Milliampere-second read-out accuracy. For those mammographic X-ray systems equipped with automatic exposure control and post-exposure mAs read-out, the indicated mAs read-out shall be within 10% of the actual mAs delivered.~~

~~9. Transmission. For X-ray systems manufactured after September 5, 1978, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 25.8 nC/kg (0.1 milliroentgen) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~10. Collimation.~~

~~a. All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than 2.0% of the SID.~~

~~b. Means for visually defining the perimeter of the X-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2.0% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.~~

~~11. Accuracy of kVp. Deviation of actual kVp from the indicated kVp shall not exceed the limits specified by the manufacturer of the X-ray system, or, the actual kVp shall be within plus or minus 2 kVp of the indicated kVp, whichever limit is more restrictive.~~

~~12. Automatic exposure control performance. In addition to 12VAC5-481-1620 D, mammographic systems in the AEC mode shall be able to maintain constant film density to within an optical density of plus or minus 0.3 of the average optical density over the kVp range used clinically, using phantoms of BR-12 or other breast equivalent material thicknesses of two centimeters to six centimeters. If the facility has established a technique chart that utilizes varying technical factors for different breast thicknesses, those adjustments in technique may be used when performing this test.~~

~~13. Radiation output minimum. At 28 kVp, with a focal spot meeting the requirements of subdivision A 5 of this section, the mammographic system shall be capable of sustaining a minimum output rate of 130 $\mu\text{C/kg/sec}$ (500 mR/sec) for at least three seconds. This output shall be measured at a point 4.2 centimeters from the surface of the breast support device when the SID is at its maximum and the effect of compression paddle attenuation is included.~~

~~14. Screen-film contact. Cassettes shall not be used for mammography if poor contact of two or more large areas (>1 cm in diameter) or a section longer than 1 cm and >2 mm in width along the chest wall edge can be seen in a 40 mesh test.~~

~~15. Image quality. The mammographic X-ray imaging system shall be capable of providing an image of a 0.75 mm fiber, 0.32 mm speck group, and a 0.75 mm mass from the Conference of Radiation Control Program Directors NEXT "92 phantom (or equivalent) on the standard mammographic image receptor system in use at a facility. Mammograms shall not be taken on patients if this minimum is not met. Any fibers, speck groups and masses larger than those specified shall also be imaged.~~

~~16. Dose. The mean glandular dose for one craniocaudal view, measured with the phantom referenced in subdivision 15 of this subsection, based on exposure measured at the breast entrance location, and using dose conversion factors specified by the Health Care Financing Administration in their Medicare Mammography Survey Protocols, shall not exceed the following values:~~

~~a. 2.0 mGy (200 millirads) for nongrid screen film systems;~~

~~b. 3.0 mGy (300 millirads) for screen film systems with grid.~~

~~17. Technique settings. The technique settings used for subdivisions 15 and 16 of this subsection shall be those used by the facility for its clinical images of a 50% adipose, 50% glandular, 4.2 cm compressed breast.~~

~~B. Quality assurance.~~

~~1. Quality assurance program required. The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic X-ray imaging system, to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement include providing qualified individuals who are to:~~

~~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 mid-density (MD) and density difference (DD) on the sensitometric control charts;~~

~~(2) Base plus fog (B+F) exceeds the established operating level by more than 0.03 in optical density.~~

~~b. Resolution—upon tube installation or replacement and every 12 months.~~

~~c. Focal spot size—upon tube installation or tube replacement only or at least every 12 months, whichever occurs first.~~

~~d. Half-value layer—12 months.~~

~~e. kVp accuracy and reproducibility—12 months.~~

~~f. Output reproducibility, mA linearity, and mR/mAs—12 months.~~

~~g. Automatic exposure control reproducibility and performance (response to kVp and phantom thickness variations)—12 months.~~

~~h. Screen-film contact and screen artifact detection—six months.~~

~~i. Compression device performance (releases, level of force, etc)—six months.~~

~~j. Collimator alignment—12 months.~~

~~k. Primary/secondary barrier transmission—upon initial X-ray system installation and significant modification of the system or the facility.~~

~~l. Image quality (using a test "phantom," that simulates the composition of the breast and includes simulations of breast structures)—weekly for stationary systems, on each day of use for mobile systems, and upon significant service or modification of any mammographic system.~~

~~m. Densitometer accuracy check—every 12 months.~~

~~n. Glandular dose—every 12 months.~~

~~o. Image quality—every 12 months.~~

~~p. Artifacts—every 12 months.~~

~~4. Additional quality control requirements. The registrant shall perform the following observations and procedures according to the frequency noted and record the results.~~

Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two-year period.

- a. Retake Analysis—three months.
- b. Viewbox uniformity—six months.
- c. Darkroom integrity (safelight condition, light leaks, etc.)—six months.
- d. Screen cleaning—weekly.
- e. Fixer retention—three months.

C. Additional facility requirements:

1. Masks. Masks shall be provided on the viewboxes to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the exposed area of the film.

2. Film processing:

- a. Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.
- b. Clinical films and phantom image quality films shall be processed within 10 hours of exposure.
- c. Facilities shall offer to process films before the patient leaves the facility. If the patient chooses not to wait, or there is not developing capabilities, the patient will be notified within two business days if additional films are necessary.

3. Instruments and devices. An image quality phantom, sensitometer, and a calibrated densitometer shall be available to each facility in order to comply with the quality control test frequencies specified in subdivision B 3 of this section.

4. Operator qualifications. The operator of the X-ray machine shall be certified by the American Registry of Radiologic Technologists and shall have had specialized training in mammography meeting the requirements set forth by the FDA under the MQSA of 1992.

5. Physician qualifications. The physician interpreting the mammograms shall be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or Board eligible, or equivalent, and shall have had specialized training in mammography and image interpretation.

6. Physicist qualifications. The person performing evaluation of mammographic system performance in accordance with these regulations shall meet the requirements set forth in 12VAC5-481-340 C.

7. Image retention. Clinical images shall be retained for a minimum of five years or 10 years if no other clinical images are obtained.

8. Retake rate. Corrective action shall be taken if the retake rate exceeds 5.0%. The retake rate shall be calculated as (repeated + rejected films)/ total number of clinical films.

9. Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density when sensitized mammographic film of the type used in the facility is exposed to darkroom conditions with safelight on for two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen or sensitometer so that after processing an optical density of at least 1.0 is achieved.

Facility qualifications. The registrant performing mammography shall be accredited by the American College of Radiology or another agency recognized as a certifying body or have their application pending. The registrant shall also be certified by the FDA or another agency recognized as an accrediting body under the MQSA of 1992 or have a provisional/interim certificate.

D. Additional state requirements.

1. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality.
2. Agency inspectors may conduct unannounced inspections during normal hours of business.

12VAC5-481-1651. Mammography requirements.

A. Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 (Public Law 105-248) and 21 CFR Part 900, shall be used for screening and diagnostic mammography.

B. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

C. A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998 and 21 CFR Part 900.

D. The operator of the mammography machine shall be certified by the American Registry of Radiologic Technologists (ARRT) and shall have had specialized training in mammography meeting the requirements set forth by the U.S. Food and Drug Administration under the Mammography Quality Standards Reauthorization Act of 1998.

E. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality.

F. Agency inspectors may conduct unannounced inspections during normal business hours.

12VAC5-481-1653. Hand-held radiographic unit.

In addition to the applicable provisions found elsewhere in this chapter, the following provisions apply to a hand-held radiographic unit.

1. A hand-held radiograph unit shall be:

- a. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.
- b. Registered with the agency in accordance with applicable parts of this chapter.
- c. Maintained and operated in accordance with the manufacturer's specifications.

2. For all uses:

- a. Operators of a hand-held radiographic unit shall be specifically trained to operate such equipment.
- b. When operating a hand-held radiographic unit, operators shall wear dosimetry unless otherwise authorized by the agency.
- c. A hand-held radiographic unit shall have the backscatter radiation shield in place to protect the operator during operation.

d. The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held radiograph unit.

e. A hand-held radiographic unit shall not be used in hallways or waiting rooms.

12VAC5-481-1655. Bone densitometry.

A. A bone densitometry system shall be:

1. Certified by the manufacturer pursuant to 21 CFR Part 803, Medical Device Reporting of the Federal Food and Drug Administration Modernization Act of 1997; 21 USC Chapter 9, Subchapter V, Part C – Electronic Product Radiation Control (EPRC) (§ 360hh et seq.) of the Federal Food, Drug and Cosmetic Act; and 21 CFR 1020.30, Diagnostic x-ray systems and their major components.

2. Registered with the agency in accordance with applicable parts of this chapter.

3. Maintained and operated in accordance with the manufacturer's specifications.

B. Equipment requirements. A system with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2.0% of the SID.

C. Operators of a bone densitometry system shall meet one of the following:

1. Be certified by the American Registry of Radiologic Technologists (ARRT):

2. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a radiologic technologist or a limited radiologic technologist for bone density operation;

3. Be licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

4. Be in an accredited program for radiologic technology and under the supervision of an individual who meets one of the criteria listed in subdivisions 1, 2, or 3 of this subsection.

D. During the operation of any bone densitometry system:

1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

2. The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

E. The registrant shall keep maintenance records for bone densitometry systems as prescribed by subdivision A 3 of this section. These records shall be maintained for inspection by the agency.

F. Bone densitometry on human patients shall be conducted only:

1. Under a prescription of an individual licensed by the Virginia Department of Health Professions, Board of Medicine as a practitioner of the healing arts; or

2. Under a screening program approved by the agency.

12VAC5-481-1657. Quality assurance program.

All registrants of diagnostic x-ray imaging equipment may be required by the agency to establish and maintain a quality assurance program consisting of quality control assessments.

12VAC5-481-2110. Area requirements.

A. Radiation Levels. The local components of an analytical ~~X-ray~~ x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group that could result in a dose to an individual present therein in excess of the dose limits given in 12VAC5-481-640. For systems utilizing ~~X-ray~~ x-ray tubes, these levels shall be met at any specified tube rating.

B. Surveys.

1. Radiation surveys, as required by 12VAC5-481-750, of all analytical ~~X-ray~~ x-ray systems sufficient to show compliance with 12VAC5-481-2440 A shall be performed:

a. Upon installation of the equipment, and at least once every ~~42 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 these regulations] ;

b. Following any change in the initial arrangement, number, or type of local components in the system;

c. Following any maintenance requiring the disassembly or removal of a local component in the system;

d. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary ~~X-ray~~ x-ray beam when any local component in the system is disassembled or removed;

e. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

f. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 12VAC5-481-630.

2. Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance with subsection A of this section to the satisfaction of the agency.

C. Posting. Each area or room containing analytical ~~X-ray~~ x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION—X-RAY EQUIPMENT" or words having a similar intent in accordance with 12VAC5-481-660.

12VAC5-481-3410. Quality management program.

The facility shall implement a quality management program. The facility shall include in the quality management program written notification to the agency within 72 hours of discovery of a reportable event or a misadministration, a recordable event, and recording written directives.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 29, 2014

TO: Virginia State Board of Health

FROM: Adrienne McFadden, MD, JD, FACEP, FAAEM, FCLM
Director, Office of Minority Health and Health Equity

SUBJECT: Regulations for General Assembly Nursing Scholarships (12VAC5-510)

Enclosed for your review are final Regulations for General Assembly Nursing Scholarships (12VAC5-510).

Sections 23-35.9 through 23.35-13 of the Code of Virginia establish a Nursing Scholarship program and mandated a Nursing Scholarship Advisory Committee appointed by the State Board of Health provide scholarships to eligible applicants on an annual basis. The General Assembly Nursing Scholarship Program is intended to address the shortage of trained medical professionals in the Commonwealth. The General Assembly Nursing Scholarship Program has been in existence for over twenty years. Although the field of nursing has evolved since that time, the regulations have not kept up with these changes. Amendments are being proposed to ensure that this program is consistent with how the industry has evolved over time. The amendments add sections pertaining to the administration of this program. These include sections pertaining to definitions, contract terms, reporting requirements, breach of contract, and waiver provisions. The new sections are comparable in nature and wording to regulations for similar programs and congruent with relevant sections of the Code of Virginia.

The proposed regulations pertaining to the currently submitted final regulations were published in the Virginia Register of Regulations on July 15, 2013. The Virginia Department of Health conducted a 60 day public comment period from July 15, 2013 until September 13, 2013. No public comment was received. However, further review of the proposed regulations by the Virginia Department of Health revealed the proposed language was unclear in certain respects. The agency drafted some amendments to the proposed regulations in the final regulations for the Guidelines for General Assembly Nursing Scholarships (12VAC5-510).

The Board of Health is requested to approve the final regulations. Should the Board of Health approve the final regulations, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the final regulations will be published in the Virginia Register of Regulations for a 30 day final adoption period.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-510
Regulation title	Regulations for General Assembly Nursing Scholarships
Action title	Amendments to establish a more comprehensive and up-to-date regulatory framework for administering the nursing scholarship program.
Date this document prepared	April 24, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Sections 23-35.9 through 23.35-13 of the Code of Virginia establish a Nursing Scholarship program and mandated a Nursing Scholarship Advisory Committee appointed by the State Board of Health provide scholarships to eligible applicants on an annual basis. The General Assembly Nursing Scholarship Program is intended to address the shortage of trained medical professionals in the Commonwealth

The General Assembly Nursing Scholarship Program has been in existence for over twenty years. Although the field of nursing has evolved since that time, the regulations have not kept up with these changes. Amendments are being proposed to ensure that this program is consistent with how the industry has evolved over time. The proposed amendments add sections pertaining to the administration of this program. These include sections pertaining to definitions, contract terms, reporting requirements, breach of contract, and waiver provisions. The new sections are comparable in nature and wording to regulations for similar programs and congruent with relevant sections of the Code of Virginia.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The Final Regulations for Guidelines for General Assembly Nursing Scholarships were approved by the Board of Health on_____.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Sections 23-35.9 through 23.35-13 of the Code of Virginia establish a Nursing Scholarship program and mandated a Nursing Scholarship Advisory Committee appointed by the State Board of Health provide scholarships to eligible applicants on an annual basis. Sections 23-35.9 through 23-35-13 define the procedures for administration of the Nursing Scholarship program, such as the composition of the Advisory Committee, the basis for awards, the requirement for a written contract etc. Item 289 Part B of the 2013 Appropriations Act mandates that the financial incentives established in §23-35.9 through 23-35.13 are awarded in accordance with regulations promulgated by the Board of Health.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Sections 23.35-9 through 23.35-13 of the Code of Virginia mandates the creation of a nursing scholarship program for part-time and full time students enrolled in undergraduate and graduate nursing programs. The intent of this regulatory action is to update the regulations. The intent of this regulatory action is to implement the program required by §§ 23-35.9 through 23-35.13 and address the shortage of trained medical professionals in the Commonwealth. The General Assembly Nursing Scholarship Program addresses the workforce shortage by providing financial assistance for education expenses for individuals who have been accepted for enrollment or are enrolled in an approved school of nursing in the Commonwealth of Virginia. Decreasing the workforce shortage of trained medical professionals in the Commonwealth helps protect the health of Virginians by increasing primary care services to underserved areas and populations.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Changes were made to the proposed regulations to add clarification to the final regulations and bring the regulatory chapter into conformity with other Virginia Department of Health Regulations. The following is a summary of the key provisions of the final regulations:

Definitions

Provides clarification on key or frequently used terms in the regulatory text.

Advisory Committee

Establishes that the Advisory Committee appointed pursuant to Va. Code § 23-35.9 shall make all scholarship awards.

Eligibility

Provides requirements regarding Virginia residency, approved educational program enrollment, a 2.5 cumulative GPA in core nursing classes if already enrolled in a program, submission of a completed application, demonstrated financial need, and no active military obligation.

Conditions of Scholarships

Provides guidance and provisions on the contract requirements, calculation of the service obligation, terms of service, employment requirements, reporting, transfer of practice site, default, waiver, partial fulfillment, hardship and default payments.

Number of applications, Amounts of scholarships & How to apply

Provides information and provisions regarding applicant renewals, award amounts, location of application form and deadline dates for submission of applications.

Scholarship contract

Provides the requirements of the scholarship contract which must be entered into by scholarship recipients including the total amount of the award and the award period, agreement to pursue a LPN or RN degree, agreement to begin full time employment within 180 days after the recipient's graduation, agreement to comply with all reporting requirements, agreement to terms of service, signature of the applicant and the commissioner, and any other provisions the commissioner deems appropriate.

Practice Site Selection

Provides that recipients of a Nursing Scholarship shall perform their service obligation in a region of the Commonwealth with a critical shortage of nurses either a health professional shortage area or a medically underserved area. This provision also provides where recipients can locate maps of these areas.

Reporting Requirements

Provides information on the reporting requirements of scholarship participants including verification of employment once every six months and prompt notification in the event of the following changes: name, address, practice site, intention to fulfill service obligation, if the participant ceases to practice as a RN or LPN, or the recipient ceases or no longer intends to complete their nursing program.

Breach of Contract

Provides what circumstances may constitute a breach of contract including: failure to complete nursing studies, failure to complete the term of obligated service under the terms of the contract, falsification of information on the program application or other required documents, and the recipient being terminated for good cause by their employer. This provision also refers recipients to the process for making default payments in the event of breach of contract.

Deferment and waivers

This section provides the limited circumstances in which a recipient may receive a deferment, waiver or variance.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage of the proposed regulatory action to the public will be an increase in the availability of adequate quality nursing care in health professional shortage areas and medically underserved areas in the Commonwealth. Further, facilities in these areas will be better positioned to retain qualified nurses because of the obligation created by accepting the scholarship funds. The Virginia Department of Health sees no disadvantage to the public, the agency or the Commonwealth associated with the proposed regulatory action.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-510-10	<p>Section 32.1-122.6:01 of the Code of Virginia provides the Board of Health the authority to award certain nursing scholarships and loan repayment funds. Fee requirements are specified in § 54.1-3011.1 of the Code of Virginia. Section 54.1-3011.2 of the Code of Virginia establishes the nursing scholarship and loan repayment fund.</p> <p>Sections 23-35.9 through 23-35.13 of the Code of Virginia authorize annual nursing scholarships for students enrolled in undergraduate and graduate nursing programs. Undergraduate nursing programs are defined as those leading to an associate degree, diploma, or baccalaureate degree in nursing. Graduate nursing</p>	<p>Sections 23-35.9 through 23-35.13 of the Code of Virginia authorize annual nursing scholarships for students enrolled in undergraduate and graduate nursing programs. Undergraduate nursing programs are defined as those leading to an associate degree, diploma, or baccalaureate degree in nursing. Graduate nursing programs are those offering masters and doctoral degrees.</p> <p>Under the law, all scholarship awards are made by an Advisory Committee appointed by the State Board of Health. The Advisory Committee consists of eight members: four deans or directors of schools of nursing, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments are for two-year terms and members may not serve</p>	<p>Removal of the unnecessary Legislative Authority Section. Moved the information regarding the advisory committee to Section 15 and moved definitions to this Section. This change brings the format of these regulations more in line with other agency regulations. This creates consistency across programs.</p>

	<p>programs are those offering masters and doctoral degrees.</p> <p>All scholarship awards are made by an Advisory Committee appointed by the State Board of Health. The Advisory Committee consists of eight members: four deans or directors of schools of nursing or their designees, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments are for two-year terms and members may not serve for more than two successive terms in addition to the portion of any unexpired term for which such a member was appointed. The State Board of Health shall schedule appointments to the Advisory Committee in such a manner that at least two persons who have not served during the previous two years are appointed to the Committee.</p> <p>The Department of Health serves as the staff element to the Advisory Committee and plays no role in the determination of scholarship recipients.</p> <p>Advisory Committee shall make the awards with due regard given to scholastic attainment, financial need, character, and adaptability to the nursing profession. With due consideration of the number of applications and the qualifications of all such applicants, the Advisory Committee will, so far as practical, award an equal number of scholarships among the various congressional districts within the Commonwealth.</p>	<p>for more than two successive terms.</p> <p>The Office of Public Health Nursing of the State Health Department serves as the staff element to the Advisory Committee and plays no role in the determination of scholarship recipients.</p> <p>The basis for determining scholarship recipients is established by the Advisory Committee with due regard given to scholastic attainment, financial need, character, and adaptability to the nursing profession.</p> <p><u>The following words and terms when used in this chapter shall have the following meanings:</u></p> <p><u>"Approved nurse education program" means an approved educational program pursuant to Chapter 30 (§ 54.1-3000 et. seq.) of Title 54.1.</u></p> <p><u>"Board" or "Board of Health" means the State Board of Health.</u></p> <p><u>"Commissioner" means the State Health Commissioner.</u></p> <p><u>"Continuous" means no breaks in service greater than a period of six weeks.</u></p> <p><u>"Department" means the Virginia Department of Health.</u></p> <p><u>"Full-time" means at least 32 hours per week for 45 weeks per year.</u></p> <p><u>"Interest" means the legal rate of interest pursuant to § 6.2-302 of the Code of Virginia.</u></p> <p><u>"Licensed Practical Nurse" or "LPN" means a person who is licensed or holds a multistate licensure privilege under the provisions of Chapter 30 of Title 54.1 of the Code of Virginia to practice practical nursing, as defined in § 54.1-3000.</u></p> <p><u>"Penalty" means twice the amount of all monetary payments to the</u></p>	
--	--	--	--

		<p><u>scholarship participant, less any service obligation completed.</u></p> <p><u>"Recipient/participant" means an eligible LPN or RN of an approved nursing program who enters into a contract with the commissioner and participates in the scholarship program.</u></p> <p><u>"Registered Nurse" or "RN" means a person who is licensed or holds a multistate licensure privilege under the provisions Chapter 30 of Title 54.1 of the Code of Virginia to practice professional nursing, as defined in § 54.1-3000.</u></p>	
<p>12VAC5-510-15</p>	<p>The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Board" or "Board of Health" means the State Board of Health.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Continuous" means that there are no breaks in service greater than a period of six weeks.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Full-time" means the equivalent of 32 or more hours per week for at least 45 weeks per year.</p> <p>"Interest" means the legal rate of interest pursuant to the Code of Virginia.</p> <p>"Licensed Practical Nurse" or "LPN" means a nurse who has successfully completed a state-approved practical nursing program, passed a licensing examination known as the NCLEX-PN, and is licensed by the Commonwealth of Virginia to provide routine</p>	<p>The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Board" or "Board of Health" means the State Board of Health.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Continuous" means that there are no breaks in service greater than a period of six weeks.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Full-time" means the equivalent of 32 or more hours per week for at least 45 weeks per year.</p> <p>"Interest" means the legal rate of interest pursuant to the Code of Virginia.</p> <p>"Licensed Practical Nurse" or "LPN" means a nurse who has successfully completed a state-approved practical nursing program, passed a licensing examination known as the NCLEX-PN, and is licensed by the Commonwealth of Virginia to provide routine care under the supervision of a licensed medical practitioner, a professional registered nurse, or other licensed health professional authorized by regulations of the Board of Nursing.</p> <p>"Penalty" means the amount of money equal to twice the amount of</p>	<p>Moved the definition information to Section 10 and moved the information regarding the Advisory Committee to this section. This change brings the format of these regulations more in line with other agency regulations. This creates consistency across programs.</p>

	<p>care under the supervision of a licensed medical practitioner, a professional registered nurse, or other licensed health professional authorized by regulations of the Board of Nursing.</p> <p>"Penalty" means the amount of money equal to twice the amount of all monetary payments to the scholarship recipient, less any service obligation completed.</p> <p>"Practice" means the provision of direct patient care as an LPN or RN in a region of the Commonwealth of Virginia with a critical shortage of nurses.</p> <p>"Recipient" means a student in an LPN or RN program who enters into a contract with the Board of Health and participates in the scholarship program.</p> <p>"Registered Nurse" or "RN" means a nurse who has graduated from an approved nursing program, passed the national licensing examination known as the NCLEX-RN, and has been licensed to practice as a registered nurse by the Board of Nursing in the Commonwealth of Virginia.</p>	<p>all monetary payments to the scholarship recipient, less any service obligation completed.</p> <p>"Practice" means the provision of direct patient care as an LPN or RN in a region of the Commonwealth of Virginia with a critical shortage of nurses.</p> <p>"Recipient" means a student in an LPN or RN program who enters into a contract with the Board of Health and participates in the scholarship program.</p> <p>"Registered Nurse" or "RN" means a nurse who has graduated from an approved nursing program, passed the national licensing examination known as the NCLEX-RN, and has been licensed to practice as a registered nurse by the Board of Nursing in the Commonwealth of Virginia. All scholarship awards shall be made by an Advisory Committee appointed pursuant to Va. Code § 23-35.9.</p>	
<p>12VAC5-510-20</p>	<p>In order to be considered for a General Assembly Nursing Scholarship, applicants must meet the following criteria:</p> <ol style="list-style-type: none"> 1. Be eligible for in-state tuition pursuant to § 23-7.4 of the Code of Virginia at the time a scholarship is awarded. 2. Be accepted or enrolled in a school of nursing in the Commonwealth of Virginia which is approved by the Board of Nursing. 3. If already enrolled in a nursing program, the 	<p>In order to be considered for a General Assembly Nursing Scholarship, an applicants must meet the following criteria shall:</p> <ol style="list-style-type: none"> 1. <u>Be a United States citizen, national, or alien holding an immigration visa or classified as a political refugee;</u> 2. 4. <u>Be a bona fide resident of the State of Virginia by being domiciled in the Commonwealth for at least one year eligible for in-state tuition pursuant to § 23-7.4 of the Code of Virginia at the time a scholarship is awarded as defined</u> 	<p>Insertion of clarifying language that brings these regulations in conformity with current practice and other agency regulations.</p>

	<p>applicant must demonstrate a cumulative grade point average of at least 2.5.</p> <p>4. Submit a completed application form and appropriate grade transcript to the department prior to the published deadline dates.</p> <p>5. Demonstrate financial need which is verified by the Financial Aid Officer/authorized person.</p> <p>Failure to comply with all of these criteria will cause the applicant to be ineligible for a scholarship.</p>	<p><u>by § 23-7.4 of the Code of Virginia:</u></p> <p>2 <u>3.</u> Be accepted for enrollment or enrolled in a <u>an approved</u> school of nursing in the Commonwealth of Virginia <u>preparing him for examination for licensure as a practical nurse or registered nurse;</u> which is approved by the State Board of Nursing.]</p> <p>3 <u>4.</u> If already enrolled in a <u>an approved nursing program in the Commonwealth of Virginia</u>, the applicant must demonstrate a cumulative grade point average of at least 2.5 <u>in core nursing classes;</u></p> <p>4 <u>5.</u> Submit a completed application form and appropriate grade transcript the department prior to the published <u>established</u> deadline dates;</p> <p>5 <u>6.</u> Demonstrate financial need which is verified by the Financial Aid Officer/authorized person <u>school's financial aid officer/authorized person as part of the application process;</u> and</p> <p><u>7. Not have an active military obligation.</u></p> <p>Failure to comply with all of these requirements will cause the applicant to be ineligible for a scholarship.</p>	
<p>12VAC5-510-30</p>	<p>The scholarship recipient agrees to engage in a term of service involving continuous full-time nursing practice in a region of the Commonwealth with a critical shortage of nurses. The maximum award amounts and terms of service are determined as per §§ 23-35.9 and 23-35.11 of the Code of Virginia. Employment must begin within 180 days of the recipient's graduation date. Time spent in an "on-call" status shall not be counted toward the</p>	<p>The scholarship recipient agrees to engage in a term of service involving continuous full-time nursing practice in a region of the Commonwealth with a critical shortage of nurses. The maximum award amounts and terms of service are determined as per §§ 23-35.9 and 23-35.11 of the Code of Virginia. Employment must begin within 180 days of the recipient's graduation date. Time spent in an "on-call" status shall not be counted toward the number of hours worked per week. Voluntary military service, even if stationed in Virginia, cannot be used to repay the service obligation. If the</p>	<p>These changes rearrange the language of the section to bring the regulations in line with current practice and other agency regulations. These changes are clarifying in nature.</p>

	<p>number of hours worked per week. Voluntary military service, even if stationed in Virginia, cannot be used to repay the service obligation. If the recipient begins employment at a practice site, but that employment is later terminated, the recipient must transfer to another approved practice site in the Commonwealth within 90 days of termination.</p>	<p>recipient begins employment at a practice site, but that employment is later terminated, the recipient must transfer to another approved practice site in the Commonwealth within 90 days of termination.</p> <p><u>A. Prior to becoming a participant in the General Assembly Nursing Scholarship program, the applicant shall enter into a contract with the commissioner agreeing to the terms and conditions upon which the scholarship is granted.</u></p> <p><u>B. For each \$2,000 of scholarship money received, the participant agrees to engage in the equivalent of one year of full-time nursing practice in a region with a critical shortage of nurses in the Commonwealth. The recipient shall notify the department, within 180 days of being awarded a nursing diploma or degree, of the type of nursing practice to be performed and give the name and address of the employer for approval. Voluntary military service, even if stationed in Virginia, cannot be used to repay the service obligation required when a scholarship is awarded.</u></p> <p><u>The participant may request approval of a change of practice site. Such requests shall be made in writing. The department in its discretion may approve such a request.</u></p> <p><u>C. If a participant fails to complete his studies, the full amount of the scholarships or scholarships received, plus the applicable interest charge, shall be repaid. A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship plus interest.</u></p> <p><u>D. If upon graduation a participant leaves the Commonwealth or fails to engage or ceases to engage in nursing practice in a region with a</u></p>	
--	---	--	--

		<p><u>critical shortage of nurses in the Commonwealth before all employment conditions of the scholarship award are fulfilled, the participant shall repay the award amount reduced by the proportion of obligated years served plus the applicable interest and penalty.</u></p> <p><u>E. All default payments shall be made payable to the Commonwealth of Virginia.</u></p>	
12VAC5-510-40	<p>Scholarships are awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in his studies, apply for and receive scholarship awards for any succeeding academic year or years. No student may receive scholarships for more than a total of four years.</p>	<p>Scholarships are <u>shall be</u> awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in his studies, <u>which is demonstrated by a cumulative grade point average of 2.5 in core nursing classes,</u> apply for and receive scholarship awards for any a succeeding academic year or years. No student may <u>shall</u> receive scholarships for more than a total of four years.</p>	<p>Minor clarifying language which brings the regulations in conformity with current practice and other agency regulations. Primarily elaborating the requirements for an applicant's renewal of scholarship.</p>
12VAC5-510-50	<p>The amount of each scholarship award is dependent upon the amount of money appropriated by the General Assembly and the number of qualified applicants. No recipient shall receive an award for less than \$150.</p>	<p>The amount <u>number</u> of each scholarships awarded is <u>shall be</u> dependent upon the amount of money appropriated by the General Assembly, <u>the amount of the funds available within the Nursing Scholarship and Loan Repayment Fund administered by the Board of Nursing pursuant to § 54.1-3011.2 of the Code of Virginia,</u> and the number of qualified applicants. No <u>Each</u> recipient shall receive an award for of less than \$150 <u>\$2,000 per year.</u></p>	<p>Minor clarifying language which brings the regulations in conformity with current practice and other agency regulations. Primarily noting the award amount and another source of funding for the Nursing Scholarship Program.</p>
12VAC5-510-60	<p>Applications and guidelines are made available to all prospective students online through the department's website.</p>	<p>Applications and guidelines are made available to all prospective students online through the department's website.</p> <p><u>Eligible applicants shall submit a complete application made available by the department on the department's website. A complete application shall include documentation of all eligibility requirements. The deadline for submission of the application shall be announced by the department</u></p>	<p>Rewording of the section. This language brings the section more in line with other agency regulations. These changes are clarifying and not substantive in nature.</p>

		<u>on the department's website.</u>	
12VAC5-510-80	<p>Applicants selected to receive scholarship awards by the Advisory Committee must sign and return a written contract to the department by the specified deadline date. Failure to return the contract by the specified deadline date may result in the award being rescinded. At minimum, the scholarship contract shall include the following elements:</p> <ol style="list-style-type: none"> 1. Agreement with the total amount of the award and the award period. 2. Agreement to pursue an LPN or RN degree in nursing at a school of nursing in the Commonwealth of Virginia that is approved by the Board of Nursing. 3. Agreement to begin continuous full-time employment within 180 days of the recipient's graduation. 4. Agreement to comply with all reporting requirements. 5. Agreement with the terms of service requiring continuous full-time nursing practice in the Commonwealth for a specified period of time and the terms and conditions associated with a breach of contract. <p>A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship</p>	<p>Applicants selected to receive scholarship awards by the Advisory Committee must shall sign and return a written contract to the department by the specified deadline date. Failure to return the contract by the specified deadline date may result in the award being rescinded. At minimum, the scholarship contract shall include the following elements:</p> <ol style="list-style-type: none"> 1. Agreement with The total amount of the award and the award period; 2. Agreement to pursue an LPN or RN degree in nursing at a school of nursing in the Commonwealth of Virginia that is approved by the Board of Nursing; 3. Agreement to begin continuous full-time employment within 180 days of the recipient's graduation; 4. Agreement to comply with all reporting requirements; 5. Agreement to the terms of service requiring continuous full-time nursing practice in the Commonwealth for a specified period of time and the terms and conditions associated with a breach of contract; 6. <u>Signature of the applicant;</u> 7. <u>Signature of the commissioner or his designee; and</u> 8. <u>Other provisions as the commissioner may deem appropriate.</u> <p>A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship plus interest.</p>	Minor technical edits.

	plus interest.		
12VAC5-510-85	N/A	Each recipient shall perform his service obligation in a region with a critical shortage of nurses in the Commonwealth. A recipient shall perform his service obligation at a practice site in either a health professional shortage area or a medically underserved area. Maps of health professional shortage areas and medically underserved areas shall be available on the department's website.	The insertion of this section clarifies where recipients of the Nursing Scholarship must perform their obligated service.
12VAC5-510-90	<p>Monitoring of the service obligation of recipients shall be conducted on an ongoing basis by the department.</p> <p>The recipient shall permit the nursing school to provide information regarding enrollment status and progress in the program.</p> <p>The recipient shall notify the department, within 180 days of being awarded a nursing diploma or degree, of the type of nursing practice to be performed and give the name and address of the employer for approval.</p> <p>The recipient shall submit to the department verification of employment documentation every four months until the contract obligation has been completely fulfilled.</p> <p>The recipient shall maintain practice records in a manner that will allow the department to readily determine compliance with the terms and conditions of the contract.</p> <p>The recipient shall notify the department in writing within 30 days of any of the following events:</p> <ol style="list-style-type: none"> 1. Recipient changes name; 2. Recipient changes 	<p>Monitoring of the service obligation of recipients shall be conducted on an ongoing basis by the department.</p> <p>The recipient shall permit the nursing school to provide information regarding enrollment status and progress in the program.</p> <p>The recipient shall notify the department, within 180 days of being awarded a nursing diploma or degree, of the type of nursing practice to be performed and give the name and address of the employer for approval.</p> <p>The recipient shall submit to the department verification of employment documentation every four months until the contract obligation has been completely fulfilled.</p> <p>The recipient shall maintain practice records in a manner that will allow the department to readily determine compliance with the terms and conditions of the contract.</p> <p><u>Each participant shall provide information as required by the department to verify compliance with all requirements of the nursing scholarship program (e.g., verification of employment by submitting a Verification of Employment form once every six months).</u></p>	Removal of unnecessary language. Insertion of minor clarifying language. These changes bring the regulations into conformity with current practice and other agency regulations.

	<p>address;</p> <p>3. Recipient changes nursing program;</p> <p>4. Recipient changes practice site;</p> <p>5. Recipient no longer intends to fulfill service obligation as a nurse in the Commonwealth; or</p> <p>6. Recipient ceases to practice as an RN or LPN.</p>	<p>The recipient shall notify the department in writing within 30 days if any of the following events occur:</p> <p>1. Recipient changes name;</p> <p>2. Recipient changes address;</p> <p>3. Recipient changes nursing program;</p> <p>4. Recipient changes practice site (<u>Recipient is required to request in writing and obtain prior approval of changes in practice site.</u>);</p> <p>5. Recipient no longer intends <u>or is unable</u> to fulfill service obligation as a nurse in the Commonwealth;</p> <p>6. Recipient ceases to practice as an RN or LPN; <u>or</u></p> <p><u>7. Recipient ceases or no longer intends to complete his nursing program.</u></p>	
<p>12VAC5-510-100</p>	<p>The following are the conditions that constitute a breach of contract:</p> <p>1. The recipient fails to complete his nursing studies.</p> <p>2. The recipient fails to begin or complete the term of obligated service within the time frames as specified in the scholarship contract.</p> <p>3. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents.</p> <p>In the event of a breach of contract where the recipient fails to complete his nursing studies, the recipient shall reimburse the Commonwealth of Virginia for the total amount of the scholarship award, plus interest.</p>	<p>The following are the conditions that may constitute a breach of contract:</p> <p>1. The recipient fails to complete his nursing studies;</p> <p>2. The recipient fails to begin or complete the term of obligated service under the terms and conditions of the scholarship contract;</p> <p>3. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents; <u>and</u></p> <p><u>4. The recipient's employment being terminated for good cause as determined by the employer and confirmed by the department. If employment is terminated for reasons beyond the participant's control (e.g., closure of site), the participant must transfer to another site approved by the board in the Commonwealth within six months</u></p>	<p>Removal of unnecessary language. The process for payment of default payments is covered in 12VAC5-510-30 so the repetitive language was eliminated from this section. Insertion of another example of a breach of contract. These changes are clarifying in nature.</p>

	<p>In the event of a breach of contract where the recipient fails to begin or complete the term of obligated service within the time frames as specified in the scholarship contract, the recipient shall reimburse the Commonwealth of Virginia for the total amount of the scholarship, plus penalty and interest.</p> <p>In the event of a breach of contract where the recipient has partially fulfilled their obligation, the total amount of reimbursement shall be prorated by the proportion of obligation completed.</p>	<p><u>of termination. Failure of participant to transfer to another site shall be deemed to be a breach of the contract.</u></p> <p>In the event of a breach of contract where the recipient fails to complete his nursing studies, the recipient shall reimburse the Commonwealth of Virginia for the total amount of the scholarship award, plus interest.</p> <p>In the event of a breach of contract where the recipient fails to begin or complete the term of obligated service within the time frames as specified in the scholarship contract, the recipient shall reimburse the Commonwealth of Virginia for the total amount of the scholarship, plus penalty and interest.</p> <p><u>In the event of a breach of contract the recipient shall make default payments as described in 12VAC5-510-30.</u> In the event of a breach of contract where the recipient has partially fulfilled their obligation, the total amount of reimbursement shall be prorated by the proportion of obligation completed.</p>	
<p>12VAC5-510-110</p>	<p>The requirement for continuous engagement in full-time nursing practice may be deferred by the board if the scholarship recipient requests a deferment to pursue a more advanced degree in nursing or a nursing-related field. This deferment, if granted, shall not relieve the recipient of the responsibility to complete the remaining portion of the obligation upon completion of the advanced nursing degree.</p> <p>If the recipient is in default due to death or permanent disability, the obligation to reimburse the Commonwealth of Virginia for the total amount of the scholarship award plus</p>	<p><u>A.</u> The requirement for continuous engagement in full-time nursing practice may be deferred by the board if the scholarship recipient requests a deferment to pursue a more advanced degree in nursing or a nursing-related field <u>an undergraduate or graduate degree</u> in nursing or related to nursing activities. This deferment, if granted, shall not relieve the recipient of the responsibility to complete the remaining portion of the obligation upon completion of the advanced nursing degree.</p> <p><u>B.</u> If the participant is in default due to death or permanent disability the obligation to reimburse the Commonwealth of Virginia for the total amount of the scholarship award plus interest may be partially or completely waived by the board upon application of the recipient or the recipient's estate to the board.</p>	<p>Insertion of clarifying language.</p>

	<p>interest may be partially or completely waived by the board upon application of the recipient or the recipient's estate to the board.</p> <p>Other individual situations involving severe hardship may be considered by the board for deferment of the service obligation or partial or total waiver of the repayment obligation. Deferment and waiver requests will not be permitted as a matter of course, but may be allowed in the most compelling cases.</p> <p>All requests for deferments or waivers must be submitted in writing to the department for consideration and final disposition by the Advisory Committee or the board.</p>	<p><u>so as not to be able to engage in nursing practice in a region with a critical shortage of nurses in the Commonwealth, the participant or his personal representative may be relieved of his obligation under the contract to engage in nursing practice, upon repayment of the total amount of scholarship received plus applicable interest. For participants completing part of the nursing obligation prior to becoming permanently disabled or in the event of death, the total amount of scholarship funds owed shall be reduced by the proportion of obligated years served. The obligation to make restitution may be waived by the board upon application of the participant or the participant's personal representative to the board.</u></p> <p>Other individual situations involving severe hardship may be considered by the board for deferment of the service obligation or partial or total waiver of the repayment obligation. Deferment and waiver requests will not be permitted as a matter of course, but may be allowed in the most compelling cases.</p> <p><u>C. Individual cases of undue hardship may be considered for a variance by the board of payment or service pursuant to § 32.1-12 of the Code of Virginia.</u></p> <p><u>D. All requests for deferments, waivers or variances must be submitted in writing to the department for consideration and final disposition by the Advisory Committee or board.</u></p>	
--	---	--	--

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

The Virginia Department of Health conducted a 60 day public comment period from July 15, 2013 until September 13th, 2013. No public comment was received.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-510-10 - Legislative Authority	12VAC5-510-10 - Definitions	<p>Sections 23-35.9 through 23-35.13 of the Code of Virginia authorize annual nursing scholarships for students enrolled in undergraduate and graduate nursing programs. Undergraduate nursing programs are defined as those leading to an associate degree, diploma, or baccalaureate degree in nursing. Graduate nursing programs are those offering masters and doctoral degrees.</p> <p>Under the law, all scholarship awards are made by an Advisory Committee appointed by the State Board of Health. The Advisory Committee consists of eight members: four deans or directors of schools of nursing, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments are for two-year terms and members may not serve for more than two successive terms.</p> <p>The Office of Public Health Nursing of the State Health Department serves as the staff element to the Advisory Committee and plays no role in the determination of scholarship recipients.</p> <p>The basis for determining scholarship recipients is established by the Advisory Committee with due regard given to scholastic attainment, financial need, character, and adaptability to the nursing profession.</p>	<p>Sections 23-35.9 through 23-35.13 of the Code of Virginia authorize annual nursing scholarships for students enrolled in undergraduate and graduate nursing programs. Undergraduate nursing programs are defined as those leading to an associate degree, diploma, or baccalaureate degree in nursing. Graduate nursing programs are those offering masters and doctoral degrees.</p> <p>Under the law, all scholarship awards are made by an Advisory Committee appointed by the State Board of Health. The Advisory Committee consists of eight members: four deans or directors of schools of nursing, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments are for two-year terms and members may not serve for more than two successive terms.</p> <p>The Office of Public Health Nursing of the State Health Department serves as the staff element to the Advisory Committee and plays no role in the determination of scholarship recipients.</p> <p>The basis for determining scholarship recipients is established by the Advisory Committee with due regard given to scholastic attainment, financial need, character, and adaptability to the nursing profession.</p> <p><u>The following words and terms when used in this chapter shall have the following meanings:</u></p> <p><u>"Approved nurse education program" means an approved educational program</u></p>

			<p><u>pursuant to Chapter 30 (§ 54.1-3000 et. seq.) of Title 54.1.</u></p> <p><u>"Board" or "Board of Health" means the State Board of Health.</u></p> <p><u>"Commissioner" means the State Health Commissioner.</u></p> <p><u>"Continuous" means no breaks in service greater than a period of six weeks.</u></p> <p><u>"Department" means the Virginia Department of Health.</u></p> <p><u>"Full-time" means at least 32 hours per week for 45 weeks per year.</u></p> <p><u>"Interest" means the legal rate of interest pursuant to § 6.2-302 of the Code of Virginia.</u></p> <p><u>"Licensed Practical Nurse" or "LPN" means a person who is licensed or holds a multistate licensure privilege under the provisions of Chapter 30 of Title 54.1 of the Code of Virginia to practice practical nursing, as defined in § 54.1-3000.</u></p> <p><u>"Penalty" means twice the amount of all monetary payments to the scholarship participant, less any service obligation completed.</u></p> <p><u>"Recipient/participant" means an eligible LPN or RN of an approved nursing program who enters into a contract with the commissioner and participates in the scholarship program.</u></p> <p><u>"Registered Nurse" or "RN" means a person who is licensed or holds a multistate licensure privilege under the provisions Chapter 30 of Title 54.1 of the Code of Virginia to practice professional nursing, as defined in § 54.1-3000.</u></p> <p>Rationale: Removal of the unnecessary Legislative Authority Section. Moved the information regarding the advisory committee to Section 15 and moved definitions to this Section. This change brings the format of these regulations more in line with other agency regulations. This creates consistency across programs.</p>
N/A	12VAC5-510-	N/A	The following words and terms when

	<p>15- Advisory Committee</p>	<p>used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Board" or "Board of Health" means the State Board of Health.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Continuous" means that there are no breaks in service greater than a period of six weeks.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Full-time" means the equivalent of 32 or more hours per week for at least 45 weeks per year.</p> <p>"Interest" means the legal rate of interest pursuant to the Code of Virginia.</p> <p>"Licensed Practical Nurse" or "LPN" means a nurse who has successfully completed a state-approved practical nursing program, passed a licensing examination known as the NCLEX-PN, and is licensed by the Commonwealth of Virginia to provide routine care under the supervision of a licensed medical practitioner, a professional registered nurse, or other licensed health professional authorized by regulations of the Board of Nursing.</p> <p>"Penalty" means the amount of money equal to twice the amount of all monetary payments to the scholarship recipient, less any service obligation completed.</p> <p>"Practice" means the provision of direct patient care as an LPN or RN in a region of the Commonwealth of Virginia with a critical shortage of nurses.</p> <p>"Recipient" means a student in an LPN or RN program who enters into a contract with the Board of Health and participates in the scholarship program.</p> <p>"Registered Nurse" or "RN" means a nurse who has graduated from an approved nursing program, passed the national licensing examination known as the NCLEX-RN, and has been licensed to practice as a registered nurse by the</p>
--	-------------------------------	--

			<p>Board of Nursing in the Commonwealth of Virginia.</p> <p><u>All scholarship awards shall be made by an Advisory Committee appointed pursuant to Va. Code § 23-35.9.</u></p> <p>Rationale: Moved the information regarding the Advisory Committee to this section. This change brings the format of these regulations more in line with other agency regulations. This creates consistency across programs.</p>
<p>12VAC5-510-20-Eligibility.</p>	<p>12VAC5-510-20- Eligibility.</p>	<p>In order to be considered for a General Assembly Nursing Scholarship, applicants must meet the following criteria:</p> <ol style="list-style-type: none"> 1. Be a resident of the State of Virginia for at least one year. 2. Be accepted or enrolled in a school of nursing in the State of Virginia which is approved by the State Board of Nursing. The only exception is for students pursuing graduate degrees not offered in the Commonwealth. 3. If already enrolled in a nursing program, the applicant must demonstrate a cumulative grade point average of at least 2.5. 4. Submit a completed application form and appropriate grade transcript to the Office of Public Health Nursing prior to the established deadline dates. 5. Demonstrate financial need which is verified by the Financial Aid Officer/authorized person. <p>FAILURE TO COMPLY WITH ALL OF THESE CRITERIA WILL CAUSE THE APPLICANT TO BE INELIGIBLE FOR A SCHOLARSHIP.</p>	<p>In order to be considered for a General Assembly Nursing Scholarship, an applicants must meet the following criteria shall:</p> <ol style="list-style-type: none"> <u>1. Be a United States citizen, national, or alien holding an immigration visa or classified as a political refugee;</u> <u>2. 4. Be a bona fide resident of the State of Virginia by being domiciled in the Commonwealth for at least one year as defined by § 23-7.4 of the Code of Virginia;</u> <u>2 3. Be accepted for enrollment or enrolled in a an approved school of nursing in the State Commonwealth of Virginia preparing him for examination for licensure as a practical nurse or registered nurse; which is approved by the State Board of Nursing. The only exception is for students pursuing graduate degrees not offered in the Commonwealth.</u> <u>3 4. If already enrolled in a an approved nursing program in the Commonwealth of Virginia , the applicant must demonstrate a cumulative grade point average of at least 2.5 in core nursing classes.</u> <u>4 5. Submit a completed application form and appropriate grade transcript to the Office of Public Health Nursing prior to the established deadline dates ;</u> <u>5 6. Demonstrate financial need which is verified by the Financial Aid Officer/authorized person school's financial aid officer/authorized person as part of the application process; and]</u>

			<p><u>7. Not have an active military obligation.</u></p> <p>FAILURE TO COMPLY WITH ALL OF THESE CRITERIA WILL CAUSE THE APPLICANT TO BE INELIGIBLE FOR A SCHOLARSHIP.</p> <p><u>Failure to comply with all of these requirements will cause the applicant to be ineligible for a scholarship.</u></p> <p>Rationale: Insertion of clarifying language that brings these regulations in conformity with current practice and other agency regulations.</p>
<p>12VAC5-510-30 - Conditions of scholarships</p>	<p>12VAC5-510-30 - Conditions of scholarships</p>	<p>It is important that all applicants fully understand the conditions of acceptance of a General Assembly Nursing Scholarship. These awards are not outright gifts. For each \$100 of scholarship money received, the recipient agrees to engage in full-time (40 hours per week) nursing practice in the Commonwealth for one month. Therefore, if a student receives \$500 in scholarship awards, they must repay that amount by working continuously for 5 months. Full-time employment must begin within 60 days of the recipient's graduation date. Voluntary military service, even if stationed in Virginia, cannot be used to repay scholarship awards.</p> <p>If a scholarship recipient fails to complete their studies, or engage in full-time nursing practice in Virginia, the full amount of money represented in the scholarship(s) received, plus an annual interest charge, must be refunded.</p> <p>If a recipient leaves the State, or ceases to engage in full-time nursing practice before all employment conditions of the scholarship award are fulfilled, the recipient must repay the balance on his/her account plus an annual interest charge.</p> <p>All refund checks should be made payable to the Commonwealth of Virginia and mailed to:</p> <p>Office of Public Health Nursing</p>	<p>It is important that all applicants fully understand the conditions of acceptance of a General Assembly Nursing Scholarship. These awards are not outright gifts. For each \$100 of scholarship money received, the recipient agrees to engage in full-time (40 hours per week) nursing practice in the Commonwealth for one month. Therefore, if a student receives \$500 in scholarship awards, they must repay that amount by working continuously for 5 months. Full-time employment must begin within 60 days of the recipient's graduation date. Voluntary military service, even if stationed in Virginia, cannot be used to repay scholarship awards.</p> <p>If a scholarship recipient fails to complete their studies, or engage in full-time nursing practice in Virginia, the full amount of money represented in the scholarship(s) received, plus an annual interest charge, must be refunded.</p> <p>If a recipient leaves the State, or ceases to engage in full-time nursing practice before all employment conditions of the scholarship award are fulfilled, the recipient must repay the balance on his/her account plus an annual interest charge.</p> <p>All refund checks should be made payable to the Commonwealth of Virginia and mailed to:</p> <p>Office of Public Health Nursing</p> <p>State Health Department</p>

		<p>State Health Department 1500 East Main Street Suite 227 Richmond, Virginia 23219</p> <p>Before any scholarship is awarded, the applicant must sign a written contract agreeing to the terms established by law and the Advisory Committee.</p>	<p>1500 East Main Street Suite 227 Richmond, Virginia 23219</p> <p>Before any scholarship is awarded, the applicant must sign a written contract agreeing to the terms established by law and the Advisory Committee. }</p> <p><u>A. Prior to becoming a participant in the General Assembly Nursing Scholarship program, the applicant shall enter into a contract with the commissioner agreeing to the terms and conditions upon which the scholarship is granted.</u></p> <p><u>B. For each \$2,000 of scholarship money received, the participant agrees to engage in the equivalent of one year of full-time nursing practice in a region with a critical shortage of nurses in the Commonwealth. The recipient shall notify the department, within 180 days of being awarded a nursing diploma or degree, of the type of nursing practice to be performed and give the name and address of the employer for approval. Voluntary military service, even if stationed in Virginia, cannot be used to repay the service obligation required when a scholarship is awarded.</u></p> <p><u>The participant may request approval of a change of practice site. Such requests shall be made in writing. The department in its discretion may approve such a request.</u></p> <p><u>C. If a participant fails to complete his studies, the full amount of the scholarships or scholarships received, plus the applicable interest charge, shall be repaid. A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship plus interest.</u></p> <p><u>D. If upon graduation a participant leaves the Commonwealth or fails to engage or ceases to engage in nursing practice in a region with a critical shortage of nurses in the Commonwealth before all employment conditions of the scholarship award are fulfilled, the participant shall</u></p>
--	--	--	---

			<p><u>repay the award amount reduced by the proportion of obligated years served plus the applicable interest and penalty.</u></p> <p><u>E. All default payments shall be made payable to the Commonwealth of Virginia.</u></p> <p>Rationale: These changes rearrange the language of the section and update the regulations to bring the regulations in line with current practice and other agency regulations. These changes are clarifying in nature.</p>
12VAC5-510-40. Number of applications per student.	12VAC5-510-40. Number of applications per student.	Scholarships are awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in his/her studies, apply for and receive scholarship awards for any succeeding academic year or years. No student may receive scholarships for more than a total of five years.	<p>Scholarships are shall be awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in his/her <u>his</u> studies, <u>which is demonstrated by a cumulative grade point average of 2.5 in core nursing classes</u>, apply for and receive scholarship awards for any a succeeding academic year or years. No student may <u>shall</u> receive scholarships for more than a total of five <u>four</u> years.</p> <p>Rationale: Minor clarifying language which brings the regulations in conformity with current practice and other agency regulations. Primarily elaborating the requirements for an applicant's renewal of scholarship.</p>
12VAC5-510-50- Amounts of scholarships.	12VAC5-510-50- Amounts of scholarships.	The amount of each scholarship award is dependent upon the amount of money appropriated by the General Assembly and the number of qualified applicants. No recipient will receive an award for less than one hundred and fifty dollars. Graduate nursing scholarships may not exceed four thousand dollars annually.	<p>The amount <u>number</u> of each scholarships awarded is <u>shall be</u> dependent upon the amount of money appropriated by the General Assembly, <u>the amount of the funds available within the Nursing Scholarship and Loan Repayment Fund administered by the Board of Nursing pursuant to § 54.1-3011.2 of the Code of Virginia</u>, and the number of qualified applicants. No <u>Each</u> recipient will <u>shall</u> receive an award for of less than one hundred and fifty dollars <u>\$2,000 per year</u>. Graduate nursing scholarships may not exceed four thousand dollars annually.</p> <p>Rationale: Minor clarifying language which brings the regulations in conformity with current practice and other agency regulations. Primarily noting the maximum award amount and another source of funding for the Nursing Scholarship Program.</p>
12VAC5-	12VAC5-510-	Applications and Guidelines are	Applications and Guidelines are available

<p>510-60 - How to apply.</p>	<p>60 - How to apply.</p>	<p>available from the Dean/Director of your school or from the Financial Aid Office.</p> <p>If a student is pursuing a graduate degree not available in Virginia, applications may be obtained directly from the Office of Public Health Nursing, State Health Department, 1500 East Main Street, Suite 227, Richmond, VA 23219.</p>	<p>from the Dean/Director of your school or from the Financial Aid Office.</p> <p>If a student is pursuing a graduate degree not available in Virginia, applications may be obtained directly from the Office of Public Health Nursing, State Health Department, 1500 East Main Street, Suite 227, Richmond, VA 23219.</p> <p><u>Eligible applicants shall submit a complete application made available by the department on the department's website. A complete application shall include documentation of all eligibility requirements. The deadline for submission of the application shall be announced by the department on the department's website.</u></p> <p>Rationale: This language brings the section more in line with other agency regulations. This change is intended to update the regulations to current practice.</p>																																								
<p>12VAC5-510-70 - Deadline dates</p>	<p>N/A</p>	<p>Applications will not be accepted in the Office of Public Health Nursing more than 6 months in advance of the following deadline dates:</p> <p>March 15 - for students already enrolled in schools of nursing.</p> <p>June 15 - for new students entering nursing programs.</p> <p>APPLICATIONS AND/OR TRANSCRIPTS RECEIVED AFTER 5:00 PM ON THE ABOVE DATES WILL NOT BE CONSIDERED FOR SCHOLARSHIP AWARDS.</p> <p>FLOW CHART OF RESPONSIBILITIES</p> <table border="1" data-bbox="565 1528 1008 1892"> <tr> <td colspan="4">D - Dean or Director</td> </tr> <tr> <td colspan="4">FAO - Financial Aid Officer</td> </tr> <tr> <td colspan="4">S-R - Student-Recipient</td> </tr> <tr> <td>RESPONSIBILITY</td> <td>D</td> <td>FAO</td> <td>S-R</td> </tr> <tr> <td>Distribute applications & Guidelines to those</td> <td>X</td> <td>X</td> <td></td> </tr> </table>	D - Dean or Director				FAO - Financial Aid Officer				S-R - Student-Recipient				RESPONSIBILITY	D	FAO	S-R	Distribute applications & Guidelines to those	X	X		<p>Applications will not be accepted in the Office of Public Health Nursing more than 6 months in advance of the following deadline dates:</p> <p>March 15 - for students already enrolled in schools of nursing.</p> <p>June 15 - for new students entering nursing programs.</p> <p>APPLICATIONS AND/OR TRANSCRIPTS RECEIVED AFTER 5:00 PM ON THE ABOVE DATES WILL NOT BE CONSIDERED FOR SCHOLARSHIP AWARDS.</p> <p>FLOW CHART OF RESPONSIBILITIES</p> <table border="1" data-bbox="1040 1602 1531 1892"> <tr> <td colspan="4">D - Dean or Director</td> </tr> <tr> <td colspan="4">FAO - Financial Aid Officer</td> </tr> <tr> <td colspan="4">S-R - Student-Recipient</td> </tr> <tr> <td>RESPONSIBILITY</td> <td>D</td> <td>FAO</td> <td>S-R</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </table>	D - Dean or Director				FAO - Financial Aid Officer				S-R - Student-Recipient				RESPONSIBILITY	D	FAO	S-R				
D - Dean or Director																																											
FAO - Financial Aid Officer																																											
S-R - Student-Recipient																																											
RESPONSIBILITY	D	FAO	S-R																																								
Distribute applications & Guidelines to those	X	X																																									
D - Dean or Director																																											
FAO - Financial Aid Officer																																											
S-R - Student-Recipient																																											
RESPONSIBILITY	D	FAO	S-R																																								

		students who otherwise could not provide sufficient funds for themselves while in school.				Distribute applications & Guidelines to those students who otherwise could not provide sufficient funds for themselves while in school.	X	X	-
		Maintain supply of current scholarship applications and guidelines. Notify the Office of Public Health Nursing when applications are needed.	X			Maintain supply of current scholarship applications and guidelines. Notify the Office of Public Health Nursing when applications are needed.	X	-	-
		Make certain all parts of the application are completed, including the Financial Aid Officer/Authorized Person and Dean/Director signatures.			X	Make certain all parts of the application are completed, including the Financial Aid Officer/Authorized Person and Dean/Director signatures.	-	-	X
		Be certain that a current transcript of grades (high school, or college if now attending) is sent to the Office of Public Health Nursing when applying for a scholarship (original and repeat requests) before deadline dates.			X	Be certain that a current transcript of grades (high school, or college if now attending) is sent to the Office of Public Health Nursing when applying for a scholarship (original and repeat requests) before deadline dates.	-	-	X
		Review entire Section V Financial Data of application. Review whatever school records are accessible to determine the individual applicant's assets and expenditures.		X		Review entire Section V Financial Data of application. Review whatever school records are accessible to determine the individual applicant's assets and expenditures.	-	-	X
		Recommend amount of scholarship to be		X		Review entire Section V Financial Data of application.	-	X	-

		awarded. Should there be a conflict between the student's request and the Financial Aid Officer's/Authorized Person's opinion of the amount that is needed, an explanation should be included.				Review whatever school records are accessible to determine the individual applicant's assets and expenditures.			
		Review the completed application form before affixing the signature thereby indicating:	X			Recommend amount of scholarship to be awarded. Should there be a conflict between the student's request and the Financial Aid Officer's/Authorized Person's opinion of the amount that is needed, an explanation should be included.	-	X	-
		A. The applicant has properly completed the application form.							
		B. The Financial Aid Officer has verified proof of need.							
		C. The applicant's entrance and graduation dates are correct.				Review the completed application form before affixing the signature thereby indicating:	X	-	-
		D. The school of nursing is recommending the applicant for a scholarship based upon potential nursing ability.				A. The applicant has properly completed the application form.	-	-	-
		Furnish whatever pertinent data that would be helpful to the scholarship committee when making the awards.	X	X	X	B. The Financial Aid Officer has verified proof of need.	-	-	-
		Forward the completed and			X	C. The applicant's entrance and graduation dates are correct.	-	-	-

		signed application to the Office of Public Health Nursing before deadline dates.				- D. The school of nursing is recommending the applicant for a scholarship based upon potential nursing ability.	-	-	-
		Submit a transcript of grades to the Office of Public Health Nursing at the end of each grading period during scholarship year.			X	Furnish whatever pertinent data that would be helpful to the scholarship committee when making the awards.	X	X	X
		Notify the Office of Public Health Nursing when student-recipient fails, transfers or withdraws from the school.	X		X	Forward the completed and signed application to the Office of Public Health Nursing before deadline dates.	-	-	X
		Notify the Office of Public Health Nursing when student-recipient graduation date is changed.	X		X	Submit a transcript of grades to the Office of Public Health Nursing at the end of each grading period during scholarship year.	-	-	X
		Notify the Office of Public Health Nursing when there is a change in recipient's name and/or address			X	Notify the Office of Public Health Nursing when student-recipient fails, transfers or withdraws from the school.	X	-	X
		Upon graduation, notify the Office of Public Health Nursing of plans for employment and beginning date of employment.			X	Notify the Office of Public Health Nursing when student-recipient graduation date is	X	-	X
		Submit verification of employment to Office of Public Health Nursing at least every 6 months until work obligation is fulfilled.			X				

			<p>changed.</p> <p>Notify the Office of Public Health Nursing when there is a change in recipient's name and/or address</p>	-	-	X
			<p>Upon graduation, notify the Office of Public Health Nursing of plans for employment and beginning date of employment.</p>	-	-	X
			<p>Submit verification of employment to Office of Public Health Nursing at least every 6 months until work obligation is fulfilled.</p>	-	-	X
			<p>Rationale: Repeal of the section. The deadline dates shall be posted on the Department's website which is noted in 12VAC5-510-60. This allows the program more fluidity and will not require a regulation change when changes to the deadlines are necessary from year to year.</p>			
N/A	12VAC5-510-80. Scholarship contract.	N/A	<p><u>Applicants selected to receive scholarship awards by the Advisory Committee shall sign and return a written contract to the department by the specified deadline date. Failure to return the contract by the specified deadline date may result in the award being rescinded. At minimum, the scholarship contract shall include the following elements:</u></p> <ol style="list-style-type: none"> <u>1. The total amount of the award and the award period;</u> <u>2. Agreement to pursue an LPN or RN degree in nursing at a school of nursing</u> 			

			<p><u>in the Commonwealth of Virginia that is approved by the Board of Nursing;</u></p> <p><u>3. Agreement to begin continuous full-time employment within 180 days of the recipient's graduation;</u></p> <p><u>4. Agreement to comply with all reporting requirements;</u></p> <p><u>5. Agreement to the terms of service requiring continuous full-time nursing practice in the Commonwealth for a specified period of time and the terms and conditions associated with a breach of contract;</u></p> <p><u>6. Signature of the applicant;</u></p> <p><u>7. Signature of the commissioner or his designee; and</u></p> <p><u>8. Other provisions as the commissioner may deem appropriate.</u></p> <p>Rationale: Creation of a new section to lay out the requirements of the scholarship contract. This section not only reiterates language regarding the contract found in the Code of Virginia, but provides greater detail regarding the structure and content of the contract. This leads to greater clarity and transparency of the regulations.</p>
N/A	<u>12VAC5-510-85. Practice Site Selection.</u>	N/A	<p><u>Each recipient shall perform his service obligation in a region with a critical shortage of nurses in the Commonwealth. A recipient shall perform his service obligation at a practice site in either a health professional shortage area or a medically underserved area. Maps of health professional shortage areas and medically underserved areas shall be available on the department's website.</u></p> <p>Rationale: The insertion of this section clarifies where recipients of the Nursing Scholarship must perform their obligated service. The addition of this section leads to greater clarity and transparency of the regulations.</p>
N/A	<u>12VAC5-510-90 Reporting requirements.</u>	N/A	<p><u>Each participant shall provide information as required by the department to verify compliance with all requirements of the nursing scholarship program (e.g.,</u></p>

			<p><u>verification of employment by submitting a Verification of Employment form once every six months).</u></p> <p><u>The recipient shall notify the department in writing within 30 days if any of the following events occur:</u></p> <ol style="list-style-type: none"> <u>1. Recipient changes name;</u> <u>2. Recipient changes address;</u> <u>3. Recipient changes nursing program;</u> <u>4. Recipient changes practice site (Recipient is required to request in writing and obtain prior approval of changes in practice site.);</u> <u>5. Recipient no longer intends or is unable to fulfill service obligation as a nurse in the Commonwealth;</u> <u>6. Recipient ceases to practice as an RN or LPN; or</u> <u>7. Recipient ceases or no longer intends to complete his nursing program.</u> <p>Rationale: The insertion of this section clarifies what the reporting requirements of recipients of the Nursing Scholarship. The reporting requirements will provide the framework for program administration, ensuring that scholarship recipients are in compliance with program requirements. The addition of this section leads to greater clarity and transparency of the regulations.</p>
<p>N/A</p>	<p><u>12VAC5-510-100- Breach of contract.</u></p>	<p>N/A</p>	<p><u>The following may constitute a breach of contract:</u></p> <ol style="list-style-type: none"> <u>1. The recipient fails to complete his nursing studies;</u> <u>2. The recipient fails to begin or complete the term of obligated service under the terms and conditions of the scholarship contract;</u> <u>3. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents; and</u> <u>4. The recipient's employment being terminated for good cause as determined by the employer and confirmed by the department. If employment is terminated</u>

			<p><u>for reasons beyond the participant's control (e.g., closure of site), the participant must transfer to another site approved by the board in the Commonwealth within six months of termination. Failure of participant to transfer to another site shall be deemed to be a breach of the contract.</u></p> <p><u>In the event of a breach of contract the recipient shall make default payments as described in 12VAC5-510-30. In the event of a breach of contract where the recipient has partially fulfilled his obligation, the total amount of reimbursement shall be prorated by the proportion of obligation completed.</u></p> <p>Rationale: The insertion of this section clarifies what actions qualify as a breach of contract of the Nursing Scholarship Program. The addition of this section leads to greater clarity and transparency of the regulations.</p>
<p>N/A</p>	<p><u>12VAC5-510-110. Deferment and waivers.</u></p>	<p>N/A</p>	<p><u>A. The requirement for continuous engagement in full-time nursing practice may be deferred by the board if the scholarship recipient requests a deferment to pursue an undergraduate or graduate degree in nursing or related to nursing activities. This deferment, if granted, shall not relieve the recipient of the responsibility to complete the remaining portion of the obligation upon completion of the degree.</u></p> <p><u>B. If the participant is in default due to death or permanent disability so as not to be able to engage in nursing practice in a region with a critical shortage of nurses in the Commonwealth, the participant or his personal representative may be relieved of his obligation under the contract to engage in nursing practice, upon repayment of the total amount of scholarship received plus applicable interest. For participants completing part of the nursing obligation prior to becoming permanently disabled or in the event of death, the total amount of scholarship funds owed shall be reduced by the proportion of obligated years served. The obligation to make restitution may be waived by the board upon application of the participant or the</u></p>

			<p><u>participant's personal representative to the board.</u></p> <p><u>C. Individual cases of undue hardship may be considered for a variance by the board of payment or service pursuant to § 32.1-12 of the Code of Virginia.</u></p> <p><u>D. All requests for deferments, waivers or variances must be submitted in writing to the department for consideration and final disposition by the board.</u></p> <p>Rationale: Currently there are no waiver provisions and recipients who encounter hardship and cannot fulfill their obligations automatically go into default status. The program will be more flexible and work with recipients and their families to allow them to defer repayment obligations and/or waive requirements of the contract in the event of unanticipated life events such as disability and death.</p>
--	--	--	---

Project 2804 - Proposed

**DEPARTMENT OF HEALTH
Amendments for technical updates in application process**

**CHAPTER 510
[REGULATIONS] [GUIDELINES] FOR GENERAL ASSEMBLY NURSING
SCHOLARSHIPS**

~~[This chapter has been prepared to familiarize scholarship applicants, Deans/Directors of nursing programs, and Financial Aid Officers with the General Assembly Nursing Scholarship Program. The legislative authority for the scholarships in addition to the actual steps involved in the application process are reviewed.~~

~~Do not hesitate to contact the Office of Public Health Nursing, Virginia State Health Department, 1500 East Main Street, Suite 227, Richmond, VA 23219, with any questions relating to the scholarship program. The phone number at the Bureau office is (804) 371- 4090.~~

~~ALL SCHOLARSHIPS ARE AWARDED WITHOUT REGARD TO RACE, COLOR, RELIGION, SEX OR NATIONAL ORIGIN.]~~

12VAC5-510-10. Legislative authority. Definitions.

~~[Sections 23-35.9 through 23-35.13 of the Code of Virginia authorize annual nursing scholarships for students enrolled in undergraduate and graduate nursing programs. Undergraduate nursing programs are defined as those leading to an associate degree, diploma, or baccalaureate degree in nursing. Graduate nursing programs are those offering masters and doctoral degrees.~~

~~Under the law, all scholarship awards are made by an Advisory Committee appointed by the State Board of Health. The Advisory Committee consists of eight members: four deans or directors of schools of nursing, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments are for two-year terms and members may not serve for more than two successive terms.~~

~~The Office of Public Health Nursing of the State Health Department serves as the staff element to the Advisory Committee and plays no role in the determination of scholarship recipients.~~

~~The basis for determining scholarship recipients is established by the Advisory Committee with due regard given to scholastic attainment, financial need, character, and adaptability to the nursing profession.]~~

~~[The following words and terms when used in this chapter shall have the following meanings:~~

~~"Approved nurse education program" means an approved educational program pursuant to Chapter 30 (§ 54.1-3000 et. seq.) of Title 54.1.~~

~~"Board" or "Board of Health" means the State Board of Health.~~

~~"Commissioner" means the State Health Commissioner.~~

~~"Continuous" means no breaks in service greater than a period of six weeks.~~

~~"Department" means the Virginia Department of Health.~~

~~"Full-time" means at least 32 hours per week for 45 weeks per year.~~

~~"Interest" means the legal rate of interest pursuant to § 6.2-302 of the Code of Virginia.~~

~~"Licensed Practical Nurse" or "LPN" means a person who is licensed or holds a multistate licensure privilege under the provisions of Chapter 30 of Title 54.1 of the Code of Virginia to practice practical nursing, as defined in § 54.1-3000.~~

"Penalty" means twice the amount of all monetary payments to the scholarship participant, less any service obligation completed.

"Recipient/participant" means an eligible LPN or RN of an approved nursing program who enters into a contract with the commissioner and participates in the scholarship program.

"Registered Nurse" or "RN" means a person who is licensed or holds a multistate licensure privilege under the provisions Chapter 30 of Title 54.1 of the Code of Virginia to practice professional nursing, as defined in § 54.1-3000.]

[12VAC5-510-15. Definitions. Advisory Committee.]

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

~~"Board" or "Board of Health" means the State Board of Health.~~

~~"Commissioner" means the State Health Commissioner.~~

~~"Continuous" means that there are no breaks in service greater than a period of six weeks.~~

~~"Department" means the Virginia Department of Health.~~

~~"Full-time" means the equivalent of 32 or more hours per week for at least 45 weeks per year.~~

~~"Interest" means the legal rate of interest pursuant to the Code of Virginia.~~

~~"Licensed Practical Nurse" or "LPN" means a nurse who has successfully completed a state-approved practical nursing program, passed a licensing examination known as the NCLEX-PN, and is licensed by the Commonwealth of Virginia to provide routine care under the supervision of a licensed medical practitioner, a professional registered nurse, or other licensed health professional authorized by regulations of the Board of Nursing.~~

~~"Penalty" means the amount of money equal to twice the amount of all monetary payments to the scholarship recipient, less any service obligation completed.~~

~~"Practice" means the provision of direct patient care as an LPN or RN in a region of the Commonwealth of Virginia with a critical shortage of nurses.~~

~~"Recipient" means a student in an LPN or RN program who enters into a contract with the Board of Health and participates in the scholarship program.~~

~~"Registered Nurse" or "RN" means a nurse who has graduated from an approved nursing program, passed the national licensing examination known as the NCLEX-RN, and has been licensed to practice as a registered nurse by the Board of Nursing in the Commonwealth of Virginia.]~~

[All scholarship awards shall be made by an Advisory Committee appointed pursuant to Va. Code § 23-35.9.]

12VAC5-510-20. Eligibility.

In order to be considered for a General Assembly Nursing Scholarship, [an] applicant [s must meet the following criteria] [shall]:

[1. Be a United States citizen, national, or alien holding an immigration visa or classified as a political refugee;]

[2.] [~~4.~~] Be a [bona fide] resident of [~~the State of~~] Virginia [by being domiciled in the Commonwealth] for at least one year [~~eligible for in-state tuition pursuant to § 23-7.4 of the Code of Virginia at the time a scholarship is awarded~~] [as defined by § 23-7.4 of the Code of Virginia;]

[~~2~~] [3]. Be accepted [for enrollment] or enrolled in [a] [an approved] school of nursing in the State Commonwealth of Virginia [preparing him for examination for licensure as a practical nurse or registered nurse;] [~~which is approved by the State~~

~~Board of Nursing.] The only exception is for students pursuing graduate degrees not offered in the Commonwealth.~~

~~[3] [4]. If already enrolled in [-a] [an approved]nursing program [in the Commonwealth of Virginia] , the applicant must demonstrate a cumulative grade point average of at least 2.5 [in core nursing classes] [-]~~

~~[4] [5]. Submit a completed application form and appropriate grade transcript to the Office of Public Health Nursing [-the department-] prior to the [-published-] [established] deadline dates [-] [;]~~

~~[5] [6]. Demonstrate financial need which is verified by the [Financial Aid Officer/authorized person] [school's financial aid officer/authorized person as part of the application process; and]~~

~~[7. Not have an active military obligation.]~~

~~FAILURE TO COMPLY WITH ALL OF THESE CRITERIA WILL CAUSE THE APPLICANT TO BE INELIGIBLE FOR A SCHOLARSHIP.~~

~~Failure to comply with all of these requirements will cause the applicant to be ineligible for [a] scholarship.~~

12VAC5-510-30. Conditions of scholarships.

~~[It is important that all applicants fully understand the conditions of acceptance of a General Assembly Nursing Scholarship. These awards are not outright gifts. For each \$100 of scholarship money received, the recipient agrees to engage in full-time (40 hours per week) nursing practice in the Commonwealth for one month. Therefore, if a student receives \$500 in scholarship awards, they must repay that amount by working continuously for 5 months. Full-time employment must begin within 60 days of the recipient's graduation date. Voluntary military service, even if stationed in Virginia, cannot be used to repay scholarship awards.~~

~~If a scholarship recipient fails to complete their studies, or engage in full-time nursing practice in Virginia, the full amount of money represented in the scholarship(s) received, plus an annual interest charge, must be refunded.~~

~~If a recipient leaves the State, or ceases to engage in full-time nursing practice before all employment conditions of the scholarship award are fulfilled, the recipient must repay the balance on his/her account plus an annual interest charge.~~

~~All refund checks should be made payable to the Commonwealth of Virginia and mailed to:~~

~~Office of Public Health Nursing
State Health Department
1500 East Main Street
Suite 227
Richmond, Virginia 23219~~

~~Before any scholarship is awarded, the applicant must sign a written contract agreeing to the terms established by law and the Advisory Committee.]~~

~~[A. Prior to becoming a participant in the General Assembly Nursing Scholarship program, the applicant shall enter into a contract with the commissioner agreeing to the terms and conditions upon which the scholarship is granted.~~

~~B. For each \$2,000 of scholarship money received, the participant agrees to engage in the equivalent of one year of full-time nursing practice in a region with a critical shortage of nurses in the Commonwealth. The recipient shall notify the department, within 180 days of being awarded a nursing diploma or degree, of the type of nursing practice to be performed and give the name and address of the employer for approval. Voluntary military service, even if stationed~~

in Virginia, cannot be used to repay the service obligation required when a scholarship is awarded.

The participant may request approval of a change of practice site. Such requests shall be made in writing. The department in its discretion may approve such a request.

C. If a participant fails to complete his studies, the full amount of the scholarships or scholarships received, plus the applicable interest charge, shall be repaid. A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship plus interest.

D. If upon graduation a participant leaves the Commonwealth or fails to engage or ceases to engage in nursing practice in a region with a critical shortage of nurses in the Commonwealth before all employment conditions of the scholarship award are fulfilled, the participant shall repay the award amount reduced by the proportion of obligated years served plus the applicable interest and penalty.

E. All default payments shall be made payable to the Commonwealth of Virginia.]

12VAC5-510-40. Number of applications per student.

Scholarships [~~are~~] [shall be] awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in [~~his/her~~] [his] studies, [which is demonstrated by a cumulative grade point average of 2.5 in core nursing classes.] apply for and receive scholarship awards for ~~any~~ [a] succeeding academic year or years. No student [~~may~~] [shall] receive scholarships for more than a total of [~~five~~] [four] years.

12VAC5-510-50. Amounts of scholarships.

The [~~amount~~] [number] of [~~each scholarship award~~] [scholarships awarded] [~~is~~] [shall be] dependent upon the amount of money appropriated by the General Assembly [, the amount of the funds available within the Nursing Scholarship and Loan Repayment Fund administered by the Board of Nursing pursuant to § 54.1-3011.2 of the Code of Virginia,] and the number of qualified applicants. [~~No~~] [Each] recipient [~~will~~] [shall] receive an award [~~for~~] [of] [~~less than one hundred and fifty dollars~~] [\$150] [\$2,000 per year.] [~~Graduate nursing scholarships may not exceed four thousand dollars annually.~~]

12VAC5-510-60. How to apply.

[~~Applications and Guidelines are available from the Dean/Director of your school or from the Financial Aid Office.~~]

[~~If a student is pursuing a graduate degree not available in Virginia, applications may be obtained directly from the Office of Public Health Nursing, State Health Department, 1500 East Main Street, Suite 227, Richmond, VA 23219.~~]

[Eligible applicants shall submit a complete application made available by the department on the department's website. A complete application shall include documentation of all eligibility requirements. The deadline for submission of the application shall be announced by the department on the department's website.]

12VAC5-510-70. Deadline dates. (Repealed.)

~~Applications will not be accepted in the Office of Public Health Nursing more than 6 months in advance of the following deadline dates:~~

~~March 15 -- for students already enrolled in schools of nursing.~~

~~June 15 -- for new students entering nursing programs.~~

~~APPLICATIONS AND/OR TRANSCRIPTS RECEIVED AFTER 5:00 PM ON THE ABOVE DATES WILL NOT BE CONSIDERED FOR SCHOLARSHIP AWARDS.~~

FLOW CHART OF RESPONSIBILITIES

D – Dean or Director FAO – Financial Aid Officer S-R – Student-Recipient			
RESPONSIBILITY	D	FAO	S-R
Distribute applications & Guidelines to those students who otherwise could not provide sufficient funds for themselves while in school.	X	X	-
Maintain supply of current scholarship applications and guidelines. Notify the Office of Public Health Nursing when applications are needed.	X	-	-
Make certain all parts of the application are completed, including the Financial Aid Officer/Authorized Person and Dean/Director signatures.	-	-	X
Be certain that a current transcript of grades (high school, or college if now attending) is sent to the Office of Public Health Nursing when applying for a scholarship (original and repeat requests) before deadline dates.	-	-	X
Review entire Section V Financial Data of application. Review whatever school records are accessible to determine the individual applicant's assets and expenditures.	-	X	-
Recommend amount of scholarship to be awarded. Should there be a conflict between the student's request and the Financial Aid Officer's/Authorized Person's opinion of the amount that is needed, an explanation should be included.	-	X	-
Review the completed application form before affixing the signature thereby indicating:	X	-	-
- A. The applicant has properly completed the application form.	-	-	-
- B. The Financial Aid Officer has verified proof of need.	-	-	-
- C. The applicant's entrance and graduation dates are correct.	-	-	-
- D. The school of nursing is recommending the applicant for a scholarship based upon potential nursing ability.	-	-	-
Furnish whatever pertinent data that would be helpful to the scholarship committee when making the awards.	X	X	X
Forward the completed and signed application to the Office of Public Health Nursing before deadline dates.	-	-	X
Submit a transcript of grades to the Office of Public Health Nursing at the end of each grading period during scholarship year.	-	-	X

Notify the Office of Public Health Nursing when student-recipient fails, transfers or withdraws from the school.	X	-	X
Notify the Office of Public Health Nursing when student-recipient graduation date is changed.	X	-	X
Notify the Office of Public Health Nursing when there is a change in recipient's name and/or address	-	-	X
Upon graduation, notify the Office of Public Health Nursing of plans for employment and beginning date of employment.	-	-	X
Submit verification of employment to Office of Public Health Nursing at least every 6 months until work obligation is fulfilled.	-	-	X

12VAC5-510-80. Scholarship contract.

~~Applicants selected to receive scholarship awards by the Advisory Committee [must] [shall] sign and return a written contract to the department by the specified deadline date. Failure to return the contract by the specified deadline date may result in the award being rescinded. At minimum, the scholarship contract shall include the following elements:~~

- ~~1. [Agreement with] The total amount of the award and the award period;~~
- ~~2. Agreement to pursue an LPN or RN degree in nursing at a school of nursing in the Commonwealth of Virginia that is approved by the Board of Nursing;~~
- ~~3. Agreement to begin continuous full-time employment within 180 days of the recipient's graduation;~~
- ~~4. Agreement to comply with all reporting requirements;~~
- ~~5. Agreement to the terms of service requiring continuous full-time nursing practice in the Commonwealth for a specified period of time and the terms and conditions associated with a breach of contract;~~
- ~~[6. Signature of the applicant;~~
- ~~7. Signature of the commissioner or his designee; and~~
- ~~8. Other provisions as the commissioner may deem appropriate.]~~

~~[A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship plus interest.]~~

12VAC5-510-85. [Practice Site Selection.]

~~[Each recipient shall perform his service obligation in a region with a critical shortage of nurses in the Commonwealth. A recipient shall perform his service obligation at a practice site in either a health professional shortage area or a medically underserved area. Maps of health professional shortage areas and medically underserved areas shall be available on the department's website.]~~

12VAC5-510-90. Reporting requirements.

~~[Monitoring of the service obligation of recipients shall be conducted on an ongoing basis by the department.~~

~~The recipient shall permit the nursing school to provide information regarding enrollment status and progress in the program.~~

~~The recipient shall notify the department, within 180 days of being awarded a nursing diploma or degree, of the type of nursing practice to be performed and give the name and address of the employer for approval.~~

~~The recipient shall submit to the department verification of employment documentation every four months until the contract obligation has been completely fulfilled.~~

~~The recipient shall maintain practice records in a manner that will allow the department to readily determine compliance with the terms and conditions of the contract.]~~

~~[Each participant shall provide information as required by the department to verify compliance with all requirements of the nursing scholarship program (e.g., verification of employment by submitting a Verification of Employment form once every six months).]~~

~~The recipient shall notify the department in writing within 30 days if any of the following events occur:~~

- ~~1. Recipient changes name;~~
- ~~2. Recipient changes address;~~
- ~~3. Recipient changes nursing program;~~
- ~~4. Recipient changes practice site [(Recipient is required to request in writing and obtain prior approval of changes in practice site.)] ;~~
- ~~5. Recipient no longer intends [or is unable] to fulfill service obligation as a nurse in the Commonwealth;~~
- ~~6. Recipient ceases to practice as an RN or LPN; [or~~
- ~~7. Recipient ceases or no longer intends to complete his nursing program.]~~

12VAC5-510-100. Breach of contract.

~~The following may constitute a breach of contract:~~

- ~~1. The recipient fails to complete his nursing studies;~~
- ~~2. The recipient fails to begin or complete the term of obligated service under the terms and conditions of the scholarship contract;~~
- ~~3. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents; and~~
- ~~4. The recipient's employment being terminated for good cause as determined by the employer and confirmed by the department. If employment is terminated for reasons beyond the participant's control (e.g., closure of site), the participant must transfer to another site approved by the board in the Commonwealth within six months of termination. Failure of participant to transfer to another site shall be deemed to be a breach of the contract.~~

~~[In the event of a breach of contract the recipient shall make default payments as described in 12VAC5-510-30.] In the event of a breach of contract where the recipient has partially fulfilled his obligation, the total amount of reimbursement shall be prorated by the proportion of obligation completed.~~

12VAC5-510-110. Deferment and waivers.

~~[A.] The requirement for continuous engagement in full-time nursing practice may be deferred by the board if the scholarship recipient requests a deferment to pursue [a more advanced degree in nursing or a nursing-related field-] [an undergraduate or graduate degree in nursing or related to nursing activities.] This deferment, if granted, shall not relieve the recipient of the responsibility to complete the remaining portion of the obligation upon completion of the [advanced nursing] degree.~~

~~[B.] If the participant is in default due to death or permanent disability [the obligation to reimburse the Commonwealth of Virginia for the total amount of the scholarship award plus interest may be partially or completely waived by the board upon application of the recipient or the recipient's estate to the board.-] [so as not to be able to engage in nursing practice in a~~

region with a critical shortage of nurses in the Commonwealth, the participant or his personal representative may be relieved of his obligation under the contract to engage in nursing practice, upon repayment of the total amount of scholarship received plus applicable interest. For participants completing part of the nursing obligation prior to becoming permanently disabled or in the event of death, the total amount of scholarship funds owed shall be reduced by the proportion of obligated years served. The obligation to make restitution may be waived by the board upon application of the participant or the participant's personal representative to the board.]

~~[Other individual situations involving severe hardship may be considered by the board for deferment of the service obligation or partial or total waiver of the repayment obligation. Deferment and waiver requests will not be permitted as a matter of course, but may be allowed in the most compelling cases.]~~

[C. Individual cases of undue hardship may be considered for a variance by the board of payment or service pursuant to § 32.1-12 of the Code of Virginia.]

[D.] All requests for deferments, waivers or variances must be submitted in writing to the department for consideration and final disposition by the [~~Advisory Committee or~~] board.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: May 5, 2014

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH
Acting Director, Office of Epidemiology

SUBJECT: Proposed Amendment to the Regulations for Disease Reporting and Control and Repeal of the Regulations for Testing Children for Elevated Blood Lead Levels

The proposed regulatory action affects two general public health topic areas: testing children for lead and testing donated gametes for human immunodeficiency virus (HIV). The action involves two components of the Regulations for Disease Reporting and Control and a related repeal of the Regulations for Testing Children for Elevated Blood Lead Levels.

Firstly, the requirements for testing children to detect elevated blood lead levels is being incorporated into the Regulations for Disease Reporting and Control by adding a section numbered 12VAC5-90-215. In the same action, the existing regulations pertaining to testing children for lead, 12VAC5-120, are being repealed. The Regulations for Disease Reporting and Control include provisions for physicians and laboratories to report to the health department elevated blood lead levels in children. Having a separate set of regulations that describe which children should be tested is confusing to the regulated community. Combining both the testing and the reporting requirements into one set of regulations, therefore, should make the process clearer.

The second major topic affected by this proposed amendment pertains to the testing of gametes for HIV infection. In this action, the language is being altered to simply align the Virginia testing requirements with the regulations of the U. S. Food and Drug Administration. This amendment will simplify the Virginia regulations and ensure conformity with those of the federal government.

The Board of Health is asked to approve this proposed amendment at its June 2014 meeting. Following approval, the proposed amendment would be submitted to the Virginia regulatory Town Hall to initiate Executive Branch review of the proposal.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation	12VAC5-90 and 12VAC5-120
Regulation title	Regulations for Disease Reporting and Control and Regulations for Testing Children for Elevated Blood Lead Levels
Action title	Updating Disease Reporting Regulations and Repealing Lead Testing Regulation
Date this document prepared	May 1, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and other details related to public health reporting and disease control. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the field of communicable and environmental disease control that are needed to protect the health of the citizens of Virginia.

The specific changes being proposed are necessary to ensure the regulations comply with recent changes in the practice of public health and in federal regulations. The agency proposes to incorporate the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and to repeal 12VAC5-120, the existing regulation pertaining to blood lead testing of children. A revision to the gamete donor Human Immunodeficiency Virus (HIV) testing regulations will ensure consistency with federal regulations.

The amendment to the cancer reporting requirements that were included in the Notice of Intended Regulatory Action will not be pursued at this time.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

No acronyms are used without being defined in context.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

Chapter 2 of Title 32.1 of the *Code of Virginia*, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. § 32.1-45.3 requires the Board to establish procedures for testing gamete donors; and § 32.1-46.1 authorizes the Board to establish a protocol for the identification of children with elevated blood lead levels. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the *Code of Virginia*.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The amendment is necessary to ensure that the regulations comply with changes in the *Code of Federal Regulations* and recommendations of national public health organizations. The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

The section on testing children to determine their blood lead levels is new to the Regulations for Disease Reporting and Control but reflects minor amendments to existing requirements that are currently included

in another set of agency regulations, 12VAC5-120. The agency decided it was a logical and efficient change to incorporate the lead testing requirements into the set of regulations that addresses the reporting of elevated blood lead levels. Having one set of regulations on this topic should reduce confusion among the regulated community.

12VAC5-120, the existing regulation pertaining to the identification of children with elevated blood lead levels is being repealed as its content is being incorporated into 12VAC5-90. Some changes to the requirements are proposed as well. The changes simplify and clarify the requirements, remove unnecessary references to guidelines and non-mandatory actions, and reflect current Centers for Disease Control and Prevention recommendations. The proposed amendment to 12VAC5-90 pertaining to blood lead levels in children reflects a similar schedule of testing, risk factors for testing, criteria for determining low risk, and need for confirmatory testing as is currently provided in 12VAC5-120.

Federal Food and Drug Administration (FDA) regulations currently require testing and other measures to prevent transmission of HIV and other infections when assisted reproductive technology (ART), including donated gametes, are used to treat infertility and related problems. These regulations reduce the risk of diseases that could result if recipients and resulting children were exposed to HIV or other infections during the use of ART. Changes to Virginia’s gamete donor HIV testing regulations are necessary due to recent advancements in HIV test technology. Because HIV can be detected earlier in the course of infection, waiting periods for delayed use of donated gametes are not always necessary. Federal regulations have changed to address the impact of improved test technology and include the option of a waiver to the waiting period between donation and use of the gametes, when specific criteria are met. In addition, federal regulations address measures to prevent multiple infections, including but not limited to HIV. A simplification of Virginia’s regulatory language referencing the federal regulations will ensure conformity.

Issues

- Please identify the issues associated with the proposed regulatory action, including:*
- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages to the public will be clearer rules for testing children for exposure to lead and less confusion that is inherent in maintaining two sets of regulations pertaining to the same subject and procedures. Similarly, federal regulations of the Food and Drug Administration sufficiently address the need to screen gamete donors for HIV infection such that Virginia does not need separate regulations to achieve the same purpose.

The primary advantages to the agency are the same as for the public. That is, elimination of the confusion caused by needing to track multiple sets of regulations or the potential for inconsistent requirements in different regulations.

No disadvantages or other pertinent matters of interest to the regulated community have been identified.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable

federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

None of these requirements is more restrictive than federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

The impact of these changes is anticipated to be similar for all localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Room 516E, Richmond VA 23218; phone 804-864-8141; fax 804-864-8139; email diane.woolard@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The proposed amendment regarding testing children’s blood lead levels pertains to physicians and other medical care providers and is anticipated to have minimal impact on their practices or procedures. The proposed change to the gamete donor testing regulations impacts donors, recipients and medical facilities that provide ART.
---	---

<p>Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million.</p>	<p>Any physician who diagnoses or treats children could be affected by the lead regulation. The Centers for Disease Control and Prevention 2011 ART Clinic Report lists 14 medical facilities in Virginia that provide ART.</p>
<p>Benefits expected as a result of this regulatory proposal.</p>	<p>Proposed changes to the lead testing requirement clarifies existing language and consolidates two regulations pertaining to the same topic into one regulation. Proposed changes to the gamete donor testing regulation removes the potential barrier resulting from complying with a waiting period that may not be clinically necessary when other criteria are met. The proposed change ensures consistency with federal regulations, allowing medical providers, donors and recipients follow a consistent set of requirements.</p>
<p>Projected cost to the <u>state</u> to implement and enforce this regulatory proposal.</p>	<p>No costs are anticipated.</p>
<p>Projected cost to <u>localities</u> to implement and enforce this regulatory proposal.</p>	<p>No costs are anticipated.</p>
<p>All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.</p>	<p>No costs are anticipated related to the proposed changes to the lead testing or gamete donor HIV testing regulations.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives have been considered, nor are there any that are advisable.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4)

the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

No lessening of testing requirements is advisable given the need to detect elevated blood lead levels in children or potentially infected gamete donors. The proposed changes do not increase the extent of existing requirements, the requirements are as necessary and as simple as possible, and the impact on small businesses is expected to be minimal.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
None	No comments were received following the publication of the NOIRA	

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes will indirectly protect and improve the health of the people of the Commonwealth. No adverse impacts on the institution of the family or on family stability are anticipated.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-90-230 through 12VAC5-90-270		HIV testing of gamete donors	<ul style="list-style-type: none"> Retains some existing definitions but otherwise strikes existing regulatory language and replaces it with one section that notes that this testing must be conducted in accordance with current federal regulations.
12VAC5-120		Regulations for testing children for elevated blood lead levels	<ul style="list-style-type: none"> Repealed and replaced with the new regulation, cited below.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-90-215	Testing children at 12 and 24 months of age for blood lead levels if they meet any of a list of criteria; confirming tests indicating elevated levels if the test was not a standard confirmatory test performed by a certified laboratory; providing test results to parents or guardians.	Similar requirement exists in 12VAC5-120, which is being repealed within this same regulatory action.	Physicians will need to assess children and determine if they meet criteria for testing for blood lead levels and provide the results and educational materials to parents/guardians for any laboratory results that indicate the child was exposed to lead. This is already a standard of practice for clinicians and a recommendation of the Centers for Disease Control and Prevention. Similar requirements are in effect in an existing agency regulation, except that the blood lead level that indicates that exposure to lead has occurred has been lowered so action will be necessary for children testing at a level lower than previously.

DEPARTMENT OF HEALTH

Update Disease Reporting and Control Regulations
and Repeal Blood Lead Testing Regulations

Part IX.

Protocol for identification of children with elevated blood lead levels

12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and information to be provided.

A. Schedule for testing. Every child shall be tested to determine the blood lead level at 12 months and 24 months of age if the health care provider determines that the child meets any of the criteria listed in subsection B of this section. Children 25 months through 72 months of age who present for medical care and meet any of criteria of subsection B of this section shall also be tested if they have either not previously been tested for blood lead level or were previously tested but experienced a change since testing that has resulted in an increased risk of lead exposure, based on the criteria listed in subsection B.

B. Criteria for testing.

1. The child is eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);
2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1960;

3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent (within the last six months) ongoing, or planned renovations;
4. The child is living in or regularly visiting a house, apartment, dwelling or other structure in which one or more persons have blood lead testing yielding evidence of lead exposure;
5. The child is living with an adult whose job, hobby, or other activity involves exposure to lead;
6. The child is living near an active lead smelter, battery recycling plant, or other industry likely to release lead;
7. The child's parent, guardian, or other person standing in loco parentis requests the child's blood be tested due to any suspected exposure; or
8. The child is a recent refugee, immigrant, or is adopted from outside of the U.S.

A child who does not meet any of the above criteria is considered to be at low risk, and testing is not indicated but may be conducted at the discretion of the health care provider. The testing requirement can also be waived if the parent, guardian or other person standing in loco parentis of a child objects to the testing on the basis that the procedure conflicts with his religious tenets or practices.

C. Confirmation of blood lead levels. Blood lead level testing shall be performed on venous or capillary blood. Tests of venous blood performed by a laboratory certified by the federal Health Care Financing Administration in accordance with Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified) are considered confirmatory. Tests of venous blood performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat

blood test, preferably venous, performed by a CLIA-certified laboratory. Such confirmatory testing shall be performed in accordance with the following schedule:

1. Within one to three months if the result of the capillary test is at or above the CDC's reference value and up to 9 micrograms of lead per deciliter of whole blood ($\mu\text{g}/\text{dL}$).
2. Within one week to one month if the result of the capillary test is 10-44 $\mu\text{g}/\text{dL}$. The higher this test result, the more urgent the need for a confirmatory test.
3. Within 48 hours if the result of the capillary test is 45-59 $\mu\text{g}/\text{dL}$.
4. Within 24 hours if the result of the capillary test is 60-69 $\mu\text{g}/\text{dL}$.
5. Immediately as an emergency laboratory test if the result of the capillary test is 70 $\mu\text{g}/\text{dL}$ or higher.

D. Information to be provided. As part of regular well-check visits for all children up to 72 months of age, the health care provider shall make available to parents, guardians, or other persons standing in loco parentis information on the dangers of lead poisoning, potential sources of lead and ways to prevent exposure, and a list of available lead-related resources. When blood lead level testing is performed, the health care provider shall share the child's blood lead level test result with the child's parent, guardian, or other person standing in loco parentis and report to the health department in accordance with the requirements of 12VAC5-90-80.

Part XI

Human Immunodeficiency Virus (HIV) Testing of Gamete Donors

12VAC5-90-230. Definitions. HIV Testing of Gamete Donors.

A. Definitions.

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

~~"Artificial insemination" means instrumental placement of semen into the vagina, cervical canal, or uterus of a recipient.~~

"Donor" means an individual who is unrelated by marriage to the recipient and who contributes sperm or ova used in the following procedures: treatment of infertility by artificial insemination; in vitro fertilization; gamete intrafallopian tube transfer; zygote intrafallopian tube transfer or any other gamete, zygote, or embryo transfer; or other intervening medical technology using sperm or ova.

~~"Embryo" means the product of a fertilized ovum prior to the eighth week of development inside a uterus.~~

"Gamete" means either sperm or ova.

~~"Gamete intrafallopian tube transfer" means placement of harvested ova and sperm into the fallopian tube or tubes of a recipient.~~

~~"HIV-1" "HIV" means the retrovirus retroviruses causing the human immunodeficiency virus infection, type 1.~~

~~"HIV-2" means the retrovirus causing the human immunodeficiency virus infection, type 2.~~

~~"In vitro fertilization" means placement of a zygote or embryo that has been fertilized outside the body into the uterus of a recipient.~~

~~"Zygote" means a fertilized ovum prior to cell cleavage.~~

~~"Zygote intrafallopian tube transfer" means placement of a zygote or zygotes into the fallopian tube or tubes of a recipient.~~

B. Requirements for assessing, testing, specimen handling, and counseling.

Any practitioner using donor gametes to treat patients for infertility shall ascertain the HIV status of the donor by assessing and testing the donor, handle gametes, and counsel recipients in accordance with regulations established by the federal Food and Drug Administration as specified in 21 CFR 1271.

12VAC5-90-240. Excluding donors with high risk factors. (Repealed.)

~~A. Practitioners using gametes for the treatment of infertility by transfer of such gametes to a recipient shall interview all gamete donors at the time of donation in order to screen for high risk behavior indicating potential exposure to HIV-1 and HIV-2.~~

~~B. Any gamete donor reporting infection with HIV-1 or HIV-2 or any of the following risk factors shall be excluded from donating:~~

- ~~1. Men who have had sex with another man within the preceding five years.~~
- ~~2. Persons who have injected drugs for a nonmedical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections of recreational or illegal drugs.~~
- ~~3. Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.~~
- ~~4. Persons who have had sex in exchange for money or drugs in the preceding five years.~~

~~5. Persons who have had sex in the preceding 12 months with any person described in subdivisions 1 through 4 of this subsection or with any person suspected of being infected with HIV-1 or HIV-2.~~

~~6. Persons who have been exposed within the last 12 months to known or suspected HIV-1 or HIV-2 infected blood through percutaneous inoculation (e.g., needle stick) or through contact with an open wound, nonintact skin, or mucous membrane.~~

~~7. Current inmates of correctional systems, including jails and prisons, and individuals who have been confined in jail or incarcerated in prison for more than 72 consecutive hours during the previous 12 months.~~

~~8. Persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months.~~

~~9. Persons who within 12 months of donation have undergone acupuncture, ear or body piercing or tattooing in which sterile procedures were not used or where it is unknown if sterile procedures were used.~~

~~10. Persons who choose to defer from donation whether or not they report any of the above potential exposures to HIV-1 or HIV-2.~~

12VAC5-90-250. ~~Storage of semen pending negative HIV tests. (Repealed.)~~

~~Semen specimens from donors shall be stored and withheld from use for at least 180 days following donation and used only if the donor tests negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least 180 days after donation.~~

~~12VAC5-90-260. Use of ova after negative HIV tests. (Repealed.)~~

~~Ova shall be used only if the donor tests negative for serum antibodies to HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at the initiation of the cycle during which the ova are harvested.~~

~~12VAC5-90-270. Notifying recipients of option to delay transfer. (Repealed.)~~

~~Practitioners using ova, embryos, or zygotes for the treatment of infertility or other medical technology involving the transfer of ova, embryos, or zygotes to a recipient shall notify these recipients of the option for having donor ova fertilized and the resultant zygotes frozen and then transferred to the recipient only if the ova donor is negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least 180 days after donation.~~

CHAPTER 120

REGULATIONS FOR TESTING CHILDREN FOR ELEVATED BLOOD-LEAD LEVELS

Part I

Definitions and General Information

~~12VAC5-120-10. Definitions. (Repealed.)~~

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

~~"Board" means the State Board of Health.~~

~~"Commissioner" means the Commissioner of Health.~~

~~"Elevated blood lead level" for children means 10 or more micrograms of lead per deciliter of whole blood in a child up to and including 72 months of age.~~

~~"Health care provider" means a physician or his designee or an official of a local health department.~~

~~"High-risk ZIP Code area" means a ZIP Code area listed in guidelines issued by the Virginia Department of Health in which 27% or more of the housing was built before 1950 or 12% or more of the children have elevated blood-lead levels based on current available data.~~

~~"Physician" means a person licensed to practice medicine in any of the 50 states or the District of Columbia.~~

~~"Point of care testing" refers to testing by a health care provider that has a CLIA Certificate of Waiver.~~

~~"Qualified laboratory" means a laboratory that is certified by the Health Care Financing Administration in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 CFR Part 493) and is participating in the Centers for Disease Control and Prevention's (CDC) Blood Lead Laboratory Proficiency Program.~~

~~"µg/dL" means micrograms of lead per deciliter of whole blood.~~

12VAC5-120-20. ~~Statement of general policy. (Repealed.)~~

~~The Commonwealth of Virginia has recognized the need for early identification of children with elevated blood-lead levels to alert parents and guardians to the need for intervention to prevent physical, developmental, behavioral, and learning problems associated with elevated blood-lead levels in children, and to prevent exposure of other children.~~

~~The purpose of this chapter is to provide a protocol for identifying children with elevated blood-lead levels.~~

~~The department encourages health care providers, parents and guardians to exercise reasonable, but liberal judgment and discretion in implementing and applying the protocol set~~

~~forth in this chapter, so that the health of all Virginia's children may be protected from lead poisoning.~~

Part II

Protocol for Identification of Children with Elevated Blood-Lead Levels

12VAC5-120-30. ~~Schedule for testing. (Repealed.)~~

~~Virginia health care providers should test all children up to and including 72 months of age for elevated blood-lead levels according to the following schedule unless they are determined under 12VAC5-120-60 to be at low risk for elevated blood-lead levels. All blood-lead samples shall be analyzed by a qualified laboratory. The use of a CDC-approved and CLIA-waived instrument for point-of-care testing, as a means of administering screening tests for elevated blood-lead levels, is exempted from the requirement to have all blood-lead samples analyzed by a qualified laboratory. However, any elevated blood-lead level found through point-of-care testing to be equal to or greater than 10 µg/dL shall be confirmed by a venous blood-lead test performed by a qualified laboratory in accordance with the requirements of 12VAC5-120-40.~~

- ~~1. Children should be tested at ages one and two years.~~
- ~~2. Children from 36 through 72 months of age should be tested if they have never been tested.~~
- ~~3. Additional testing may be ordered by the health care provider.~~
- ~~4. Children should be tested at the request of a parent or guardian due to any suspected exposure.~~

12VAC5-120-35. Information about lead poisoning. (Repealed.)

~~The health care provider shall make available to parents information on the dangers of lead poisoning, along with a list of available resources, as part of regular well-check visits for all children up to 72 months of age.~~

12VAC5-120-40. Confirmation of blood-lead levels. (Repealed.)

~~Testing may be performed on venous or capillary blood collected in tubes or on filter paper. If a test of capillary blood reveals an elevated blood-lead level, the results shall be confirmed by a repeat blood test (preferably venous):~~

- ~~1. Within three months if the result of the capillary test is 10 µg/dL to 19 µg/dL.~~
- ~~2. Within one week to one month if the result of the capillary test is 20 µg/dL to 44 µg/dL. The higher this test result, the more urgent the need for a confirmation test.~~
- ~~3. Within 48 hours if the result of the capillary test is 45 µg/dL to 59 µg/dL.~~
- ~~4. Within 24 hours if the result of the capillary test is 60 µg/dL to 69 µg/dL.~~
- ~~5. Immediately as an emergency laboratory test if the result of the capillary test is 70 µg/dL or higher.~~

~~Elevated blood lead results from venous blood testing shall be deemed a confirmed test.~~

12VAC5-120-50. Risk factors requiring testing. (Repealed.)

~~A health care provider shall test any child for elevated blood-lead level, or have such a child tested, if the provider determines, in the exercise of medical discretion, that such testing is warranted, and that the child meets one or more of the following criteria:~~

- ~~1. Eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);~~
- ~~2. Living in a high-risk zip code area;~~

- ~~3. Living in or regularly visiting a house or child care facility built before 1950;~~
- ~~4. Living in or regularly visiting a house, apartment, dwelling or other structure, or a child care facility built before 1978, with peeling or chipping paint or with recent (within the last six months), ongoing, or planned renovations;~~
- ~~5. Living in or regularly visiting a house, apartment, dwelling or other structure in which one or more persons have elevated blood-lead levels;~~
- ~~6. Living with an adult whose job or hobby involves exposure to lead as described in Preventing Lead Poisoning in Young Children (CDC, 1991);~~
- ~~7. Living near an active lead smelter, battery recycling plant, or other industry likely to release lead;~~
- ~~8. The child's parent or guardian requests the child's blood be tested due to any suspected exposure; or~~
- ~~9. A health care provider recommends the child's blood be tested due to any suspected exposure.~~

~~The Department of Health will maintain a list of high-risk zip code areas in Virginia.~~

~~12VAC5-120-60. Determination of low risk for elevated blood-lead levels. (Repealed.)~~

~~Blood-lead testing is not indicated for children determined by a health care provider to be at low risk for elevated blood-lead levels. A health care provider may determine a child to be at low risk for elevated blood-lead level if the child meets none of the criteria listed in 12VAC5-120-50, but is encouraged to cause a child to be tested if, in the exercise of discretion and consideration of the various means by which exposure to lead may occur, such exposure cannot be clearly ruled out.~~

12VAC5-120-70. ~~Samples submitted to a qualified laboratory. (Repealed.)~~

~~A. All blood samples submitted to a qualified laboratory for analysis shall be accompanied by a completed laboratory requisition with all of the required data as determined by the Department of Health.~~

~~B. All qualified laboratories accepting blood samples for lead analysis under this chapter shall submit all required data to the board within 10 business days of analysis. The data shall be sent by a secure electronic means that has been approved by the Department of Health.~~

~~C. Any laboratory reporting under this section shall be deemed in compliance with the stipulations of § 32.1-36 of the Code of Virginia and 12VAC5-90-90 of the Board of Health Regulations for Disease Reporting and Control.~~

12VAC5-120-80. ~~Follow-up testing and information. (Repealed.)~~

~~The Department of Health will establish guidelines for follow-up testing for children with confirmed elevated blood lead levels, provide or recommend appropriate information for parents, and disseminate through various available means the protocol and other information to all relevant health care professionals. The department encourages health care professionals to conduct whatever follow-up testing is indicated or warranted in the exercise of medical or clinical judgment and discretion.~~

12VAC5-120-90. ~~Exclusion from testing when risk is low and on religious grounds. (Repealed.)~~

~~In accordance with § 32.1-46.2 of the Code of Virginia, every child in the Commonwealth should be tested for elevated blood lead levels or determined to be at low risk for elevated blood lead levels unless the parent, guardian or other person standing in loco parentis obtains a determination that the child is at low risk for elevated blood lead levels or unless the parent,~~

~~guardian or other person having control or charge of such child objects to such testing on the basis that the procedure conflicts with his religious tenets or practices.~~

May 7, 2014

Memorandum

To: State Board of Health

From: Laurie Forlano, D.O., M.P.H.
Acting Director, Office of Epidemiology

Subject: Final *Regulations for Rabies*

Enclosed for your review is the final language of the *Rabies Regulations*.

The State Board of Health has been directed to adopt regulations to implement the provisions of the legislation that became effective on July 1, 2010. These regulations are necessary to implement the revisions made to certain rabies-related sections of the *Code of Virginia* (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) during the 2010 General Assembly session. In addition, a rabies related section (§ 3.2-6562.1) was added to the Code of Virginia during that session.

The proposed amendments were published in the Virginia Register of Regulations on November 4, 2013. The Virginia Department of Health conducted a 60-day public comment period that closed on January 31, 2014. No comments were received.

The Board of Health is requested to approve the final language. Should the Board of Health approve these new regulations, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the final regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day final adoption period will begin, after which the new regulations will become effective.



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-105
Regulation title	Rabies Regulations
Action title	Rabies response, prevention, and control regulations.
Date this document prepared	4/3/2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Virginia Department of Health, in collaboration with numerous stakeholder groups, has developed proposed regulatory language to support the implementation of five rabies-related sections of the Code of Virginia. The proposed language defines common terms and addresses the procedure for rabies vaccination exemptions, the development of a rabies response plan by local health departments, and recordkeeping associated with rabies clinics.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The State Board of Health approved the final Regulations on June 5, 2014.

Legal Basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

In 2010, five rabies-related sections of the Code of Virginia (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) were amended. In addition, a rabies-related section (§ 3.2-6562.1) was added to the *Code of Virginia*. As part of this action, the State Board of Health was directed to promulgate regulations to implement provisions of the act that became effective on July 1, 2010.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

This regulatory action provides language to support the implementation of rabies-related sections of the *Code*. The proposed language specifically addresses rabies vaccination exemptions and provides a model rabies response plan. It was developed in cooperation with stakeholders such as local health departments, animal control agencies, veterinary associations, humane groups, wildlife agencies, agriculture agencies, the Board of Veterinary Medicine, and local government associations. These stakeholders were engaged to discuss issues such as the entity that grants rabies exemptions and restrictions placed on animals that are exempt, as well as the authority local health directors have to direct animal control officers in the pursuit of their duties in certain circumstances. The intent of the collaborative approach is proposed language that is clearly written, understandable, and functional for all those involved in rabies prevention, control, and response efforts.

Goals of the proposed language include: (i) to define commonly used terms in the rabies-related sections of the *Code of Virginia* to increase the likelihood these terms would be interpreted and applied in a consistent way, (ii) to improve the recordkeeping associated with rabies clinics to increase the likelihood that an animal's vaccinations status can be verified in response to a rabies exposure, (iii) to outline the procedure a veterinarian must use to apply for a rabies vaccination exemption and the role of local authorities in that process, and (iv) to offer a model rabies response plan that localities may use to comply with § 3.2-6562.1 of the *Code of Virginia*.

These regulations are essential to protect public health and welfare. Rabies is nearly 100 percent fatal and is highly endemic in the Commonwealth. It is very important that human and animal exposures are addressed promptly and correctly.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The provisions in these new regulations address defining commonly used terms in the rabies-related sections of the *Code of Virginia*; the health department's recordkeeping responsibilities associated with

rabies clinics; establishing a mechanism whereby dogs and cats may be granted a rabies vaccination exemption; and communication and coordination among local government authorities in response to rabies exposure events. These provisions fulfill the requirement, as enacted by the 2010 General Assembly, for the Board of Health to develop a model plan that may be used by localities to comply with the requirements of § 3.2-6562.1.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages to individual private citizens, veterinarians in private practice, and the Commonwealth include: (i) promoting the application and interpretation of terms used in the rabies-related sections of the *Code of Virginia* in a consistent way across all local health districts, (ii) improving the ability to verify rabies vaccination status of animals vaccinated during rabies clinics, (iii) providing a mechanism for granting rabies vaccination exemptions when appropriate while remaining in compliance with local licensing laws and protecting public health and (iv) improving coordination and communication among local government authorities in response to rabies exposure events. A potential disadvantage involves the amount of time and effort veterinarians in private practice may need to complete the application for vaccination exemption.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section Number	Requirement at Proposed Stage	What has Changed	Rationale for Change
<u>12VAC5-105-40</u>	12VAC5-105-40 B Section VII A	<u>9. Notifying any human exposure victims of positive results within two hours of receiving the result and referringreferring the victim to the LHD nursing staff in regard to PEP treatment options.</u>	The typographical error for the word “referring” was corrected.
<u>12VAC5-105-40</u>	12VAC5-105-40 B Section VII C	<u>C. LocalityLHD Epidemiology Staff. LocalityLHD epidemiology staff members are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:</u> <u>1. Collecting and maintaining the following data in</u>	The word “locality” was used in error when the acronym for local health department (LHD) is used throughout the model plan in association with the various local health department

Section Number	Requirement at Proposed Stage	What has Changed	Rationale for Change
		<p><u>coordination/consultation with the environmental health staff and nursing staff for animal exposures/bites, animal bites to humans, and other human exposures:</u> <u>[2a]. Demographics of person exposed;</u> <u>[3b]. Information about the animal and its owner;</u> <u>[4c]. Details of exposure;</u> <u>[5d]. PEP recommendations and actions;</u> <u>[6e]. Animal euthanasia secondary to suspect rabies; and</u> <u>[7f]. Animal quarantine or confinement</u></p>	<p>representatives involved in rabies response.</p> <p>The typographical error in the numbering sequence for the list of data introduced in Item 1 was corrected.</p>

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

No public comment received.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current Requirement	Proposed change and rationale
n/a	2VAC5-105-10. Definitions	none	This section defines common terms contained in the <i>Code of Virginia</i> . These terms used in, or applicable to, rabies-related sections of the <i>Code of Virginia</i> are not found in the definitions section of the <i>Code of Virginia's</i> comprehensive animal laws (§ 3.2-6500). All of these or similar terms are used in the <i>Code of Virginia</i> , and defining them will increase the likelihood they would be interpreted and applied in a consistent way. The language used in the proposed regulations supports current agency interpretations of these terms.

Current section number	Proposed new section number, if applicable	Current Requirement	Proposed change and rationale
n/a	12VAC5-105-20. Rabies clinics	none	This new regulation instructs the local health departments to maintain for 48 months information about rabies clinics held with the approval of the local governing body. Although the <i>Code of Virginia's</i> comprehensive animal laws (§ 3.2-6521), in part, address rabies clinics and the recordkeeping responsibilities of other stakeholders involved in these clinics, this new regulation will increase the likelihood that vaccination status and/or history through rabies clinics is verifiable.
n/a	12VAC5-105-30. Rabies vaccine exemptions	none	The <i>Code of Virginia's</i> comprehensive animal laws (§ 3.2-6521) require owners to have their dogs and cats 4 months of age and older vaccinated. In some cases, a dog or cat is likely to have a life threatening reaction in response to vaccination. This new regulation instructs the Board of Health to provide an exemption to the vaccination requirement provided it would not present a risk to public health and safety. Veterinarians, as well as dog and cat owners, may be impacted in regard to the time and effort needed to apply for an exemption.
n/a	12VAC5-105-40. Model plan for localities	none	The <i>Code of Virginia's</i> comprehensive animal laws (§ 3.2-6521) require localities to adopt a plan for controlling and responding to the risk of rabies exposure to persons and companion animals. This new regulation provides a model plan for local health departments to use for effective coordination and communication with local government authorities during response to rabies exposure-related events. In addition, it ensures residents receive timely and accurate guidance about rabies.

DEPARTMENT OF HEALTH
Rabies Regulations

CHAPTER 105
RABIES REGULATIONS

12VAC5-105-10. Definitions.

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

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

"Department" means the Virginia Department of Health.

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

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

"Rabies vaccination certificate" means a document provided by a licensed veterinarian or a licensed veterinary establishment indicating a specific animal has been vaccinated or revaccinated in accordance with the National Association of State Public Health Veterinarian's Compendium of Animal Rabies Prevention and Control or as described on the U.S. Department of Agriculture approved vaccine label and includes at least, but is not limited to, the following: signature of the veterinarian, the animal owner's name and address, the locality where the animal resides, the species of the animal, the sex, whether or not the animal is spayed or neutered, the age, the color, the primary breed, the certificate expiration date, and the vaccination number, also known as the serial lot number. In lieu of individual certificates, a herd certificate can be issued for livestock other than horses that includes at least the signature of

the veterinarian, the owner's name and address, the species of animal, the sex, the approximate age, the primary breed, date of vaccination, the rabies vaccine product name, the vaccination number, identifying information for each animal such as ear tag number, tattoo or other permanent identification, and the name and contact information of the veterinarian who administered the vaccine. In lieu of individual certificates, a certificate of veterinary inspection for use in shipping equine may be generated for horses that includes at least the signature of the veterinarian, the owner's name and address, the sex, the approximate age, the date of vaccination, the rabies vaccine product name, the vaccination number, identifying information for each horse such as name, color, markings, tattoo or brand, and the name and contact information for the veterinarian who administered the vaccine.

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

12VAC5-105-20. Rabies clinics.

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

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

12VAC5-105-30. Rabies vaccine exemptions.

A. The local health director, in consultation with the state public health veterinarian, may grant an exemption to the requirement for rabies vaccination as articulated in § 3.2-6521 of the Code of Virginia if a vaccination would likely endanger the animal's life due to a previously diagnosed disease or other previously documented medical considerations as documented by a licensed veterinarian.

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

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

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

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

B. Model plan.

Title: Human and Companion Animal Rabies Exposure Protocol.

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

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

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

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

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

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

Section III. Legal Authority. Authority for the local health director to develop a local authority and responsibility plan that shall provide for those within the locality with a duty to control or

respond to a risk of rabies exposure and to be directed by the local health director for such purposes is articulated in § 3.2-6562.1 of the Code of Virginia (included below).

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

The local health director, in conjunction with the governing body of the locality, shall adopt a plan to control and respond to the risk of rabies exposure to persons and companion animals. Such plan shall set forth a procedure that promptly ensures the capture, confinement, isolation, or euthanasia of any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies. The plan shall identify the authority and responsibility of the local health department, law-enforcement officers, animal control officers, and any other persons with a duty to control or respond to a risk of rabies exposure. The plan shall provide for law-enforcement officers, animal control officers, and other persons to report to and be directed by the local health director for such purposes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Conducting a site visit to investigate a human exposure and coordinating a site visit with a companion animal owner with locality animal control services when necessary within 24 hours of the report.

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

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

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

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

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

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

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

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

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

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

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

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

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

17. In coordination with the local health director, LHD nursing staff, and LHD epidemiology staff, developing and maintaining a training program that can be used to review locality rabies control and response procedures with locality animal control services on an as needed basis and/or as new staff are hired.

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

1. Ensuring that any humans involved in a possible rabies exposure incident are appropriately counseled/treated to control the risk of rabies viral infection.

2. Notifying the environmental health staff of a human or companion animal exposure within two hours of receiving a report if the report did not originate with environmental health staff.

3. Coordinating human exposure follow up with environmental health staff and assisting with human exposure assessment interviews within 24 hours of receiving a report of an exposure.

4. Coordinating the notifying of human exposure victims with environmental health staff immediately after receiving a positive test result.

5. Coordinating the notifying of human exposure victims with environmental health staff within 24 hours of receiving a negative test result.

6. Discussing PEP treatment options within the locality with human exposure victim(s).

7. Discussing medical conditions and history with human exposure victims that may affect PEP treatment.

8. Maintaining a record of medical information associated with all human exposure victims interviewed and counseled, including the exposure victim's decision concerning PEP treatment and if treatment was completed.

9. Notifying the LHD epidemiology staff when a human exposure victim initiates PEP treatment and providing any information about the situation necessary for statistical purposes.

10. Coordinating follow up with exposure victims if PEP treatment recommendations are not followed.

11. Coordinating the notification of human exposure victims with environmental health staff in regard to confinement release results within 24 hours after the confinement period.

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

1. Collecting and maintaining the following data in coordination/consultation with the environmental health staff and nursing staff for animal exposures/bites, animal bites to humans, and other human exposures:

[2a]. Demographics of person exposed;

[3b]. Information about the animal and its owner;

[4c]. Details of exposure;

[5d]. PEP recommendations and actions;

[6e]. Animal euthanasia secondary to suspect rabies; and

[7f]. Animal quarantine or confinement

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

1. Developing memoranda of understanding with locality animal control services for the purpose of organizing an integrated response to human and companion animal exposures within the locality and acknowledging the need for locality animal control services to be directed by the local health director in certain rabies related situations.

2. Overseeing companion animal and human exposure response within the locality.

3. Providing medical advice and consultation in regard to human exposure victims to environmental health staff, nursing staff, and human exposure victims within the locality.

4. Providing medical advice and consultation about rabies and rabies PEP treatment with health care providers within the locality.

5. Developing a guidance document for locality animal control services that contains examples of rabies response and control situations requiring locality animal control services staff to be specifically directed by the local health director.

FORMS (12VAC5-105)

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

REQUEST FOR RABIES VACCINATION EXEMPTION FOR LICENSING AND INSPECTION PURPOSES

Virginia Department of Health

3/2012

Please submit this completed form as directed by your local health department. A directory of local health departments can be found at <http://www.vdh.virginia.gov/>.

According to the *Code of Virginia* §3.2-6521, the Board of Health shall, by regulation, provide an exemption to rabies vaccination requirements if an animal suffers from an underlying medical condition that is likely to result in a life-threatening condition in response to vaccination and such exemption would not risk public health and safety. For the purposes of rabies exposure response, such exemption shall mean that the animal is considered **not** currently vaccinated for rabies. For the purposes of dog and cat licensing and inspection by designated authorities, such exemption shall be considered in place of a current certificate of vaccination. Each exemption request is reviewed on an individual basis, and the submitting veterinarian may be asked to provide additional information as needed. Please submit the following information, including all associated medical information to support your request, for review. Please print clearly and fill in all information.

Veterinarian Information		
Name:		
Virginia License #:		
Address:		
City:	State:	Zip:
Practice name:		
Address:		
City:	State:	Zip:
Phone	FAX:	
Patient Information		
Patient name:	Age:	Date of birth:
Species: <input type="checkbox"/> Feline <input type="checkbox"/> Canine		
Breed:		
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female		
Reproductive Status: <input type="checkbox"/> Spayed <input type="checkbox"/> Neutered <input type="checkbox"/> Intact		

Owner Information		
Owner Name:	Phone:	
Address:		
City:	State:	Zip:
Medical History of Animal		
Reason for requesting exemption:		
Pre-existing conditions:		
Date(s) of diagnosis:		
Clinical signs:		
Rabies Vaccination History		
List all previous rabies vaccinations given. Specify date(s) of vaccination, type(s) of vaccine given and the manufacturer(s) of the vaccine:		
<hr/>		

Owner Education
Has the owner been informed that this is an exemption only for licensing and inspection purposes by designated authorities and that, if this animal is exposed to rabies, the locality will require euthanasia or 6 months strict isolation? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has the owner been informed about the possibility that the locality may require some restrictions in regard to this animal's movement? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has the owner been informed that businesses such as privately owned veterinary hospitals, grooming facilities, boarding facilities and dog parks may not accept an exemption certificate in lieu of a current rabies certificate and, therefore, an exempted animal's access to these facilities may be limited? <input type="checkbox"/> Yes <input type="checkbox"/> No

Signature of Veterinarian

Date

The veterinarian whose signature appears above has reviewed the Owner Education section of this application with me and I, the undersigned, understand that if my pet is granted a rabies vaccine exemption, the concepts presented in this section will or may apply.

Name of owner (printed)

Date

Signature of Owner



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 22, 2014

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services

SUBJECT: The Proposed Regulations for Gravelless Material and Drip Dispersal

Va. Code Section 32.1-164.9 mandates the Board of Health to promulgate regulations for chamber and bundled expanded polystyrene systems, and other technologies as deemed necessary. The Board of Health approved emergency regulations for gravelless material and drip dispersal during the September 12, 2013 meeting and submitted the emergency regulations for executive branch review. The emergency regulations were approved by Governor McDonnell and became effective on January 2, 2014.

As part of the process to promulgate emergency regulations, the agency submitted a Notice of Intended Regulatory Action to create permanent regulations for gravelless material and drip dispersal. The draft proposed regulations amend 12VAC5-610 (the Sewage Handling and Disposal Regulations) by permanently incorporating the requirements of the emergency regulations, with several minor revisions (see Form TH-02, "Detail of changes").

Agency staff convened two technical advisory committees to review public comments and propose revisions to the emergency regulation. Karri Atwood, Assistant Attorney General, determined the Board of Health has authority to promulgate the draft proposed regulations.

Upon approval by the Board of Health, the proposed regulations will undergo executive branch review and approval. Following publication of the proposed regulation, there will be a 60-day public comment period. After considering public comments, the Board of Health will have an opportunity to consider adopting final regulations.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	Board of Health – Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-610
Regulation title	Sewage Handling and Disposal Regulations (“the Regulations”)
Action title	Establish requirements for the physical construction, design, and installation of gravelless material, and requirements for the physical construction, design, and installation of drip dispersal.
Date this document prepared	April 13, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The proposed revisions to the Regulations (12VAC5-610) will permanently incorporate the requirements for gravelless material and drip dispersal established by emergency regulations (January 2, 2014). These requirements can be summarized as follows:

- 1) Specifications for the physical construction of gravelless material including minimum exterior width, height, effluent storage capacity, and structural capacity.
- 2) Requirements for a permeable interface between gravelless material and trench sidewall soil surfaces for the absorption of effluent.
- 3) Criteria for the allowable slope, maximum length, minimum sidewall depth, and minimum lateral separation of gravelless material absorption trenches.
- 4) Criteria for determining the minimum absorption area required when utilizing gravelless material.

- 5) Criteria for the substitution of gravelless material in place of gravel for gravity percolation lines and low pressure distribution systems.
- 6) Specifications for the physical construction of drip dispersal system components.
- 7) Minimum requirements for the design of drip dispersal systems.
- 8) Minimum installation requirements for drip dispersal systems.

The proposed regulation has several minor revisions compared to the emergency regulations for gravelless material and drip dispersal. The revisions are based on public comments and comments from two technical advisory committees (the Chamber and Bundled Expanded Polystyrene Technical Advisory Committee, and the Drip Dispersal Technical Advisory Committee).

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

Acronyms

CBEP TAC – the Chamber and Bundled Expanded Polystyrene Technical Advisory Committee

DD TAC – the Drip Dispersal Technical Advisory Committee

GMP – Virginia Department of Health Guidance, Memorandum, and Policies

OEHS – Virginia Department of Health's Office of Environmental Health Services

OSE – Licensed Onsite Soil Evaluator

PE – Licensed Professional Engineer

STE – Septic Tank Effluent

Definitions

Drip Dispersal means an onsite sewage system that applies wastewater in an even and controlled manner over an absorption area. Drip dispersal components may include treatment components, a flow equalization pump tank, a filtration system, a flow measurement method, supply and return piping, small diameter pipe with emitters, air/vacuum release valves, redistribution controls, and electromechanical components or controls.

Gravelless Material means a proprietary product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chamber, bundled expanded polystyrene, and multi-pipe systems.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Va. Code Section 32.1-164.9 mandates the Board of Health (“the Board”) to promulgate regulations for physical construction, design, and installation of chamber and bundled expanded polystyrene systems. Additionally, the Board is authorized pursuant to Title 32.1-12 of the Code of Virginia to promulgate and enforce regulations. Title 32.1-164 of the Code authorizes the Board to promulgate regulations governing the collection, conveyance, transportation, treatment, and disposal of sewage by onsite sewage systems to protect public health, surface water, and ground water.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The need for the proposed regulation is to implement Va. Code Section 32.1-164.9 and incorporate requirements for gravelless material and drip dispersal. The emergency regulations currently include construction, design, and installation requirements for gravelless material and drip dispersal systems. Since 2002, VDH has recognized through policies that gravelless material is an acceptable means of dispersing effluent. VDH has recognized through policies that drip dispersal is an acceptable means of transmitting effluent. The goal of the proposed regulation is to permanently add the construction, design, and installation standards for gravelless material and drip dispersal found in the emergency regulations. The regulations are essential in order to comply with the provisions of the Code of Virginia.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

No substantive changes were made to existing requirements of the emergency regulations.

The term “soil gravel or sand interface” used in sections 920 and 950(A) of the Regulations was modified to ensure inclusion of gravelless material and drip dispersal. The proposed regulation establishes minimum physical construction, design, and installation requirements for gravelless

material and drip dispersal. The proposed regulation permanently incorporates sections 930(F), 940(D), 950(D), Table 5.4, and 955 of the emergency regulations, with a few minor revisions.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

The proposed regulation poses no disadvantage to the public or the Commonwealth. The proposed revisions permanently incorporate the emergency regulations for gravelless material and drip dispersal. The proposed regulations provide a benefit to the public by providing a clear regulation for use of gravelless material and drip dispersal.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no known localities that would be particularly affected by the proposed regulation. The Regulations apply to all localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the Board is seeking

information on impacts on small businesses as defined in Va. Code Section 2.2-4007.1. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to **Lance Gregory, Environmental Health Coordinator, 109 Governor Street, Richmond, Virginia, 23219, (804) 864-7491 (phone), (804) 864-7476 (fax), or lance.gregory@vdh.virginia.gov (email).** Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

A public hearing will be held after this regulatory stage is published in the *Virginia Register of Regulations* and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi>). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

<p>Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board</p>	<p>The proposed regulation may affect applicants for onsite sewage system construction permits and businesses providing services related to onsite sewage systems; onsite soil evaluators, professional engineers, onsite sewage system installers, and product manufacturers. Applicants and service providers are only affected when gravelless material or drip dispersal components are selected.</p>
<p>Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million.</p>	<p>In calendar year 2013, the agency processed approximately 13,000 applications.</p> <p>The agency estimates that there are approximately 400 licensed individuals providing site evaluation and design services for onsite sewage systems. Additionally, there are approximately 215 individuals licensed to</p>

	install onsite sewage systems. The vast majority of these service providers are small businesses.
Benefits expected as a result of this regulatory proposal.	The proposed regulation provides a benefit to both the public and the agency by providing a clear regulation for use of gravelless material and drip dispersal.
Projected cost to the state to implement and enforce this regulatory proposal.	None
Projected cost to localities to implement and enforce this regulatory proposal.	None
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	The proposed regulation does not create any new costs for individuals or small business. The proposed regulation simply codifies additional onsite sewage system component options previously covered under agency policies, and currently covered under the emergency regulations for gravelless material and drip dispersal.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

None. Va. Code Section 32.1-164.9 mandates that the Board must promulgate regulations for physical construction, design, and installation of chamber and bundled expanded polystyrene systems. Drip dispersal technology could be addressed through agency policy but regulations are required by the Code of Virginia.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The proposed regulation provides applicants and designers additional options when selecting onsite sewage system components. The proposed regulation directly implements Va. Code Section 32.1-164.9.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
<p>W.R. Russell</p>	<p>The commenter stated there is no scientific basis for reduced sizing, and no national standard for gravelless material.</p> <p>The commenter believes VDH has no expertise in the evaluation of onsite sewage system components, has a poor track record of follow up to assure components are effective, and must prove they have the capacity to determine if a product can deliver the performance defined by the manufacturer.</p> <p>The commenter does not disagree that gravelless materials have a use, but stated it is unclear whether the proposed absorption area reductions will result in “premature failure from insufficient capacity”.</p> <p>The commenter stated the Board should interview private onsite soil evaluators and professional engineers that refuse to allow any reduction in absorption area sizing when using gravelless material, as well as VDH field staff that have evaluated failing systems that use gravelless material.</p> <p>The commenter stated some manufacturers do not agree with using reduced absorption area sizing, and will not warranty their product.</p>	<p>Thank you for your comment. The agency reviewed experiences from other jurisdictions, available technical literature, and scientific reports as part of the development of agency policies and the emergency regulations for gravelless material. VDH engineering staff review product efficacy, including relevant literature, product manuals, and applicable national standards.</p> <p>The National Sanitation Foundation (NSF) Standard 240 was recently established to evaluate minimum material, design, construction and performance requirements for dispersal drainfield products used as alternatives to traditional stone or gravel trenches.</p> <p>All manufacturers of gravelless material were represented on the CBEP TAC, and all were supportive of the proposed minimum absorption area sizing.</p>
<p>Karl Rudolph</p>	<p>The commenter stated that the emergency regulations for gravelless material specify very minimal standards when enhanced flow distribution is <u>required</u> for open bottom gravelless materials (e.g. chambers). However, the emergency regulations do not address instances where enhanced flow distribution is not required, but is incorporated by the designer. The commenter suggested that the regulations should specify a maximum pump dose and a</p>	<p>Thank you for your comment. The CBEP TAC was reconvened following the end of the public comment period. A revision to 12VAC5-930.F.7 was made to address this comment.</p> <p>The minimum 400 square foot absorption area sizing also applies to conventional systems using gravelless material.</p>

	<p>maximum pumping rate for open bottom gravelless material.</p> <p>The commenter asked whether a septic tank effluent gravel and pipe drainfield, sized at 400 square feet, can be reduced by 15 percent down to a 340 square foot gravelless material drainfield?</p> <p>The commenter asked whether a treatment level 2 or treatment level 3 gravel and pipe drainfield, sized at 320 square feet, can be reduced by 15 percent down to a 272 square feet gravelless material drainfield?</p>	<p>“Double dipping”, taking reductions for both treatment and the use of gravelless material, was not supported by the CBEP TAC or the agency, and would not be allowed by the proposed regulation.</p>
<p>Anonymous Onsite Sewage System Designer</p>	<p>The commenter stated that for the past 20 years the footprint of a drip dispersal system absorption area has been equivalent in size to low pressure distribution absorption area footprints. Drip dispersal footprints were increased in size due to slope, similar to low pressure distribution. The emergency regulation for drip dispersal eliminates the slope correction factor which will dramatically decrease the size of a drip dispersal absorption area footprint.</p> <p>The commenter asked what empirical evidence was used to make this decision. This is significantly different from previous agency policies.</p> <p>The commenter suggested eliminating the slope factor for designs under Va. Code Section 32.1-163.6. Designs under Va. Code Section 32.1-163.5 should include the slope correction.</p>	<p>Thank you for your comment. In developing the emergency regulations, stakeholders and experts reported that the landscape linear loading rate is the critical design component. The proposed regulation includes revisions to set specific landscape linear loading rate requirements.</p>
<p>OSE</p>	<p>The commenter asked the following questions: In the past 12 years how many gravel and pipe, and gravelless material drainfields were installed in Virginia? How many of those systems failed?</p> <p>How many practicing OSEs and gravelless manufacturers were on the TAC?</p> <p>Why are there so many private sector OSEs who will not use gravelless material, or allow a reduction for gravelless material?</p> <p>Why has negative anecdotal evidence regarding chambers been ignored?</p> <p>Why does this regulation discriminate against</p>	<p>Thank you for your comments. A number of factors can lead to an onsite sewage system failure, and in many cases it is a combination of factors that creates a system failure. To better understand and track these causes, the agency has developed a “malfunction report” to allow field staff to enter additional data on system failures.</p> <p>The CBEP TAC consisted of representatives from each of the gravelless material manufacturers with approved products in Virginia, a private sector OSE representing VOWRA, a private sector OSE representing VAPSS, two</p>

	<p>gravel manufacturers?</p> <p>The commenter suggested providing gravel and pipe systems the same reduction as gravelless material.</p>	<p>Environmental Health Managers representing VDH staff, a representative for onsite sewage system installers, a PE representing VSPE, and a PE representing ACECVA.</p>
<p>Multiple - VDH Employee; OSE VDH, anonymous EHS, anonymous</p>	<p>The commenter asked why VDH OSEs are forced to allow a design change while private sector licensees are not.</p>	<p>Thank you for your comment. Agency employees must approve designs and products that meet minimum regulatory requirements.</p>
<p>homeowner</p>	<p>“As a concerned owner and user for one of these systems, I would like to say no to changing the design. We had this done at our home in 2006. Within months, we began having problems. The company did come back and add additional area to our septic which should have been there according to our permit and we also paid to have the area installed. Talk to your licensed professional before you agree to any changes by your contractor. In our case, we were told that these were the only systems being approved by the county.</p> <p>I feel we were misled by the county health department and our contractor. No one told us what the impacts making the septic design smaller would do and that it was at the discretion of the contractor. How could the person responsible for the design not be able to stop this?”</p>	<p>Thank you for your comment. Shifting policy into regulations will provide a clear framework for use of gravelless material, and reduce inconsistency.</p> <p>A number of factors can lead to premature failure of an onsite sewage system, and in many cases it is a combination of factors that creates a system failure.</p>
<p>Paul Davis</p>	<p>The commenter stated the following in regards to proposed section 12VAC5-610-955.L: “Why should the regulations mandate a inspection for drip systems? Is this because one of the sponsors of this nonsense charges almost \$2000.00 for their start up inspection? This sets a bad precedent about disclosure to the process. Inspections should be detailed in the design so an owner understands what he/she is paying for.”</p>	<p>Thank you for your comment. The Regulations require that all onsite sewage systems be inspected prior to operation of the system. Members of the DD TAC stated that a startup inspection is part of any drip dispersal inspection, that it is important to verify the design, and that the startup inspection provides vital information for system operators. A revision to the emergency regulation language is proposed.</p>
<p>Kym Harper</p>	<p>The commenter stated that VDH should publish the scientific documentation that warrants an across the board 25 percent reduction in absorption area sizing for gravelless material.</p>	<p>Thank you for your comments. The proposed regulations provide a 15 percent reduction for gravelless material in texture group IV soils.</p>

	<p>“As a private sector AOSE I rarely spec gravelless systems and I never take a reduction.”</p> <p>The commenter stated she had two experiences with premature failures of gravelless material systems, and is concerned with the lack of restrictions due to site and soil conditions.</p> <p>The commenter asked whether it would be appropriate to take a 25 percent reduction on a site with a very shallow water table.</p> <p>The commenter asked whether it would be appropriate to take a 25 percent reduction in combination with other reductions for water saving devices or secondary treatment.</p> <p>The commenter asked for more investigation on the reduction. “The only person that truly loses when these systems prematurely fail is the Home Owner.”</p>	<p>The agency reviewed experiences from other jurisdictions, available technical literature, and scientific reports as part of the development of agency policies and the emergency regulations for gravelless material.</p> <p>As previously stated, a number of factors can lead to premature failure of an onsite sewage system, and in many cases it is a combination of factors that creates a system failure.</p> <p>As previously stated, “double dipping”, taking reductions for both treatment and the use of gravelless material, was not supported by the CBEP TAC or the agency, and would not be allowed by the proposed regulation. However, the combination of water saving devices and gravelless material is not considered “double dipping”, as the overall design flow of the system is reduced. This reduces the minimum required absorption area for any onsite sewage system design. Additionally, designs based on water saving devices result in the issuance of a conditional permit which is recorded into the land records.</p>
<p>Bob Marshall</p>	<p>The commenter asked the following questions:</p> <p>Given GMP #116 was rescinded on the effective date of the Board’s emergency regulations, what has become of VDH’s requirement for manufacturer’s to warranty gravelless material?</p> <p>Given GMP #116 was rescinded on the effective date of the Board’s emergency regulations, what has become of VDH’s requirement for responsibility resting with the person who designed the “Substituted System” or with the contractor who installed the system?</p> <p>Given GMP #116 was rescinded on the effective date of the Board’s emergency regulations, what has become of VDH’s requirement for the owner to preserve and maintain the total area required for a gravel and pipe system, and not disturb the area in any manner?</p>	<p>Thank you for your comment. The requirement for a manufacturer warranty is not authorized by Va. Code Section 32.1-164.9. The Regulations do not require a warranty for any other onsite sewage system component that has received general approval from the agency.</p> <p>The CBEP TAC discussed the suggested revision to section 930.F.2.e and the term “effluent” was added.</p> <p>The CBEP TAC discussed the proposed revision to section 930.F.2.f, and several members felt that the proposed revision would be redundant with existing regulations. No changes were made to this section.</p> <p>The CBEP TAC members considered</p>

	<p>The commenter suggested 12VAC5-610-930.F.2.e of the emergency regulations be amended as follows: “Gravelless material shall also be constructed to maintain structural integrity such that it will be non-degradable by wastewater effluent.”</p> <p>The commenter suggested 12VAC5-610-930.F.2.f of the emergency regulations be amended as follows: “All gravelless materials must be capable of withstanding typical construction equipment and residential use loads without deformation, cave-in, subsidence, or collapse.”</p> <p>The commenter suggested a new section, 12VAC5-610-930.F.9, be added as follows: “Gravelless systems must be supplied with observation or access ports, which allow for post construction inspection access to head off clogging events, and future access for cleaning out any sludge accumulation in the absorption trenches. Locate access ports in or near the middle third of the trench and both upstream and downstream of the absorption area.”</p> <p>The commenter stated that the amended language under 12VAC5-610-950.D.2 of the emergency regulations bases the minimum area requirement on the width of a trench excavation without knowing the amount of “overdig” in the excavation. The commenter suggested this section be revised to read as follows: “When gravelless material is proposed, the design width of the trench shall be used to calculate minimum area requirements for absorption trenches.”</p> <p>The commenter suggested that 12VAC5-610-920 be revised as follows to better describe the application of effluent to the area over which that effluent is being distributed: “The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the application of effluent to the soil absorption area.”</p>	<p>the idea of access ports, but no consensus for change developed.</p> <p>Revisions to sections 950.D.2 and 920 of the Regulations are proposed.</p>
<p>John Q Public</p>	<p>The commenter voiced concern that the substitution of gravelless material by a contractor will result in a shorter lifespan of the onsite sewage system. The commenter suggested that owners always insist that</p>	<p>Thank you for your comment. The commenter did not provide a specific revision the regulation.</p>

	<p>construction bids be based on the approved design.</p>	
<p>David Lentz</p>	<p>“The proposed rulemaking is related directly to an effort to consolidate and codify several long-standing GMPs, under which thousands of gravelless drainfield systems have been installed since VDH first began allowing chamber system installations in 1987. Moving gravelless system management from policy to regulation meets the intent of 12VAC5-610-448.(A), which addresses codification of technologies that have been granted general approval under a VDH-issued policy. In addition to broadening the single option Virginians have historically had for constructing a drainfield under the regulations, the effort also opens the door to future innovation, allowing VDH to adopt new gravelless technologies under a flexible rule structure.”</p> <p>“Infiltrator Systems supports the use [of] a uniform 25% reduction for all soil percolation rates. Industry does not support what is referred to as double dipping, or taking a reduction as allowed for gravelless technology on top of a reduction associated with advanced treatment.”</p> <p>The commenter stated that industry believes the collective changes from agency policies to regulations for sizing gravelless systems simplifies the use of gravelless products and represent a net improvement to the Commonwealth.</p> <p>The commenter stated that gravelless materials are approved in all 50 states and 10 Canadian provinces, with over 3 million system installed over the past 25 years.</p> <p>“The International Association of Plumbing and Mechanical Officials (IAPMO), allows a 30% sizing efficiency for gravelless technologies.”</p> <p>“The use of a sizing reduction for gravelless products compared to the size of a stone and pipe drainfield is a proven method that is supported by independent research...Taken as a whole, the weight of scientific evidence from these studies shows that the performance of reduced-size gravelless systems is consistent with that of conventional stone and pipe.”</p>	<p>Thank you for your comment. A uniform 25 percent reduction (extending also to texture group IV soils) was initially considered by the CBEP TAC. However, several CBEP TAC members voiced concern with such reductions for texture group IV soils, and stated that the 15 percent reduction previously allowed by GMP 135 is more appropriate. The CBEP TAC considered a uniform 25 percent reduction but no consensus for change developed.</p>

	<p>“The North Carolina Department of Environmental and Natural Resources (NC DENR) conducted a field performance study of 900 systems in total, including 303 stone and pipe, 303 chamber, and 306 expanded polystyrene systems in 2005....At a 95% upper confidence level, the NC DENR found no statistical difference in malfunction rates between stone and pipe and gravelless systems.”</p> <p>The commenter mentioned that North Carolina’s minimum trench bottom area requirements are consistently smaller than Virginia’s.</p> <p>“The University of Maine conducted a study on chamber systems at least 20, and up to 30 years in age. Regulatory agency records showed that, at a 95% upper confidence level, gravelless systems at a 50% sizing reduction compared to the sizing of a stone and pipe system outperformed stone and pipe relative to number of required repairs.”</p> <p>“The Colorado School of Mines conducted a treatment efficacy study on operating gravel and chamber systems aged up to 11 years...No significant difference was observed in hydraulic or treatment performance between the gravel and 50% reduced length chamber systems.”</p>	
<p>lady of justice</p>	<p>The commenter stated that it appears the agency is removing benefits to the Commonwealth for advantages to a manufacturer. The commenter included a reference from GMP 116: “VDH recognizes that installation of gravelless systems at manufacturer’s recommended specifications may provide benefits to consumers, provided the absorption area is adequate to assure the long-term treatment and dispersal of septic tank effluent or other treated effluents. Sizing a drainfield smaller than specified in the Regulations may not result in adverse effects to public health or groundwater because this does not change the fundamental processes by which septic effluent trenches function. Such sizing may, however, reduce the operational life of the soil absorption system (i.e. shorten the time to failure). As long as the overall absorption area is maintained “in reserve” replacing the clogged trenches becomes a matter of long-term</p>	<p>Thank you for your comment. The statement referenced in this comment is part of now rescinded GMP 116. GMP 116 allowed for up to a 50 percent reduction in absorption area sizing for gravelless material when compared with gravel and pipe sizing. This area reduction allowance was not carried over to the emergency regulations, and is not included in the proposed regulation based on work and recommendations from the CBEP TAC.</p>

	operation and management and not one of public health or environmental protection.”	
Tom Ashton	<p>“The Sewage Handling and Disposal Regulations is the prescriptive regulation. By definition, drip dispersal is not a conventional system and thus design/review is covered by Chapter 613 Regulations for Alternative Onsite Sewage Systems as a 163.6 submission. Engineering criteria for LPD and now drip are in the 610 regulations. Current application (design) of treatment and dispersal under site and sizing criteria in 613 has evolved from the criteria, the approach in 610 regarding the concepts in ground, shallow placed, and fill systems. Reference to those sections is incomplete and at best cumbersome.”</p> <p>The commenter suggested striking the first sentence of 12VAC5-610-955.B.3 of the emergency regulations and replacing with: “Drip systems designed to disperse septic tank effluent require at least 12 inches of soil cover over the soil treatment area”.</p> <p>“PE designs under 32.1-163.6 pursuant to the AOSS Regs (613), regarding STE must have an 18” separation to limitation from the point of application and a minimum of 12” cover. The AOSS regulations are silent as to depth of installation of STE and pretreated effluents.”</p> <p>“Why not have proprietary drip system packages that meet the regulations be reviewed and listed?</p>	<p>Thank you for your comment. The DD TAC discussed these ideas. DD TAC members commented that the Regulations set expectations for the dispersal of septic tank effluent, and that the suggested revision would create a conflict within the regulations. Another DD TAC member commented that Va. Code Section 32.1-163.6 provides PEs latitude in designs, while designs completed under Va. Code Section 32.1-163.5 must adhere to prescriptive requirement contained within the Regulations.</p> <p>Listing package drip dispersal systems was also discussed. Several DD TAC members voiced concern that drip dispersal systems are site specific, and highly variable. Listing of package drip dispersal systems could not account for all of the site specific variables.</p>
anonymous	<p>“The notion that a government agency established to regulate an industry for the benefit of society acts instead for the benefit of the industry. In effect, the government agency is captured by the industry it is regulating. The capture theory of regulation indicates that government regulator acts as the decision-making head of a now monopolized industry.”</p>	<p>Thank you for your comment. The commenter did not suggest a specific revision to the regulation.</p>
anonymous, EHS	<p>The commenter asked how many gravelless material systems are installed in Virginia.</p> <p>“As it stands, the proposed regulations are going to require zero input from the licensed designer who works for VDH.”</p> <p>“VDH employees are being forced to ignore competence and professional experience issues</p>	<p>Thank you for your comment. The CBEP TAC included two VHD field staff. The DD TAC also included VDH field staff. Additional feedback was elicited from all Environmental Health Managers.</p> <p>As previously stated, agency employees must approve materials that</p>

	<p>in designing conventional onsite septic fields that are to be replaced by these proprietary options.”</p> <p>“Both the Technical Advisory Committee and Sewage Handling and Disposal Advisory Committees voiced strong and consistent opposition in allowing anyone other than the licensed professional responsible for preparing the design to make any changes. Exploiting VDH to enforce ministerial duties that are less than or in conflict with actual design requirements is not in the public’s best interest.”</p>	<p>meet minimum regulatory requirements.</p>
<p>Wesle B. Lower</p>	<p>The commenter voiced concern that gravelless material, installed with a reduced footprint, do not provide all of the necessary components for onsite sewage systems to function properly. Additionally, the commenter stated that the majority of failed systems result from contractor substitution of gravelless material for gravel and pipe. The commenter stated the NC DENR study revealed a higher rate of failure with gravelless material.</p> <p>The commenter voiced concern regarding a lack of data, and commented that several localities restrict the use of gravelless material.</p> <p>“As the single largest design firm staff is compelled to utilize these products despite production by a sole manufacturer and only two nationwide distributors.”</p> <p>“The field of designers is concerned and surprised that the conflict of interest revealed within this process has not attracted the attention of the AG, or the press.”</p>	<p>Thank you for your comment. The commenter did not suggest a specific revision to the regulation.</p>
<p>owner</p>	<p>“Who pays for this in the end; the owner does! Indemnification will protect agency staff from any wrong doing or lack of guidance provided during the consultation for designing the septic design. Only the manufacturers win this game. The broke of unfunctioning [<i>sic</i>] system will be paid for by the consumer.”</p>	<p>Thank you for your comment. The commenter did not suggest a change to the regulations.</p>
<p>VDH Employee</p>	<p>“Based on my years of experience drainfields with chambers have a much higher rate of failure (with or without a reduction. The regulations should require an increase in drainfield size when using chambers.</p> <p>Why is EZflow, or any other similar product,</p>	<p>Thank you for your comment. The CBEP TAC discussed this comment and the proposed regulation represents consensus among the CBEP TAC.</p>

	<p>better than gravel? It's not. There should be a 1 for 1 substitution with this product.</p> <p>It's amazing how we've completely lost all leadership in the health department. The manufacturers and private sector now run the sewage and water programs. I feel sorry for the homeowners that get stuck with these products.</p>	
Owner	<p>"Everyone knows that this is one of the dumbest regulations ever proposed. But what do you expect from an agency that has no leadership. Get over it. Yes, this regulation will hurt homeowners. There will be more malfunctions. And, we may need to boil our drinking water to be safe. Or, we can just move to a state that has better environmental leadership."</p>	<p>Thank you for your comment. The commenter did not offer a change to the regulations.</p>
Engineer	<p>"Give a 50% reduction for the use of gravel and then let's see what VDH does next when the gravelless manufacturers cry foul."</p>	<p>Thank you for your comment. The proposed regulation represents stakeholder consensus.</p>
James B. Slusser	<p>The commenter suggested that 12VAC5-610-930.F.8 of the emergency regulations be revised to read as follows: "Gravelless material may be substituted for gravel in accordance with this chapter, provided that the certifying licensed professional engineer or onsite soil evaluator approves the substitution <u>in writing prior to system construction</u>. The certifying licensed professional engineer or onsite soil evaluator shall..."</p> <p>The commenter suggested that 12VAC5-610-950 of the emergency regulations be revised to read as follows: "<u>4. Any substitution that decreases the "Area Required per Bedroom" or "Area Required per 100 gallons" listed in Table 5.4 shall be supported by saturated hydraulic conductivity percolation testing.</u>"</p> <p>The commenter suggested that 12VAC5-610-940.C.7.c of the emergency regulations be revised to read as follows: "Placement and alignment. Pressure percolation lines shall be placed so that the holes face vertically downward <u>upward except the distal hole.</u>"</p>	<p>Thank you for your comment. The CBEP TAC discussed revision to the regulations. Revisions were made where consensus was reached.</p> <p>The term "certifying" is taken from the reference to section 330 of the Regulations. Section 330 of the Regulations is a reference to Va. Code Section 32.1-164.1.E which specifically uses the term "certifying". The proposed language provides the appropriate reference to existing language within the Regulations and the Code.</p>
EHS, STAFFORD CO	<p>"Table 5.4 conflicts with local ordinances for minimum sizing. Owners may be subject to larger size septic fields than what this table allows. Our local ordinance has been tested for more years than these new systems."</p>	<p>Thank you for your comment. The proposed regulation would set the minimum requirements for gravelless material and drip dispersal in the Commonwealth. Local ordinances are not addressed.</p>

<p>Ken Carbaugh</p>	<p>The commenter stated there is no conflict with the proposed regulations regarding drip dispersal.</p> <p>The commenter stated that he objects to an unauthorized substitution of materials. He added that health department staff issuing permits should be licensed, and should be given the same latitude to accept or reject the substitutions of materials.</p> <p>The commenter stated that he does not agree with reductions for expanded polystyrene or tire chips.</p> <p>The commenter stated his primary concern with chamber systems is the lack of pipe; splash plates are unacceptable. Additionally, the commenter stated that for pump to trench systems, a dosing volume equal to gravel is excessive. The commenter also voiced concern with the installation of chambers in various soil classes, specifically soils with high mica content.</p> <p>The commenter asked for more data to make an educated, public health based, decision. The commenter suggested that the reduction in footprint should require Ksat test to ensure suitability of the entire absorption area.</p> <p>The commenter objects to contractor substitutions.</p>	<p>Thank you for your comment. Tire chips are not an approved gravelless material.</p>
<p>Private sector OSE</p>	<p>“VDH must have a great deal of faith in these gravel replacement products to require their OSE’s to add the statement to all permits that gravelless material may be used in accordance with Table 5.4 (reductions). This decision should involve the permitting VDH OSE and a homeowner who has had the opportunity to be educated regarding the choices-particularly when it comes to reducing area. The contractor is given a blanket “go ahead” to make the decision to use the material of his choice, but will be relieved of responsibility for that choice. Who is running the show here? The contractors...the manufacturers?”</p>	<p>Thank you for your comment. The commenter did not identify a specific change. The proposed regulations represents consensus among the CBEP TAC.</p>

Private sector OSE	“I started designing with chambers years ago when they first published the GMP, and my GMP 135 systems are still working today. There is lots of opposition to the rules that came from that house bill last year, but its worked here in the Richmond area over the long haul. I stay the course.”	Thank you for your comment.
--------------------	---	-----------------------------

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory action will have no family impact.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

Proposed revisions to the Sewage Handling and Disposal Regulations: Pre-emergency regulation.

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
30	Identifies other potentially applicable regulations and clarifies areas of responsibility between the agency and the Department of Environmental Quality (DEQ).	9VAC25-31 9VAC25-32 9VAC25-740	Section 30 identifies other potentially applicable regulations and <u>clarify</u> areas of responsibility between the agency and DEQ.
920	“The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the <u>soil gravel or sand interface application of effluent to the soil absorption area.</u> ”	NA	This revision ensures the changes address gravelless material and drip dispersal instead of only addressing gravel.

<p>930.F</p>	<p><u>“Gravelless material is a proprietary product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chamber, bundled expanded polystyrene, and multi-pipe systems. The division shall maintain a list of all generally approved gravelless material. Gravelless material on the generally approved list may be used in accordance with Table 5.4 of 12VAC5-610-950.”</u></p>	<p>NA</p>	<p>This section provides a definition of gravelless material and identifies that the agency will maintain a list of approved gravelless materials.</p>
<p>930.F.1</p>	<p><u>“Gravelless material that received general approval as of December 12, 2013, shall retain such status when used in accordance with the requirements of this chapter. After December 12, 2013, the division shall review and evaluate new applications for general approval pursuant to the requirements of this chapter.</u></p> <p><u>a. Any manufacturer of gravelless material may submit an application for general approval to the division using a form provided by the division. A complete application shall include the manufacturer's contact information, product specifications, product approvals in other states or territories, installation manual, and other information deemed necessary by the division to determine compliance with this chapter.</u></p> <p><u>b. The manufacturer of gravelless material shall identify in the application for general approval any recommendation that deviates from the requirements of this chapter. If the recommendation is approved by the division, then the manufacturer shall include the deviation in the gravelless material's installation manual.”</u></p>	<p>NA</p>	<p>This section allows previously approved gravelless material to retain approval status, and to provide a process for evaluating new products.</p>
<p>930.F.2.a</p>	<p><u>“The minimum exterior width shall be at least 90 percent of the total width of the absorption trench. The exterior width of a chamber system shall be measured at the edge or outer limit of the product's contact with the trench bottom unless the division determines a different measurement is required based on the</u></p>	<p>NA</p>	<p>This section creates a minimum exterior width for gravelless material as required by Va. Code Section 32.1-164.9.</p>

	<u>gravelless material's design. The exterior width of bundled expanded polystyrene and multi-pipe systems shall be measured using the outside diameter of the bundled gravelless material unless the division determines a different measurement is required based on the gravelless material's design. The division shall establish the exterior width of any gravelless material that is not considered a chamber, bundled expanded polystyrene, or multi-pipe system."</u>		
930.F.2.b	<u>"Gravelless material shall have a minimum height of eight inches to provide a continuous exchange of air through a permeable interface."</u>	NA	This section creates a minimum height requirement for gravelless material as required by Va. Code Section 32.1-164.9.
930.F.2.c	<u>"Gravelless material shall have a permeable interface that shall be located along the trench bottom and trench sidewalls within the absorption trench."</u>	NA	This section creates a requirement for a permeable interface between gravelless material and the trench sidewall as required by Va. Code Section 32.1-164.9.
930.F.2.d	<u>"Gravelless material shall provide a minimum storage capacity of 1.3 gallons per square foot of trench bottom area."</u>	NA	This section creates a minimum storage capacity requirement for gravelless material as required by Va. Code Section 32.1-164.9. The required storage capacity is equivalent to the storage capacity below the pipe in a gravel trench system.
930.F.2.e	<u>"Gravelless material shall pose no greater risk to surface water and groundwater quality than gravel in absorption trenches. Gravelless material shall be constructed to maintain structural integrity such that it does not decay or corrode when exposed to effluent."</u>	NA	This section creates a minimum structural capacity requirement for gravelless material as required by Va. Code Section 32.1-164.9.
930.F.2.f	<u>"Gravelless material shall have a minimum load rating of H-10 or H-20 from the American Association of State Highway and Transportation Officials or equivalent when installed in accordance with the manufacturer's specifications and minimum specified depth of cover in non-traffic or traffic areas, respectively."</u>	NA	This section creates a minimum structural capacity requirement for gravelless material as required by Va. Code Section 32.1-164.9.
930.F.3	<u>"For designs using gravelless material, the absorption trenches shall receive an equal volume of effluent per square foot of trench. Trench bottom area shall be</u>	NA	This section requires that effluent be dispersed evenly throughout a gravelless system and that the trench bottom be

	<u>equal to or greater than the minimum area requirements contained in Table 5.4 of 12VAC5-610-950. Trench sidewall shall not be included when determining minimum area requirements. When open-bottom gravelless material is utilized, it shall provide a splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity.”</u>		protected from erosion. These requirements are based on current requirements in the Regulations and comments from the CBEP TAC.
930.F.4	<u>“Installation of gravelless material shall comply with this chapter unless the department grants a deviation pursuant to 12VAC5-610-660 or the division has granted a deviation identified in the installation manual.”</u>	NA	Requires gravelless material to be designed and installed in compliance with existing requirements contained in the Regulations. This section allows gravelless material installations to deviate from the Regulations if approved by the division as part of the product’s general approval or if granted an exception pursuant to 12VAC5-610-660. This section implements Va. Code Section 32.1-164.9.
930.F.5	<u>“Gravelless material shall contain a pressure percolation line along the entire length of the trench when low pressure distribution is utilized pursuant to 12VAC5-610-940 D.”</u>	12VAC5-613	This section, along with 940.D, sets minimum requirements for low pressure distribution systems that use gravelless material to bed the pressure percolation lines. These minimums are based on requirements in previous agency policies and recommendations from the CBEP TAC. This section is also intended to meet requirements of Va. Code Section 32.1-164.9.
930.F.6 & 7	<u>“6. When pumping effluent to overcome gravity, any open-bottom gravelless material shall provide a high-flow splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity.</u> <u>7. When enhanced flow distribution is used, open-bottom gravelless material shall contain a percolation pipe that extends a minimum of 10 feet from the trench's intersection with the header line. The percolation pipe shall be installed in accordance with the manufacturer's</u>	NA	Section 930(F)(6) and 930(F)(7) set minimum requirements for pump-to-gravity, open-bottom gravelless material. These requirements ensure that effluent velocity is reduced prior to entering the absorption. Dosing volume requirements are based on 12VAC5-610-890.C.

	<u>approved installation manual. The dosing volume shall be a minimum 39 gallons per 100 linear feet of absorption trench.”</u>		
930.F.8	<u>“Gravelless material may be substituted for gravel in accordance with this chapter, provided that the certifying licensed professional engineer or onsite soil evaluator approves the substitution. The certifying licensed professional engineer or onsite soil evaluator shall identify the substitution on the inspection report submitted in accordance with 12VAC5-610-330. A new construction permit pursuant to 12VAC5-610-310 is not required for the substitution.”</u>	NA	This section sets criteria for the substitution of gravelless material in lieu of gravel when gravelless material is not specified as part of the system design. Substitution of gravelless material does not require a new permit and requires approval by the certifying PE or OSE. This section implements Va. Code Section 32.1-164.9.
940.C.7.c	<u>“However, under no circumstance shall the invert of the pressure percolation lines be placed closer than 16-1/2 inches to the seasonal water table as defined in 12VAC5-610-950-A-3 12VAC5-610-470 D.”</u>	NA	This revision removes an inaccurate reference to the definition of “seasonal water table”.
940.D	<u>“Gravelless material with general approval may be used for low pressure distribution in accordance with the manufacturer's approved installation manual, Table 5.4 of 12VAC5-610-950, and the applicable requirements of this chapter.”</u>	12VAC5-613	This section, along with 930.F.5, sets minimum requirements for low pressure distribution systems that use gravelless material to bed the pressure percolation lines. This section implements Va. Code Section 32.1-164.9.
950.A	<u>“The absorption area is the undisturbed soil medium beginning at the soil gravel or sand interface which is utilized for absorption of the effluent. The absorption area includes the infiltrative surface in the absorption trench and the soil between and around the trenches <u>when trenches are used.</u>”</u>	NA	This revision ensures inclusion of gravelless material and drip dispersal within the Regulations.
950.D.2	<u>“Area reduction. See Table 5.4 for percent area reduction when <u>gravelless material or</u> low pressure distribution is utilized. A reduction in area shall not be permitted when flow diversion is utilized with low pressure distribution. <u>When gravelless material is utilized, the design width of the trench shall be used to calculate minimum area requirements for absorption trenches.</u>”</u>	NA	This section, along with Table 5.4, sets criteria for determining the minimum area requirements for gravelless material.
Table 5.4	Revisions to Table 5.4 include minimum sizing for gravelless material equivalent	NA	This section, along with section 950.D.2, sets criteria for

	to a 25 percent reduction when compared to gravel and pipe sizing in texture group I, II, and III soils, and equivalent to a 15 percent reduction when compared to gravel and pipe sizing in texture group IV soils.		determining the minimum area requirements for gravelless material. This section implements Va. Code Section 32.1-164.9.
955.A	<u>“Drip dispersal applies wastewater in an even and controlled manner over an absorption area. Drip dispersal system components may include treatment components, a flow equalization pump tank, a filtration system, a flow measurement method, supply and return piping, small diameter pipe with emitters, air/vacuum release valves, redistribution control, and electromechanical components or controls.”</u>	12VAC5-613	This section provides a definition of drip dispersal.
955.B	<u>“Drip dispersal system tubing shall be color coded and certified by the manufacturer as designed and manufactured for the dispersal of wastewater. All drip dispersal system tubing shall be equipped with emitters approved for use with wastewater. For the application of septic tank effluent, the tubing must have self cleaning emitters. “</u>	12VAC5-613	This section sets minimum physical construction criteria for drip dispersal system.
955.B.1	<u>“The minimum linear feet of tubing in the system shall be one-half of the minimum soil absorption area in square feet.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.B.2	<u>“All tubing shall be placed on contour.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.B.3	<u>“Except as provided by 12VAC5-613, drip systems dispersing septic tank effluent shall comply with the requirements of 12VAC5-610-594. Drip systems dispersing secondary effluent or better require a minimum of six inches of cover over the tubing. Cover may be achieved by a combination of installation depth and Group II or Group III soil cover or other approved material over the drip field.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.B.4	<u>“The discharge rate of any two emitters shall not vary by more than 10 percent in order to ensure that the effluent is uniformly distributed over the entire drip field or zone.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.

955.B.5	<u>“The emitters shall be evenly spaced along the length of the drip tubing at not less than six inches or more than 24 inches apart.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.B.6	<u>“The system design shall protect the drip emitters and system from the effects of siphoning, or backflow through the emitters.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.C.1	<u>“For the dispersal of septic tank effluent, the minimum soil absorption area for a drip system shall be calculated by multiplying the trench bottom area required for a low pressure distribution system in Table 5.4 of this chapter, by three.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.C.2	<u>“For the dispersal of secondary or better effluent, the minimum soil absorption area shall be calculated by multiplying the trench bottom area for pressure distribution systems in accordance with 12VAC5-613-80.10 by three.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.C.3	<u>“Landscape linear loading rates shall be considered for sloping absorption areas. For sites where effluent flow is primarily horizontal, linear loading rates shall be less than 4 gallons per day per linear foot. For sites where the flow is primarily vertical, the linear loading rates shall be less than 10 gallons per day per linear foot.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.C.4	<u>“Air/vacuum release valves shall be located at the high points of the supply and return manifolds to each zone.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.D	<u>“All drip dispersal systems shall be equipped with devices or methods to restrict effluent from draining by gravity to portions of a zone or laterals lower in elevation. Variable distribution due to gravity drainage shall be 10 percent or less within a zone.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.E	<u>“A minimum of six hours of emergency storage above the high water alarm in the pump chamber shall be provided. The equalization volume shall be equal to 18 hours of storage. The equalization volume shall be measured from the pump off level to the high water alarm level. An</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.

	<u>audio/visual alarm meeting the requirements of 12VAC5-610-880.B.8 shall be provided for the pump chamber.”</u>		
955.F	<u>“Each drip dispersal zone shall be time-dosed over a 24 hour period. The dose volume and interval shall be set to provide unsaturated flow conditions. Demand dosing is prohibited. Minimum dose volume per zone shall be 3.5 times the liquid capacity of the drip laterals in the zone plus the liquid capacity of the supply and return manifold lines (which drain between doses) accounting for instantaneous loading and drain back.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.F.1	<u>“At each dosing cycle, the system design shall only allow a full dose volume to be delivered.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.F.2	<u>“For design flows greater than 1,000 gallons per day, a means to take each zone off line separately shall be provided. The system shall have the capability to bypass each zone that is taken out of service such that each subsequent dose is dispersed to the next available zone in sequence.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.G	<u>“Filtration shall be provided to remove suspended solids and prevent clogging of emitters. The filtration design shall meet the drip tubing manufacturer’s particle size requirements for protection of the emitters at a flow rate equal to or greater than the rate of forward flushing. Filter flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.H	<u>“A means for measuring or estimating total flow dispersed to the soil absorption area and to verify field dosing and field flushing rates shall be provided.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.I	<u>“The system shall provide forward field flushing to achieve scouring velocity as specified by the drip tubing manufacturer. Field flushing shall occur on a routine schedule to prevent excessive solids accumulation and</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.

	<u>clogging. Flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system.”</u>		
955.J	<u>“Electrical components shall be Underwriters Laboratory (UL) listed for the intended purpose. The designer shall provide a description with a schematic diagram of the electrical and control functions in the operation and maintenance manual. The electrical control equipment shall be mounted within a National Electrical Manufacturers Association (NEMA) 4X rated enclosure with a rigid latching door. All switches shall be clearly identified and all internal wiring shall be factory installed. All wiring shall be installed according to applicable electrical safety codes and the manufacturer’s installation schematic.”</u>	12VAC5-613	This section sets minimum design criteria for drip dispersal system.
955.K	<u>“All components in a drip dispersal system shall be rated to withstand contact with wastewater and recommended for this application by the manufacturer. All components shall be protected from freezing.”</u>	12VAC5-613	This section sets minimum physical construction criteria for drip dispersal system.
955.L	<u>“The startup inspection conducted by the designer of the drip dispersal system shall verify the dosing rates, the flushing rates, and other parameters critical to the proper operation of the system. A summary of the startup inspection shall be included in the operation and maintenance manual and shall include, at a minimum, the dosing volume; the forward flow flushing rate; the pressure head of the system; and verification of proper cycling between zones.”</u>	12VAC5-613	This section sets minimum installation inspection criteria for drip dispersal system.

Proposed changes made since the publication of the emergency regulations.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
920		Current regulatory language: “The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the point of effluent application to the soil absorption area.”	Proposed revision: “The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the point of effluent application of <u>effluent</u> to the soil absorption area.” This revision addresses a public comment, as agreed to by the CBEP TAC.
930.F.1.a		Current regulatory language: “Any manufacturer of gravelless material may submit an application for general approval to the division using the form provided by the division.”	Proposed revision: “Any manufacturer of gravelless material may submit an application for general approval to the division using the <u>a</u> form provided by the division.”
930.F.2.a		Current regulatory language: “The minimum exterior width shall be at least 90% of the total...”	Proposed revision: “The minimum exterior width shall be at least 90% <u>percent</u> of the total...”
930.F.2.e		Current regulatory language: “Gravelless material shall pose no greater risk to surface water and groundwater quality than gravel in absorption trenches. Gravelless material shall be constructed to maintain structural integrity such that is does not decay or corrode when exposed to sewage.”	Proposed revision: “Gravelless material shall pose no greater risk to surface water and groundwater quality than gravel in absorption trenches. Gravelless material shall be constructed to maintain structural integrity such that is does not decay or corrode when exposed to <u>sewage effluent</u> .” This revision addresses a public comment, as agreed to by the CBEP TAC.
930.F.2.f		Current regulatory language: “Gravelless material shall have a minimum load rating of H-10 or H-20 from the American Association of State Highway and Transportation Officials or equivalent when installed in accordance with the manufacturer’s minimum specified depth of compacted cover in non-traffic or traffic areas, respectively.”	Proposed revision: “Gravelless material shall have a minimum load rating of H-10 or H-20 from the American Association of State Highway and Transportation Officials or equivalent when installed in accordance with the manufacturer’s <u>specifications and</u> minimum specified depth of compacted cover in non-traffic or traffic areas, respectively.” This revision addresses a comment from the CBEP TAC. The addition of “specifications and”

			conveys the need to adhere to all manufacturer instructions, not just depth of cover.
930.F.7		Current regulatory language: “When enhanced flow distribution is required by this chapter,…”	Proposed revision: “When enhanced flow distribution is required by this chapter <u>used</u> ,…” This revision addresses a public comment.
940.C.7.c		Current regulatory language: “However, under no circumstance shall the invert of the pressure percolation lines be placed closer than 16-1/2 inches to the seasonal water table.”	Proposed revision: “However, under no circumstance shall the invert of the pressure percolation lines be placed closer than 16-1/2 inches to the seasonal water table <u>as defined in 12VAC5-610-470 D.</u> ” This revision addresses a comment from the CBEP TAC that a reference to the definition of seasonal water table is necessary. Under the emergency regulations an inaccurate reference to 12VAC5-610-950.A.3 was removed.
950.D.2		Current regulatory language: “When gravelless material is utilized, the width of the trench excavation shall be used to calculate minimum area requirements for absorption trenches.”	Proposed revision: “When gravelless material is utilized, the <u>design</u> width of the trench excavation shall be used to calculate minimum area requirements for absorption trenches.” This revision addresses a public comment, as recommend by the CBEP TAC.
955.B.4		Current regulatory language: “The discharge rate of any two emitters shall not vary by more than 10% in order to…”	Proposed revision: “The discharge rate of any two emitters shall not vary by more than 10% <u>percent</u> in order to…”
955.B.6		NA	Proposed revision: “ <u>The system design shall protect the drip emitters and system from the effects of siphoning or backflow through the emitters.</u> ” This revision addresses a comment from the DD TAC that several drip dispersal systems, designed in accordance with GMP 107 (the basis for the emergency regulations), malfunctioned during rain events because surface runoff was back flowing into the drip tubing on shallow sloping sites; clogging the emitters with uniform fine sand particles. Designers had determined several methods for eliminating this issue, but felt it necessary to make other designers aware of potential backflow issues.

<p>955.C.3</p>		<p>Current regulatory language: “Landscape linear loading rates shall be considered for sloping absorption areas to the greatest extent possible. The landscape linear loading rate is the volume of effluent (gallons) applied per day per linear foot of the system along the natural contour (gallon per day/foot).”</p>	<p>Proposed revision: “Landscape linear loading rates shall be considered for sloping absorption areas to the greatest extent possible. The landscape linear loading rate is the volume of effluent (gallons) applied per day per linear foot of the system along the natural contour (gallon per day/foot). <u>For sites where effluent flow is primarily horizontal, linear loading rates shall be less than 4 gallons per day per linear foot. For sites where the flow is primarily vertical, the linear loading rates shall be less than 10 gallons per day per linear foot.</u>”</p> <p>This revision is based on comments from the DD TAC that the proposed regulations should set specific prescriptive requirements. “[T]o the greatest extent possible” is vague and does not set an enforceable requirement.</p>
<p>955.L</p>		<p>Current regulatory language: “The designer of the drip dispersal system shall conduct a startup inspection that verifies the dosing rates, the flushing rates, and other parameters critical to the proper operation of the system.”</p>	<p>Proposed revision: “The designer of the drip dispersal system shall conduct a startup inspection that <u>verifies the dosing rates, the flushing rates, and other parameters critical to the proper operation of the system at the startup inspection.</u>”</p>

DEPARTMENT OF HEALTH
Proposed Regulations For Gravelless Material and Drip Dispersal

12VAC5-610-30. Relationship to Virginia Joint Sewerage Other Regulations.

~~This chapter is supplemental to the current Virginia Sewerage Regulations, or their successor, which were adopted jointly by the State Board of Health and the Department of Environmental Quality pursuant to § 62.1-44.19 of the Code of Virginia. This chapter addresses the handling and disposal of sewage not regulated by a Virginia Pollutant Discharge Elimination System (VPDES) Permit.~~

A. This chapter addresses the handling and disposal of those portions of sewage flows not regulated by a Virginia Pollutant Discharge Elimination System (VPDES) or a Virginia Pollutant Abatement (VPA) Permit issued in accordance with 9VAC25-31 or 9VAC25-32, respectively.

B. Reclamation and reuse of sewage may be subject to permitting by the Department of Environmental Quality under 9VAC25-740.

12VAC5-610-920. Distribution methods.

The term distribution methods refers to the piping, flow splitting devices, gravel, and other appurtenances beginning at the point of flow splitting and ending at the ~~soil-gravel or sand interface~~ application of effluent to the soil absorption area. Two basic methods are considered:

- A. Gravity; and
- B. Pressure.

12VAC5-610-930. Gravity distribution.

Gravity distribution is the conveyance of effluent from a distribution box through the percolation lines at less than full flow conditions. Flow to the initial distribution box may be initiated by pump, siphon or gravity.

A. Enhanced flow distribution. Enhanced flow distribution is the initiation of the effluent flow to the distribution box by pump or siphon for the purpose of assuring more uniform flow splitting to the percolation lines. Enhanced flow distribution shall be provided on systems where the flow is split more than 12 times or the system contains more than 1200 linear feet of percolation lines. For the purpose of this chapter, enhanced flow distribution is considered to produce unsaturated soil conditions.

B. System size. Distribution systems containing 1800 or more linear feet of percolation piping shall be split into multiple systems containing a maximum of 1200 linear feet of percolation piping per system.

C. Distribution boxes. The distribution box is a device for splitting flow equally by gravity to points in the system. Improperly installed distribution boxes are a cause for absorption field malfunction.

1. Materials. The preferred material for use in constructing distribution boxes is concrete (3000 psi). Other materials may be considered on a case-by-case basis. All materials must be resistant to both chemical and electrolytic corrosion and must have sufficient structural strength to contain sewage and resist lateral compressive and bearing loads.

2. Design. Each distribution box shall be designed to split the influent flow equally among the multiple effluent ports. All effluent ports shall be at the same elevation and be of the same diameter. The elevation of the effluent ports shall be at a lower elevation than the influent port. The placement of the influent ports shall be such as to prevent short circuiting unless baffling is provided to prevent short circuiting. The minimum inside width of a gravity flow distribution box

shall be equal to or greater than 12 inches. The inside bottom shall be at least four inches below the invert of the effluent ports and at least five inches below the invert of the influent port. A minimum of eight inches freeboard above the invert of the effluent piping shall be provided. The distribution box shall be fitted with a watertight, removable lid for access.

3. Installation. The hole for placement of the distribution box shall be excavated to undisturbed soil. The distribution box shall be placed in the excavation and stabilized. The preferred method of stabilizing the distribution box is to bond the distribution box to a four inch poured in place Portland cement concrete pad with dimensions six inches greater than the length and width dimensions of the distribution box. The box shall be permanently leveled and checked by water testing. Conduits passing through the walls of a distribution box shall be provided with a water stop.

D. Lead or header lines. Header or lead lines are watertight, semirigid or rigid lines that convey effluent from a distribution box to another box or to the percolation piping.

1. Size. The lead or header lines shall have an internal diameter of four inches.

2. Slope. Minimum slope shall be two inches per 100 feet.

3. Materials. The lead or header lines shall have a minimum crush strength of 1500 pounds per foot and may be constructed of cast iron, plastic, vitrified clay or other material resistant to the corrosive action of sewage.

4. Appurtenances.

a. Joints. Lead or header lines shall have joints of the compressions type with the exception of plastic lead or header lines which may be welded sleeve, chemically fused or clamped (noncorrosive) flexible sleeve.

b. Adapters. Joining of lead or header lines of different size and/or material shall be accomplished by use of a manufactured adapter specifically designed for the purpose.

c. Valves. Valves shall be constructed of materials resistant to the corrosive action of sewage. Valves placed below ground level shall be provided with a valve box and a suitable valve stem so that it may be operated from the ground surface.

5. Construction.

a. Bedding. All lead or header lines shall be bedded to supply uniform support and maintain grade and alignment along the length of the lead or header lines. Special care shall be taken when using semirigid pipe.

b. Backfilling and tamping. Lead and header lines shall be backfilled and tamped as soon as possible after the installation of the lead or header lines has been approved. Material for backfilling shall be free of large stones and debris.

6. Termination. Header or lead lines shall extend for a minimum distance of two feet into the absorption trenches.

E. Gravity percolation lines. Gravity percolation lines are perforated or open joint pipes that are utilized to distribute the effluent along the length of the absorption trenches.

1. Size. All gravity percolation lines shall have an internal diameter of four inches.

2. Slope. The slope of the lines shall be uniform and shall not be less than two inches or more than four inches per 100 feet.

3. Design. Effluent shall be split by the distribution system so that all gravity percolation lines installed shall receive an equal volume of the total design effluent load per square foot of trench, i.e., the fraction of the flow received by each percolation line divided by the length of the gravity percolation lines shall be equal for all gravity percolation lines in a system.

4. Length. No individual gravity percolation line shall exceed 100 feet in length.

5. Materials.

a. Clay. Clay tile shall be extra-strength and meet current ASTM standards for clay tile.

b. Perforated plastic drainage tubing. Perforated plastic drainage tubing shall meet ASTM standards. At not greater than 10 feet intervals the pipe shall be plainly marked, embossed or engraved thereby showing the manufacturer's name or hallmark and showing that the product meets a bearing load of 1,000 lb. per foot. In addition, a painted or other clearly marked line or spot shall be marked at not greater than 10 feet intervals to denote the top of the pipe.

The tubing shall have three holes, 1/2 to 3/4 inch in diameter evenly spaced and placed within an arc of 130 degrees, the center hole being directly opposite the top marking.

Spacing of each set of three holes shall be at four inch intervals along the tube. If there is any break in the continuity of the tubing, an appropriate connection shall be used to join the tubing.

6. Installation

a. Crushed stone or gravel. Clean gravel or crushed stone having a size range from 1/2 inch to 1-1/2 inches shall be utilized to bed the gravity percolation lines.

Minimum depth of gravel or crushed stone beneath the percolation lines shall be six inches. Clean course silica sand (does not effervesce in presence of dilute hydrochloric acid) may be substituted for the first two inches (soil interface) of the require six inches of gravel beneath the percolation lines. The absorption trench shall be backfilled to a depth of two inches over the gravity percolation lines with the same gravel or crushed stone. Clean sand, gravel or crushed stone shall be free of fines, clay and organic materials.

b. Grade boards and/or stakes. Grade boards and/or stakes placed in the bottom or sidewalls of the absorption trench shall be utilized to maintain the grade on the gravel for placement of the gravity percolation lines. Grade stakes shall not be placed on centers greater than 10 feet.

c. Placement and alignment. Perforated gravity percolation piping shall be placed so that the center hole is in the horizontal plane and interfaces with the minimum six inches of graded gravel. When open joint piping is utilized the upper half of the top of the 1/4-inch open space shall be covered with tar paper or building paper to block the entrance of fines into the pipe during the backfilling operation. All gravity percolating piping shall be placed in the horizontal center of the absorption trench and shall maintain a straight alignment and uniform grade.

d. Backfilling. After the placement of the gravity percolation piping the absorption trench shall be backfilled evenly with crushed stone or gravel to a depth of two inches over the piping. Untreated building paper, or other suitable material shall be placed at the interface of the gravel and soil to prevent migration of fines to the trench bottom. The remainder of the trench shall be backfilled with soil to the ground surface.

F. Gravelless material is a proprietary product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chamber, bundled expanded polystyrene, and multi-pipe systems. The division shall maintain a list of all generally approved gravelless material. Gravelless material on the generally approved list may be used in accordance with Table 5.4 of 12VAC5-610-950.

1. Gravelless material that received general approval as of December 12, 2013, shall retain such status when used in accordance with the requirements of this chapter. After December 12, 2013, the division shall review and evaluate new applications for general approval pursuant to the requirements of this chapter.

a. Any manufacturer of gravelless material may submit an application for general approval to the division using a form provided by the division. A complete application shall include the manufacturer's contact information, product specifications, product approvals in other states or territories, installation manual, and other information deemed necessary by the division to determine compliance with this chapter.

b. The manufacturer of gravelless material shall identify in the application for general approval any recommendation that deviates from the requirements of this chapter. If the recommendation is approved by the division, then the manufacturer shall include the deviation in the gravelless material's installation manual.

2. Gravelless material shall have the following minimum characteristics for general approval:

a. The minimum exterior width shall be at least 90 percent of the total width of the absorption trench. The exterior width of a chamber system shall be measured at the edge or outer limit of the product's contact with the trench bottom unless the division determines a different measurement is required based on the gravelless material's design. The exterior width of bundled expanded polystyrene and multi-pipe systems shall be measured using the outside diameter of the bundled gravelless material unless the division determines a different measurement is required based on the gravelless material's design. The division shall establish the exterior width of any gravelless material that is not considered a chamber, bundled expanded polystyrene, or multi-pipe system.

b. Gravelless material shall have a minimum height of eight inches to provide a continuous exchange of air through a permeable interface.

c. Gravelless material shall have a permeable interface that shall be located along the trench bottom and trench sidewalls within the absorption trench.

d. Gravelless material shall provide a minimum storage capacity of 1.3 gallons per square foot of trench bottom area.

e. Gravelless material shall pose no greater risk to surface water and groundwater quality than gravel in absorption trenches. Gravelless material shall be constructed to maintain structural integrity such that it does not decay or corrode when exposed to effluent.

f. Gravelless material shall have a minimum load rating of H-10 or H-20 from the American Association of State Highway and Transportation Officials or equivalent when installed in accordance with the manufacturer's specifications and minimum specified depth of cover in non-traffic or traffic areas, respectively.

3. For designs using gravelless material, the absorption trenches shall receive an equal volume of effluent per square foot of trench. Trench bottom area shall be equal to or greater than the minimum area requirements contained in Table 5.4 of 12VAC5-610-950. Trench sidewall shall not be included when determining minimum area requirements. When open-bottom gravelless material is utilized, it shall provide a splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity.

4. Installation of gravelless material shall comply with this chapter unless the department grants a deviation pursuant to 12VAC5-610-660 or the division has granted a deviation identified in the installation manual.

5. Gravelless material shall contain a pressure percolation line along the entire length of the trench when low pressure distribution is utilized pursuant to 12VAC5-610-940 D.

6. When pumping effluent to overcome gravity, any open-bottom gravelless material shall provide a high-flow splash plate at the inlet of the trench or other suitable method approved by the manufacturer to reduce effluent velocity.

7. When enhanced flow distribution is used, open-bottom gravelless material shall contain a percolation pipe that extends a minimum of 10 feet from the trench's intersection with the header line. The percolation pipe shall be installed in accordance with the manufacturer's approved installation manual. The dosing volume shall be a minimum 39 gallons per 100 linear feet of absorption trench.

8. Gravelless material may be substituted for gravel in accordance with this chapter, provided that the certifying licensed professional engineer or onsite soil evaluator approves the substitution. The certifying licensed professional engineer or onsite soil evaluator shall identify the substitution on the inspection report submitted in accordance with 12VAC5-610-330. A new construction permit pursuant to 12VAC5-610-310 is not required for the substitution.

12VAC5-610-940. Low pressure distribution.

Low pressure distribution is the conveyance of effluent through the pressure percolation lines at full flow conditions into the absorption area with the prime motive force being a pump or siphon. Low pressure systems are limited to a working pressure of from one to four feet of head at the distal end of the pressure percolation lines. For the purpose of this chapter low pressure distribution is considered to provide unsaturated soil conditions.

A. Dosing cycle. Systems shall be designed so that the effluent volume applied to the absorption area per dosing cycle is from seven to 10 times the volume of the distribution piping, however, the volume per dosing cycle should not result in a liquid depth in the absorption trench greater than two inches.

B. Manifold lines. Manifold lines are watertight lines that convey effluent from the initial point of flow splitting to the pressure percolation lines.

1. Size. The manifold line shall be sized to provide a minimum velocity of two feet per second and a maximum velocity of eight feet per second.

2. Materials. All pipe used for manifolds shall be of the pressure type with pressure type joints.

3. Bedding. All manifolds shall be bedded to supply uniform support along its length.

4. Backfilling and tamping. Manifold trenches shall be backfilled and tamped as soon as possible after the installation of the manifold has been approved. Material for backfilling shall be free of large stones and debris.

5. Valves. Valves for throttling and check valves to prevent backflow are required wherever necessary. Each valve shall be supplied with a valve box terminating at the surface.

C. Pressure percolation lines. Pressure percolation lines are perforated pipes utilized to distribute the flow evenly along the length of the absorption trench.

1. Size. Pressure percolation lines should normally have a 1-1/4 inch inside diameter.

2. Hole size. Normal hole size shall be 3/16 inch to 1/4 inch.

3. Hole placement. Center to center hole separation shall be between three and five feet.

4. Line length. Maximum line length from manifold should not exceed 50 feet.

5. Percent flow variation. Actual line size, hole size and hole separation shall be determined on a case-by-case basis based on a maximum flow variation of 10% along the length of the pressure percolation lines.

6. Materials and construction. The preferred material is plastic, either PVC or ABS, designed for pressure service. The lines shall have burr free and counter sunk holes (where possible) placed in a straight line along the longitudinal axis of the pipe. Joining of pipes shall be accomplished with manufactured pressure type joints.

7. Installation.

a. Crushed stone or gravel. Clean gravel or crushed stone having a size range from 1/2 inch to 3/4 inch shall be utilized to bed the pressure percolation lines. Minimum depth of gravel or crushed stone beneath the percolation lines shall be 8-1/2 inches. Clean course silica sand (does not effervesce in the presence of dilute hydrochloric acid) may be substituted for the first two inches (soil interface) of the required 8-1/2 inches of gravel beneath the pressure percolation lines. The absorption trench shall be backfilled to a depth of two inches over the pressure percolation lines with the same gravel or crushed stone. Clean sand, gravel or crushed stone shall be free of fines, clay and organic materials.

b. Grade boards and/or stakes. Grade boards and/or stakes placed in the bottom or sidewalls of the absorption trench shall be utilized to maintain the gravel level for placement of the pressure percolation lines. Grade stakes shall not be placed on centers greater than 10 feet.

c. Placement and alignment. Pressure percolation lines shall be placed so that the holes face vertically downward. All pressure percolation piping shall be placed at the same elevation, unless throttling valves are utilized, and shall be level. The piping shall be placed in the horizontal center of the trench and shall maintain a straight alignment. Normally the invert of the pressure percolation lines shall be placed 8-1/2 inches above the trench bottom. However, under no circumstance shall the invert of the pressure percolation lines be placed closer than 16-1/2 inches to the seasonal water table as defined in ~~12VAC5-610-950 A-3~~ 12VAC5-610-470 D. When the invert of the pressure percolation lines must be placed at an elevation greater than 8-1/2 inches above the trench bottom, landscaping over the absorption area may be required to provide the two inches of gravel and six inches of fill over the pressure percolation lines required in subdivision 7 a of this subsection.

d. Backfilling. After the placement of the pressure percolation piping the absorption trench shall be backfilled evenly with crushed stone or gravel to a depth of two inches over the opening. Untreated building paper or other suitable material shall be placed at the interface of the gravel and soil to prevent migration of fines to the trench bottom. The remainder of the trench shall be backfilled with soil to the ground surface.

8. Appurtenances. The distal (terminal) end of each pressure percolation lines shall be fitted with a vertical riser and threaded cap extending to the ground surface. Systems requiring throttling valves will be supplied with couplings and threaded riser extensions at least four feet long so that the flow may be adjusted in each line.

D. Gravelless material with general approval may be used for low pressure distribution in accordance with the manufacturer's approved installation manual, Table 5.4 of 12VAC5-610-950, and the applicable requirements of this chapter.

12VAC5-610-950. Absorption area design.

A. The absorption area is the undisturbed soil medium ~~beginning at the soil gravel or sand interface which is~~ utilized for absorption of the effluent. The absorption area includes the infiltrative surface in the absorption trench and the soil between and around the trenches when trenches are used.

B. Suitability of soil horizon. The absorption trench bottom shall be placed in the soil horizon or horizons with an average estimated or measured percolation rate less than 120 minutes per inch. Soil horizons are to be identified in accordance with 12VAC5-610-480. The soil horizon must meet the following minimum conditions:

1. It shall have an estimated or measured percolation rate equal to or less than 120 minutes per inch.

2. The soil horizon or horizons shall be of sufficient thickness so that at least 12 inches of absorption trench sidewall is exposed to act as an infiltrative surface; and

3. If no single horizon meets the conditions in subdivision 2 of this subsection, a combination of adjacent horizons may be utilized to provide the required 12-inch sidewall infiltrative surface. However, no horizon utilized shall have an estimated or measured percolation rate greater than 120 minutes/inch.

C. Placement of absorption trenches below soil restrictions. Placement of the soil absorption trench bottom below soil restrictions as defined in 12VAC5-610-490 D, whether or not there is evidence of a perched water table as indicated by free standing water or gray mottlings or coloration, requires a special design based on the following criteria:

1. The soil horizon into which the absorption trench bottom is placed shall be a Texture Group I, II or III soil or have an estimated or measured percolation rate of less than 91 minutes per inch.

2. The soil horizon shall be a minimum of three feet thick and shall exhibit no characteristics that indicate wetness or restriction of water movement. The absorption trench bottom shall be placed so that at least two feet of the soil horizon separates the trench bottom from the water table and/or rock. At least one foot of the absorption trench side wall shall penetrate the soil horizon.

3. A lateral ground water movement interceptor (LGMI) shall be placed upslope of the absorption area. The LGMI shall be placed perpendicular to the general slope of the land. The invert of the LGMI shall extend into, but not through, the restriction and shall extend for a distance of 10 feet on either side of the absorption area (See 12VAC5-610-700 D 3).

4. Pits shall be constructed to facilitate soil evaluations as necessary.

D. Sizing of absorption trench area.

1. Required area. The total absorption trench bottom area required shall be based on the average estimated or measured percolation rate for the soil horizon or horizons into which the absorption trench is to be placed. If more than one soil horizon is utilized to meet the sidewall infiltrative surface required in subsection B of this section, the absorption trench bottom area shall be based on the average estimated or measured percolation rate of the "slowest" horizon. The trench bottom area required in square feet per 100 gallons (Ft²/100 Gals) of sewage applied for various soil percolation rates is tabulated in Table 5.4. The area requirements are based on the equation:

$$\log y = 2.00 + 0.008 (x)$$

where $y = \text{Ft}^2/100 \text{ Gals}$

$x = \text{Percolation rate in minutes/inch}$

Notwithstanding the above, the minimum absorption area for single family residential dwellings shall be 400 square feet.

2. Area reduction. See Table 5.4 for ~~percent~~ area reduction when gravelless material or low pressure distribution is utilized. A reduction in area shall not be permitted when flow diversion is utilized with low pressure distribution. When gravelless material is utilized, the design width of the trench shall be used to calculate minimum area requirements for absorption trenches.

E. Minimum cross section dimensions for absorption trenches.

1. Depth. The minimum trench sidewall depth as measured from the surface of the mineral soil shall be 12 inches when placed in a landscape with a slope less than 10%. The installation depth shall be measured on the downhill side of the absorption trench. When the installation depth is less than 18 inches, the depth shall be measured from the lowest elevation in the microtopography. All systems shall be provided with at least 12 inches of cover to prevent frost penetration and provide physical protection to the absorption trench; however, this requirement for additional cover shall not apply to systems installed on slopes of 30% or greater. Where additional soil cover must be provided to meet this minimum, it must be added prior to construction of the absorption field, and it must be crowned to provide positive drainage away from the absorption field. The minimum trench depth shall be increased by at least five inches for every 10% increase in slope. Sidewall depth is measured from the ground surface on the downhill side of the trench.

2. Width. All absorption trenches utilized with gravity distribution shall have a width of from 18 inches to 36 inches. All absorption trenches utilized with low pressure distribution shall have a width of eight inches to 24 inches.

F. Lateral separation of absorption trenches. The absorption trenches shall be separated by a center to center distance no less than three times the width of the trench for slopes up to 10%. However, where trench bottoms are two feet or more above rock, pans and impervious strata, the absorption trenches shall be separated by a center to center distance no less than three times the width of the trench for slopes up to 20%. The minimum horizontal separation distance shall be increased by one foot for every 10% increase in slope. In no case shall the center to center distance be less than 30 inches.

G. Slope of absorption trench bottoms.

1. Gravity distribution. The bottom of each absorption trench shall have a uniform slope not less than two inches or more than four inches per 100 feet.

2. Low pressure distribution. The bottom of each absorption trench shall be uniformly level to prevent ponding of effluent.

H. Placement of absorption trenches in the landscape.

1. The absorption trenches shall be placed on contour.

2. When the ground surface in the area over the absorption trenches is at a higher elevation than any plumbing fixture or fixtures, sewage from the plumbing fixture or fixtures shall be pumped.

I. Lateral ground water movement interceptors. Where subsurface, laterally moving water is expected to adversely affect an absorption system, a lateral ground water movement interceptor (LGMI) shall be placed upslope of the absorption area. The LGMI shall be placed perpendicular to the general slope of the land. The invert of the LGMI shall extend into, but not through, the restriction and shall extend for a distance of 10 feet on either side of the absorption area.

Table 5.4.
Area Requirements for Absorption Trenches.

Percolation Rate (Minutes/Inch)	Area Required (Ft ² /100 Gals)			Area Required (Ft ² /Bedroom)		
	Gravity	<u>Gravity Gravelless</u>	Low Pressure Distribution	Gravity	<u>Gravity Gravelless</u>	Low Pressure Distribution

5	110	<u>83</u>	110	165	<u>127</u>	165
10	120	<u>90</u>	120	180	<u>124</u>	180
15	132	<u>99</u>	132	198	<u>135</u>	198
20	146	<u>110</u>	146	218	<u>149</u>	218
25	158	<u>119</u>	158	237	<u>164</u>	237
30	174	<u>131</u>	164	260	<u>178</u>	255
35	191	<u>143</u>	170	286	<u>195</u>	260
40	209	<u>157</u>	176	314	<u>215</u>	264
45	229	<u>172</u>	185	344	<u>236</u>	279
50	251	<u>188</u>	193	376	<u>258</u>	293
55	275	<u>206</u>	206	412	<u>282</u>	309
60	302	<u>227</u>	217	452	<u>309</u>	325
65	331	<u>248</u>	228	496	<u>339</u>	342
70	363	<u>272</u>	240	544	<u>372</u>	359
75	398	<u>299</u>	251	596	<u>408</u>	375
80	437	<u>328</u>	262	656	<u>447</u>	394
85	479	<u>359</u>	273	718	<u>492</u>	409
90	525	<u>394</u>	284	786	<u>539</u>	424
95	575	<u>489</u>	288	862	<u>590</u>	431
100	631	<u>536</u>	316	946	<u>733</u>	473
105	692	<u>588</u>	346	1038	<u>804</u>	519
110	759	<u>645</u>	379	1138	<u>882</u>	569
115	832	<u>707</u>	416	1248	<u>967</u>	624
120	912	<u>775</u>	456	1368	<u>1061</u>	684

J. Controlled blasting. When rock or rock outcroppings are encountered during construction of absorption trenches the rock may be removed by blasting in a sequential manner from the top to remove the rock. Percolation piping and sewer lines shall be placed so that at least one foot of compacted clay soil lies beneath and on each side of the pipe where the pipe passes through the area blasted. The area blasted shall not be considered as part of the required absorption area.

12VAC5-610-955. Drip Dispersal.

A. Drip dispersal applies wastewater in an even and controlled manner over an absorption area. Drip dispersal system components may include treatment components, a flow equalization pump tank, a filtration system, a flow measurement method, supply and return

pipng, small diameter pipe with emitters, air/vacuum release valves, redistribution control, and electromechanical components or controls.

B. Drip dispersal system tubing shall be color coded and certified by the manufacturer as designed and manufactured for the dispersal of wastewater. All drip dispersal system tubing shall be equipped with emitters approved for use with wastewater. For the application of septic tank effluent, the tubing must have self cleaning emitters.

1. The minimum linear feet of tubing in the system shall be one-half of the minimum soil absorption area in square feet.

2. All tubing shall be placed on contour.

3. Except as provided by 12 VAC 5-613, drip systems dispersing septic tank effluent shall comply with the requirements of 12 VAC 5-610-594. Drip systems dispersing secondary effluent or better require a minimum of six inches of cover over the tubing. Cover may be achieved by a combination of installation depth and Group II or Group III soil cover or other approved material over the drip field.

4. The discharge rate of any two emitters shall not vary by more than 10 percent in order to ensure that the effluent is uniformly distributed over the entire drip field or zone.

5. The emitters shall be evenly spaced along the length of the drip tubing at not less than six inches or more than 24 inches apart.

6. The system design shall protect the drip emitters and system from the effects of siphoning, or backflow through the emitters.

C. Drip dispersal systems shall comply with the following minimum soil absorption area requirements:

1. For the dispersal of septic tank effluent, the minimum soil absorption area for a drip system shall be calculated by multiplying the trench bottom area required for a low pressure distribution system in Table 5.4 of this chapter, by three.

2. For the dispersal of secondary or better effluent, the minimum soil absorption area shall be calculated by multiplying the trench bottom area for pressure distribution systems in accordance with 12VAC5-613-80.10 by three.

3. Landscape linear loading rates shall be considered for sloping absorption areas. For sites where effluent flow is primarily horizontal, linear loading rates shall be less than 4 gallons per day per linear foot. For sites where the flow is primarily vertical, the linear loading rates shall be less than 10 gallons per day per linear foot.

4. Air/vacuum release valves shall be located at the high points of the supply and return manifolds to each zone.

D. All drip dispersal systems shall be equipped with devices or methods to restrict effluent from draining by gravity to portions of a zone or laterals lower in elevation. Variable distribution due to gravity drainage shall be 10 percent or less within a zone.

E. A minimum of six hours of emergency storage above the high water alarm in the pump chamber shall be provided. The equalization volume shall be equal to 18 hours of storage. The equalization volume shall be measured from the pump off level to the high water alarm level. An audio/visual alarm meeting the requirements of 12VAC5-610-880.B.8 shall be provided for the pump chamber.

F. Each drip dispersal zone shall be time-dosed over a 24 hour period. The dose volume and interval shall be set to provide unsaturated flow conditions. Demand dosing is prohibited. Minimum dose volume per zone shall be 3.5 times the liquid capacity of the drip laterals in the zone plus the liquid capacity of the supply and return manifold lines (which drain between doses) accounting for instantaneous loading and drain back.

1. At each dosing cycle, the system design shall only allow a full dose volume to be delivered.

2. For design flows greater than 1,000 gallons per day, a means to take each zone off line separately shall be provided. The system shall have the capability to bypass each zone that is taken out of service such that each subsequent dose is dispersed to the next available zone in sequence.

G. Filtration shall be provided to remove suspended solids and prevent clogging of emitters. The filtration design shall meet the drip tubing manufacturer's particle size requirements for protection of the emitters at a flow rate equal to or greater than the rate of forward flushing. Filter flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system.

H. A means for measuring or estimating total flow dispersed to the soil absorption area and to verify field dosing and field flushing rates shall be provided.

I. The system shall provide forward field flushing to achieve scouring velocity as specified by the drip tubing manufacturer. Field flushing shall occur on a routine schedule to prevent excessive solids accumulation and clogging. Flush water shall be returned to the treatment system at a point where the residuals and volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic design capacity of the treatment system.

J. Electrical components shall be Underwriters Laboratory (UL) listed for the intended purpose. The designer shall provide a description with a schematic diagram of the electrical and control functions in the operation and maintenance manual. The electrical control equipment shall be mounted within a National Electrical Manufacturers Association (NEMA) 4X rated enclosure with a rigid latching door. All switches shall be clearly identified and all internal wiring shall be factory installed. All wiring shall be installed according to applicable electrical safety codes and the manufacturer's installation schematic.

K. All components in a drip dispersal system shall be rated to withstand contact with wastewater and recommended for this application by the manufacturer. All components shall be protected from freezing.

L. The designer of the drip dispersal system shall verify the dosing rates, the flushing rates, and other parameters critical to the proper operation of the system at the startup inspection. A summary of the startup inspection shall be included in the operation and maintenance manual and shall include, at a minimum, the dosing volume; the forward flow flushing rate; the pressure head of the system; and verification of proper cycling between zones.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 29, 2014

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services

SUBJECT: *The Sanitary Regulations for Marinas and Boat Moorings*
("Marina Regulations," 12VAC5-570-10)

The Board of Health adopted the Marina Regulations in 1968 and revised them in 1990. In the fall of 2010, the Virginia Department of Health (VDH) performed a periodic review of the regulations pursuant to Virginia Code Section 2.2-4017 and Executive Order 14 (2010). The periodic review determined a need to revise the regulations to address changes in the marina industry. On February 28, 2011, VDH published the Notice of Intended Regulatory Action (NOIRA) to amend the marina regulations in the Virginia Register of Regulations. In addition, VDH convened an ad hoc advisory committee to get input from experts as to how the marina regulations should be modified.

The Board of Health approved proposed regulations in 2012 based on the ad hoc committee's recommendations. The proposed regulations were published in the Virginia Register for a 60-day comment period on November 17, 2013. One commenter suggested that the Board of Health require a holding tank (for sewage) sized on the total number of slips rather than the total number of boats at a marine facility. This change, along with three other changes developed by VDH staff, was incorporated into the final amendments; otherwise, the draft final amendments are identical to the proposed amendments.

VDH worked with the Virginia Department of Housing and Community Development to make sure the building code requirements and Marina Regulations are consistent with one another. The Marina Regulations maintain functional design for sewerage systems serving marinas and other places where boats are moored.

This is the final stage in the regulatory process. Following the Board of Health's approval, the final regulations will be subject to executive branch review and approval. Upon executive branch approval, the regulations will be published in the Virginia Register for a 30 day final adoption period.



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-570-10 et seq.
Regulation title	Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings
Action title	Amend the regulations to reflect current state of marina industry
Date this document prepared	April 29, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Board of Health's *Sanitary Regulations for Marinas and Boat Moorings* ("Marina Regulations") establish minimum standards for sewage handling and disposal at regulated facilities. Sewerage facilities, sewerage systems, and treatment works that serve marinas, other places where boats are moored, and boating access facilities with 50 or more parking spaces for boat trailers should be sufficient to serve the number of boat slips or persons using such facilities. The proposed revisions to the marina regulations are designed to: (1) ensure the number of sewerage fixtures required at marinas is based on the number of slips including but not limited to dry storage spaces; (2) clarify existing requirements by combining sewerage fixture requirements into one simplified table; (3) add a requirement that boating access sites with 50 or more parking spaces for boat trailers be equipped with appropriate sewerage facilities; (4) simplify procedures for assigning wastewater design flows by providing only one sewage design flow value per slip; (5) require pump-out systems at marinas and other place(s) where boats are moored which provide live-aboard slips or that serve boats with marine sanitary devices; and (6) provide an exemption from the requirement that regulated facilities install a dump station if such facilities have a pump-out system that is capable of pumping out portable sewerage containers located on boats.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The final amendments to the Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings were approved by the State Board of Health on June 5, 2014.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The Board is authorized, pursuant to Va. Code § 32.1-12 to promulgate and enforce regulations. Under Va. Code § 32.1-246 the Board of Health is authorized to promulgate regulations establishing minimum requirements as to the adequacy of sewerage facilities at marinas and other places where boats are moored. Va. Code § 32.1-164 provides that the Board's regulations may require that "residences, buildings, structures and other places designed for human occupancy as the Board may prescribe be provided with a sewerage system or treatment works."

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Board's Marina Regulations are essential to protect public health and the environment by ensuring sewage generated from boats and onshore boating facilities is treated and disposed of properly. The Board has not revised the Marina Regulations since adopting amendments in 1990. Property development has increased dramatically in the Chesapeake Bay watershed and other tributaries and around Virginia's inland lakes over the past 25 years. At the same time the public's awareness of and susceptibility to impaired water quality has also increased. Boating has increased in popularity with more than 12 million boats in use nationwide. While the number of large commercial marinas has steadily grown, Virginia has also seen an increase in the number of smaller facilities, such as neighborhood marinas and public boat ramps. The proposed amendments simplify and clarify many regulatory requirements and address the need to modify the regulatory requirements for two facilities in particular: a. marinas that serve owners who live aboard their boats, and b. public boating access facilities (boat ramps) that receive heavy use (i.e. that have parking spaces for 50 or more boat trailers). In addition, the proposed amendments reflect the evolution in the methods of conveying and disposing human waste aboard boats; the proposed amendments address the advent of waste disposal via a "marine sanitation device" or a portable toilet. In addition to these methods, the Marina Regulations also require pump-outs to safely and properly handle waste disposal. Some of the changes, particularly those that simplify the method for determining sewage flow as a function of the number of slips, are intended to provide marinas and other place(s) where boats are moored flexibility to redefine business models regarding the types of boats and boating activities serviced.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The amendments cover six main areas: (1) definitions of terms; (2) requirements for sanitary fixtures based on the number of slips and dry storage spaces; (3) sewerage facility requirements at boating access facilities (boat ramps), (4) sewage design flows based on the number of slips rather than the type of slip with a specific flow assigned to all slips used as "live-aboard" slips, (5) a new section for onshore facility requirements; and, (6) an exemption from the requirement for a sewage dump station for any facility that has a sewage pump-out and the correct appurtenance for pumping out portable toilets.

The agency amended 12VAC5-570-10 to define boating access facility as an installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers. The agency expanded the definition for dry storage to include boatels, valet storage, pigeon hole storage, stackominiums, or where boats rest on racks or trailers located on land. The agency added a definition for "live-aboard slip." The agency defined regulated facilities as marinas, other places where boats are moored, and boating access facilities with 50 or more parking spaces for boat trailers.

The agency amended 12VAC5-570-150 to provide an allowance for smaller boating facilities to construct unisex bathrooms.

The agency amended 12VAC5-570-160 to require sewerage facilities at boating access facilities that have 50 or more parking spaces for boat trailers.

The agency amended 12VAC5-570-180 to prohibit marinas or other places that provide live-aboard slips or boats with a marine sanitation device to invoke an exemption to provide a pump-out service.

The agency amended 12VAC5-570-190 to allow marinas with a pump-out facility equipped with a specialized device (i.e. porta-potty wand) to use the device to excavate sewage from portable sewage containers instead of installing a dump station.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages provided to the public by implementing these amendments is improved sewage handling in sensitive waterfront areas and the assurance that regulated facilities have adequate sewerage fixtures to meet their needs. The availability of sewerage facilities in such locations reduces the potential that human wastes will be improperly dumped into the waters of the Commonwealth. The requirement for smaller-sized marinas to install shower facilities poses an additional economic burden on smaller marina owners. However, this burden is offset by allowing smaller facilities to install a unisex bathroom instead of constructing separate facilities for men and women. The proposed amendments create advantages to the public and VDH by simplifying the regulatory program; specifically, the number of sewerage fixtures

required at regulated facilities is no longer driven by the type of slip (seasonal or transient) but rather by the total number of slips and dry storage spaces. This proposed amendment allows owners the freedom to accommodate both short-term and long-term boaters without impacting future growth. The amendments propose a higher sewage flow for live-aboard slips to reflect the higher water usage associated with these residences. While this change may pose an economic impact, this change provides public health protection from raw sewage discharge by ensuring sewerage systems and treatment works are sized adequately to handle anticipated wastewater loads.

VDH collaborated with an ad hoc group of stakeholders in developing the proposed amendments. While that group was unable to review all of the proposed amendments, it valued the need to update the regulations and generally supported the substantive changes proposed.

Additionally, during the proposed regulatory stage, VDH worked with the Department of Housing and Community Development (DHCD) to translate the requirements for the minimum sewerage fixtures at marinas, based on the number of slips, into the Virginia Construction Code. VDH anticipates that these changes will be adopted by DHCD during July 2014.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	"Certificate" means a written approval from the Commissioner commissioner or his designated representative indicating that plans for sanitary facilities and sewage sewerage <u>sanitary facilities, sewerage system, and treatment works</u> meet or satisfy the minimum requirements of this chapter and § 32.1-246, of the Code of Virginia.	"Certificate" [or " <u>Certificate to operate</u> "] means a written approval from the Commissioner <u>commissioner</u> or his designated representative indicating that plans for sanitary facilities and sewage sewerage <u>sanitary facilities, sewerage system, and treatment works</u> meet or satisfy the minimum requirements of this chapter and § <u>32.1-246</u> , of the Code of Virginia.	<i>Revised for clarity.</i>
70*	12VAC5-570-70. Application for certificate <u>construction permit</u> . A. <u>A.</u> Any owner, or his duly authorized representative, may make application shall apply <u>shall apply</u> for a certificate of approval of sanitary or sewerage facilities <u>certificate of approval of sanitary or sewerage facilities construction permit</u> by applying <u>submitting an application</u> to the local health department in the jurisdiction where the proposed marina or, place	12VAC5-570-70. Application for certificate <u>construction permit</u> . <u>A.</u> Any owner, or his duly authorized representative, may make application <u>shall apply</u> for a certificate of approval of sanitary or sewerage facilities <u>certificate of approval of sanitary or sewerage facilities construction permit</u> by applying <u>submitting an application</u> to the local health department in the jurisdiction where the proposed marina or, place <u>places</u> where boats are moored, or boating access facility <u>or boating access facility</u> is to be located. The application shall be made on a form supplied by the local health	<i>Revised for clarity and includes construction permit requirements.</i>

	<p>other place <u>places</u> where boats are moored, or boating access facility is to be located. The application shall be made on a form supplied by the local health department approved by the division. The application shall consist of the following:</p> <ol style="list-style-type: none"> 1. A completed application form which shall set forth the essential <u>Essential</u> data to determine the sewerage facilities <u>and sewerage system</u> necessary to serve the proposed installation;₂ 2. Maps, plans, and specifications of the sanitary sewerage facilities and sewerage facilities system describing how and what the type of facilities that will be provided and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility. The preliminary design plans shall establish the location of the sanitary sewerage facilities and sewerage system in relation to other facilities; <u>they are intended to serve.</u> 3. A description of the proposed method of sewage or existing offsite sewerage system or treatment works used for the ultimate treatment or and disposal. <u>Approval of sewage.</u> The applicant shall <u>apply for and obtain approval of the new offsite sewerage systems or treatment works or disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter.</u> 4. Any other data as may be pertinent to show the adequacy of sanitary or the sewerage facilities and sewerage system to be provided. 	<p>department approved by the division. The application shall consist of the following:</p> <ol style="list-style-type: none"> 1. A completed application form which shall set forth the essential <u>Essential</u> data to determine the sewerage facilities <u>and sewerage system</u> necessary to serve the proposed installation;₂ 2. Maps, plans, and specifications of the sanitary sewerage facilities and sewerage facilities system describing how and what the type of facilities that will be provided and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility. The preliminary design plans shall establish the location of the sanitary sewerage facilities and sewerage system in relation to other facilities; <u>they are intended to serve.</u> 3. A description of the proposed method of sewage or existing offsite sewerage system or treatment works used for the ultimate treatment or and disposal. <u>Approval of sewage.</u> The applicant shall <u>apply for and obtain approval of the new offsite sewerage systems or treatment works or disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter.</u> 4. Any other data as may be pertinent to show the adequacy of sanitary or the sewerage facilities and sewerage system to be provided. <p><u>B. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.</u></p> <p><u>[C. The department shall issue a permit to construct the proposed marina, other place where boats are moored, or boating access facility after review of a complete application that demonstrates compliance with the requirements of this chapter and § 32.1-246 of the Code of Virginia.]</u></p>	
--	---	---	--

<p>80*</p>	<p><u>B. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.</u></p> <p>12VAC5-570-80. Receipt of data <u>application.</u></p> <p><u>Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.</u></p> <p><u>A. Construction. Upon completion of construction of the sanitary sewerage facilities and sewerage facilities systems at marinas and other places where boats are moored, or boating access facilities, the owner of the facility, or his duly authorized representative, shall notify the local health department so that it may inspect the construction. A certificate to operate shall be issued by the Health Department when it When the division, in consultation with the local health department, has been determined that construction is in compliance with the approved plan, it shall issue a certificate.</u></p> <p><u>B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia. The owner shall post the certificate in a place where it is readily observable by members of the public who transact business with the facility.</u></p>	<p>12VAC5-570-80. [Receipt of data application. Certificate to operate.]</p> <p><u>Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.</u></p> <p><u>A. Construction. Upon completion of construction of the sanitary sewerage facilities [, and] sewerage facilities systems [, and treatment works] at marinas and other places where boats are moored, or boating access facilities, the owner of the facility, or his duly authorized representative, shall notify the local health department so that it may inspect the construction. A certificate to operate shall be issued by the Health Department when it When the division, in consultation with the local health department, has been determined that construction is in compliance with the approved plan, it shall issue a certificate [to operate to the owner of the marina, other place where boats are moored, or boating access facility. The certificate to operate shall remain valid in accordance with this section.]</u></p> <p><u>B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia. The owner shall post the certificate [to operate] in a place where it is readily observable by members of the public who transact business with the facility.</u></p> <p><u>[C. All marinas, other places where boats are moored, and boating access facilities shall be subject to a five year, renewable certificate to operate. The owner of the marina, other place where boats are moored, and boating access facility shall request a new certificate to operate at least 90 days prior to the expiration date of the existing certificate</u></p>	<p><i>Revised for clarity and to shift agency policy regarding inspections into the regulations.</i></p>
------------	---	--	--

<p>200*</p> <p>Forms</p>	<p>Table 2: Minimum Holding Tank Volume</p> <table border="1"> <thead> <tr> <th>Total Number of Boats Serviced Annually with Marine Sanitation Devices</th> <th>Minimum Holding Tank Volume (gallons)</th> </tr> </thead> <tbody> <tr> <td>1-60</td> <td>725</td> </tr> <tr> <td>61-80</td> <td>1000</td> </tr> <tr> <td>81-100</td> <td>1200</td> </tr> <tr> <td>100+</td> <td>2000</td> </tr> </tbody> </table> <p>NA</p>	Total Number of Boats Serviced Annually with Marine Sanitation Devices	Minimum Holding Tank Volume (gallons)	1-60	725	61-80	1000	81-100	1200	100+	2000	<p>to operate. The division shall issue the new certificate to operate provided the sewerage facilities, sewerage system, and treatment works meet or satisfy the minimum requirements of this chapter and § 32.1-246 of the Code of Virginia.</p> <p>D. If the commissioner grants a variance, or the division approves any exception to this chapter, then the certificate to operate shall contain that information. The owner of the marina, other place where boats are moored, or boating access facility shall follow any condition or requirement listed on the certificate to operate.</p> <p>E. As a condition of the certificate to operate, owners of marinas, other places where boats are moored, or boating access facilities shall allow the department to perform one or more inspections per year of the sewerage facilities, sewerage systems, and treatment works to ensure compliance with this chapter and § 32.1-246 of the Code of Virginia. The division may revoke the certificate to operate pursuant to 12VAC5-570-100.]</p> <p>Table 2: Minimum Holding Tank Volume</p> <table border="1"> <thead> <tr> <th>Total Number of [Boats Serviced Annually with Marine Sanitation Devices Slips]</th> <th>Minimum Holding Tank Volume (gallons)</th> </tr> </thead> <tbody> <tr> <td>[1-60</td> <td>725</td> </tr> <tr> <td>61-80</td> <td>1000</td> </tr> <tr> <td>81-100</td> <td>1200</td> </tr> <tr> <td>100+</td> <td>2000</td> </tr> <tr> <td>1 - 300</td> <td>1000</td> </tr> <tr> <td>301 - 450</td> <td>1500</td> </tr> <tr> <td>451+</td> <td>2000]</td> </tr> </tbody> </table> <p>Application for Construction Permit</p>	Total Number of [Boats Serviced Annually with Marine Sanitation Devices Slips]	Minimum Holding Tank Volume (gallons)	[1-60	725	61-80	1000	81-100	1200	100+	2000	1 - 300	1000	301 - 450	1500	451+	2000]	<p>The difficulty in evaluating whether a vessel employs a Type III Marine Sanitation Device in addition to the mobility of vessels traveling from one marina to another makes the determination of what holding tank size a marina shall have problematic. Holding tank sizes proposed are commonly used in onsite sewage system construction</p> <p>New form referenced in Section 70.</p>
	Total Number of Boats Serviced Annually with Marine Sanitation Devices	Minimum Holding Tank Volume (gallons)																											
1-60	725																												
61-80	1000																												
81-100	1200																												
100+	2000																												
Total Number of [Boats Serviced Annually with Marine Sanitation Devices Slips]	Minimum Holding Tank Volume (gallons)																												
[1-60	725																												
61-80	1000																												
81-100	1200																												
100+	2000																												
1 - 300	1000																												
301 - 450	1500																												
451+	2000]																												

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Peter Brooks, PMBA	12VAC570-200 Table #2: Is it feasible to replace # of boats served with # of slips?	The agency concedes that sewage holding tank volume should be based on the number of slips rather than the number of boats that have a Marine Sanitation Device. Marinas are limited by the number of slips they are permitted to possess and boaters are flexible in where they desire to moor. The regulations have been amended accordingly.

Enter any other statement here

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed Change and Rationale
10		As used in these regulations, the following words and terms hereinafter set forth shall have the following meanings respectively, unless the context clearly requires a different meaning.	<p>As used in this chapter, the The following words and terms hereinafter set forth <u>when used in this chapter</u> shall have the following meanings respectively, unless the context clearly requires a different meaning. <u>indicates otherwise:</u></p> <p><u>"Boating access facility" means any installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers.</u></p> <p><i>Boating access facilities were previously unregulated despite the fact that the Board has authority to regulate. Under the proposed amendments these facilities will be regulated when there are 50 or more parking spaces for boat trailers. The rationale is to afford the same public health protections afforded to marinas and other places where boats are moored.</i></p> <p>"Certificate" means a written approval from the Commissioner or</p> <p>"Certificate" [or "Certificate to operate"] means a written approval from the</p>

		<p>his designated representative indicating that plans for sanitary facilities and sewage facilities meet or satisfy the minimum requirements of this chapter and § 32.1-246 of the Code of Virginia.</p> <p>"Commissioner" means the State Health Commissioner whose duties are prescribed in § 32.1-19 of the Code of Virginia.</p> <p>"Division" means the Division of Wastewater Engineering, Department of Health.</p> <p>"Dry storage" means a boat storage or parking space, whether covered or uncovered, at a marina or other place where boats are moored for the purpose of storing boats on land between use.</p>	<p>Commissioner commissioner or his designated representative indicating that plans for sanitary facilities and sewage <u>sewerage facilities, sewerage system, and treatment works</u> meet or satisfy the minimum requirements of this chapter and § 32.1-246, of the Code of Virginia. <i>Certificate to Operate is issued when plans or existing boat facility satisfies the minimum requirements regarding sewerage facilities. Revised for clarity.</i></p> <p>"Commissioner" means the State Health Commissioner whose duties are prescribed in § 32.1-19 of the Code of Virginia.</p> <p><u>"Department" means the Virginia Department of Health.</u> <i>Revised for clarity.</i></p> <p>"Division" means the Division of Wastewater Engineering, Department of Health <u>Onsite Sewage and Water Services, Environmental Engineering, and Marina Programs, Office of Environmental Health Services of the department or its administrative successor.</u> <i>Reflects program realignments within the Office of Environmental Health Services.</i></p> <p>"Dry storage" means a boat storage, <u>including boatels, valet storage, pigeon hole storage, stackminiums, or parking space where boats rest on racks or trailers located on land,</u> whether covered or uncovered, at a marina or other place <u>places</u> where boats are moored for the purpose of storing boats on land between use.</p> <p><i>Clarifies the definition to reflect different means of storing boats out of the water.</i></p> <p><u>"Expanded" means any change to a regulated facility that results in an increase in sewage volume or strength due to the addition of slips, dry storage spaces, boat trailer parking spaces, or ancillary operations.</u> <i>New definition added for clarity.</i></p> <p><u>"Live-aboard slip" means any slip where a boat is moored and used principally as a residence or a place of business. Charter and commercial fishing boats are not included unless used as a residence.</u> <i>Establishes a new category of slips with a higher wastewater flow number.</i></p> <p><u>"Local health department" means the branch of the State Health Department, established in accordance with § 32.1-30 of the Code of Virginia, that has jurisdiction in the city or county where the regulated facility is located.</u> <i>Added for clarity.</i></p>
--	--	---	---

	<p>"Marina" means any installation, operating, under public or private ownership, which provides dockage or moorage for boats (exclusive of paddle or rowboats) and provides, through sale, rental or fee basis, any equipment, supply or service (fuel, electricity or water) for the convenience of the public or its leasee, renters or users of its facilities.</p> <p>"Marine sanitation device" means any equipment, piping and appurtenances such as holding tanks for installation on board a boat which is designed to receive, retain, treat or discharge sewage and any process to treat such sewage.</p> <p>"Other place(s) where boats are moored" means any installation operating under public or private ownership, which provides dockage, moorage or mooring for boats (exclusive of paddle or rowboats) either on a free, rental or fee basis or for the convenience of the public.</p> <p>"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm or company organized or existing under</p>	<p>"Marina" means any installation operating, under public or private ownership, which that provides dockage or moorage for boats (exclusive of, other than paddle or rowboats) rowboats, and provides, through sale, rental or fee, or free basis, any equipment, supply, or service (fuel including fuel, electricity, or water) water for the convenience of the public or its leasee the lessee, renters, or users of its the facilities. <i>Revised for clarity.</i></p> <p>"Marine sanitation device" means any equipment, piping, <u>holding tanks,</u> and appurtenances such as holding tanks for installation on board onboard a boat which is designed to receive, retain, treat, or discharge sewage and any process to treat such sewage. <i>Revised for clarity.</i></p> <p><u>"No Discharge Zone" means an area where a state has received an affirmative determination from the U.S. Environmental Protection Agency that there are adequate facilities for the removal of sewage from vessels (holding tank pump-out facilities) in accordance with § 312(f)(3) of the Clean Water Act (33 USC § 1251 et seq.) and where federal approval has been received allowing a complete prohibition of all treated or untreated discharges of sewage from all vessels. Definition added for clarity. The definition parallels the definition for "No Discharge Zone" found in the State Water Control Board's Regulations Governing the Discharge of Sewage and Other Wastes From Boats (9VAC25-71-10 et seq.)</u></p> <p><u>"Office" means the Office of Environmental Health Services.</u> <i>Definition added to reflect program administration.</i></p> <p>"Other places where boats are moored" means any installation operating under public or private ownership, which that provides dockage, or moorage or mooring for boats, other than (exclusive of paddle or rowboats) rowboats, either on a free, rental, or fee basis or for the convenience of the public boater. <i>Revised for clarity.</i></p> <p>"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm, or company organized or existing under the laws of this or any other state or county, or any person or group of persons acting individually or as a group who owns or</p>
--	--	--

		<p>the laws of this or any other state or county, or any person or group of persons acting individually or as a group who owns a marina or other place where boats are moored.</p> <p>"Pump-out facilities" means any device, equipment or method of removing sewage from a marine sanitation device. Also, it shall include any holding tanks either portable, movable or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats.</p> <p>"Sanitary facilities" means bathrooms, toilets, closets and other enclosures where commodes, stools, water closets, lavatories, showers, urinals, sinks or other such plumbing fixtures are installed.</p> <p>"Seasonal slips" means any slip which is used, rented, leased or otherwise made available for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days.</p> <p>"Sewage" means the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks.</p>	<p><u>proposes to own a marina, or other place places where boats are moored, or boating access facility.</u> <i>Revised for clarity.</i></p> <p>"Pump-out facilities <u>facility</u>" means any device, equipment, or method of <u>for</u> removing sewage from a marine sanitation device. Also, it shall include and conveying such sewage to a sewerage system or treatment works including any portable, movable, or permanent holding tanks either portable, movable or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats. <i>Revised for clarity.</i></p> <p>"Sanitary facilities" <u>"Sewerage facility"</u> means bathrooms, toilets, closets and other enclosures, <u>including portable toilets,</u> where commodes, stools, water closets, lavatories, showers, urinals, sinks, or other such plumbing fixtures are installed. <i>Revised for clarity and to include portable toilets as an option. The term was changed from "sanitary" to "sewerage" in order to better align the regulations with Va. Code § 32.1-246.</i></p> <p>"Seasonal slips" means any slip which is used, rented, leased, or otherwise made available for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days. Definition deleted to simplify as the amendments eliminated the distinction between seasonal and transient slips.</p> <p>"Sewage" means the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks. <u>water-carried and nonwater-carried human excrement, kitchen, laundry, shower, bath, or lavatory waste, separately or together with such underground, surface, storm, and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, boats, industrial establishments, or other places.</u> <i>Revised for clarity and to conform to Va. Code § 32.1-163.</i></p> <p>"Sewage dump station" means a facility <u>specifically designed to receive waste from portable sewage containers carried on boats and to convey such sewage to a sewerage system or a treatment works.</u> <i>Definition added for clarity.</i></p>
--	--	---	--

		<p>"Sewage treatment or disposal systems" means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge to another approved system, or an approved discharge to state waters or disposal through an approved subsurface drainfield or other acceptable method, such as incineration.</p> <p>"Sewerage facilities" means entire sewage collection and disposal system including commodes, toilets, lavatories, showers, sinks and all other plumbing fixtures which are connected to a collection system consisting of sewer pipe, conduit, holding tanks, pumps and all appurtenances, including the sewage treatment or disposal system.-</p> <p>"Transient slips" means temporary docking or mooring space which may be used for short periods of time, including overnight, days, or weeks, but less than 30 days.</p>	<p>"Sewage treatment or disposal systems" means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge to another approved system, or an approved discharge to state waters or disposal through an approved subsurface drainfield or other acceptable method, such as incineration. <i>Deleted for clarity. Other terms in common usage were added- "sewerage systems" and "treatment works."</i></p> <p>"Sewerage facilities <u>system</u>" means entire <u>sewage collection and disposal system including commodes, toilets, lavatories, showers, sinks and all other plumbing fixtures which are connected to a collection system consisting of sewer pipe, conduit, holding tanks, pumps and all appurtenances, including the sewage treatment or disposal system pipelines or conduits, pump stations and force mains, and all other construction, devices, and appliances used for the collection and conveyance of sewage to a treatment works or point of ultimate disposal.</u> <i>Definition revised for clarity and to conform to the definition found in Va. Code § 32.1-163.</i></p> <p><u>"Slip" means a berth or space where a boat may be secured to a fixed or floating structure, including a dock, finger pier, boat lift, or mooring buoy.</u> <i>Definition added to simplify the regulation, as the distinction between seasonal and transient slips has been eliminated.</i></p> <p>"Transient slips" means temporary docking or mooring space which may be used for short periods of time, including lodging overnight, days, or weeks, but less than 30 days. <i>Definition deleted to simplify the regulation, as the distinction between seasonal and transient slips has been eliminated.</i></p> <p>"Treatment works" means any device or system used in the storage, treatment, disposal, or reclamation of sewage or combinations of sewage and industrial wastes, including but not limited to pumping, power and other equipment and appurtenances, septic tanks, and any works, including land, that are or will be (i) an integral part of the treatment process or (ii) used for ultimate disposal of residues or effluents resulting from such treatment. <i>Definition added for clarity. Definition conforms to the definition of "treatment works" found in Va. Code § 32.1-163</i></p>
--	--	--	---

			<p><u>"VMRC" means the Virginia Marine Resources Commission.</u></p> <p><i>Added for clarity.</i></p>
20.		<p>Sections 32.1-12 and 32.1-246 of the Code of Virginia provides that the State Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and places are designed to accommodate, regardless of whether such establishments serve food.</p>	<p>12VAC5-570-20. Authority for regulations. (Repealed.)</p> <p>Section 32.1-12 and 32.1-246 of the Code of Virginia provides that the State Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and places are designed to accommodate, regardless of whether such establishments serve food.</p> <p><i>Repeal proposed by the Virginia Registrar of Regulations, as reference to authority is unnecessary.</i></p>
30.		<p>This chapter has been promulgated by the State Board of Health to:</p> <ol style="list-style-type: none"> 1. Ensure adequate sanitary facilities and pump-out facilities, as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, are provided at all marinas and other places where boats are moored; 2. Establish minimum requirements as to the adequacy of sewerage facilities at marinas and other places where boats are moored; 3. Guide the State Board of Health in its determination of the adequacy of the sewerage facilities to serve marinas and other places where boats are moored; 4. Guide the State Board of Health in its approval of plans and other data and the issuance of a certificate as to the adequacy of sanitary and sewerage facilities. 	<p>12VAC5-570-30. Purpose of regulations.</p> <p>This chapter <u>The board has been promulgated by the State Board of Health this chapter to:</u></p> <p><u>Ensure 1. Protect public health and water quality by ensuring that adequate sanitary sewerage facilities and, pump-out facilities, as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, sewage dump stations, and sewerage systems are provided at all marinas and, other places where boats are moored; and boating access facilities.</u></p> <p>2. Establish minimum requirements as to the adequacy of sewerage facilities <u>and sewerage systems at all marinas and, other places where boats are moored; and boating access facilities.</u></p> <p><u>3. Protect public health and the environment by ensuring that all sewage generated from all regulated facilities is conveyed to an approved sewerage system or treatment works.</u></p> <p>3. <u>4. Guide the State Board of Health commissioner or his designee in its his determination of the adequacy of the sewerage systems and sewerage facilities to serve serving all marinas and, other places where boats are moored; and boating access facilities.</u></p> <p>4. <u>5. Guide the State Board of Health commissioner or his designee in its approval</u></p>

		<p>5. Notify the Marine Resources Commission that a certificate has been issued; and</p> <p>6. Assist the owner or his authorized engineer in the preparation of an application and supporting data, as may be required. (See 12VAC5-570-70)</p>	<p><u>his evaluation</u> of plans and other data and in the issuance of a certificate as to the adequacy of sanitary and sewerage facilities; and <u>sewerage systems.</u></p> <p>5. Notify the Marine Resources Commission that a certificate has been issued; and</p> <p>6. Assist the owner or his authorized engineer in the preparation of an application and supporting data, as may be required. (See 12VAC5-570-70)</p> <p><i>Amendments in this section are for clarity and to ensure that proposed or existing regulated facilities address sewerage facility and sewerage system needs. Boating access facilities are added as a new group of regulated facilities.</i></p>
<p>40.</p>		<p>These regulations are administered by the following parties:</p> <p>1. The State Board of Health has responsibility for promulgating, amending and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.</p> <p>2. The State Health Commissioner.</p> <p>3. The Division of Wastewater Engineering is designated as the primary reviewing agent of the board for the purpose of administering this chapter. It examines and passes upon the technical aspects of all applications, plans and specifications for sewerage facilities to serve marinas and other places where boats are moored. It issues all certificates attesting to the adequacy of the sewerage facilities and notifies the Marine Resources Commission when a certificate is issued or denied.</p>	<p>12VAC5-570-40. Administration of regulations.</p> <p>These regulations are administered by the following parties:</p> <p>1. The State Board of Health has responsibility for promulgating, amending, and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.</p> <p>2. A. The State Health Commissioner commissioner is the chief executive officer of the Virginia Department of Health. The commissioner has the authority to act for the board when it is not in session. The commissioner may delegate his powers under this chapter with the exception of his power to issue variances under 12VAC5-570-90.</p> <p>3. B. The Division of Wastewater Engineering division is designated as the primary reviewing agent of the board commissioner for the purpose of administering this chapter. Upon receipt of the application from the local health department, the division examines and passes upon the technical aspects of all applications, plans and specifications grants or denies the application for sewerage facilities to serve marinas and other places where boats are moored, and boating access facilities. The division issues all certificates attesting to the adequacy of the sewerage facilities and notifies the Marine Resources Commission VMRC when a certificate is issued or denied.</p> <p>4. The Deputy Commissioner for Community Health Services directs and supervises the activities of the local health departments in</p>

		<p>4. The Deputy Commissioner for Community Health Services directs and supervises the activities of the local health departments in the administration of assigned duties and responsibilities under the chapter.</p> <p>5. The local health department in each jurisdiction, city, town or county in which there exists, or is proposed, a marina or other place where boats are moored shall (i) be responsible for the processing of all applications submitted by owners, (ii) inspect sites and facilities provided, (iii) issue such permits as required by law, rules or regulations for sewerage facilities and, (iv) lacking in authority to issue a permit, will process such applications in accordance with the policies and procedures of the department. The local health department shall conduct a surveillance program and enforce the provisions of this chapter to ensure proper sanitation and cleanliness of the facilities provided.</p> <p>6. The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.</p>	<p>the administration of assigned duties and responsibilities under the chapter.</p> <p>5. C. The local health department in each jurisdiction, city, town or county in which there exists, or is proposed, a marina or other place where boats are moored shall (i) be responsible for the processing of all applications submitted by owners, (ii) inspect and for inspecting sites and facilities provided, (iii) issue such permits as required by law, rules or regulations for sewerage facilities and, (iv) lacking in authority to issue a permit, will process such applications in accordance with the policies and procedures of the department. The local health department shall conduct a surveillance program and enforce the provisions of this chapter to ensure proper sanitation and cleanliness of the facilities provided for compliance with this chapter.</p> <p>6. The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.</p> <p><i>Revised for clarity and to update language to reflect the current command structure and delegations of authority within the agency.</i></p>
<p>50.</p>	<p>.</p>	<p>A. Marinas or other places where boats are moored which are not in compliance with the Rules and Regulations of the Board of Health Governing Sanitary and Sewerage Facilities at Marinas and Other Places Where Boats Are Moored which became effective November 15, 1975 [repealed], shall comply with this chapter.</p>	<p>12VAC5-570-50. Application of regulations to marinas and other places where boats are moored <u>Applicability.</u></p> <p>A. Marinas or other places where boats are moored which are not in compliance with the Rules and Regulations of the Board of Health Governing Sanitary and Sewerage Facilities at Marinas and Other Places Where Boats Are Moored which became effective November 15, 1975 [repealed], shall comply with this chapter. Marinas, other places where boats are moored, and boating access</p>

		<p>B. All planned or new marinas or other places where boats are moored which do not exist on the effective date of this chapter shall comply with all provisions of this chapter prior to commencing operation.</p> <p>C. All sanitary or sewerage facilities shall conform to the requirements of this chapter when the marina or other places where boats are moored are either expanded, altered or modified.</p>	<p><u>facilities in operation prior to the effective date of this chapter shall be subject to the regulations in effect at the time the marina, other places where boats are moored, or boating access facility was permitted unless such marina, other places where boats are moored, or boating access facility is expanded after (insert the effective date of this chapter).</u></p> <p><i>Revised for clarity to be fair to regulants, the new requirements don't apply retroactively to existing facilities unless there is an expansion.</i></p> <p>B. All planned or new marinas or other places where boats are moored which do not exist <u>This chapter shall apply to all marinas, other places where boats are moored, and boating access facilities placed into operation on or after (insert the effective date of this chapter) shall comply with all provisions of this chapter prior to commencing operation.</u> <i>Revised for clarity.</i></p> <p>C. All sanitary or sewerage facilities and sewerage systems shall conform to the requirements of this chapter when the marina or other place places where boats are moored are either, or boating access facility that is served by the sewerage facilities and sewerage systems is expanded, altered or modified. <i>Revised for clarity and to conform to the definitions in section 10.</i></p> <p>D. <u>This chapter shall apply to sewerage facilities and sewerage systems (i) serving marinas, other places where boats are moored, or boating access facilities and (ii) located on property owned by the marina, other places where boats are moored, or boating access facility. Sewerage systems or treatment works installed or proposed to be installed on property owned by someone other than the marina, other places where boats are moored, or boating access facility owner are regulated by Chapter 6 (§ 32.1-163 et seq.) of Title 32.1 of the Code of Virginia or Title 62.1 of the Code of Virginia, as applicable.</u></p> <p><i>New section that clarifies that this chapter applies only to those sewerage systems and facilities that are located on the owner's property. Remote facilities are subject to other applicable regulations.</i></p>
60.		No owner shall operate a marina or other place where boats are moored	12VAC5-570-60. Certification general <u>Permits and certificate.</u>

		<p>unless he complies with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and this chapter. Owners shall have in their possession a permit from the Marine Resources Commission to operate a marina or place where boats are moored when so required by § 62.1-3 of the Code of Virginia. Where state-owned bottom lands are involved, a plan approved by the department shall be issued prior to construction and the issuance of a certificate to operate.</p>	<p>No owner shall operate <u>construct</u> a marina or other place <u>places</u> where boats are moored, or a boating access facility unless he complies with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and <u>has obtained a construction permit in accordance with</u> this chapter. <u>No owner shall operate a marina, other places where boats are moored, or a boating access facility until the local health department has inspected and approved construction and has issued a certificate to operate.</u> Owners shall have in their possession <u>obtain</u> a permit from the Marine Resources Commission <u>VMRC</u> to operate a marina, or place <u>other places</u> where boats are moored, or a boating access facility when so required by §62.1-3, of the Code of Virginia. Where state-owned bottom lands are involved, <u>the owner shall submit a plan approved preliminary design and receive approval by the department</u> shall be issued <u>division</u> prior to construction and the issuance of a certificate to operate.</p> <p><i>Revised for clarity and to add boating access facilities as a regulated category.</i></p>
70.		<p>Any owner, or his duly authorized representative, may make application for a certificate of approval of sanitary or sewerage facilities by applying to the local health department in the jurisdiction where the proposed marina or other place where boats are moored is to be located. The application shall be made on a form supplied by the local health department. The application shall consist of the following:</p> <ol style="list-style-type: none"> 1. A completed application form which shall set forth the essential data to determine the sewerage facilities necessary to serve the proposed installation; 2. Maps, plans and specifications of the sanitary and sewerage facilities describing how and what facilities will be provided. The plans shall establish the location of the sanitary facilities in relation to other facilities; 	<p>12VAC5-570-70. Application for certificate <u>construction permit</u>.</p> <p><u>A.</u> Any owner, or his duly authorized representative, may make application <u>shall apply</u> for a <u>certificate of approval of sanitary or sewerage facilities construction permit</u> by applying <u>submitting an application</u> to the local health department in the jurisdiction where the proposed marina or other place <u>places</u> where boats are moored, or boating access facility is to be located. The application shall be made on a form supplied by the local health department <u>approved by the division</u>. The application shall consist of the following:</p> <ol style="list-style-type: none"> 1. A completed application form <u>which shall set forth the essential</u> <u>Essential</u> data to determine the sewerage facilities <u>and sewerage system</u> necessary to serve the proposed installation; 2. Maps, plans, and specifications of the <u>sanitary sewerage facilities</u> and sewerage <u>facilities system</u> describing <u>how and what the type of facilities that</u> will be provided <u>and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility</u>. The <u>preliminary design</u> plans shall establish the location of the <u>sanitary sewerage facilities and sewerage system</u> in relation to other facilities; <u>they are intended to serve.</u>

		<p>3. A description of the proposed method of sewage treatment or disposal. Approval of the treatment works or disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and</p> <p>4. Any other data as may be pertinent to show the adequacy of sanitary or sewerage facilities to be provided.</p>	<p>3. A description of the proposed method of sewage or existing offsite sewerage system or treatment works used for the ultimate treatment of and disposal. <u>Approval of sewage. The applicant shall apply for and obtain approval of the new offsite sewerage systems or treatment works or disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter.</u></p> <p>4. Any other data as may be pertinent to show the adequacy of sanitary or the <u>sewerage facilities and sewerage system</u> to be provided.</p> <p><u>B. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.</u></p> <p><u>[C. The department shall issue a permit to construct the proposed marina, other place where boats are moored, or boating access facility after review of a complete application that demonstrates compliance with the requirements of this chapter and § 32.1-246 of the Code of Virginia.]</u></p> <p><i>Revised for clarity and include construction permit requirements.</i></p>
<p>80.</p>		<p>Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.</p> <p>A. Construction. Upon completion of construction of the sanitary and sewerage facilities at marinas and other places where boats are moored, the owner of the facility, or his duly authorized representative, shall notify the local health department. A certificate to operate shall be issued by the Health Department when it has been determined that construction is in compliance with the approved plan.</p>	<p>12VAC5-570-80. [Receipt of data application. <u>Certificate to operate.</u>]</p> <p>Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.</p> <p>A. Construction. Upon completion of construction of the <u>sanitary sewerage facilities [, and] sewerage facilities systems [, and treatment works]</u> at marinas <u>and</u>, other places where boats are moored, <u>or boating access facilities</u>, the owner of the facility, or his duly authorized representative, shall notify the local health department <u>so that it may inspect the construction.</u> A certificate to operate shall be issued by the Health Department when it <u>When the division, in consultation with the local health department, has been determined that construction is in compliance with the</u></p>

		<p>B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia.</p>	<p><u>approved plan, it shall issue a certificate [to operate to the owner of the marina, other place where boats are moored, or boating access facility. The certificate to operate shall remain valid in accordance with this section.]</u></p> <p>B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia. The owner shall post the certificate [to operate] in a place where it is readily observable by members of the public who transact business with the facility.</p> <p><u>[C. All marinas, other places where boats are moored, and boating access facilities shall be subject to a five year, renewable certificate to operate. The owner of the marina, other place where boats are moored, and boating access facility shall request a new certificate to operate at least 90 days prior to the expiration date of the existing certificate to operate. The division shall issue the new certificate to operate provided the sewerage facilities, sewerage system, and treatment works meet or satisfy the minimum requirements of this chapter and § 32.1-246 of the Code of Virginia.</u></p> <p><u>D. If the commissioner grants a variance, or the division approves any exception to this chapter, then the certificate to operate shall contain that information. The owner of the marina, other place where boats are moored, or boating access facility shall follow any condition or requirement listed on the certificate to operate.</u></p> <p><u>E. As a condition of the certificate to operate, owners of marinas, other places where boats are moored, or boating access facilities shall allow the department to perform one or more inspections per year of the sewerage facilities, sewerage systems, and treatment works to ensure compliance with this chapter and § 32.1-246 of the Code of Virginia. The division may revoke the certificate to operate pursuant to 12VAC5-570-100.]</u></p> <p><i>Revised for clarity and to shift agency policy regarding inspections into the regulations.</i></p>
90.		<p>The commissioner may grant a variance to any requirement of this chapter if, after investigation, it is determined that the hardship imposed upon the owner or the public by compliance with this chapter outweigh the benefits that the chapter confers, or that there is</p>	<p><u>A. The commissioner may grant a variance to any requirement of this chapter if, after investigation, it is determined the commissioner determines that the hardship imposed upon the owner or the public by compliance with this chapter outweigh outweighs the benefits that the chapter confers, or that there is no and that granting a variance will not result in a potential or</u></p>

		<p>no potential or actual public health hazard.</p> <p>A. Effect of variance. A variance is a conditional waiver of a specific regulation which is granted to a particular or designated marina or other place where boats are moored. It is nontransferrable and it shall be attached to the certificate of the marina or other place where boats are moored to which it was granted. The variance is a condition of the certificate which is revoked if the certificate is revoked.</p> <p>B. Application for a variance. Any owner of a marina or other place where boats are moored may apply in writing for a variance. This application shall be submitted to the local health department in the jurisdiction in which the marina or other place where boats are moored is located. This application shall include:</p> <ol style="list-style-type: none"> 1. A citation to the chapter from which a variance is requested; 2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted, and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; and 3. Facts supporting the need and justification for the variance. 	<p>actual public health hazard.</p> <p>A. Effect of variance. B. A variance is a conditional waiver of a specific regulation which that is granted to a particular or designated marina or other place where boats are moored an owner of a marina, other places where boats are moored, or a boating access facility. It is nontransferrable. Variances are not transferrable between owners, and it any variance shall be attached to the certificate of the marina or, other place places where boats are moored, or boating access facility to which it was granted. The variance is a condition of the certificate, which is revoked if the certificate is revoked.</p> <p>B. Application for a variance. C. Any owner of a marina or, other place places where boats are moored, or a boating access facility may apply in writing for a variance. This application shall be submitted to the local health department in the jurisdiction in which the marina or, other place places where boats are moored, or boating access facility is located. This application shall include:</p> <ol style="list-style-type: none"> 1. A citation to referencing the specific requirements of this chapter from which a variance is requested and a statement describing the hardships imposed by the specific requirements of this chapter; 2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted, and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; and 3. Facts supporting the need and justification for the variance; 4. The nature and duration of the variance request; 5. Other information, if any, believed by the applicant to be pertinent; and 6. Such other information as the division, local health department, or the commissioner may require. <p>D. If the commissioner denies any request for a variance, such denial shall be in writing and shall state the reasons for the denial.</p> <p><i>Revised for clarity and to conform to the agency processes for variances in other programs.</i></p>
100.		<p>The board may revoke or suspend a certificate for failure to construct and operate the sewerage facilities in</p>	<p>12VAC5-570-100. Suspension or revocation Revocation of a certificate.</p>

		accordance with the conditions of the application and certificate issued or for any violation of this chapter.	<p>The board Either by emergency order under the authority of § 32.1-13 of the Code of Virginia or following an opportunity for an informal fact-finding proceeding as provided by § 2.2-4019 of the Code of Virginia, the commissioner or his designee may revoke or suspend a certificate for failure to construct and operate the sewerage facilities <u>and sewerage system</u> in accordance with the conditions of the application and certificate issued or for any violation of this chapter.</p> <p><i>Revised for clarity and to conform to applicable delegations of authority. The authority to suspend has been eliminated.</i></p>
110.		Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia.	<p>12VAC5-570-110. <u>Administration appeals Applicability of the Administrative Process Act.</u></p> <p>Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the The Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia. (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the decision of cases under this chapter.</p> <p><i>Revised for clarity and to conform to the requirements of the Administrative Process Act.</i></p>
Part II Article I		Required Facilities for Marinas and Other Places Where Boats are Moored and Their Operation	<p>Required <u>Sewerage Facilities and Sewerage Systems</u> for Marinas and Other Places Where Boats are <u>Are Moored, and Boating Access Facilities</u> and Their Operation</p> <p><i>Title revised for clarity.</i></p>
120.		A. All marinas or other places where boats are moored shall provide the minimum number of sanitary facilities for their patrons. These facilities shall be maintained in a clean and sanitary condition. They shall be equipped with toilet tissue, lights where electricity is available and soap and towels where handwashing facilities are required. These facilities shall be available to patrons and users of these facilities at all times during	<p>A. All <u>owners</u> of marinas or other places where boats are moored, <u>and boating access facilities</u> shall provide the minimum number of <u>sanitary sewerage facilities required by this chapter</u> for their patrons. <u>These Owners shall maintain their facilities shall be maintained</u> in a clean and <u>sanitary operable</u> condition. <u>They shall be equipped Owners shall equip their facilities</u> with toilet tissue, lights where electricity is available, and soap and towels where handwashing facilities are required. <u>These Owners shall make their facilities shall be available during normal business hours</u> to patrons and users of these</p>

		<p>the normal boating season.</p> <p>B. Marinas which are operated as part of residential developments, overnight lodging facilities, restaurants or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted from providing separate sanitary facilities, as long as the sanitary facilities at the residence, lodging establishment, restaurant or commercial establishment are available to all users of the marina. This exemption does not apply to</p> <p>(i) marinas associated with restaurants or commercial establishments which allow overnight occupancy of boats and</p> <p>(ii) marinas associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.</p> <p>C. Exempt from the requirements of subsection A of this section are other places where boats are moored which serve residents of homes (houses, condominiums, apartments or mobile homes), their bona fide house guests, or registered guests of tourist establishments which provide adequate sanitary facilities that are located within 1,000 feet of the shore end of the pier.</p> <p>D. In order to qualify for an exemption under subsections B or C of this section, the owner of such marinas or other places where boats are moored shall provide to the department a signed, notarized statement that all conditions set forth in the aforementioned sections will be complied with by users of the</p>	<p>facilities at all times during the normal boating season <u>for that facility.</u></p> <p>B. Marinas which are located within 1,000 feet of the shore end of the pier that are operated as part of residential developments, overnight lodging facilities, restaurants, or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted <u>exempt</u> from providing separate <u>sanitary sewerage</u> facilities, as long as the <u>sanitary sewerage</u> facilities at the residence, lodging establishment, restaurant, or commercial establishment are <u>made</u> available to all users of the marina. This <u>The</u> exemption set forth in <u>this subsection</u> does not apply to (i) marinas:</p> <p><u>1. Marinas</u> associated with restaurants or commercial establishments which that allow overnight occupancy of boats; and (ii) marinas</p> <p><u>2. Marinas</u> associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.</p> <p>C. Exempt from the requirements of subsection A of this section are other <u>Other</u> places where boats are moored which serve and boating access facilities are exempt from the requirements of subsection A of this section, provided that the other places where boats are moored or boating access facility:</p> <p><u>1. Serves</u> residents of homes (houses, condominiums, apartments, or mobile homes), their bona fide house guests, or registered guests of tourist establishments which provide; and are exempt from the requirements of subsection A of this section, provided that the other places where boats are moored or boating access facility:</p> <p><u>2. Provides</u> adequate <u>sanitary sewerage</u> facilities that are located within 1,000 feet of the shore end of the pier.</p> <p>D. In order to qualify for an exemption under subsections <u>subsection</u> B or C of this section, the owner of such marinas or a marina, other places where boats are moored, <u>or a boating access facility</u> shall provide to the department <u>division</u> a signed, notarized statement that all conditions set forth in the aforementioned sections <u>this section</u> will be complied with by users of the facilities.</p> <p><i>Revised for clarity.</i></p>
--	--	---	--

130.		<p>facilities.</p> <p>Adequate sanitary facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock they are intended to serve or within a reasonable distance under unusual circumstances as determined by the division. It may be necessary to provide sanitary facilities in more than one location in order to meet the needs of the particular site developed.</p>	<p>Adequate sanitary Owners shall conveniently locate their sewerage facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock they <u>the facilities</u> are intended to serve or within a reasonable. On a case-by-case basis the <u>division may approve a greater distance under if unusual circumstances as determined by the division, such as topography or resource protection areas, prevent compliance with this requirement. ‡</u> <u>The division may be necessary require the owner to provide sanitary sewerage facilities in more than one location in order to meet the needs of the particular site developed. In addition, the division may require additional fixtures, beyond the minimum number specified in Table 1 (12VAC5-570-150), if it determines that additional fixtures are necessary to accommodate the site layout and use of the marina, other places where boats are moored, or boating access facility.</u></p> <p><i>Allows the Division to approve sewage facilities at distances greater than 500' on a case by case basis; allows the Division to require additional facilities on a case by case basis when necessary to accommodate the specific needs of a particular facility.</i></p>
140.		<p>The sanitary facilities shall be so located that they are available and readily accessible to users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities.</p>	<p>12VAC5-570-140. Availability and marking of <u>sanitary facilities.</u></p> <p>The sanitary Owners shall locate the sewerage facilities shall be so that they are available and readily reasonably accessible to all users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities <u>The location and use of all sewerage facilities shall be clearly indicated by appropriate signage.</u></p> <p><i>Revised for clarity.</i></p>
150.		<p>A. Minimum number of fixtures to be provided in sanitary facilities. It shall be understood that in many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the Board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined. Where dry storage space is provided, each dry storage space is</p>	<p>12VAC5-570-150. <u>Marinas Sewerage facilities for marinas.</u></p> <p>A. Minimum The minimum number of sewerage fixtures to be provided in sanitary facilities. It shall be understood that at marinas is found in many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined <u>Table 1.</u></p> <p><u>B. Where dry storage space is provided, each dry storage space is equivalent to one-</u></p>

equivalent to one-third of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate facilities for male and female personnel shall be provided in a structure or structures.

Table #1

Number of Seasonal Slips	Fixtures		
	Commodes		Urinals
	Male	Female	Male
0-49	1	1	0
50-99	1	2	1
100-149	2	3	1
150-199	2	4	2
200-249	3	5	2

Number of Seasonal Slips	Fixtures	
	Lavatories	
	Male	Female
0-49	1	1
50-99	1	1
100-149	2	2
150-199	3	3
200-249	4	4

Number of Seasonal Slips	Fixtures	
	Showers	
	Male	Female
0-49	0	0
50-99	0	0
100-149	1	1
150-199	2	2
200-249	2	2

third of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate sewerage facilities for male and female personnel shall be provided in a structure or structures, but shall not be counted toward the minimum number of fixtures required to accommodate users of the marina.

Table 1

Number of Slips	Fixtures		
	Commodes		Urinals
	Male	Female	Male
1-24	4		0
25-49	4	2	4
50-99	2	3	4
100-149	3	4	4
150-199	3	5	2
200-249	4	6	2

Table 1

Number of Slips	SEWERAGE FIXTURES		
	Commodes		Additional Urinal or Commode
	Male	Female	Male
1 - 24	1		0
25 - 49	1	2	1
50 - 99	2	3	1
100 - 149	3	4	1
150 - 199	3	5	2
200 - 249	4	6	2

Lavatories		Showers	
Male	Female	Male	Female
1		1	
2	2	1	1
2	2	1	1
3	3	2	2

4	4	2	2
5	5	3	3

Table #1

Number of Seasonal Slips	Fixtures		
	Commodes		Urinals
	Male	Female	Male
0-49	1	1	0
50-99	1	2	1
100-149	2	3	1
150-199	2	4	2
200-249	3	5	2

Number of Seasonal Slips	Fixtures	
	Lavatories	
	Male	Female
0-49	1	1
50-99	1	1
100-149	2	2
150-199	3	3
200-249	4	4

Number of Seasonal Slips	Fixtures	
	Showers	
	Male	Female
0-49	0	0
50-99	0	0
100-149	1	1
150-199	2	2
200-249	2	2

When the number of seasonal slips exceeds those above on Table No. 1 additional fixtures shall be provided. One commode, lavatory and shower will be provided for each sex for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.

B. Transient slip. When transient slips are available additional sanitary facilities shall be provided. Table No. 2 below shows the minimum number of additional fixtures required.

~~C. When the number of seasonal slips exceeds those above on prescribed by Table No. 1, the owner shall provide additional fixtures shall be provided. One The owner shall provide one commode, lavatory, and shower will be provided for each sex gender for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.~~

~~B. Transient slip. When transient slips are available additional sanitary facilities shall be provided. Table No. 2 below shows the minimum number of additional fixtures required. These fixtures may be included in a structure or structures with those fixtures provided for the seasonal slip, provided the accessibility and convenience standards of 12VAC5-570-130 and 12VAC5-570-140 of this chapter are met.~~

These fixtures may be included in a structure or structures with those fixtures provided for the seasonal slip, provided the accessibility and convenience standards of 12VAC5-570-130 and 12VAC5-570-140 of this chapter are met.

Table #2

Number of Transient Slips	Fixtures		
	Commodes		Urinals
	Male	Female	Male
0-24	1	1	1
25-49	1	2	1
50-74	2	3	1
75-100	2	4	2

Number of Transient Slips	Fixtures	
	Lavatories	
	Male	Female
0-24	1	1
25-49	2	2
50-74	2	2
75-100	3	3

Number of Transient Slips	Fixtures	
	Showers	
	Male	Female
0-24	1	1
25-49	2	2
50-74	2	2
75-100	3	3

For each 24 or fraction thereof of transient slips or moorings in excess of those shown in Table No. 2 above, one commode, lavatory and shower shall be provided for each sex. In addition, one urinal shall be provided for each 50 or fraction thereof transient slips in excess of the number shown in Table No. #2.

Table #2

Number of Transient Slips	Fixtures		
	Commodes		Urinals
	Male	Female	Male
0-24	1	1	1
25-49	1	2	1
50-74	2	3	1
75-100	2	4	2

Number of Transient Slips	Fixtures	
	Lavatories	
	Male	Female
0-24	1	1
25-49	2	2
50-74	2	2
75-100	3	3

Number of Transient Slips	Fixtures	
	Showers	
	Male	Female
0-24	1	1
25-49	2	2
50-74	2	2
75-100	3	3

For each 24 or fraction thereof of transient slips or moorings in excess of those shown in Table No. 2 above, one commode, lavatory, and shower shall be provided for each sex. In addition, one urinal shall be provided for each 50 or fraction thereof transient slips in excess of the number shown in Table No. 2.

Eliminates "seasonal" and "transient" slips as the basis for determining sewerage fixture needs. Combining the sewerage fixture requirements into one table will lessen the restrictions placed on facility owners allowing them to attract different types of boaters as well as making it easier for the Department to estimate sewage flow. The proposed number of fixtures will provide for the protection of public health and the environment.

160.

Where piped water is available, sanitary facilities shall consist of a minimum of one commode and one lavatory for females and one commode and one lavatory for males for each 100 seasonal slips or fraction thereof and each 50 transient slips or fraction thereof. Requirements for dry storage boat usage shall be identical to those specified in 12VAC5-570-150 for

12VAC5-570-160. Sanitary Sewerage facilities at other places where boats are moored and boating access facilities.

A. Sewerage facilities are required at other places where boats are moored and boating access facilities in accordance with this section.

B. Where piped potable water is available, sanitary sewerage facilities for other places where boats are moored shall consist of a

		<p>marinas. Sanitary facilities may consist of privies where piped water is not available. Walking distance to these facilities shall comply with 12VAC5-570-130.</p>	<p>minimum of one commode and one lavatory, and one shower for females and one commode and one lavatory for males for each gender, for each 100 seasonal slips or fraction thereof and each 50 transient slips or fraction thereof.</p> <p>C. Requirements for dry storage boat usage shall be are identical to those specified in 12VAC5-570-150 for marinas.</p> <p>Sanitary D. Where piped potable water is not available, sewerage facilities for other places where boats are moored may consist of privies where piped water is not available.</p> <p>E. Sewerage facilities at boating access facilities shall consist of at least one privy or portable toilet and shall be sufficient in number to accommodate facility usage.</p> <p>F. Walking distance to these facilities shall comply with 12VAC5-570-130.</p> <p><i>This section was revised for clarity. New sewerage facility requirements added for boat ramps with more than 50 parking spaces for boat trailers. Requiring the availability of sewerage facilities at these types of boating facilities will ensure the protection of public health and the environment.</i></p>
<p>170.</p>		<p>Public or municipal sewage treatment facilities shall be used if there is reasonable access to sewers. When such municipal means of disposal is not available, the owner shall have designed and installed an approved method of sewage treatment. Approved methods of sewage treatment are set forth in the Sewerage Regulations (1977) (12VAC5-580-10 et seq.) Sewage Handling and Disposal Regulations (1982, as amended), 12VAC5-610-10 et seq. If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division.</p> <p>A. The following shall be used to determine the amount of sewage flow. It is assumed that each slip or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 10 gallons per</p>	<p>12VAC5-570-170. Sewage treatment. <u>A.</u> Public or municipal sewage <u>sewerage systems and treatment facilities shall works</u> should be used if there is reasonable access to sewers. When such municipal means of disposal is <u>are</u> not available, the owner shall have designed and installed an approved method of sewage treatment. Approved methods of sewage treatment are set forth in the Sewerage Regulations (1977) (12VAC5-580-10 et seq.) Sewage Handling and Disposal Regulations (1982, as amended), 12VAC5-610-10 et seq. If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division sewerage system or treatment works. An approved sewerage system or treatment works is (i) a system for which a certificate to operate has been issued jointly by the department and the Department of Environmental Quality, (ii) a system approved by the Department of Environmental Quality in accordance with Title 62.1 of the Code of Virginia, or (iii) a system approved by the commissioner in accordance with Title 32.1 of the Code of</p>

		<p>person per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. For dry storage facilities the sewage flow shall be calculated using one-third the number of dry storage spaces. In addition, for marinas or other places where boats are moored which have a boat launching ramp and provide boat trailer parking spaces only while the boat is in use, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.</p> <p>B. Where restaurants or motels are operated in connection with a marina or place where boats are moored the following shall be used as a basis for determining the amount of sewage flow: Motels - 65 gallons per person per day or a minimum of 130 gallons per room per day. Restaurant - 50 to 180 gallons per seat per day. Each installation will be evaluated according to conditions.</p> <p>C. The occupancy level of boats used for design of sewage treatment or disposal facilities will be those levels listed in 12VAC5-570-170 A. It is recognized that the type of activity and utilization of marina or other places where boats are moored varies and, therefore, additional facilities to provide capacity up to maximum may be required if the need arises. The local health director serving the area in which the marina is located shall make such determination.</p>	<p><u>Virginia.</u></p> <p>A. The following shall be used to determine the amount of sewage flow. It is assumed that B. The sewage design flow for each slip or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 10 25 gallons per person slip per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. For dry storage facilities the sewage flow shall be calculated using one-third the number of dry storage spaces. Where dry storage is provided, each dry storage space shall be equivalent to one-third of a slip. The sewage design flow for each live-aboard slip shall be 50 gallons per slip per day. When marinas or other places where boats are moored are constructed in conjunction with another structure or facility, the sewage design flows prescribed in this section shall be added to the sewage design flow governing the associated structure or facility.</p> <p>In addition, for marinas C. For marinas or other places where boats are moored which have that have a boat launching ramp and provide boat trailer parking spaces only while the boat is in use boating access facility, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.</p> <p>B. Where restaurants or motels are operated in connection with a marina or place where boats are moored the following shall be used as a basis for determining the amount of sewage flow:</p> <p>Motels - 65 gallons per person per day or a minimum of 130 gallons per room per day.</p> <p>Restaurant - 50 to 180 gallons per seat per day. Each installation will be evaluated according to conditions.</p> <p>C. The occupancy level of boats used for design of sewage treatment or disposal facilities will be those levels listed in 12VAC5-570-170 A. It is recognized that the type of activity and utilization of marina or other places where boats are moored varies and, therefore, additional facilities to provide capacity up to maximum may be required if the need arises. The local health director serving the area in which the marina is</p>
--	--	--	---

			<p>located shall make such determination.</p> <p><u>D. The division may approve a reduction in the sewage flow requirements specified in subsection B of this section if the owner provides documented flow data sufficient to justify the reduction.</u></p> <p><i>The revisions simplify the method for estimating sewage flows by basing flows on "slips" rather than the existing method which relies on "seasonal," "transient" and other slip designations. The revisions also establish a new requirement for "live-aboard" slips that are used as residences. The proposed sewage design flows provide a more accurate representation of the volume of sewerage waste generated at the boating facility. The sewage design flows also factor in the use of showers and laundry facilities.</i></p>
180.		<p>Other places where boats are moored which allow overnight docking or mooring of boats and all marinas, regardless of size or number of boat moorings, shall provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other places where boats are moored which do not allow boats with an installed toilet with a discharge overboard or a sewage holding tank to use any of the services provided, including moorage, except in an emergency. In order to qualify for this exemption, the owner of such marina or other place where boats are moored shall provide the department with a signed notarized statement that boats with installed toilets with overboard discharges or sewage holding tanks shall not be permitted to use the marina or other places facilities.</p> <p>A. Availability and operation. Where pump-out facilities are required, the owner shall install, maintain in</p>	<p>Other <u>A. Owners of other places where boats are moored which that allow overnight docking or mooring of boats and owners of all marinas, regardless of size or number of boat moorings slips, shall provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other places where boats are moored which that do not have live-aboard slips or allow boats with an installed toilet with a discharge overboard or a sewage holding tank a marine sanitation device to use any of the services provided, including moorage, except in an emergency. In order to qualify for this exemption, the owner of such marina or other places where boats are moored shall provide the Department with a signed notarized statement indicating that there are no live-aboard slips and that boats with installed toilets with overboard discharges or sewage holding tanks marine sanitation devices shall not be permitted to use the marina or other places facilities facility except in an emergency.</u></p> <p>A. Availability and operation. Where pump-out facilities are required, the owner shall install, maintain in good operating condition and provide pump-out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this</p>

		<p>good operating condition and provide pump-out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump-out service.</p> <p>B. Alternate pump-out service. Marinas and other places where boats are moored which provide less than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted from the requirement to install pump-out facilities. Such exemption will be granted by the director of the division whenever alternate pump-out service is provided at a nearby marina or other place where boats are moored, and is evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the division. Such alternate pump-out service will only be approved by the division when the following criteria are met:</p> <ol style="list-style-type: none"> 1. That the alternate pump-out service will not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the boat sewage holding tank pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed twenty minutes; 2. That the alternate pump-out 	<p>section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump-out service. <u>B. The owner shall make sewage pump-out facilities available to all users of the marina or other places where boats are moored during normal operating hours. The owner shall maintain the pump-out equipment in serviceable condition and shall keep the equipment located in an area convenient for utilization.</u></p> <p><u>C. The owner shall use placards or signs to identify the sewage pump-out location and use restrictions.</u></p> <p>B. Alternate pump-out service. <u>D. Marinas and other places where boats are moored which that provide less fewer than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted exempt from the requirement to install pump-out facilities unless such marinas or other places where boats are moored are located in a No Discharge Zone. Such exemption will shall be granted by the director of the division whenever alternate pump-out service is provided at a nearby marina or other place <u>places</u> where boats are moored, and is as evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the division. Such <u>The division shall only approve such</u> alternate pump-out service will only be approved by the division when in accordance with the following criteria are met:</u></p> <ol style="list-style-type: none"> 1. That the <u>The</u> alternate pump-out service will <u>shall</u> not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the boat sewage holding tank <u>marine sanitation device</u> pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed twenty <u>20</u> minutes;. 2. That the <u>The</u> alternate pump-out service shall be located within three <u>nautical</u> miles, as measured along the water route, of the exempt facility using the agreement unless the alternate pump-out service is located along the normal travel route to open water, in
--	--	--	--

		<p>service shall be located within three miles, as measured along the water route, of the facility using the agreement unless the alternate pump-out service is located along the normal travel route to open water, in which case the facility using the agreement shall be within five miles of the alternate pump-out service;</p> <p>3. That the alternate pump-out service capacity is sufficient to handle the demand for pump-out service, in accordance with subsection C of this section, that is expected for all of the marinas or other places where boats are moored entering into the above-mentioned agreement;</p> <p>4. That a notice shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump-out service, that specifies the location of the alternate pump-out service; and</p> <p>5. The terms of the agreement provide:</p> <p>a. That the alternate pump-out service will be available to all boats moored at each facility and it will state that the alternate pump-out facility will furnish pump-out services to anybody referred to it by the establishment using the agreement to provide pump-out service, as specified by this chapter; and</p> <p>b. That the agreement will be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day termination notice to the other and to the director of the division</p>	<p>which case the <u>exempt facility using the agreement</u> shall be within five <u>nautical miles</u> of the alternate pump-out service;</p> <p>-</p> <p>3. That the <u>The</u> alternate pump-out service capacity is shall be sufficient to handle the demand for pump-out service, in accordance with subsection C of this section, that is expected for all of the marinas or other places where boats are moored entering into the above-mentioned agreement; <u>referenced in this subsection.</u></p> <p>4. That a notice shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump-out service, that specifies the location of the alternate pump-out service; and <u>The owner of the exempt facility shall post in a conspicuous location appropriate signage that specifies the location of the alternate pump-out service and the associated charge for its use.</u></p> <p>5. The terms of the agreement <u>shall</u> provide <u>that</u>:</p> <p>a. That the <u>The</u> alternate pump-out service will shall be available to all boats moored at each facility and it will state that the alternate pump-out facility will furnish pump-out services to anybody boaters referred to it by the establishment using the agreement to provide pump-out service, <u>exempt facility</u> as specified by this chapter; and</p> <p>b. That the <u>The</u> agreement will shall be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day termination notice to the other and to the Director of the division prior to the renewal date.</p> <p>6. If a termination notice is issued to a <u>an exempt facility using an agreement to provide alternate pump-out service,</u> in accordance with 12VAC5-570-180 B <u>this subsection,</u> then that facility shall either provide pump-out service or obtain a new written agreement, in accordance with 12VAC5-570-180 B, <u>this subsection</u> by the effective date of the termination of alternate pump-out service.</p>
--	--	---	---

		<p>prior to the renewal date.</p> <p>6. If a termination notice is issued to a facility using an agreement to provide alternate pump-out service, in accordance with 12VAC5-570-180 B, then that facility shall either provide pump-out service or obtain a new written agreement, in accordance with 12VAC5-570-180 B, by the effective date of the termination of alternate pump-out service.</p> <p>C. Minimum design criteria for pump-out facilities. The purpose of these minimum design criteria is to provide the owner and the Department of Health with acceptable methods for pumping, storing, conveying and treatment of the contents from boat holding tanks. The owner shall furnish the following information for each proposed pump-out facility:</p> <p>1. Pumping equipment. Pump equipment may be fixed or portable; however, this equipment shall be conveniently located for usage and clearly identified or placarded by signs or other notices, indicating any fees, restrictions or other operating instructions, as necessary. A minimum pump capacity of 10 gpm is acceptable at the operating head required to transport the flow to the proper collection or treatment location with such residual head as may be required; however, at marinas with 51 or more slips, greater pumping capacity may be required. Pumps shall be of a macerator type or have sufficient size suction and discharge openings to prevent clogging. Manually operated pumps are not permitted. Pump data from the manufacturer shall include:</p>	<p>C. Minimum design criteria for pump-out facilities. E. The purpose of these minimum design criteria is to provide the owner and the Department of Health department with acceptable methods for pumping, storing, and conveying and treatment of the contents from boat holding tanks marine sanitation devices. The owner shall furnish the following information for each proposed pump-out facility A proposed pump-out facility shall meet the following minimum design criteria:</p> <p>1. Pumping equipment. Pump equipment may be fixed or portable; however, this equipment shall be conveniently located for usage and clearly identified or placarded by signs or other notices, indicating any fees, restrictions, or other operating instructions, as necessary. A minimum pump capacity of 10 gpm gallons per minute (gpm) is acceptable at the operating head required to transport the flow to the proper collection or treatment location with such residual head as may be required; however, at marinas with 51 or more slips, greater pumping capacity may be required. Pumps To prevent clogging, pumps shall be of a macerator type or have sufficient size suction and discharge openings to prevent clogging the pumps shall be able to pass a 2-inch spherical solid. Manually operated pumps are not permitted acceptable at marinas and other places where boats are moored that offer fewer than 26 slips. Pump data from the manufacturer shall include:</p> <p>a. The type of pump (diaphragm or (positive displacement, centrifugal, and power) vacuum, macerator, etc.);</p> <p>b. Rated capacity (gpm, hp, and head) Pump power source (electric motor, gasoline engine, etc.) and output (HP);</p> <p>c. Motor type (electric or gas); and Pump capacity, including a performance curve;</p> <p>d. Suction and discharge opening size. Pump solids-handling ability; and</p> <p>e. A schematic showing relevant pump dimensions, such as height, size, and location of suction and discharge openings, etc.</p> <p>2. Location schematic. If fixed pump-out equipment is proposed, a schematic of the</p>
--	--	--	--

		<p>a. The type of pump (diaphragm or centrifugal, and power);</p> <p>b. Rated capacity (gpm, hp. and head);</p> <p>c. Motor type (electric or gas); and</p> <p>d. Suction and discharge opening size.</p> <p>2. Location schematic. If fixed pump-out equipment is proposed, a schematic of the location with elevations for subsections a, b, c, d and e, as described below, shall be included, or if portable pump-out equipment is proposed, a schematic shall indicate elevations for subsections a, c, f and g, as described below:</p> <p>a. Mean low water level;</p> <p>b. Elevation of dock;</p> <p>c. Greatest elevation of suction center line of pump;</p> <p>d. Elevation of discharge point;</p> <p>e. Highest point in discharge line;</p> <p>f. Type of dock (floating or stationary); and</p> <p>g. Greatest elevation of any dock.</p> <p>All elevations shall be measured with respect to mean low water. If the elevation of mean low water is not known, assume it to be zero.</p> <p>3. Fittings and hoses (piping) – fittings and hoses (piping) which are used in operation of</p>	<p>location with elevations for subsections a, b, c, d and e, as described below, shall be included, or if portable pump-out equipment is proposed, a schematic shall indicate elevations for subsections a, c, f and g, as described below: A schematic of the proposed facilities shall be provided and include the following minimum information:</p> <p>a. Mean low water level <u>elevation</u>;</p> <p>b. Elevation of dock <u>Suction hose diameter, length, and highest elevation</u>;</p> <p>c. Greatest elevation of suction center line of pump <u>Pump elevation</u>;</p> <p>d. Elevation of discharge point <u>Discharge hose/pipe diameters, lengths, and highest elevation</u>;</p> <p>e. Highest point in discharge line <u>Discharge point elevation</u>;</p> <p>f. Type of dock (floating or stationary); and</p> <p>g. Greatest elevation of any dock; <u>and</u></p> <p>h. <u>Distance between pump-out location and slips.</u></p> <p>All elevations shall be measured with respect to mean low water. If the elevation of mean low water is not known, assume it to be zero.</p> <p>3. Fittings and hose (piping). Fittings <u>This subdivision sets forth the minimum design criteria for fittings and hoses (piping) which are used in the operation of a pump-out facility shall meet the following:</u></p> <p>a. Suction hose <u>hoses shall meet the following criteria:</u></p> <p>(1) A friction nozzle (right angle preferred) or wand-type attachment is to be provided on the end of the suction hose. Adapters shall be provided to fit any discharge connection from 4.5 <u>1.25</u> to <u>4 2</u> inches in diameter.</p> <p>(2) A check valve shall be provided on the suction hose at the nozzle.</p> <p>(3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis <u>by the division.</u></p> <p>(4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for</p>
--	--	---	---

		<p>a pump-out facility shall meet the following:</p> <p>a. Suction hose.</p> <p>(1) A friction nozzle (right angle preferred) or wand-type attachment is to be provided on the end of the suction hose. Adapters shall be provided to fit any discharge connection from 1.5 to 4 inches in diameter.</p> <p>(2) A check valve shall be provided on the suction hose at the nozzle.</p> <p>(3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis.</p> <p>(4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for service, a gate valve shall be provided on the pump end of the suction line.</p> <p>b. Discharge hose and piping.</p> <p>(1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections.</p> <p>(2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing.</p>	<p>service, a gate <u>full port ball</u> valve shall be provided on the pump end of the suction line.</p> <p>b. Discharge hose and piping- <u>shall meet the following criteria:</u></p> <p>(1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections.</p> <p>(2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing.</p> <p>c. Discharge line <u>lines shall meet the following criteria:</u></p> <p>(1) A gate <u>full port ball</u> valve shall be provided on the discharge line at the pump;</p> <p>(2) Suitable connections on the end of the discharge line shall be provided to prevent it from coming loose <u>dislodging</u> during discharge; all nozzles and fittings are to be positive locking, male and female.</p> <p>(3) The discharge line must <u>shall</u> not be subject to freezing or leaking into the water course.</p> <p>(4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (12VAC5-590-10 et seq.) (12VAC5-590) and the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.) (12VAC5-610).</p> <p>(5) The discharge line connection to the pump-out receiving facility shall be fixed in place in such a manner as to prevent it from coming loose <u>dislodging</u> during discharge.</p> <p>d. Pump-out facilities shall include equipment for rinsing the boats' <u>holding tanks associated with marine sanitation devices</u>. Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type vacuum breaker shall be provided.</p> <p>4. Other devices or methods of removal. Other devices or methods of removal of contents from boat holding tanks <u>marine sanitation devices</u> may be approved by the Commissioner <u>division</u> on an individual case basis.</p>
--	--	--	--

		<p>c. Discharge line.</p> <p>(1) A gate valve shall be provided on the discharge line at the pump;</p> <p>(2) Suitable connections on the end of the discharge line shall be provided to prevent it from coming loose during discharge; all nozzles and fittings are to be positive locking, male and female.</p> <p>(3) The discharge line must not be subject to freezing or leaking into the water course.</p> <p>(4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (12VAC5-590-10 et seq.) and the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.).</p> <p>(5) The discharge line connection to the pump-out receiving facility shall be fixed in place in such a manner as to prevent it from coming loose during discharge.</p> <p>d. Rinse equipment. Pump-out facilities shall include equipment for rinsing the boats' holding tanks. Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type</p>	<p>5. Onshore facilities. Contents from boat holding tanks shall be discharged to (i) a public wastewater collection system in which sewage is conveyed to an approved treatment facility; (ii) a holding tank whereby sewage may be stored until it is taken in an approved manner to an approved treatment facility; or (iii) directly to an approved sewage treatment facility.</p> <p>a. For discharge to a public wastewater collection system, the following will be required: The owner of the marina or other place where boats are moored shall submit evidence, in writing, (i) of consent from the owner of the system, (ii) from the owner of any conveyance systems located downstream, which may be affected, and (iii) from the owner of the ultimate treatment facility. Verification shall be given that there are satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.</p> <p>b. If sewage is to be stored in a holding tank, the holding tanks shall be sized, constructed and located to meet the criteria.</p> <p>(1) Size of holding tank.</p> <p>Marinas or other places where boats are moored shall size the holding tanks based upon the following tabulations:</p> <table border="1" data-bbox="997 1545 1432 1894"> <thead> <tr> <th>Total Number of Boats Serviced with Holding Tanks</th> <th>Required Onshore Holding Tank Volume (gallons) Minimum</th> </tr> </thead> <tbody> <tr> <td>1 - 20</td> <td>250</td> </tr> <tr> <td>21 - 40</td> <td>500</td> </tr> <tr> <td>41 - 60</td> <td>725</td> </tr> <tr> <td>61 - 80</td> <td>1000</td> </tr> <tr> <td>81 - 100</td> <td>1200</td> </tr> </tbody> </table>	Total Number of Boats Serviced with Holding Tanks	Required Onshore Holding Tank Volume (gallons) Minimum	1 - 20	250	21 - 40	500	41 - 60	725	61 - 80	1000	81 - 100	1200
Total Number of Boats Serviced with Holding Tanks	Required Onshore Holding Tank Volume (gallons) Minimum														
1 - 20	250														
21 - 40	500														
41 - 60	725														
61 - 80	1000														
81 - 100	1200														

		<p>vacuum breaker shall be provided.</p> <p>4. Other devices or methods of removal. Other devices or methods of removal of contents from boat holding tanks may be approved by the Commissioner on an individual case basis.</p> <p>5. Onshore facilities. Contents from boat holding tanks shall be discharged to (i) a public wastewater collection system in which sewage is conveyed to an approved treatment facility; (ii) a holding tank whereby sewage may be stored until it is taken in an approved manner to an approved treatment facility; or (iii) directly to an approved sewage treatment facility.</p> <p>a. For discharge to a public wastewater collection system, the following will be required: The owner of the marina or other place where boats are moored shall submit evidence, in writing, (i) of consent from the owner of the system, (ii) from the owner of any conveyance systems located downstream, which may be affected, and (iii) from the owner of the ultimate treatment facility. Verification shall be given that there are satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.</p> <p>b. If sewage is to be stored in a holding tank, the holding tanks shall be sized, constructed and located to meet the criteria.</p> <p>(1) Size of holding tank. Marinas or other places where boats are moored shall size the holding tanks based upon the following tabulations:</p>	<table border="1"> <tr> <th data-bbox="997 205 1214 239">100+</th> <th data-bbox="1214 205 1438 239">2000</th> </tr> </table> <p>(2) Construction of holding tank.</p> <p>(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.</p> <p>(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.</p> <p>(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.</p> <p>(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.</p> <p>(e) The holding tank shall be fixed in place unless it is part of an approved mobile pump-out unit.</p> <p>(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.</p> <p>(g) The holding tank shall be adequately vented. Screened, elbowed down vents installed at the top of the tank will serve this requirement.</p> <p>(h) The inlet/outlet of the holding tank shall be</p>	100+	2000	
100+	2000					

		<table border="1" data-bbox="480 235 896 491"> <thead> <tr> <th>Total Number of Boats Serviced with Holding Tanks</th> <th>Required Onshore Holding Tank Volume (gallons) Minimum</th> </tr> </thead> <tbody> <tr> <td>1-20</td> <td>250</td> </tr> <tr> <td>21-40</td> <td>500</td> </tr> <tr> <td>41-60</td> <td>725</td> </tr> <tr> <td>61-80</td> <td>1000</td> </tr> <tr> <td>81-100</td> <td>1200</td> </tr> <tr> <td>100+</td> <td>2000</td> </tr> </tbody> </table> <p data-bbox="594 525 906 579">(2) Construction of holding tank.</p> <p data-bbox="630 583 919 764">(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.</p> <p data-bbox="630 768 919 1402">(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.</p> <p data-bbox="630 1407 919 1612">(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.</p> <p data-bbox="630 1617 919 1797">(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.</p> <p data-bbox="630 1801 919 1890">(e) The holding tank shall be fixed in place unless it is part</p>	Total Number of Boats Serviced with Holding Tanks	Required Onshore Holding Tank Volume (gallons) Minimum	1-20	250	21-40	500	41-60	725	61-80	1000	81-100	1200	100+	2000	<p data-bbox="1088 210 1435 298">compatible with the proposed method of removal.</p> <p data-bbox="1088 310 1435 466">(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.</p> <p data-bbox="1088 483 1390 512">(3) Holding tank location.</p> <p data-bbox="1088 529 1435 772">Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.)</p> <p data-bbox="1088 789 1435 1121">(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.).</p> <p data-bbox="948 1146 1435 1478">c. Sewage treatment plant. Disposal of holding tank wastes shall not be allowed at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewer system of a large sewage treatment facility or transported for eventual treatment at a large plant.</p> <p data-bbox="948 1554 1435 1890"><i>This section was edited for clarity. Adds marinas and other place(s) where boats are moored that do not allow live-aboard slips and claim an exemption from the requirement to provide pump-out facilities. Adds requirement that pump-out facilities be conveniently located in order to accommodate users of the facility. Adds a number of technical requirements for pumps (must pass 2-inch spherical solid), plans and</i></p>
Total Number of Boats Serviced with Holding Tanks	Required Onshore Holding Tank Volume (gallons) Minimum																
1-20	250																
21-40	500																
41-60	725																
61-80	1000																
81-100	1200																
100+	2000																

		<p>of an approved mobile pump-out unit.</p> <p>(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.</p> <p>(g) The holding tank shall be adequately vented. Screened, elbowed down vents installed at the top of the tank will serve this requirement.</p> <p>(h) The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.</p> <p>(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.</p> <p>(3) Holding tank location. Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.)</p> <p>(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.).</p> <p>c. Sewage treatment plant. Disposal of holding tank wastes shall not be allowed</p>	<p><i>specifications, etc. to more accurately reflect current technology and industry standards. Changes are intended to simplify the need for additional information while educating the facility owner as to where the pump-out equipment should be located. These changes will also assist the health department in evaluating the system so as to assure the safe and sanitary conveyance and disposal of sewage.</i></p>
--	--	--	---

		<p>at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewer system of a large sewage treatment facility or transported for eventual treatment at a large plant.</p>	
<p>190.</p>		<p>A. All marinas and other places where boats are moored, regardless of size or number of boat moorings, shall have an acceptable receiving station for sewage from portable toilets used on boats. The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision are marinas or other places where boats are moored, which also qualify for the 12VAC5-570-120 B or C exemption, provided the owner of the sanitary facility will allow the dumping of the contents of portable toilets into the sanitary facilities.</p> <p>B. Availability and operation. Where a sewage dump station is required, the owner shall install, maintain in good operating condition and provide the facilities to users of the marina or other places where boats are moored.</p> <p>C. Minimum design criteria for a sewage dump station. The purpose of these minimum design criteria is to provide the owner and the Department of Health with acceptable methods of discharging sewage from a portable container into a sewage holding tank or a sewage treatment system. The same criteria as set forth in 12VAC5-570-180 C 5 for contents from</p>	<p>A. All marinas and other places where boats are moored, regardless of size or number of boat moorings, shall have an <u>acceptable a proper and adequate</u> receiving station for sewage from portable toilets <u>containers</u> used on boats. The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision <u>subsection</u> are marinas or other place(s) where boats are moored which that also qualify for the exemption contained in 12VAC5-570-120 B or C exemption, provided that the owner of the <u>sanitary sewerage</u> facility will allow consents to the dumping of the contents of portable toilets <u>sewage containers</u> into the <u>sanitary sewerage</u> facilities.</p> <p>B. Availability and operation. Where a sewage dump station is required, the owner shall install, <u>and maintain in good operating condition, and provide it in a serviceable and sanitary condition and in compliance with this chapter.</u> The owner shall make provide the facilities <u>available</u> to users of the marina or other places where boats are moored. <u>The owner shall locate the sewage dump station in an area convenient for use and the owner shall use placards or signs to identify its location and restrictions.</u></p> <p>C. Minimum design criteria for a sewage dump station. The purpose of these <u>the</u> minimum design criteria is to provide the owner and the Department of Health <u>department</u> with acceptable methods of discharging sewage from a portable containers <u>containers</u> into a sewage holding tank or a <u>sewage sewerage</u> treatment <u>works.</u> system. The same criteria as set forth in 42VAC5-570-180 C 5 <u>12VAC5-570-200 A</u> for contents from boat holding tanks <u>marine sanitation devices</u> will <u>shall</u> apply for sewage dump stations. The sewage dump station receiving unit shall be a minimum of 12</p>

		<p>boat holding tanks will apply for sewage dump stations. The sewage dump station receiving unit shall be a minimum of 12 inches in diameter and be equipped with a cover that has a lip of sufficient size to prevent it from accidentally being removed. If the unit is designed to drain, the drain shall be a minimum of four inches in diameter and equipped with a fly tight cover.</p>	<p>inches in diameter and be equipped with a cover that has a lip of sufficient size to prevent it from accidentally being removed prohibit accidental removal. If the unit is designed to drain, the drain shall be a minimum of four inches in diameter and equipped with a fly tight cover.</p> <p><u>D. Marinas and other place(s) where boats are moored that have an operational pump-out facility equipped with a device to pump portable sewage containers are exempt from the requirement of subsection C of this section.</u></p> <p><i>Revised for clarity. Provides owners with facilities that have proper sanitary waste pump-out services an alternative to installing a sanitary waste dump station. The wand attachment is now commonly used at boating facilities with sanitary waste pump-out systems because it is easy to use and limits the boater's opportunity to spill sanitary waste into the water thereby protecting the environment. Requirement for convenient location added to accommodate facility users and the public.</i></p>
(None)	200. Onshore facilities	See 180 C.	<p><u>12VAC5-570-200. Onshore facilities.</u></p> <p><u>A. Contents from marine sanitation devices and portable sewage containers used on boats shall be discharged to:</u></p> <ol style="list-style-type: none"> <u>1. A public sewerage system for conveyance to an approved treatment works as described in 12VAC5-570-170 A;</u> <u>2. A holding tank whereby sewage may be stored until it is transported in accordance with the Sewage Handling and Disposal Regulations to an approved treatment works as described in 12VAC5-570-170 A; or</u> <u>3. An approved sewage treatment works as described in 12VAC5-570-170 A.</u> <p><u>B. Disposal of sewage waste from a marine sanitation device shall be prohibited at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewerage system of a large sewage treatment facility or transported for eventual treatment at a large sewage treatment facility.</u></p> <p><u>C. For discharge to a public sewerage system, the owner of the marina or other places where boats are moored shall submit</u></p>

			<p>to the division, in writing:</p> <ol style="list-style-type: none"> 1. Evidence of consent to the discharge from the owner of the conveyance system; 2. Evidence of consent to discharge from the owner of any conveyance systems located downstream that may be affected; and 3. Evidence of consent to discharge from the owner of the treatment works where the sewage is to be disposed. <p>The owner shall verify that there are satisfactory provisions for emptying the contents from portable sewage containers in a sanitary manner.</p> <p>D. If sewage is to be stored by the marina or other places where boats are moored in a holding tank, the holding tank or tanks shall be sized, constructed, and located to meet the following criteria:</p> <ol style="list-style-type: none"> 1. Sewage holding tanks shall be sized in accordance with the requirements of Table 2. <p style="text-align: center;"><u>Table 2: Minimum Holding Tank Volume</u></p> <table border="1" data-bbox="951 970 1432 1449"> <thead> <tr> <th data-bbox="951 970 1195 1129">Total Number of [Boats Served Annually with Marine Sanitation Devices Slips]</th> <th data-bbox="1195 970 1432 1129">Minimum Holding Tank Volume (gallons)</th> </tr> </thead> <tbody> <tr> <td data-bbox="951 1129 1195 1176">[1 - 60</td> <td data-bbox="1195 1129 1432 1176">725</td> </tr> <tr> <td data-bbox="951 1176 1195 1222">61 - 80</td> <td data-bbox="1195 1176 1432 1222">1000</td> </tr> <tr> <td data-bbox="951 1222 1195 1268">81 - 100</td> <td data-bbox="1195 1222 1432 1268">1200</td> </tr> <tr> <td data-bbox="951 1268 1195 1314">100+</td> <td data-bbox="1195 1268 1432 1314">2000</td> </tr> <tr> <td data-bbox="951 1314 1195 1360">1 - 300</td> <td data-bbox="1195 1314 1432 1360">1000</td> </tr> <tr> <td data-bbox="951 1360 1195 1407">301 - 450</td> <td data-bbox="1195 1360 1432 1407">1500</td> </tr> <tr> <td data-bbox="951 1407 1195 1449">451+</td> <td data-bbox="1195 1407 1432 1449">2000]</td> </tr> </tbody> </table> <ol style="list-style-type: none"> 2. Holding tanks shall be constructed in accordance with the following criteria: <ol style="list-style-type: none"> a. The holding tank shall be watertight and not subject to any infiltration or leakage. b. When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or 	Total Number of [Boats Served Annually with Marine Sanitation Devices Slips]	Minimum Holding Tank Volume (gallons)	[1 - 60	725	61 - 80	1000	81 - 100	1200	100+	2000	1 - 300	1000	301 - 450	1500	451+	2000]
Total Number of [Boats Served Annually with Marine Sanitation Devices Slips]	Minimum Holding Tank Volume (gallons)																		
[1 - 60	725																		
61 - 80	1000																		
81 - 100	1200																		
100+	2000																		
1 - 300	1000																		
301 - 450	1500																		
451+	2000]																		

			<p><u>frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater, and saltwater.</u></p> <p><u>c. When holding tanks are made of material other than concrete, the external surface of the holding tank shall be protected from corrosion.</u></p> <p><u>d. The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.</u></p> <p><u>e. The holding tank shall be located onshore and fixed in place unless it is part of an approved mobile pump-out unit.</u></p> <p><u>f. Provisions shall be made to the satisfaction of the department to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.</u></p> <p><u>g. The holding tank shall be adequately vented. This requirement may be met with screened, elbowed down vents installed at the top of the tank.</u></p> <p><u>h. The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.</u></p> <p><u>i. There shall be provisions for emptying the contents from portable sewage containers in a sanitary manner.</u></p> <p><u>3. The required separation distances between holding tank and various structures and features are contained in Table 4.1 of the Sewage Handling and Disposal Regulations (12VAC5-610-597 D).</u></p> <p><u>4. Any person who removes, or contracts to remove and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the commissioner in accordance with the Sewage Handling and Disposal Regulations (12VAC5-610).</u></p> <p><i>Clarifies the requirement that all sewage must be properly disposed of, either to an approved treatment works, or by conveyance to an approved treatment works. Construction criteria for holding</i></p>
--	--	--	--

			<p>tanks intended to protect public health and the environment from sewage leakage is included. Technical changes are intended to make the regulation more consistent with other regulations and to better reflect the state of the wastewater and marina industries. Setback requirements and pump and haul requirements are derived from the Board's Sewage Handling and Disposal Regulations which regulate the safe and sanitary treatment, conveyance and disposal of sewage. Table 2 was originally located in Section 180, revised based on public comment and moved to Section 200.</p>
Form		NA	<p><u>Application for Construction Permit</u></p> <p>New form referenced in Section 70 clarifies the information required to complete the application.</p>

Enter any other statement here

Project 2688 - Proposed

DEPARTMENT OF HEALTH

Amend marina regulations to reflect current state of marina industry

Part I
Introduction
Article 1
Definitions

12VAC5-570-10. Definitions.

~~As used in this chapter, the~~ The following words and terms hereinafter set forth when used in this chapter shall have the following meanings ~~respectively,~~ unless the context clearly ~~requires a different meaning.~~ indicates otherwise:

"Board" means the State Board of Health.

"Boat" means any vessel or other watercraft, privately owned or owned by the Commonwealth or any political subdivision thereof, whether moved by oars, paddles, sails, or other power mechanism, inboard or outboard, or any other vessel or structure floating on water in the Commonwealth of Virginia, whether or not capable of self-locomotion, including but not limited to cruisers, cabin cruisers, runabouts, houseboats and barges. Excluded from this definition are commercial, passenger and cargo carrying vessels subject to the Quarantine Regulation of the United States Public Health Service adopted pursuant to Title 42 of the United States Code and ships or vessels of the U.S. Government and boats which are tenders to larger boats moored or stored at the same facility.

"Boating access facility" means any installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers.

"Certificate" [or "Certificate to operate"] means a written approval from the ~~Commissioner commissioner~~ or his designated representative indicating that plans for ~~sanitary facilities and sewage sewerage~~ facilities, sewerage system, and treatment works meet or satisfy the minimum requirements of this chapter and § 32.1-246, of the Code of Virginia.

"Commissioner" means the State Health Commissioner ~~whose duties are prescribed in § 32.1-19 of the Code of Virginia.~~

"Department" means the Virginia Department of Health.

"Division" means the Division of ~~Wastewater Engineering, Department of Health Onsite Sewage and Water Services, Environmental Engineering, and Marina Programs, Office of Environmental Health Services of the department or its administrative successor.~~

"Dry storage" means a boat storage, including boatels, valet storage, pigeon hole storage, stackominiums, or parking space where boats rest on racks or trailers located on land, whether covered or uncovered, at a marina or other ~~place~~ places where boats are moored ~~for the purpose of storing boats on land between use.~~

"Expanded" means any change to a regulated facility that results in an increase in sewage volume or strength due to the addition of slips, dry storage spaces, boat trailer parking spaces, or ancillary operations.

"Live-aboard slip" means any slip where a boat is moored and used principally as a residence or a place of business. Charter and commercial fishing boats are not included unless used as a residence.

"Local health department" means the branch of the State Health Department, established in accordance with § 32.1-30 of the Code of Virginia, that has jurisdiction in the city or county where the regulated facility is located.

"Marina" means any installation operating, under public or private ownership, ~~which that~~ provides dockage or moorage for boats ~~(exclusive of, other than paddle or rowboats)~~ rowboats, and provides, through sale, rental ~~or~~, fee, or free basis, any equipment, supply, or service ~~(fuel including fuel, electricity, or water)~~ water for the convenience of the public or ~~its leasee~~ the lessee, renters, or users of its the facilities.

"Marine sanitation device" means any equipment, piping, holding tanks, and appurtenances ~~such as holding tanks for installation on board~~ onboard a boat which is designed to receive, retain, treat, or discharge sewage ~~and any process to treat such sewage.~~

"No Discharge Zone" means an area where a state has received an affirmative determination from the U.S. Environmental Protection Agency that there are adequate facilities for the removal of sewage from vessels (holding tank pump-out facilities) in accordance with § 312(f)(3) of the Clean Water Act (33 USC § 1251 et seq.) and where federal approval has been received allowing a complete prohibition of all treated or untreated discharges of sewage from all vessels.

"Office" means the Office of Environmental Health Services.

"Other places where boats are moored" means any installation operating under public or private ownership, ~~which that~~ provides dockage, or moorage ~~or mooring~~ for boats, ~~other than (exclusive of paddle or rowboats)~~ rowboats, either on a free, rental, or fee basis or for the convenience of the public boater.

"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm, or company organized or existing under the laws of this or any other state ~~or county~~, or any person or group of persons acting individually or as a group who owns or proposes to own a marina, ~~or other place~~ places where boats are moored, ~~or boating access facility.~~

"~~Pump-out facilities~~ facility" means any device, equipment, or method ~~of~~ for removing sewage from a marine sanitation device. ~~Also, it shall include and conveying such sewage to a sewerage system or treatment works including any portable, movable, or permanent holding tanks either portable, movable or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats.~~

~~"Sanitary facilities~~ "Sewerage facility" means bathrooms, toilets, closets and other enclosures, including portable toilets, where commodes, ~~stools~~, water closets, lavatories, showers, urinals, sinks, or other such plumbing fixtures are installed.

"Seasonal slips" means any slip which is used, rented, leased, or otherwise made available ~~for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days.~~

"Sewage" means ~~the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks.~~ water-carried and nonwater-carried human excrement, kitchen, laundry, shower, bath, or lavatory waste, separately or together with such underground, surface, storm, and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, boats, industrial establishments, or other places.

"Sewage dump station" means a facility specifically designed to receive waste from portable sewage containers carried on boats and to convey such sewage to a sewerage system or a treatment works.

~~"Sewage treatment or disposal systems" means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge~~

~~to another approved system, or an approved discharge to state waters or disposal through an approved subsurface drainfield or other acceptable method, such as incineration.~~

~~"Sewerage facilities system" means entire sewage collection and disposal system including commodes, toilets, lavatories, showers, sinks and all other plumbing fixtures which are connected to a collection system consisting of sewer pipe, conduit, holding tanks, pumps and all appurtenances, including the sewage treatment or disposal system pipelines or conduits, pump stations and force mains, and all other construction, devices, and appliances used for the collection and conveyance of sewage to a treatment works or point of ultimate disposal.~~

~~"Slip" means a berth or space where a boat may be secured to a fixed or floating structure, including a dock, finger pier, boat lift, or mooring buoy.~~

~~"Transient slips" means temporary docking or mooring space which may be used for short periods of time, including overnight, days, or weeks, but less than 30 days.~~

~~"Treatment works" means any device or system used in the storage, treatment, disposal, or reclamation of sewage or combinations of sewage and industrial wastes, including but not limited to pumping, power and other equipment and appurtenances, septic tanks, and any works, including land, that are or will be (i) an integral part of the treatment process or (ii) used for ultimate disposal of residues or effluents resulting from such treatment.~~

~~"VMRC" means the Virginia Marine Resources Commission.~~

Article 2

General Information

12VAC5-570-20. Authority for regulations. (Repealed.)

~~Section 32.1-12 and 32.1-246 of the Code of Virginia provides that the State Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and places are designed to accommodate, regardless of whether such establishments serve food.~~

Article 2

General Information

12VAC5-570-30. Purpose of regulations.

~~This chapter~~ The board has been promulgated by the ~~State Board of Health~~ this chapter to:

Ensure 1. Protect public health and water quality by ensuring that adequate sanitary sewerage facilities and pump-out facilities, as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, sewage dump stations, and sewerage systems are provided at all marinas and other places where boats are moored; and boating access facilities.

2. Establish minimum requirements as to the adequacy of sewerage facilities and sewerage systems at all marinas and other places where boats are moored; and boating access facilities.

3. Protect public health and the environment by ensuring that all sewage generated from all regulated facilities is conveyed to an approved sewerage system or treatment works.

~~3.~~ 4. Guide the State Board of Health commissioner or his designee in its his determination of the adequacy of the sewerage systems and sewerage facilities to serve serving all marinas and other places where boats are moored; and boating access facilities.

4. ~~5. Guide the State Board of Health commissioner or his designee in its approval his evaluation of plans and other data and in the issuance of a certificate as to the adequacy of sanitary and sewerage facilities; and sewerage systems.~~
5. ~~Notify the Marine Resources Commission that a certificate has been issued; and~~
6. ~~Assist the owner or his authorized engineer in the preparation of an application and supporting data, as may be required. (See 12VAC5-570-70)~~

12VAC5-570-40. Administration of regulations.

This chapter is administered by the following parties:

1. ~~The State Board of Health has responsibility for promulgating, amending, and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.~~
2. ~~A. The State Health Commissioner commissioner is the chief executive officer of the Virginia Department of Health. The commissioner has the authority to act for the board when it is not in session. The commissioner may delegate his powers under this chapter with the exception of his power to issue variances under 12VAC5-570-90.~~
3. ~~B. The Division of Wastewater Engineering division is designated as the primary reviewing agent of the board commissioner for the purpose of administering this chapter. Upon receipt of the application from the local health department, the division examines and passes upon the technical aspects of all applications, plans and specifications grants or denies the application for sewerage facilities to serve marinas and other places where boats are moored, and boating access facilities. The division issues all certificates attesting to the adequacy of the sewerage facilities and notifies the Marine Resources Commission VMRC when a certificate is issued or denied.~~
4. ~~The Deputy Commissioner for Community Health Services directs and supervises the activities of the local health departments in the administration of assigned duties and responsibilities under the chapter.~~
5. ~~C. The local health department in each jurisdiction, city, town or county in which there exists, or is proposed, a marina or other place where boats are moored shall (i) be responsible for the processing of all applications submitted by owners, (ii) inspect and for inspecting sites and facilities provided, (iii) issue such permits as required by law, rules or regulations for sewerage facilities and, (iv) lacking in authority to issue a permit, will process such applications in accordance with the policies and procedures of the department. The local health department shall conduct a surveillance program and enforce the provisions of this chapter to ensure proper sanitation and cleanliness of the facilities provided for compliance with this chapter.~~
6. ~~The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.~~

12VAC5-570-50. Application of regulations to marinas and other places where boats are moored Applicability.

~~A. Marinas or other places where boats are moored which are not in compliance with the Rules and Regulations of the Board of Health Governing Sanitary and Sewerage Facilities at Marinas and Other Places Where Boats Are Moored which became effective November 15, 1975 [repealed], shall comply with this chapter. Marinas, other places where boats are moored, and boating access facilities in operation prior to the effective date of this chapter shall be subject to the regulations in effect at the time the marina, other places where boats are moored,~~

or boating access facility was permitted unless such marina, other places where boats are moored, or boating access facility is expanded after (insert the effective date of this chapter).

B. All planned or new marinas or other places where boats are moored which do not exist This chapter shall apply to all marinas, other places where boats are moored, and boating access facilities placed into operation on or after (insert the effective date of this chapter) shall comply with all provisions of this chapter prior to commencing operation.

C. All sanitary or sewerage facilities and sewerage systems shall conform to the requirements of this chapter when the marina or other place places where boats are moored are either, or boating access facility that is served by the sewerage facilities and sewerage systems is expanded, altered or modified.

D. This chapter shall apply to sewerage facilities and sewerage systems (i) serving marinas, other places where boats are moored, or boating access facilities and (ii) located on property owned by the marina, other places where boats are moored, or boating access facility. Sewerage systems or treatment works installed or proposed to be installed on property owned by someone other than the marina, other places where boats are moored, or boating access facility owner are regulated by Chapter 6 (§ 32.1-163 et seq.) of Title 32.1 of the Code of Virginia or Title 62.1 of the Code of Virginia, as applicable.

Article 3
Procedure

12VAC5-570-60. Certification general Permits and certificate.

No owner shall operate construct a marina or other place places where boats are moored, or a boating access facility unless he complies with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and has obtained a construction permit in accordance with this chapter. No owner shall operate a marina, other places where boats are moored, or a boating access facility until the local health department has inspected and approved construction and has issued a certificate to operate. Owners shall have in their possession obtain a permit from the Marine Resources Commission VMRC to operate a marina, or place other places where boats are moored, or a boating access facility when so required by § 62.1-3, of the Code of Virginia. Where state-owned bottom lands are involved, the owner shall submit a plan approved preliminary design and receive approval by the department shall be issued division prior to construction and the issuance of a certificate to operate.

12VAC5-570-70. Application for certificate construction permit.

A. Any owner, or his duly authorized representative, may make application shall apply for a certificate of approval of sanitary or sewerage facilities construction permit by applying submitting an application to the local health department in the jurisdiction where the proposed marina or other place places where boats are moored, or boating access facility is to be located. The application shall be made on a form supplied by the local health department approved by the division. The application shall consist of the following:

1. A completed application form which shall set forth the essential Essential data to determine the sewerage facilities and sewerage system necessary to serve the proposed installation;
2. Maps, plans, and specifications of the sanitary sewerage facilities and sewerage facilities system describing how and what the type of facilities that will be provided and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility. The preliminary design plans shall establish the location of the sanitary sewerage facilities and sewerage system in relation to other facilities; they are intended to serve.

3. A description of the proposed method of sewage or existing offsite sewerage system or treatment works used for the ultimate treatment or and disposal. Approval of sewage. The applicant shall apply for and obtain approval of the new offsite sewerage systems or treatment works or disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter.
4. Any other data as may be pertinent to show the adequacy of sanitary or the sewerage facilities and sewerage system to be provided.

B. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.

[C. The department shall issue a permit to construct the proposed marina, other place where boats are moored, or boating access facility after review of a complete application that demonstrates compliance with the requirements of this chapter and § 32.1-246 of the Code of Virginia.]

12VAC5-570-80. [Receipt of data application. Certificate to operate.]

Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.

A. Construction. Upon completion of construction of the sanitary sewerage facilities [, and] sewerage facilities systems [, and treatment works] at marinas and, other places where boats are moored, or boating access facilities, the owner of the facility, or his duly authorized representative, shall notify the local health department so that it may inspect the construction. A certificate to operate shall be issued by the Health Department when it When the division, in consultation with the local health department, has been determined that construction is in compliance with the approved plan, it shall issue a certificate [to operate to the owner of the marina, other place where boats are moored, or boating access facility. The certificate to operate shall remain valid in accordance with this section.]

B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia. The owner shall post the certificate [to operate] in a place where it is readily observable by members of the public who transact business with the facility.

[C. All marinas, other places where boats are moored, and boating access facilities shall be subject to a five year, renewable certificate to operate. The owner of the marina, other place where boats are moored, and boating access facility shall request a new certificate to operate at least 90 days prior to the expiration date of the existing certificate to operate. The division shall issue the new certificate to operate provided the sewerage facilities, sewerage system, and treatment works meet or satisfy the minimum requirements of this chapter and § 32.1-246 of the Code of Virginia.

D. If the commissioner grants a variance, or the division approves any exception to this chapter, then the certificate to operate shall contain that information. The owner of the marina, other place where boats are moored, or boating access facility shall follow any condition or requirement listed on the certificate to operate.

E. As a condition of the certificate to operate, owners of marinas, other places where boats are moored, or boating access facilities shall allow the department to perform one or more inspections per year of the sewerage facilities, sewerage systems, and treatment works to ensure compliance with this chapter and § 32.1-246 of the Code of Virginia. The division may revoke the certificate to operate pursuant to 12VAC5-570-100.]

12VAC5-570-90. Variances.

~~A.~~ The commissioner may grant a variance to any requirement of this chapter if, after investigation, ~~it is determined~~ the commissioner determines that the hardship imposed upon the owner or the public by compliance with this chapter ~~outweigh~~ outweighs the benefits that the chapter confers, ~~or that there is no~~ and that granting a variance will not result in a potential or actual public health hazard.

~~A. Effect of variance.~~ B. A variance is a conditional waiver of a specific regulation ~~which that~~ is granted to a particular or designated marina or other place where boats are moored an owner of a marina, other places where boats are moored, or a boating access facility. ~~It is nontransferrable~~ Variances are not transferrable between owners, and ~~it~~ any variance shall be attached to the certificate of the marina ~~or,~~ other place places where boats are moored, ~~or boating access facility~~ to which it was granted. The variance is a condition of the certificate, which is revoked if the certificate is revoked.

~~B. Application for a variance.~~ C. Any owner of a marina ~~or,~~ other place places where boats are moored, ~~or a boating access facility~~ may apply in writing for a variance. This application shall be submitted to the local health department in the jurisdiction in which the marina ~~or,~~ other place places where boats are moored, ~~or boating access facility~~ is located. This application shall include:

1. A citation ~~to~~ referencing the specific requirements of this chapter from which a variance is requested and a statement describing the hardships imposed by the specific requirements of this chapter;
2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted, and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; ~~and~~
3. Facts supporting the need and justification for the variance-;
4. The nature and duration of the variance request;
5. Other information, if any, believed by the applicant to be pertinent; and
6. Such other information as the division, local health department, or the commissioner may require.

D. If the commissioner denies any request for a variance, such denial shall be in writing and shall state the reasons for the denial.

12VAC5-570-100. ~~Suspension or revocation~~ Revocation of a certificate.

~~The board~~ Either by emergency order under the authority of § 32.1-13 of the Code of Virginia or following an opportunity for an informal fact-finding proceeding as provided by § 2.2-4019 of the Code of Virginia, the commissioner or his designee may revoke ~~or suspend~~ a certificate for failure to construct and operate the sewerage facilities and sewerage system in accordance with the conditions of the application and certificate issued or for any violation of this chapter.

12VAC5-570-110. ~~Administration appeals~~ Applicability of the Administrative Process Act.

~~Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the~~ The Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia. (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the decision of cases under this chapter.

Part II

Required Sewerage Facilities and Sewerage Systems for Marinas and Other Places Where Boats are Are Moored, and Boating Access Facilities and Their Operation

12VAC5-570-120. General.

A. All owners of marinas or other places where boats are moored, and boating access facilities shall provide the minimum number of sanitary sewerage facilities required by this chapter for their patrons. ~~These Owners shall maintain their facilities shall be maintained~~ in a clean and sanitary operable condition. ~~They shall be equipped~~ Owners shall equip their facilities with toilet tissue, lights where electricity is available, and soap and towels where handwashing facilities are required. ~~These Owners shall make their facilities shall be available~~ during normal business hours to patrons and users of these facilities ~~at all times during the normal boating season for that facility.~~

B. Marinas ~~which are located within 1,000 feet of the shore end of the pier that are operated as part of residential developments, overnight lodging facilities, restaurants, or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted~~ exempt from providing separate sanitary sewerage facilities, as long as the sanitary sewerage facilities at the residence, lodging establishment, restaurant, or commercial establishment are made available to all users of the marina. ~~This~~ The exemption set forth in this subsection does not apply to (i) ~~marinas;~~

1. Marinas associated with restaurants or commercial establishments ~~which that~~ allow overnight occupancy of boats; and (ii) ~~marinas~~

2. Marinas associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.

C. ~~Exempt from the requirements of subsection A of this section are other~~ Other places where boats are moored ~~which serve and boating access facilities are exempt from the requirements of subsection A of this section, provided that the other places where boats are moored or boating access facility;~~

1. Serves residents of homes (houses, condominiums, apartments, or mobile homes), their bona fide house guests, or registered guests of tourist establishments ~~which provide; and~~

2. Provides adequate sanitary sewerage facilities that are located within 1,000 feet of the shore end of the pier.

D. In order to qualify for an exemption under ~~subsections~~ subsection B or C of this section, the owner of ~~such marinas or a marina, other places where boats are moored, or a boating access facility~~ shall provide to the department division a signed, notarized statement that all conditions set forth in ~~the aforementioned sections~~ this section will be complied with by users of the facilities.

12VAC5-570-130. Location.

~~Adequate sanitary~~ Owners shall conveniently locate their sewerage facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock ~~they the facilities~~ are intended to serve ~~or within a reasonable~~. On a case-by-case basis the division may approve a greater distance under if unusual circumstances as determined by the division, such as topography or resource protection areas, prevent compliance with this requirement. # The division may be necessary require the owner to provide sanitary sewerage facilities in more than one location in order to meet the needs of the particular site developed. In addition, the division may require additional fixtures, beyond the minimum number specified in Table 1 (12VAC5-570-150), if it determines that additional fixtures are necessary to accommodate the site layout and use of the marina, other places where boats are moored, or boating access facility.

12VAC5-570-140. Availability and marking of sanitary facilities.

The sanitary Owners shall locate the sewerage facilities shall be so that they are available and readily reasonably accessible to all users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities. The location and use of all sewerage facilities shall be clearly indicated by appropriate signage.

12VAC5-570-150. Marinas Sewerage facilities for marinas.

A. Minimum The minimum number of sewerage fixtures to be provided in sanitary facilities. It shall be understood that at marinas is found in many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined Table 1.

B. Where dry storage space is provided, each dry storage space is equivalent to one-third of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate sewerage facilities for male and female personnel shall employees may be provided in a structure or structures, but shall not be counted toward the minimum number of fixtures required to accommodate users of the marina.

Table # 1

Number of Seasonal Slips	FIXTURES						
	Commodes		Urinals	Lavatories		Showers	
	Male	Female	Male	Male	Female	Male	Female
0-49	1	1	0	1	1	0	0
50-99	1	2	1	1	1	0	0
100-149	2	3	1	2	2	1	1
150-199	2	4	2	3	3	2	2
200-249	3	5	2	4	4	2	2

Table 1

Number of Slips	SEWERAGE FIXTURES						
	Commodes		Additional Urinal or Commode	Lavatories		Showers	
	Male	Female	Male	Male	Female	Male	Female
1 - 24	1		0	1		1	
25 - 49	1	2	1	2	2	1	1
50 - 99	2	3	1	2	2	1	1
100 - 149	3	4	1	3	3	2	2
150 - 199	3	5	2	4	4	2	2
200 - 249	4	6	2	5	5	3	3

~~C. When the number of seasonal slips exceeds those above on prescribed by Table No. 1, the owner shall provide additional fixtures shall be provided. One The owner shall provide one commode, lavatory, and shower will be provided for each sex gender for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.~~

~~B. Transient slip. When transient slips are available additional sanitary facilities shall be provided. Table No. 2 below shows the minimum number of additional fixtures required. These fixtures may be included in a structure or structures with those fixtures provided for the seasonal slip, provided the accessibility and convenience standards of 12VAC5-570-130 and 12VAC5-570-140 of this chapter are met.~~

Table # 2

Number of Transient Slips	FIXTURES						
	Commodes		Urinals	Lavatories		Showers	
	Male	Female	Male	Male	Female	Male	Female
0-24	1	1	1	1	1	1	1
25-49	1	2	1	2	2	2	2
50-74	2	3	1	2	2	2	2
75-100	2	4	2	3	3	3	3

~~For each 24 or fraction thereof of transient slips or moorings in excess of those shown in Table No. 2 above, one commode, lavatory, and shower shall be provided for each sex. In addition, one urinal shall be provided for each 50 or fraction thereof transient slips in excess of the number shown in Table No. 2.~~

12VAC5-570-160. Sanitary Sewerage facilities at other places where boats are moored and boating access facilities.

A. Sewerage facilities are required at other places where boats are moored and boating access facilities in accordance with this section.

B. Where piped potable water is available, sanitary sewerage facilities for other places where boats are moored shall consist of a minimum of one commode and one lavatory, and one shower for females and one commode and one lavatory for males for each gender, for each 100 seasonal slips or fraction thereof and each 50 transient slips or fraction thereof.

C. Requirements for dry storage boat usage shall be are identical to those specified in 12VAC5-570-150 for marinas.

Sanitary D. Where piped potable water is not available, sewerage facilities for other places where boats are moored may consist of privies where piped water is not available.

E. Sewerage facilities at boating access facilities shall consist of at least one privy or portable toilet and shall be sufficient in number to accommodate facility usage.

F. Walking distance to these facilities shall comply with 12VAC5-570-130.

12VAC5-570-170. Sewage treatment.

A. Public or municipal sewage sewerage systems and treatment facilities shall works should be used if there is reasonable access to sewers. When such municipal means of disposal is are not available, the owner shall have designed and installed an approved method of sewage treatment. Approved methods of sewage treatment are set forth in the Sewerage Regulations (1977) (12VAC5-580-10 et seq.) Sewage Handling and Disposal Regulations (1982, as

~~amended), 12VAC5-610-10 et seq. If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division sewerage system or treatment works. An approved sewerage system or treatment works is (i) a system for which a certificate to operate has been issued jointly by the department and the Department of Environmental Quality, (ii) a system approved by the Department of Environmental Quality in accordance with Title 62.1 of the Code of Virginia, or (iii) a system approved by the commissioner in accordance with Title 32.1 of the Code of Virginia.~~

~~A. The following shall be used to determine the amount of sewage flow. It is assumed that B. The sewage design flow for each slip or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 40 25 gallons per person slip per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. For dry storage facilities the sewage flow shall be calculated using one-third the number of dry storage spaces. Where dry storage is provided, each dry storage space shall be equivalent to one-third of a slip. The sewage design flow for each live-aboard slip shall be 50 gallons per slip per day. When marinas or other places where boats are moored are constructed in conjunction with another structure or facility, the sewage design flows prescribed in this section shall be added to the sewage design flow governing the associated structure or facility.~~

~~In addition, for marinas C. For marinas or other places where boats are moored which have that have a boat launching ramp and provide boat trailer parking spaces only while the boat is in use boating access facility, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.~~

~~B. Where restaurants or motels are operated in connection with a marina or place where boats are moored the following shall be used as a basis for determining the amount of sewage flow:~~

~~Motels – 65 gallons per person per day or a minimum of 130 gallons per room per day.~~

~~Restaurant - 50 to 180 gallons per seat per day. Each installation will be evaluated according to conditions.~~

~~C. The occupancy level of boats used for design of sewage treatment or disposal facilities will be those levels listed in 12VAC5-570-170 A. It is recognized that the type of activity and utilization of marina or other places where boats are moored varies and, therefore, additional facilities to provide capacity up to maximum may be required if the need arises. The local health director serving the area in which the marina is located shall make such determination.~~

~~D. The division may approve a reduction in the sewage flow requirements specified in subsection B of this section if the owner provides documented flow data sufficient to justify the reduction.~~

12VAC5-570-180. Pump-out.

~~Other A. Owners of other places where boats are moored which that allow overnight docking or mooring of boats and owners of all marinas, regardless of size or number of boat moorings slips, shall provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures, and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other places where boats are moored which that do not have live-aboard slips or allow boats with an installed toilet with a discharge overboard or a sewage holding tank a marine sanitation device to use any of the services provided, including moorage,~~

except in an emergency. In order to qualify for this exemption, the owner of such marina or other ~~place~~ places where boats are moored shall provide the department with a signed, notarized statement indicating that there are no live-aboard slips and that boats with installed toilets with overboard discharges or sewage holding tanks marine sanitation devices shall not be permitted to use the marina or other places facilities facility except in an emergency.

~~A. Availability and operation. Where pump-out facilities are required, the owner shall install, maintain in good operating condition and provide pump-out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump-out service.~~ B. The owner shall make sewage pump-out facilities available to all users of the marina or other places where boats are moored during normal operating hours. The owner shall maintain the pump-out equipment in serviceable condition and shall keep the equipment located in an area convenient for utilization.

C. The owner shall use placards or signs to identify the sewage pump-out location and use restrictions.

~~B. Alternate pump-out service. D. Marinas and other places where boats are moored which that provide less fewer than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted exempt from the requirement to install pump-out facilities unless such marinas or other places where boats are moored are located in a No Discharge Zone. Such exemption will shall be granted by the director of the division whenever alternate pump-out service is provided at a nearby marina or other place places where boats are moored, and is as evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the division. Such The division shall only approve such alternate pump-out service will only be approved by the division when in accordance with the following criteria are met:~~

1. ~~That the~~ The alternate pump-out service ~~will~~ shall not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the ~~boat sewage holding tank~~ marine sanitation device pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed ~~twenty~~ 20 minutes;_
2. ~~That the~~ The alternate pump-out service shall be located within three nautical miles, as measured along the water route, of the ~~exempt~~ facility using the agreement unless the alternate pump-out service is located along the normal travel route to open water, in which case the ~~exempt~~ facility using the agreement shall be within five nautical miles of the alternate pump-out service;_
3. ~~That the~~ The alternate pump-out service capacity is ~~shall be~~ sufficient to handle the demand for pump-out service, ~~in accordance with subsection C of this section,~~ that is expected for all of the marinas or other places where boats are moored entering into the ~~above-mentioned agreement;~~ referenced in this subsection.
4. ~~That a notice shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump-out service, that specifies the location of the alternate pump-out service; and~~ The owner of the exempt facility shall post in a conspicuous location appropriate signage that specifies the location of the alternate pump-out service and the associated charge for its use.
5. The terms of the agreement shall provide that:
 - a. ~~That the~~ The alternate pump-out service ~~will~~ shall be available to all boats moored at each facility and ~~it will state that the alternate pump-out facility will furnish pump-~~

out services to anybody boaters referred to it by the establishment using the agreement to provide pump-out service, exempt facility as specified by this chapter; and

b. That the The agreement will shall be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day termination notice to the other and to the director of the division prior to the renewal date.

6. If a termination notice is issued to a an exempt facility using an agreement to provide alternate pump-out service, in accordance with ~~12VAC5-570-180 B~~ this subsection, then that facility shall either provide pump-out service or obtain a new written agreement, in accordance with ~~12VAC5-570-180 B,~~ this subsection by the effective date of the termination of alternate pump-out service.

~~G. Minimum design criteria for pump-out facilities.~~ E. The purpose of these minimum design criteria is to provide the owner and the ~~Department of Health~~ department with acceptable methods for pumping, storing, and conveying ~~and treatment of the contents from boat holding tanks marine sanitation devices.~~ The owner shall furnish the following information for each proposed pump-out facility A proposed pump-out facility shall meet the following minimum design criteria:

1. ~~Pumping equipment.~~ Pump equipment may be fixed or portable; however, this equipment shall be ~~conveniently located for usage and~~ clearly identified or placarded by signs or other notices, indicating any fees, restrictions, or other operating instructions, as necessary. A minimum pump capacity of 10 ~~gpm~~ gallons per minute (gpm) is acceptable at the operating head required to transport the flow to the proper collection or treatment location with such residual head as may be required; however, at marinas with 51 or more slips, greater pumping capacity may be required. ~~Pumps~~ To prevent clogging, pumps shall be of a macerator type or ~~have sufficient size suction and discharge openings to prevent clogging~~ the pumps shall be able to pass a 2-inch spherical solid. ~~Manually operated pumps are not permitted~~ acceptable at marinas and other places where boats are moored that offer fewer than 26 slips. Pump data from the manufacturer shall include:

- a. The type of pump (~~diaphragm or~~ (positive displacement, centrifugal, and ~~power)~~ vacuum, macerator, etc.);
- b. ~~Rated capacity (gpm, hp. and head)~~ Pump power source (electric motor, gasoline engine, etc.) and output (HP);
- c. ~~Motor type (electric or gas); and~~ Pump capacity, including a performance curve;
- d. ~~Suction and discharge opening size.~~ Pump solids-handling ability; and
- e. A schematic showing relevant pump dimensions, such as height, size, and location of suction and discharge openings, etc.

2. ~~Location schematic.~~ If fixed pump-out equipment is proposed, a schematic of the location with elevations for subsections a, b, c, d and e, as described below, shall be included, or if portable pump-out equipment is proposed, a schematic shall indicate elevations for subsections a, c, f and g, as described below: A schematic of the proposed facilities shall be provided and include the following minimum information:

- a. Mean low water level elevation;
- b. Elevation of dock Suction hose diameter, length, and highest elevation;
- c. Greatest elevation of suction center line of pump Pump elevation;

- d. ~~Elevation of discharge point~~ Discharge hose/pipe diameters, lengths, and highest elevation;
- e. ~~Highest point in discharge line~~ Discharge point elevation;
- f. Type of dock (floating or stationary); ~~and~~
- g. Greatest elevation of any dock; ~~and~~
- h. Distance between pump-out location and slips.

All elevations shall be measured with respect to mean low water. If the elevation of mean low water is not known, assume it to be zero.

3. ~~Fittings and hose (piping). Fittings~~ This subdivision sets forth the minimum design criteria for fittings and hoses (piping) which are used in the operation of a pump-out facility shall meet the following:

a. ~~Suction hose~~ hoses shall meet the following criteria:

- (1) A friction nozzle (right angle preferred) or wand-type attachment is to be provided on the end of the suction hose. Adapters shall be provided to fit any discharge connection from ~~4-5~~ 1.25 to 4 2 inches in diameter.
- (2) A check valve shall be provided on the suction hose at the nozzle.
- (3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis by the division.
- (4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for service, a ~~gate~~ full port ball valve shall be provided on the pump end of the suction line.

b. ~~Discharge hose and piping;~~ shall meet the following criteria:

- (1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections.
- (2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing.

c. ~~Discharge line~~ lines shall meet the following criteria:

- (1) A ~~gate~~ full port ball valve shall be provided on the discharge line at the pump;
- (2) Suitable connections on the end of the discharge line shall be provided to prevent it from ~~coming loose~~ dislodging during discharge; all nozzles and fittings are to be positive locking, male and female.
- (3) The discharge line ~~must~~ shall not be subject to freezing or leaking into the water course.
- (4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (~~12VAC5-590-10 et seq.~~) (12VAC5-590) and the Sewage Handling and Disposal Regulations (~~12VAC5-610-10 et seq.~~) (12VAC5-610).
- (5) The discharge line connection to the pump-out receiving facility shall be fixed in place in such a manner as to prevent it from ~~coming loose~~ dislodging during discharge.

d. Pump-out facilities shall include equipment for rinsing ~~the boats'~~ holding tanks associated with marine sanitation devices. Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type vacuum breaker shall be provided.

4. ~~Other devices or methods of removal.~~ Other devices or methods of removal of contents from boat holding tanks marine sanitation devices may be approved by the Commissioner division on an individual case basis.

5. ~~Onshore facilities.~~ Contents from boat holding tanks shall be discharged to (i) a public wastewater collection system in which sewage is conveyed to an approved treatment facility; (ii) a holding tank whereby sewage may be stored until it is taken in an approved manner to an approved treatment facility; or (iii) directly to an approved sewage treatment facility.

a. ~~For discharge to a public wastewater collection system, the following will be required: The owner of the marina or other place where boats are moored shall submit evidence, in writing, (i) of consent from the owner of the system, (ii) from the owner of any conveyance systems located downstream, which may be affected, and (iii) from the owner of the ultimate treatment facility. Verification shall be given that there are satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.~~

b. ~~If sewage is to be stored in a holding tank, the holding tanks shall be sized, constructed and located to meet the criteria.~~

~~(1) Size of holding tank.~~

~~Marinas or other places where boats are moored shall size the holding tanks based upon the following tabulations:~~

Total Number of Boats Serviced with Holding Tanks	Required Onshore Holding Tank - Volume (gallons) Minimum
1 - 20	250
21 - 40	500
41 - 60	725
61 - 80	1000
81 - 100	1200
100+	2000

~~(2) Construction of holding tank.~~

~~(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.~~

~~(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.~~

~~(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.~~

~~(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.~~

~~(e) The holding tank shall be fixed in place unless it is part of an approved mobile pump-out unit.~~

~~(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.~~

~~(g) The holding tank shall be adequately vented. Screened, elbows down vents installed at the top of the tank will serve this requirement.~~

~~(h) The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.~~

~~(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.~~

~~(3) Holding tank location.~~

~~Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.)~~

~~(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.).~~

~~e. Sewage treatment plant. Disposal of holding tank wastes shall not be allowed at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewer system of a large sewage treatment facility or transported for eventual treatment at a large plant.~~

12VAC5-570-190. Sewage dump station.

A. All marinas and other places where boats are moored, regardless of size or number of boat moorings, shall have ~~an acceptable~~ a proper and adequate receiving station for sewage from portable toilets ~~containers~~ used on boats. ~~The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision subsection~~ are marinas or other places where boats are moored which that also qualify for the exemption contained in 12VAC5-570-120 B or C exemption, provided that the owner of the sanitary sewerage facility will allow consents to the dumping of the contents of portable toilets sewage containers into the sanitary sewerage facilities.

B. ~~Availability and operation.~~ Where a sewage dump station is required, the owner shall install, and maintain in good operating condition, and provide it in a serviceable and sanitary condition and in compliance with this chapter. ~~The owner shall make the facilities available to users of the marina or other places where boats are moored. The owner shall locate the sewage dump station in an area convenient for use, and the owner shall use placards or signs to identify its location and restrictions.~~

C. ~~Minimum design criteria for a sewage dump station.~~ The purpose of these the minimum design criteria is to provide the owner and the ~~Department of Health~~ department with acceptable methods of discharging sewage from a portable ~~container~~ containers into a sewage holding tank or a ~~sewage sewerage treatment system works.~~ The same criteria as set forth in 12VAC5-570-180 C 5 12VAC5-570-200 A for contents from boat holding tanks will marine sanitation devices shall apply for sewage dump stations. The sewage dump station receiving unit shall be a minimum of 12 inches in diameter and be equipped with a cover that has a lip of sufficient size to ~~prevent it from accidentally being removed~~ prohibit accidental removal. If the unit is designed to drain, the drain shall be a minimum of four inches in diameter and equipped with a fly tight cover.

D. Marinas and other places where boats are moored that have an operational pump-out facility equipped with a device to pump portable sewage containers are exempt from the requirements of subsection C of this section.

12VAC5-570-200. Onshore facilities.

A. Contents from marine sanitation devices and portable sewage containers used on boats shall be discharged to:

1. A public sewerage system for conveyance to an approved treatment works as described in 12VAC5-570-170 A;
2. A holding tank whereby sewage may be stored until it is transported in accordance with the Sewage Handling and Disposal Regulations to an approved treatment works as described in 12VAC5-570-170 A; or
3. An approved sewage treatment works as described in 12VAC5-570-170 A.

B. Disposal of sewage waste from a marine sanitation device shall be prohibited at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewerage system of a large sewage treatment facility or transported for eventual treatment at a large sewage treatment facility.

C. For discharge to a public sewerage system, the owner of the marina or other places where boats are moored shall submit to the division, in writing;

1. Evidence of consent to the discharge from the owner of the conveyance system;
2. Evidence of consent to discharge from the owner of any conveyance systems located downstream that may be affected; and
3. Evidence of consent to discharge from the owner of the treatment works where the sewage is to be disposed.

The owner shall verify that there are satisfactory provisions for emptying the contents from portable sewage containers in a sanitary manner.

D. If sewage is to be stored by the marina or other places where boats are moored in a holding tank, the holding tank or tanks shall be sized, constructed, and located to meet the following criteria:

1. Sewage holding tanks shall be sized in accordance with the requirements of Table 2.

Table 2: Minimum Holding Tank Volume

<u>Total Number of [Boats Served Annually with Marine Sanitation Devices Slips]</u>	<u>Minimum Holding Tank Volume (gallons)</u>
<u>[1-60</u>	<u>725</u>
<u>61-80</u>	<u>1000</u>
<u>81-100</u>	<u>1200</u>
<u>100+</u>	<u>2000</u>
<u>1 - 300</u>	<u>1000</u>
<u>301 - 450</u>	<u>1500</u>
<u>451+</u>	<u>2000]</u>

2. Holding tanks shall be constructed in accordance with the following criteria;
 - a. The holding tank shall be watertight and not subject to any infiltration or leakage.
 - b. When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the

manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater, and saltwater.

c. When holding tanks are made of material other than concrete, the external surface of the holding tank shall be protected from corrosion.

d. The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.

e. The holding tank shall be located onshore and fixed in place unless it is part of an approved mobile pump-out unit.

f. Provisions shall be made to the satisfaction of the department to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.

g. The holding tank shall be adequately vented. This requirement may be met with screened, elbowed down vents installed at the top of the tank.

h. The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.

i. There shall be provisions for emptying the contents from portable sewage containers in a sanitary manner.

3. The required separation distances between holding tank and various structures and features are contained in Table 4.1 of the Sewage Handling and Disposal Regulations (12VAC5-610-597 D).

4. Any person who removes, or contracts to remove and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the commissioner in accordance with the Sewage Handling and Disposal Regulations (12VAC5-610).

FORMS (12VAC5-570)

Application for Construction

Commonwealth of Virginia
 Department of Health
 Division of Onsite Sewage, Water Services, Environmental
 Engineering and Marina Programs

Application for Construction Permit

Date _____

Name of Establishment _____

Address _____

County/City _____

Location of Establishment _____

Latitude/ Longitude _____

Owner Name _____

City, State, Zip _____

Owner Telephone _____

- 1. Marina _____
 Total number of boat slips _____
 Total number of dry storage spaces _____
- 2. Other places where boats are moored _____
 Maximum number of boats that can be accommodated _____
 Total number of dry storage spaces _____
- 3. Boating Access Facility _____

4. Sanitary Fixtures	Marina Men/Women	Other Places Men/Women	Dry Storage Men/Women	Boating Access Facility Men/Women
Commodes	___ / ___	___ / ___	___ / ___	___ / ___
Urinals	___ / ___	___ / ___	___ / ___	___ / ___
Lavatories	___ / ___	___ / ___	___ / ___	___ / ___
Showers	___ / ___	___ / ___	___ / ___	___ / ___
Privy	NA	___ / ___	___ / ___	___ / ___

5. Total maximum daily sewage flow _____ gpd (based on flow criteria in marina regulations)

Name of Establishment _____

6. Sewage Collection, Treatment, and Disposal

a) Domestic Waste Treatment (excluding contents from holding tanks on boats)

- i. Name and location of sewage treatment facility to handle the **domestic wastes** from marina or other places where boats are moored (**excluding contents from holding tanks on boats**).

- If this is a new discharge, submit a copy of the NPDES permit/application with this application.
- If this is an existing discharge, submit evidence of acceptance of your wastewater flow from the owner of the treatment facility.

- ii. If a sewage system is used to handle the domestic waste from the marina and other places where boats are moored, (excluding contents from holding tanks on boats or boating access facilities) has the system been approved by the local Health Department? **Yes** _____ **No** _____ (check one)

- iii. Other (Please describe)

b) Pump-Out Facilities for Removing Contents from Holding Tanks on Boats.

- i. Submit data from manufacturer which includes:
 - Equipment rating
pump type (diaphragm, centrifugal, etc.) _____ gpm @ _____ ft. TD
pump motor type (gasoline, electric) _____ rate _____ hp @ _____ rpm

- Type and size of pumping appurtenances

	Type	Size
Suction Line	_____	_____
Rinse Line	_____	_____
Discharge Line	_____	_____
Nozzles	_____	_____
Fittings	_____	_____
Valves	_____	_____

Name of Establishment _____

ii. Enclose a schematic of proposed equipment installation showing all important relative elevations above mean low water levels which include:

- Mean low water level. (If known, date, and time recorded. If not known, assume zero and measure with respect to this.
- Elevation of dock
- Elevation of center line of pump
- Elevation of point of discharge
- High point in discharge line

iii. If potable water supply is to be used for rinsing holding tanks, and has an anti backflow preventer been provided? **Yes** _____ **No** _____ (check one)

iv. Is the connection to the receiving facility (end of pump-out discharge line) capable of being locked in place when pump-out facility is in operation? **Yes** _____ **No** _____ (check one)

If no, what provisions have been made to prevent the discharge line from coming loose during pump-out? Please Describe

v. What provisions have been made to prevent leakage of wastewater or discharge of wastewater to the water course and dock area? (spill pan for pump, nozzle which prevents flow-out of suction line when pump is shut off, water tight fittings and couplings on discharge line, etc.)

vi. Pump-out to be available (months, days of week, hours of day)

Name of Establishment _____

c) Pump-out Facility for Pumping Contents from Holding Tanks on Boats Discharges Wastewater Directly to: (Check One)

_____ Municipal or privately owned sewer system. If so, do the following:

- Attach the name and location of the sewer system an evidence of acceptance of flow from the owner for the sewer system.
- Attach Evidence of acceptance of flow from the owner of any downstream conveyance system affected and from the owner of the ultimate treatment facility.

_____ Holding Tank. If so, do the following:

- Indicate the proposed size in gallons, list appurtenances to be provided, sketch the proposed location with respect to water supply and marina facilities (see attached example), indicate provision so to prevent the holding tank from leaking and any other information available.
- Briefly describe method of pump and haul, indicating who owns pump and haul equipment, what type of equipment (indicate size) and proposed point of discharge. When pump and haul is to be used, include evidence of approval of method of local Health Department and evidence of approved point of discharge.

_____ Other (Please Describe)

7. Water Supply Source Serving Marina

Water supplies for new installations or enlargements for existing installations shall comply with criteria in the Commonwealth of Virginia, Department of Health Waterworks Regulations adopted by the State Board of Health on June 23, 1993. Describe the source of water serving marina.

Please read the following paragraph carefully before signing this application.

It is fully recognized and understood that additional sewage facilities and holding tanks will be required should the need arise and this understanding is hereby acknowledged in this application. It is further understood that failure to provide the additional facilities as may be required will result in revocation of the State Health Department Certificate. I certify that I have filled out this application completely and accurately to the best of my knowledge.

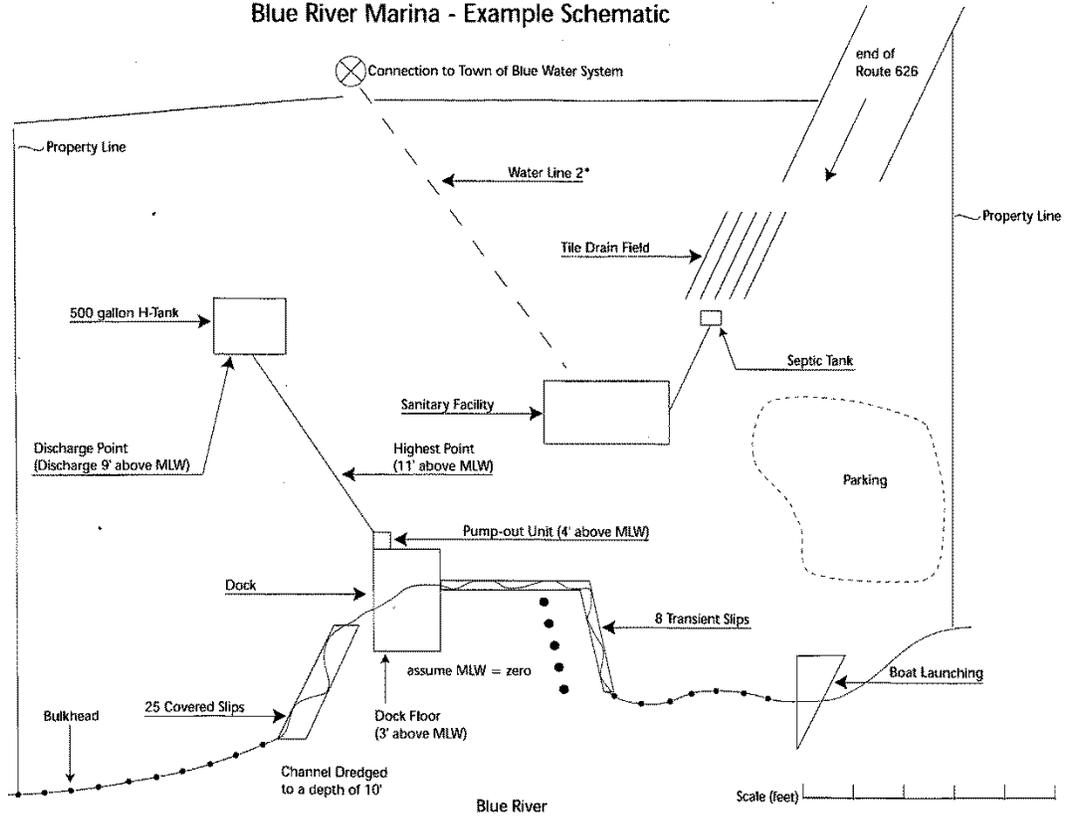
Signed _____

Title _____

Date _____

Name of Establishment _____

Blue River Marina - Example Schematic





COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 22, 2014

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services

SUBJECT: *The Regulations Governing Fees for Onsite Sewage Disposal Systems, Alternative Discharge Systems and Private Wells*
("Fee Regulations," 12VAC5-620)

The Board of Health adopted the Fee Regulations in 1989. In the fall of 2010, VDH determined that the regulations should be revised to incorporate new programs, changes to the Code of Virginia, and policies implemented since 1989. VDH published the Notice of Intended Regulatory Action (NOIRA) to amend the Fee Regulations in the Virginia Register of Regulations on April 25, 2011.

The Board of Health approved proposed regulations in 2012 based on the ad hoc committee's recommendations. The proposed regulations were published in the Virginia Register for a 60-day comment period on December 16, 2013. A total of 27 comments were received and a number of editorial changes were made to the regulations to clarify specific requirements. Many of the comments addressed issues that are beyond the authority of the Board and the scope of the regulations. For example, multiple comments were received concerning additional fees adopted by local governments.

The Fee Regulations are an effort to incorporate into a single, up-dated document changes to the Code of Virginia, regulations, and policies that have occurred since the adoption of the original regulations in 1989.

This is the final stage in the regulatory process. Following the Board of Health's approval, the final regulations will be subject to executive branch review and approval. Upon executive branch approval, the regulations will be published in the Virginia Register for a 30 day final adoption period.



Virginia

Regulatory
Town Hall
townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-620
Regulation title	Regulations Governing Fees for Onsite Sewage Disposal Systems, Alternative Discharge Systems, and Private Wells
Action title	Amendments following a periodic review
Date this document prepared	April 21, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Amendments to the regulation will:

1. Clarify that an application fee is required for an alternative discharging sewage system;
2. Clarify that an application fee is required for a letter certifying that a site is suitable for installation of an onsite sewage disposal system;
3. Clarify the application fee for closed-loop geothermal well systems;
4. Establish fees for various applications;
5. Provide for the waiver of fees in certain situations; and
6. Clarify that an applicant may not receive a refund for denial of an application if the applicant is actively pursuing an administrative appeal of the denial.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

On June 5, 2014 the Board of Health approved final amendments to the Regulations Governing Fees for Onsite Sewage Disposal Systems, Alternative Discharge Systems and Private Wells (12VAC5-620).

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The authority for these regulations is found in the following sections of the *Code of Virginia*:

1. Virginia Code §32.1-12 provides the authority to make, adopt and promulgate regulations necessary to carry out the provisions of Title 32.1 of the Code of Virginia;
2. Virginia Code §32.1-164.C provides the authority to charge a fee for filing an application for an onsite sewage system or an alternative discharging sewage system permit with the Department, to waive application fees for persons whose income is below the federal poverty guidelines or whose application is for the construction of a pit privy, and to refund the application fee when the Department denies a permit for land upon which the applicant proposed to construct his principle place of residence;
3. Virginia Code §32.164.E provides the authority to charge fees for installation and monitoring inspections of alternative discharging systems;
4. Virginia Code §32.164.G provides the authority to charge fees for "letters recognizing the appropriateness of onsite sewage site conditions in lieu of issuing onsite sewage system permits" (i.e., "certification letters");
5. Virginia Code §32.1-164.1:2.C provides the authority to charge fees for betterment loan eligibility letter requests.
6. Virginia Code §32.1-166.10 provides the authority to "establish a reasonable fee to be charged to the appealing party commensurate with the time and expenses related to the handling of each appeal to the Review Board;
7. Virginia Code §32.1-176.4.B authorizes fees for private well construction permits, the waiver of fees for persons whose incomes are below the federal poverty guideline or when the application is for a replacement well, and the refund of the application fee when a permit is denied for land on which the applicant seeks to construct his principle place of residence; and
8. Virginia Code §32.1-176.4.C authorizes a fee for geothermal well system applications which will be equal to the fee for a private well construction permit and mandates a single fee for any geothermal system.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The current regulation is out of date because applicable sections of the Code of Virginia have been amended since the regulation was initially promulgated. The regulation is essential to protecting the public in that it explains to individuals the requirements for application fees, the potential right to a waiver of the fees, their potential right to obtain a refund of the fee in the event that an application is denied, and the Board's procedures for refunds.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The proposed regulation incorporates the current schedule of fees established by policy, and in response to the Appropriations Act, for private well and sewage applications. The schedule of fees establishes a lower fee for applications considered to be minor modifications of an existing system, where an application is required but the amount of work required to process the application is minimal. Additionally, the proposed regulations incorporate Code requirements related to fees for alternative discharging sewage systems for single family homes.

The proposed changes waive the fee for an application to abandon a well at the owner's primary residence; provide for a refund of the application fee for a replacement well after the existing well is properly abandoned rather than waive the fee at the time of application; and clarify that a request for refund must be made in writing and within 12 months of final agency action on the application.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

The proposed changes incorporate current Code requirements and agency policy into a single, up-dated document. Both the agency and the public may experience some benefit from the revisions due to better clarity and more consistent application of regulations and policies. There are no disadvantages to the public or to the Commonwealth.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-620-10	None	Added definition of “decommission” in regard to wells	Provide clarity
12VAC5-620-10	Definition of “minor modification” did not mention voluntary upgrades	Added voluntary upgrade to the definition	Clarify that voluntary upgrades are not included in the definition of minor modification
12VAC5-620-10	Defined “voluntary upgrade”	Modified definition	Clarify definition
12VAC5-620.70.C	Stated that the current fees would be the maximum allowed by the Appropriations Act	Removed the language and inserted a table listing the fees by category	Provide clarity
12VAC5-620.70.C	Stated that the application fee for a minor modification would be one-half the regular fee	Removed the language from the text and added a \$100 fee for minor modification to the table	Provides clarity and simplifies the fee structure; \$100 is less than one-half the lowest regular application fee
12VAC5-620.70.D	Stated that the fee for a hearing before the Sewage Handling and Disposal Appeal Review Board shall be \$135	Removed the language and added the fee to the table	Provide clarity
12VAC5-620.75.B	Required the owner of a newly installed alternative discharge system to pay an inspection fee prior to the required inspection	Deleted the section	Conflicts with requirement of the Alternative Discharge Regulations
12VAC5-620.80.F	None	Added a statement alternative discharge permits will only be renewed if the construction permit complies with the requirements of DEQ’s VPDES general permit	Clarify the requirements; VDH does not have the authority to issue or renew a construction permit that does not comply with the VPDES permit

12VAC5-620-80.G	None	Added denial of application for a certification letter to the items for which the application fee would be waived if a subsequent application is received within 90 days	Correct an oversight in construction of the previous language
12VAC5-620-100	Required documented proof of income	Added language to clarify that income includes both employment and non-employment income and that documentation in additional forms of documentation may be acceptable	Provide clarity

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Whitney Wright, VDH	<p>Proposed language addition to 12VAC5-620-80 G.</p> <p>Propose the following language addition to 12VAC5-620-80. Waiver of Fees:</p> <p>G. Any person whose application for a certification letter or permit to construct an onsite sewage disposal system, alternative discharging system, or private well is denied may file one subsequent application for the same site-specific construction permit for which the application fee shall be waived, provided that:</p> <p>The addition of certification letter in this section is consistent with the proposed revisions in 12VAC5-620-90. Refunds of application fees. If left unchanged it may take away the Departments ability to waive the state fees when an applicant files an application within 90 days of a certification letter denial.</p>	<p>The omission noted by the commenter was an unintentional oversight during the drafting of the regulations. The language has been added.</p>
Robert B. Charnley III	<p>Prior to updating the Fee Regulations, the appropriation act deserves clarification. The 2014 Budget Bill still</p>	<p>Although the Appropriations Act language may not be completely up-to-date, we believe that</p>

<p>Jeff T. Walker; President of VAPSS</p>	<p>references "authorized" onsite soil evaluator on several occasions. VDH authorization of onsite soil evaluators expired in 2009.</p> <p>In addition, the 2014 Budget Bill appears to promote a "fee for service" expectation that the VDH will perform site evaluation and design services that are in direct competition with private sector small business. It is my understanding that the VDH will be expected to:</p> <ol style="list-style-type: none"> 1.) Address direct competition with private sector small business. 2.) Define the role of the VDH to avoid direct competition with small business. 3.) Develop a plan to cease delivery of services in direct competition with small business. 4.) Identify legislative and regulatory changes to implement the plan. <p>I believe this was agreed to in lieu of HB 409 (2014), and the VDH will report their findings to members of the Health, Welfare, and Institutions committee later this year. The Fee Regulations should reflect these findings.</p> <p>The Fee Regulations should be updated once these issues are addressed. Thank you for your consideration.</p> <p>I object to the Economic Impact Analysis which shows no impact to small business or use of private property.</p> <p>While I acknowledge the need to consider revisions to the fee schedule I believe further consideration must be given to small businesses than has been reported. Specifically according to the report the proposed regulations "do not impose any direct costs on these small businesses," and "The proposed changes are not expected to have a significant direct effect on the use and value of private</p>	<p>the intent of the legislation is clear and that where the term "authorized onsite soil evaluators" is used, the legislation can be applied to licensed onsite soil evaluators.</p> <p>The agency has not yet received any communication and so cannot respond directly to this comment. The agency recognizes that changes to the Code of Virginia or to public policy may require future changes to these regulations.</p> <p>These regulations make only a single change to existing fees. The fees, with the exception of an application for a "minor modification to an existing system" will remain the maximum allowed by the Appropriations Act until such time as the regulations are revised. The proposed regulations establish some of the items that must be considered by the Commissioner in establishing changes to the fees. The primary purpose of the currently proposed regulations is to up-date certain sections due to changes to the Code of Virginia.</p>
---	--	--

	<p>property.”</p> <p>No analysis is offered the consequence of fees or refunds to small business. and the value of private property. Specifically consider: 12VAC5-620-90. Refunds of application fee.</p> <p><u>An applicant for a construction permit or certification letter whose application is denied may apply for a refund of the application fee.</u></p> <p>In my opinion the refund policy clearly impacts small business:</p> <ol style="list-style-type: none"> 1. A design firm cannot compete with free services, and is restrained from trade by any offer of free or subsidized services. 2. Following evaluation and denial of a site application by VDH staff a design firm has a higher burden of proof which must be paid for by our client. A consequence to the consumer is the additional expense of site evaluation and design for an advanced or engineered design. 3. A denial casts an encumbrance on that parcel despite being an incomplete evaluation. (VDH policy allows for evaluation of 2 sites for conventional design) These limitations are not disclosed in writing to the applicant. 4. The VDH local offices do not disclose to applicants that public servants are limited in consideration of the owner's interests and may not design advanced systems which a consulting firm is authorized to provide. <p>Consider further: 2VAC5-620-70.</p>	<p>The refund policy applies to all applications for a construction permit where the construction is to serve the actual or intended primary residence of the applicant. The Code of Virginia §32.1-164.C requires the agency to refund the application fee in this circumstance.</p>
--	---	---

	<p>Application <u>Establishing fees.</u></p> <p><u>"fees to be charged by the department for services related to construction, maintenance, and repair or replacement of onsite sewage disposal systems,"</u></p> <p>Small business owners are in direct competition with the services offered for a subsidized fee by VDH offices.</p> <p>Dr. Larry Getzler (DPB) provided fee analysis during SHIFT indicating that application fees support ~20-23% of the cost of delivering services by VDH onsite program. VDH's Environmental Health Director acknowledged that the agency does not know the cost of providing this service. In documents released since 2010 there is no indication of any time or cost studies by the agency.</p> <p>The cost to the VDH for delivering services has a fiscal impact which should be considered by the fee regulations. During FY2012, refunds of fees for denied or withdrawn applications exceeded \$232,300. FY 2012 data showed 10,736 permit applications, including well, septic, OSE and "bare applications" Total permit revenue is reported as \$4,219,253.</p> <p>In light of the incomplete analysis in support of this fee regulation, I believe the report should be revised to reflect current costs of VDH providing direct services, and changing economic and policy considerations including the concern over public services in competition with licensed professionals and engineering design firms.</p> <p>I also suggest that the comments offered in a previous Town Hall Comment forum which closed in May of 2011 have not been addressed in a public response by the responsible agencies which should include VDH, DPOR and Department of Planning & Budget.</p> <p>In light of these shortcomings, and the history of these problems which were considered by JLARC 2002, and</p>	
--	---	--

<p>James B Slusser</p>	<p>other studies I ask that consideration of the impact of fees and policies on professionals licensed to serve the public be incorporated into any regulatory changes.</p> <p>12VAC 5-620-80 Waiver of Fees 1- G1: Should be made consistent with current Agency processing of applications and utilize a consistent schedule of business days</p> <p>2- Language should be incorporated to resolve denial of permits due to LOCAL ORDINANCES. Local requirements that exceed the State Regulations often require the use of additional licensed professionals, reviews by other local departments, etc., all of which typically takes more than 90 days to accomplish.</p>	<p>The Code of Virginia establishes multiple requirements for timely processing of applications in a mix of business days and calendar days. In this instance, the agency believes that a 90 calendar day limit is more clear than 56 business day limit.</p> <p>The agency believes that licensed professionals are responsible for being aware of local government requirements that exceed state requirements when working in that locality.</p>
<p>Mark Knowles</p>	<p>Fee Schedule I do not think it is good for any agency to set fees without a legislative disclosure. The current fees do not capture the FULL task of VDH duties.</p>	<p>The agency agrees that the fees allowed by the Appropriations Act are insufficient to fully fund the agency.</p>
<p>Janet Swords</p>	<p>12VAC5-620 After reading this document I say "no" to VDH controlling the fee schedule. I say "yes" to needed changes such as a reduced fee for component replacement that is not covered otherwise along with a need for a change in well permits that require a fee for abandonment only this should not be required. But don't change fees for well replacement with proper abandonment leave this alone. I don't understand the numbers stated in the <i>Business and Entities Affected</i> and again under <i>Small Business</i>, are the 350 individuals both private and public sector individuals combined? Under <i>Projected Impact on Employment</i> it is stated that these proposed changes are expected to reduce administrative staff time that would be necessary to update the regulations through the standard regulatory process on a frequent basis. If these administrative staff people will be constantly looking at</p>	<p>VDH only controls the fee schedule to the extent of the authority provided by the General Assembly in the Code of Virginia and the Appropriations Act.</p>

	<p>the "high frequency of legislative actions affecting fees" to adjust the VDH fee schedule, then these same staff people should not have to spend any more time on taking the changes through the Regulatory process.</p>	
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-80.F Waiver of Fees This section appears to conflict with 12VAC5-630-220, 12VAC5-630-300, 12VAC5-640-220 and 12VAC5-640-220.</p>	<p>This section extends a benefit (waiving the fee for a one-time renewal of the permit) to private well and alternative discharge regulations. The agency is in the process of up-dating the 12VAC5-640 and will do the same for 12VAC5-630.</p>
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-80.G I have personally experienced the abuse of the 90-day, one-time resubmittal regulation. In several instances my permits were denied based on trivial issues and I was "put on notice" that if I did not correct ALL DEFECTS on the next submittal, my client would be charged a new fee.</p> <p>In another instance, Loudoun County waited until the 58th day of the 60-day time allotment to deny my client's permit for the second time. There was no dialog or notice that a defect in the permit application existed until the denial letter was sent. There was no opportunity to perfect the application before the second denial was issued. The defect noted on the denial concerned an old easement that was being abandoned and the client was trying to coordinate with various entities, including the County Circuit Court Clerk's office. The result of the health department's action required a new \$1,400 permit fee.</p>	<p>The agency is not required to waive the fees for resubmittals of incomplete or imperfect applications. However, the agency is aware that even in the best of circumstances, errors and omissions may occur. Therefore, the agency has opted, when an application is denied, to allow one resubmittal of a corrected application within with no additional application fee. The 90 day time limit starts on the date that the notice of denial of the original application is received by the applicant.</p>
<p>Joel S. Pinnix, PE</p>	<p>I strongly object to the 90-day one time submittal rule. An applicant should have a total of 90-days to perfect the application with as many corrections and submittals as necessary before incurring a new application fee.</p>	<p>The agency believes that it is important to limit the number of re-submittals to provide for orderly administration of the program. We believe that a single fee waiver is reasonable, since each re-submittal requires additional staff time for tracking, reviewing and responding to application materials.</p>
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-10 - Definition of Owner The proposed definition of "Owner" is not consistent with the statutory</p>	<p>The agency believes that the definition of "owner", when read in conjunction with the definition of "person" is consistent with the definitions in the Code of Virginia.</p>

<p>Morgan A Kash</p>	<p>definition in 32.1-163 and 32.1-167.</p> <p>12VAC5-620-70 The regulations should be amended to identify that all "schedule of fees" disclose those fees necessary for administering Title 32.1 by the Agency</p> <p>This disclosure will enable greater transparency to the consumer.</p>	<p>The schedule of fees is based on legislation which authorizes the agency to implement fees determined to be necessary by the legislature.</p>
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-10 - Definition of Voluntary Upgrade The definition should read: <u>"Voluntary upgrade" means a change to or replacement of an existing non-failing onsite or alternative discharging sewage disposal system for the purposes of reducing threats to the public health, or to ground and surface waters, including the reduction of nitrogen discharges, without an increase in the permitted volume or strength of the sewage, in accordance with the regulations for repairing failing systems.</u></p>	<p>The definition of "voluntary up-grade" has been modified to provide clarity.</p>
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-70. A - Maintenance Fees</p> <p>Regarding: <u>A. The commissioner shall establish a schedule of fees to be charged by the department for services related to construction, maintenance, and repair or replacement of onsite sewage disposal systems, alternative discharge systems, and private wells and for appeals before the Review Board.</u></p> <p>Why is the term "maintenance" included in the above? Is it VDH's intention to establish "maintenance fees"?</p> <p>I strongly object to the term maintenance and request that it be removed.</p>	<p>The agency does not anticipate establishing any fees not explicitly authorized by legislation. The term "maintenance" was included because certain fees established by Code might be considered to be related to maintenance; for example, the annual inspection fee for alternative discharging systems and the operation and maintenance reporting fee.</p>

<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-75. B - Installation Inspection Fee What is an "Installation Inspection Fee"? Where is the statutory authority to establish and charge this fee? Why would an applicant pay for an application fee (that supposedly includes inspection) and then have to pay an inspection fee? I object to the inclusion of the Installation Inspection Fee.</p>	<p>This section of the regulations has been removed. Determination of when an alternative discharging system must be inspected will be determined in the proposed alternative discharging regulations.</p>
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-90.F - currently active application What is a "Currently Active Application"? It appears from the narrative that a case decision would have been made resulting in a denial. The narrative suggests that an applicant would have to pay another application in order to appeal the denial.</p>	<p>This section has been revised to eliminate reference to "currently active application" and to provide clarity. The intent is that a person who requests a refund of the application fee may not simultaneously pursue an appeal of the denial.</p>
<p>Joel S. Pinnix, PE</p>	<p>12VAC5-620-100 - proof of income From B. ..."check stubs, written letter from an employer, W-2 forms, etc., in order to..." The term "etc." is not appropriate for the Virginia's Administrative Code. Something more formal like: "...shall include, but not limited to check stubs, written letter from an employer, and W-2 forms, in order to..." Also - there is no mention of Virginia or Federal Income Tax Returns. I suggest adding both of these to list. From C. "Proof of income must include:..." How is someone of a fixed income - such as disability, social security, or retirement income going to provide proof of income from an employer?</p>	<p>The regulations intend to consider all sources of income, whether from employment or non-employment. This section of the proposed regulations has been edited to provide clarity in that regard.</p>
<p>Joel S. Pinnix, PE</p>	<p>Regarding the Economic Impact Analysis</p>	<p>The comments will be considered as the agency develops and revises policies related to the onsite sewage program.</p>

	<p>The economic impact analysis on the effect on small businesses is cursory – at best. These regulations and implied authority claimed by the Virginia Health Department (VDH) as a direct service provider of proprietary services is devastating to the private sector. The EIA states the “majority” of the private sector service providers are estimated to be small businesses. In my opinion, “majority” underestimates the number of small businesses in this particular industry. My experience over the past 12 years is that ALL of the private sector providers are small businesses. The overarching analysis that the proposed changes “do not impose any significant adverse impact on the small businesses” may be technically correct given the narrow scope of the EIA. The reality of VDH, Inc.’s current business model is:</p> <ol style="list-style-type: none"> 1. VDH, Inc. is the largest single provider of direct site evaluation and design services in the Commonwealth of the Virginia – providing between 7,000 and 10,000 fee-for-hire service contracts per year. 2. The gross income of the fee-for-hire services ranges between \$2.5 million and \$4.25 million per year. 3. All of VDH, Inc.’s fee-for-hire services are almost entirely tax subsidized. 4. VDH, Inc.’s net fee for a certification letter is \$30 per site. 5. VDH, Inc.’s net fee for a conventional site evaluation and septic system design is \$200 per site. <p>Compare VDH, Inc. with a private sector small business - the real cost of a site evaluation and preparation a certification letter submittal ranges between \$500 and \$1,500 per site. The real cost of a conventional septic system evaluation and design ranges</p>	
--	---	--

<p>Virginia Association of Onsite Soil Evaluators ("VAAOSE")</p>	<p>\$800 and \$2,500 per site. Therefore, tax payers subsidize nearly 100% of the cost of service for VDH, Inc.'s direct service business. It is easy to recognize the devastating impact on small businesses when forced to compete with a competitor of such magnitude coupled with the advantage of tax payer funding. Consider the loss of tax revenue to the Commonwealth of Virginia. If the private sector provided 100% of the fee-for-service business in this industry, the tax revenue would be about \$1 million per year. Contrast this revenue stream with the tax subsidy cost of \$3.4 million per year. The economics do not work. Instead of gaining \$1 million per year, the Commonwealth of Virginia is actually spending \$3.4 million per year to provide a fee-for-service to individuals for improvements to their real property.</p> <p>Another way to analyze the issue is the overall cost of this service to lot owner. Consider the cost of a house is about \$250,000 and the cost of the lot is \$75,000. The subsidy provided by the tax payer amounts to a trivial 0.5% of the overall project cost. Of course this percentage drops proportionally as the cost of the project increases. In many cases, the subsidy amounts to less than 0.1%. Why is the Commonwealth of Virginia subsidizing a service to some of its citizens that the private sector can provide at a significant cost to the entire taxpaying citizenry? This regulation should be put on hold until the fee-for-service issue is resolved.</p> <p>Respectfully Request VDH to Seek Attorney General Perspicuity</p> <p>The Virginia Department of Health ("VDH" or "Agency") is attempting to promulgate broad-ranging Regulations to adjust and or recover fees not historically collected. The current proposal may have a greater probability of affecting small businesses than reported or was investigated. Additionally, clarity is sought to better understand the underlying administrative duties</p>	<p>The proposed regulations do not add any new fees. The proposed regulations mirror the current agency policy of charging the maximum fees allowed, except in the case of "minor modifications" or where the fee is waived entirely.</p> <p>The agency may in the future and within the limits established by legislation, establish lower fees than the maximum allowed. Such changes would be required to follow the requirements of the Administrative Process Act.</p>
--	---	---

	<p>expressed under Title 32.1 et. seq. and regulated duties within Title 54.1 Code of Virginia.</p> <p>In the Proposed Fee regulations, VDH acknowledges that the Agency seeks to recover and amend costs without legislative review. At this time, we respectfully request VDH to seek Attorney General perspicuity on all <i>anti competitive effects</i> as required in Title 59.1_9.4.b of the Code of Virginia.</p> <p>The questions present are:</p> <ol style="list-style-type: none"> 1. Whether existing Agency fees utilized to administer Title 32.1 of the Code of Virginia cover actual or estimated cost. 2. Whether the Fee Regulations authorize VDH to charge a fee for duties provided under Title 54.1 of the Code of Virginia. 3. Whether a conflict exists whereas the Agency may be collecting ministerial fees for administration of Title 32.1 of the Code of Virginia and fees for service delivery of a regulated professional trade by Title 54.1 of the Code of Virginia. 4. Whether the Department of Planning and Budget (“DPB”) incorrectly assessed the impact(s) on small businesses within the Economic Impact Analysis, whereas the current practice of VDH providing “free soil evaluation and design services” have established <i>anti competitive effects and restraints of trade</i>. <p>In 2007, the General Assembly mandated licensure to best protect public health, safety, and welfare within the Commonwealth. Confusion</p>	
--	---	--

<p>Bill Sledjeski</p>	<p>between purpose and authority has perpetuated disparity within the industry. As a result, VDH has evolved into the largest provider of soil evaluation and design services within the Commonwealth.</p> <p>Greater understanding of VDH continuing to offer “free” services of a regulated trade is not without conflict. The deleterious impact of a State Agency competing with a regulated trade was neither the purpose nor intent of licensure. The proposed Fee Regulations should be revised to reflect <i>only</i> the authority granted under Title 32.1, Code of Virginia. Therefore, given the significance and importance of supporting small businesses in the Commonwealth, the VAAOSE strongly objects in authorizing VDH to update any fee schedule without further legislative input.</p> <p>Fee Structure 12VAC5-620-30, 70, 80 12VAC5-620-30 Apparently a distinction is being made between an “application fee” and a “services provided fee”. Fees should be established for both conditions. Application fees should be strictly administrative</p> <p>VDH “services provided fee” should encompass the total hourly process of administrative services, technical siting and planning discussions, FOIA requests, site visits, sanitary surveys, field evaluations, client discussions, percolation testing, surveys, system specifications, abbreviated designs, level 1 and 2 reviews and document revisions, et. al. <i>(A. The commissioner shall establish a schedule of fees to be charged by the department for services related to construction, maintenance, and repair or replacement of onsite sewage disposal systems, alternative discharge systems, and private wells and for appeals before the Review Board. B. In establishing fees, the commissioner shall consider the actual or estimated average cost to the agency of delivering each service</i></p>	<p>The Code of Virginia and the Appropriations Act authorize or require the agency to establish certain fees. Some are specifically referred to as application fees in the legislation; others might be considered service fees, since they are not tied directly to an application for a permit.</p> <p>The agency gives consideration to the costs associated with processing applications and providing services, but in many cases, the maximum fees authorized by legislation are insufficient to cover the entire cost.</p>
-----------------------	--	---

<p>Manufacture / Virginia residence</p>	<p><i>included in the schedule of fees.)</i></p> <p>OSE/PE supported documentation should require an application fee only. VDH will require “services provided and application fees”</p> <p>12VAC5-620-70 A.B. appears to satisfy this distinction.</p> <p>12VAC5-620-80 F5, G1. There should be no time constraints placed on any application.</p> <p>Property Transfer fees I have two concerns that I hope can be addressed.</p> <p>1. As a homeowner I want to know, when I purchase a home the septic / treatment works has been inspected by a licensed, experienced, and trained individual. It is not of matter who does the inspection, just that the inspection is carried out. I will submit that anyone that is not licensed by DPOR as a service provider, an employee of the VDH or a licensed engineer is not and should not be doing these types of inspections. It would seem to me that anyone who markets themselves as a home inspector and does not have a DPOR license as a service provider to inspect septic systems is breaking the law. I think it is only a matter of time before, an informed homeowner who understands the regulations will successfully sue a home inspector, who does not have a DPOR license for a treatment works problem that is unforeseen. As a homebuyer I might realize I can hire my own inspector, but I also realize that most homeowners would believe that a generic home inspector is good enough. I think at a minimum the home buyer needs to understand what he or she is purchasing and that information should be part of a property transaction.</p> <p>2. As a manufactures representative of alternative treatment systems we get calls from homeowners who want to understand what they just purchased.</p>	<p>VDH is aware that transfers of property served by onsite sewage or alternative discharging sewage systems sometimes create problems, especially when the new owner is not fully aware of the condition of the existing system or the operation and maintenance requirements of the system. VDH's regulations for alternative onsite sewage disposal systems attempt to address this issue to some extent by requiring that operation and maintenance manuals be provided for alternative onsite sewage systems.</p> <p>The agency may not have the authority to require inspections of sewage disposal systems at the time of property transfer and does not believe that this set of regulations would be the most appropriate place to do so in any case. The Department of Professional and Occupational Regulation may be the most appropriate agency to establish requirements for persons who do such inspections.</p>
---	---	---

<p>W.R. Willoughby Jr.</p>	<p>Of course we lead the homeowner to a service provider and it is only then they understand the cost of owning a home with an alternative treatment works. In some cases this leads to extensive repairs.</p> <p>In the interest of protecting uninformed homebuyers, I believe there needs to be an inspection of treatment works at the time of property transfer. The inspection should be done by a licensed DPOR service provider, a VDH employee, or an engineer. It could be a combination of anyone of the two. I have done some research and there are two states that I can find already doing this Rhode Island and Iowa and there may be more. I believe that a fee should be incorporated into the new fee structure for the VDH to do these inspections. The inspection could be done with a licensed service provider or engineer. I would submit a total fee of \$200-\$400 at time of property transfer would be reasonable and would protect the home buyer. This is a small cost to pay and could be rolled into closing cost of the property transfer. Another reasonable advantage would be that this fee would help already financially strapped Health Departments fund their programs.</p> <p>While I am an industry stakeholder I do not write this as a stakeholder, As a stakeholder there is no advantage for manufactures. I write this as an informed citizen interested in protecting homebuyers, thus I choose to remain anonymous.</p> <p>Proposed changes to Regulations Governing Fees for Construction Permits for Onsite Sewage Disposal</p> <p>Regulations Governing Applications Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells (12 VAC 5 - 602) should not be amended by VDH for the following reasons:</p>	<p>The agency believes that it is acting within the authority provided by the Code of Virginia in making the proposed regulatory changes.</p> <p>As of this date, VDH has not received any communication from the Health, Welfare and Institutions Committee referenced by the commenter.</p>
----------------------------	---	---

	<p>1. The change should be made by the Legislators not by VDH</p> <p>2. VDH has been directed by the Health, Welfare, and Institutions Committee to provide an impact report on the private sector to the Committee by Oct. 1, 2014 and no changes to fees by VDH should be proposed before this report is given to the Committee. This impact statement was directed in lieu of H B 409.</p> <p>3. It appears to me that VDH is trying to get more money from the tax payers so that they can continue to unfairly compete with the private sector. This opinion is based on my prior experience with VDH.</p>	
<p>James B Slusser, AOSE</p>	<p>Definition of "Fee Schedule" 12VAC5-620-10 Consider addition of "LOCAL FEE SCHEDULE" to 12VAC5-620-10 <i>Definitions</i> of the proposed regulations. I would suggest adding language to create disclosure whereas the commissioner shall keep a record of all localities authorized by the General Assembly to establish local fees (see 15.2-2157.1 Code of Virginia) that are in addition to the Virginia Department Health (VDH) Fee Schedule.</p>	<p>The agency does not have the authority to regulate fees established by local governments and therefore declines to add reference to such fees to these regulations.</p> <p>The agency will consider how it might increase awareness among applicants of fees related to onsite sewage systems, alternative discharge systems and private wells that are established by local governments.</p>
<p>James B Slusser, AOSE</p>	<p>12VAC 5-620-10 "Minor Modification of an existing sewage disposal system" 1) 12VAC5-620-10 is not clear if a permit is required to "modify an existing system". Lacking the necessity of a permit, this regulation may be in conflict with Local Ordinances that do require permits for modifications and alterations. 2) Are Local Fees for Service applicable to <i>Minor Modifications</i> as defined by these proposed regulations?</p>	<p>The requirements for submitting applications are included in the relevant regulations governing onsite sewage disposal systems, alternative discharge systems and private wells. This set of regulations is intended to implement the collection of fees when an application is required.</p> <p>VDH does not have the authority to interpret the applicability of fees established by local governments.</p>
<p>James B Slusser, AOSE</p>	<p>12VAC5-620-90 (C) Add language to identify "decommissioned".</p>	<p>The term "decommissioned", in reference to wells, is the industry standard for what in the past was referred to as "permanent abandonment". The definition has been added.</p>

<p>James B Slusser, AOSE</p>	<p>Pulling a well pump may be considered "decommissioned", thus rendering the well inoperable.</p> <p>FEES FOR SERVICE Authorizing the Commissioner of Health to charge the maximum allowable fees per the Code of Virginia or Appropriations Act ignores local fees. A reduction in states fees provides no incentive to owners if localities are allowed to continue marking up state FEE FOR SERVICES without legislative consideration.</p>	<p>The agency does not have the authority to limit fees imposed through local government ordinances.</p>
<p>Bob Marshall / cloverleaf env. cnslt., inc</p>	<p>Proposed Amendments to 12 VAC 5? 620 As others have already expressed their concerns about the direction of any such amendments, please consider the following points:</p> <p>(i) New amendments should reflect Virginia's decade long transition to a performance-based regulatory program in onsite sewage. The regulatory framework is currently overdue for synthesizing this transition into the policies of the Onsite Sewage Program "with the least possible intrusion in the lives of citizens".</p> <p>(ii) Regulatory alternatives were established in 2007 for VA licensed individuals to provide supporting documents necessary for approval of certification letters and construction permits. This opportunity has been under utilized in several Health Districts across the State.</p> <p>(iii) The <i>Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems & Private Wells</i> (12VAC5-620 et seq.) remained unchanged until the 2010-2012 Biennium Appropriations Act. As result, specific limits were set on a variety of application fees with amounts "<i>not to be exceeded</i>". These amounts effective July 1, 2010 have become</p>	<p>The department has considered these comments and believes that the proposed regulation addresses the comments insofar as practical at this time. Some of the comments are beyond the scope of this regulatory action and will be considered further as the agency undertakes future policy and regulatory change.</p>

<p>Tony Bible, SWEC</p>	<p>problematic on a variety of levels. Several counties and health districts have add-on fees that, in some cases, increase the cost of all applications (with/without supporting documentation) by several hundred dollars or more.</p> <p>(iv) Looking over the revenues recently collected from the source codes for onsite sewage fees under REVENUE CLASS: 02 RIGHTS AND PRIVILEGES, as of 12/31/2010, it could be argued that the present fee-structure and policy are not operating in the most efficient, cost-effective manner. The Health Department is essentially giving away services and setting the stage for costly hiring to keep pace with the potential demand and workload.</p> <p>(v) There's a certain sense of confusion in some Health Districts that the AUTHORIZED ONSITE SOIL EVALUATOR REGULATIONS (12 VAC 5-615) obligates these District to pursue "bare applications" as long as no 15-day backlog exists for processing applications submitted without supporting documentation from an AOSE/PE.</p> <p>(vi) Small businesses providing documentation with client applications are required to pay fees only slightly lower than the Health District charges for performing the work themselves.</p> <p>Keep feeding the VDH, Inc. BEAST! While many businesses have suffered from the building recession, the Virginia Department of Health (VDH, Inc.) remains healthy. VDH staffing levels remain virtually unchanged even though the number of permits has decreased substantially since 2008. VDH, Inc. has accomplished this by taking market share from private sector designers many or most of whom are now essentially defunct due to unfair competition from VDH, Inc.</p> <p>I am convinced that VDH, Inc. will go to any length necessary to keep designing septic systems even</p>	<p>The agency will consider the comments in developing future policies and regulations.</p>
-----------------------------	---	---

	<p>though they have no mandate to do so and refuse to accept liability for damages that occur due to their design decisions. So go ahead and give them the ability to do whatever they want to do with fees. This would be the final tool VDH, Inc. needs to function as an effective monopoly on design services.</p> <p>With all the focus on VDH, Inc. designing septic systems, is anyone actually following up to see if they are keeping their food inspections complete and recent? That would seem like a more important public health issue than designing septic systems.</p>	
--	---	--

Enter any other statement here

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
12VAC5-620-20		Cites the authority for onsite sewage application fees and private well application fees.	Adds references to code sections related to alternative discharging sewage systems, certification letters, betterment loan eligibility letters, and geothermal well systems. These sections of the Code did not exist when the existing regulations were written.
12 VAC 5-620-70		Establishes application fees in the following amounts: \$50.00 for onsite sewage construction permit; \$40.00 for a private well construction permit; \$50.00 to revalidate an onsite sewage construction permit; and \$25.00 to revalidate a private well construction permit.	Requires the Commissioner of Health to establish a schedule of fees based on actual costs of services and the requirements of the Code of Virginia and the Appropriation Act, and includes a list of current fees. The fees are the maximum currently allowed by the Code of Virginia and the Appropriations Act, except that that the application fee for a minor modification is set at \$100 and the fee for an appeal to the Sewage Handling and Disposal Regulations Appeal Board is \$135.

<p>12VAC5-620-80</p>	<p>12VAC5-620-75</p>	<p>Waives the fee for applications to install pit privies, repair a failing onsite sewage disposal system or replace a private well. Waives any application fee for a person whose family income is below the federal poverty level.</p>	<p>Clarifies that fees must be paid prior to delivery of service and that applications without the appropriate fee are incomplete. Adds a fee waiver for an application to properly and permanently abandon or decommission a private well located at the owner's primary residence. This may encourage the proper abandonment of wells that present health, safety and environmental hazards.</p> <p>Provides that construction permits may be renewed one time for a period of 18 months beyond the original expiration date when a building permit has been obtained or construction has commenced. This reflects a requirement of the Code of Virginia.</p> <p>Provides that one subsequent application for the same specific site may be submitted at no charge within 90 days following denial of the first permit application. Multiple submittals are frequently necessary to obtain an application that is complete and meets all regulatory requirements; allowing a 90 day period to perfect the application provides an opportunity for the applicant to correct errors without paying an additional fee.</p> <p>Removes the fee waiver for replacement wells. This is replaced by a provision in 12VAC5-620-90 that the application fee will be refunded when the existing well is properly and permanently abandoned (i.e., that the well is actually a replacement well) pursuant to 12VAC5-630-310.</p>
<p>12VAC5-620-90</p>		<p>Provides for a refund of the application fee when a permit is denied.</p>	<p>Adds a provision that the application fee may be refunded if the application is withdrawn before the agency makes a site visit. This is long-standing agency policy.</p> <p>Provides that the application fee for a replacement well will be refunded after the existing well is replaced. This change is proposed to improve compliance with the requirement to properly abandon wells when the well is replaced. Currently, many owners receive a fee waiver for a replacement well but then do not comply with the requirement to abandon the existing well.</p>

			<p>Provides that applications for refunds must be made in writing and within 12 months of denial of the permit, withdrawal of the application or conclusion of the appeals process. This provision is intended to limit confusion surrounding the procedures for refunds.</p> <p>Provides that an applicant may not receive a refund of the application fee while pursuing an appeal of the denial of an application. This is intended to limit the applicant to one administrative procedure at a time.</p>
--	--	--	--

Enter any other statement here

Project 2718 - Proposed

**DEPARTMENT OF HEALTH
Update regulations to reflect changes in the Code of VA**

CHAPTER 620
REGULATIONS GOVERNING APPLICATION FEES FOR CONSTRUCTION PERMITS FOR
ONSITE SEWAGE DISPOSAL SYSTEMS, ALTERNATIVE DISCHARGE SYSTEMS, AND
PRIVATE WELLS

Part I
Definitions

12VAC5-620-10. Definitions.

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

"Agent" means a legally authorized representative of the owner.

"Alternative discharging system" means any device or system that results in a point source discharge of treated sewage for which the board may issue a permit authorizing construction and operation when the system is regulated by the State Water Control Board pursuant to a general Virginia Pollutant Discharge Elimination System permit for an individual single family dwelling with flows less than or equal to 1,000 gallons per day.

"Board" means the State Board of Health.

"Certification letter" means a letter issued by the commissioner in lieu of a construction permit, which identifies a specific site and recognizes the appropriateness of the site for an onsite wastewater disposal system.

"Commissioner" means the State Health Commissioner.

"Construction of private wells" means acts necessary to construct private wells, including the location of private wells, the boring, digging, drilling, or otherwise excavating a well hole and installing casing with or without well screens, or well curbing.

["Decommission" means to permanently seal an existing private well in accordance with the requirements of the Private Well Regulations.]

"Department" means the Virginia Department of Health.

"Dewatering well" means a driven well constructed for the sole purpose of lowering the water table and kept in operation for a period of 60 days or less. Dewatering wells are used to allow construction in areas where a high water table hinders or prohibits construction and are always temporary in nature.

"Family" means the economic unit which shall include the owner, the spouse of the owner, and any other person actually and properly dependent upon or contributing to the family's income for subsistence. A husband and wife who have been separated and are not living together, and who are not dependent on each other for support, shall be considered separate family units. The family unit, which is based on cohabitation, is considered to be a separate family unit for determining if an application fee ~~is waivable~~ may be waived. The ~~cohabiting~~ cohabiting partners and any children shall be considered a family unit.

"Fee schedule" means a listing by item of the fees to be charged by the department for processing applications and for other services rendered by the department.

"Income" means total cash receipts of the family before taxes from all sources. These include money wages and salaries before any deductions, but do not include food or rent in lieu of wages. These receipts include net receipts from nonfarm or farm self-employment (e.g.,

receipts from the family's own business or farm after deductions for business or farm expenses.) They include regular payments from public assistance (including Supplemental Security Income), social security or railroad retirement, unemployment and worker's compensation, strike benefits from union funds, veterans' benefits, training stipends, alimony, child support, and military family allotments or other regular support from an absent family member or someone not living in the household; private pensions, government employee pensions, and regular insurance or annuity payment; and income from dividends, interest, rents, royalties, or periodic receipts from estates or trusts. These receipts further include funds obtained through college work study programs, scholarships, and grants to the extent said funds are used for current living costs. Income does not include the value of food stamps, WIC checks, fuel assistance, money borrowed, tax refunds, gifts, lump sum settlements, inheritances or insurance payments, withdrawal of bank deposits, earnings of minor children, money received from the sale of property. Income also does not include funds derived from college work study programs, scholarships, loans, or grants to the extent such funds are not used for current living costs.

"Minor modification of an existing sewage disposal system" means an alteration that is not a repair [,voluntary up-grade] or routine maintenance, does not result in an increase in treatment level or volume of the system, and does not require evaluation of the soil conditions prior to issuance of a permit. Minor modifications include but are not limited to relocation of a system component or an additional plumbing connection to the system that does not increase the actual or estimated flow of the system.

"Onsite sewage disposal system" means a sewerage system or treatment works designed not to result in a point source discharge.

"Owner" means any person who owns, leases, or proposes to own or lease a private well or an onsite sewage disposal system, or both an alternative discharging system.

"Person" means the Commonwealth or any of its political subdivisions, including sanitary districts, sanitation district commissions and authorities, any individual, any group of individuals acting individually or as a group, or any public or private institution, corporation, company, partnership, firm or association which owns or proposes to own a sewerage system, treatment works or private well.

"Principal place of residence" means the dwelling unit, single family dwelling, or mobile home where the owner lives.

"Private well" means any water well constructed for a person on land which is owned or leased by that person and is usually intended for household, groundwater source heat pump, agricultural use, industrial use, use as an observation or monitoring well, or other nonpublic water well. A dewatering well, for the purposes of this chapter, is not a private well.

~~"Repair of a failing onsite sewage disposal system" means the construction of an onsite sewage disposal system or parts thereof to correct an existing and failing sewage disposal system for an occupied structure with indoor plumbing.~~

"Repair" means the construction or replacement of all or parts of a sewage disposal system or private well to correct a failing, damaged, or improperly functioning system or well when such construction or replacement is required by the board's regulations.

"Replacement of a private well" means the construction of a private well to be used in lieu of an existing private well.

"Review Board" means the State Sewage Handling and Disposal Appeals Review Board.

"Sewage" means water-carried and nonwater-carried human excrement, kitchen, laundry, shower, bath or lavatory wastes separately or together with such underground, surface, storm and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments or other places.

"Sewerage system" means pipelines or conduits, pumping stations and force mains and all other construction, devices and appliances appurtenant thereto, used for the collection and conveyance of sewage to a treatment works or point of ultimate disposal.

"Treatment works" means any device or system used in the storage, treatment, disposal or reclamation of sewage or combinations of sewage and industrial wastes, including but not limited to pumping, power and other equipment and appurtenances, septic tanks and any works, including land, that are or will be (i) an integral part of the treatment process or (ii) used for ultimate disposal of residues or effluents resulting from such treatment.

["Voluntary upgrade" means ~~a change to or replacement of an existing nonfailing onsite or alternative discharging sewage disposal system, without an increase in the permitted volume or strength of the sewage, in accordance with the regulations for repairing failing systems an~~ improvement to an existing onsite sewage disposal system or alternative discharging system not required for compliance with any law or regulation and which results in no net increase in the permitted volume or strength of sewage dispersed by the system.]

"Well" means any artificial opening or artificially altered natural opening, however made, by which groundwater is sought or through which groundwater flows under natural pressure or is intended to be artificially drawn; provided this definition shall not include wells drilled for the purpose of exploration or production of oil or gas, for building foundation investigation and construction, elevator shafts, grounding of electrical apparatus, or the modification or development of springs.

Part II
General Information

12VAC5-620-20. Authority for regulations. (Repealed.)

~~Sections 32.1-164#C and 32.1-176.4#B of the Code of Virginia provide that the State Board of Health has the power to prescribe a reasonable fee to be charged for filing an application for an onsite sewage disposal system permit and a reasonable fee to be charged for filing an application for a private well construction permit.~~

Part II
General Information

12VAC5-620-30. Purpose of regulations.

The board has promulgated these regulations to:

- ~~1. Establish a fee for filing an application for a permit to construct an onsite sewage disposal system or for the construction of a private well; and~~ Establish a procedure for determining the fees for services provided by the department for onsite sewage systems, alternative discharge systems, and private wells;
- ~~2. Establish a procedure for the waiver of fees for an owner whose income of his family is at or below the federal poverty guidelines established by the United States Department of Health and Human Services, or when the application is for a pit privy, the replacement of a private well, or the repair of a failing onsite sewage disposal system.~~
2. Establish procedures for the refund of fees; and
3. Establish procedures for the waiver of fees.

12VAC5-620-40. Compliance with the Administrative Process Act.

The provisions of the Virginia Administrative Process Act (§ ~~9-6.14:1~~ 2.2-4000 et. seq. of the Code of Virginia) shall govern the promulgation and administration of these regulations and shall be ~~applicable to the appeal of any case decision based upon~~ govern the decisions of cases under this chapter.

12VAC5-620-50. Powers and procedures of regulations not exclusive.

The ~~Commissioner~~ commissioner may enforce these regulations through any means lawfully available.

Part III
Fees

12VAC5-620-70. Application Establishing fees.

~~A. A fee of \$50 shall be charged to the owner for filing an application for an onsite sewage disposal system permit with the department. The fee shall be paid to the Virginia Department of Health by the owner or his agent at the time of filing the application and the application shall not be processed until the fee has been collected. Applications shall be limited to one site specific proposal. When site conditions change, or the needs of an applicant change, or the applicant proposes and requests another site be evaluated, and a new site evaluation is conducted, a new application and fee is required.~~

~~B. A fee of \$25 shall be charged to the owner for filing an application for the construction of a private well with the department. The fee shall be paid to the Virginia Department of Health by the owner or his agent at the time of filing the application and the application shall not be processed until the fee has been collected. Applications shall be limited to one site specific proposal. When site conditions change, or the needs of an applicant change or the applicant proposes and requests another site be evaluated, and a new site evaluation is conducted, a new application and fee is required.~~

~~C. A person seeking revalidation of a construction permit for an onsite sewage disposal system shall file a completed application and shall pay a fee of \$50.~~

~~D. A person seeking revalidation of a permit for the construction of a private well shall file a completed application and shall pay a fee of \$25.~~

A. The commissioner shall establish a schedule of fees to be charged by the department for services related to construction, maintenance, and repair or replacement of onsite sewage disposal systems, alternative discharge systems, and private wells and for appeals before the Review Board.

B. In establishing fees, the commissioner shall consider the actual or estimated average cost to the agency of delivering each service included in the schedule of fees.

[C. The fees shall be the maximum allowable fees as established by the Code of Virginia or the appropriation act except that the fee for an application for a permit to make minor modifications of existing systems shall be 50% of the application fee for an onsite sewage disposal system construction permit. The following fee schedule is hereby established:

Table
Schedule of fees.

<u>Application or Service</u>	<u>Fee</u>
<u>Certification letter, no OSE/PE documentation (no charge for well)</u>	<u>\$350</u>
<u>Certification letter with OSE/PE documentation, ≤1,000 gpd</u>	<u>\$320</u>
<u>Certification letter with OSE/PE documentation, >1,000 gpd</u>	<u>\$1,400</u>
<u>Construction permit for treatment works only, no OSE/PE documentation</u>	<u>\$425</u>
<u>Combined well and treatment works construction permit, no OSE/PE documentation</u>	<u>\$725</u>

<u>Combined well and treatment works construction permit with OSE/PE documentation, ≤1,000 gpd</u>	<u>\$525</u>
<u>Construction permit for treatment works only with OSE/PE documentation, ≤1,000 gpd</u>	<u>\$225</u>
<u>Construction permit for treatment works only with OSE/PE documentation, >1,000 gpd</u>	<u>\$1,400</u>
<u>Combined well and treatment works construction permit with OSE/PE documentation, >1,000 gpd</u>	<u>\$1,700</u>
<u>Private well construction or abandonment permit, with or without OSE/PE documentation</u>	<u>\$300</u>
<u>Closed-loop geothermal well system (one fee per well system)</u>	<u>\$300</u>
<u>Alternative discharge system inspection fee</u>	<u>\$75</u>
<u>Minor modification to an existing system</u>	<u>\$100</u>
<u>Appeal before the Sewage Handling and Disposal Appeal Review Board</u>	<u>\$135</u>

~~[D. The fee for filing an application for an administrative hearing before the Review Board shall be \$135.]~~

12VAC5-620-75. Fee remittance; application completeness.

A. Each applicant shall remit any required application fee to the department at the time of making application. In any case where an application fee is required, including requests for hearings before the Review Board, the application will be deemed to be incomplete and will not be accepted or processed until the fee is paid.

~~[B. The owner of a newly installed alternative discharge system shall pay the installation inspection fee prior to the required department inspection.]~~

[C B] . The owner of an alternative discharge system shall pay the monitoring fee to the department for monitoring inspections conducted by the department that are mandated by 12VAC5-640. The department shall waive the monitoring fee when it conducts a monitoring inspection that is not mandated by 12VAC5-640.

12VAC5-620-80. Waiver of fees.

A. An owner whose ~~income of his family~~ income is at or below the ~~1988~~ 2013 Poverty Income Guidelines ~~For All~~ for the 48 Contiguous States (Except Alaska and Hawaii) and ~~The~~ the District of Columbia established by the Department of Health and Human Services, ~~53 FR 4213 (1988)~~ 78 FR 5182 (January 24, 2013), or any successor guidelines, shall not be charged a fee for ~~filing an application for an onsite sewage disposal system permit or a private well construction permit pursuant to this chapter.~~

B. Any person applying for a permit to construct a pit privy shall not be charged a fee for filing the application.

C. Any person applying for a permit ~~to construct an onsite sewage disposal system~~ to repair ~~a failing an~~ an onsite sewage disposal system or alternative discharging system shall not be charged a fee for filing the application.

D. Any person applying for a construction permit for the replacement of a private well shall ~~not~~ may be charged a fee for filing the application. Any application fee paid for a construction permit for a replacement well shall be refunded in full upon receipt by the department of a

Uniform Water Well Completion Report, pursuant to 12VAC5-630-310, indicating that the well that was replaced has been permanently and properly abandoned or decommissioned.

E. Any person applying for a permit to properly and permanently abandon or decommission an existing well on property that is his principle place of residence shall not be charged a fee for filing the application.

F. Any person who applies to renew a construction permit for an onsite sewage disposal system, alternative discharge system, or private well shall not be charged a fee for filing the application, provided that:

1. The site and soil conditions upon which the permit was issued have not changed;
2. The legal ownership of the property has not changed;
3. A building permit for the facility to be served by the sewage system or well has been obtained or construction of the facility has commenced;
4. No previous renewal of the permit has been granted; [and]
5. The expiration date of the renewed permit shall be the date 18 months following the expiration date of the original permit [;and]

[6. Where the construction permit is for an alternative discharging system, the permit must comply with the current Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Domestic Sewage Discharges of Less Than or Equal to 1,000 Gallons per Day issued by the Department of Environmental Quality.]

G. Any person whose application for a [certification letter or for a] permit to construct an onsite sewage disposal system, alternative discharging system, or private well is denied may file one subsequent application for the same site-specific construction permit for which the application fee shall be waived, provided that:

1. The subsequent application is filed within 90 days of receiving the notice of denial for the first application;
2. The denial is not currently under appeal; and
3. The application fee for the first application has not been refunded.

12VAC5-620-90. Refunds of application fee.

~~An application fee shall be refunded to the owner (or agent, if applicable) if the department denies a permit on his land on which the owner seeks to construct his principal place of residence. Such fee shall not be refunded by the department until final resolution of any appeals made by the owner from the denial.~~

A. An applicant for a construction permit or certification letter whose application is denied may apply for a refund of the application fee. The application fee shall be refunded to the owner or agent, if applicable, if the department denies an application for the land upon which the owner intends to build his principal place of residence. When the application was made for both a sewage disposal system and a private well, both fees may be refunded at the owner's request. [Any such request shall be considered a withdrawal of the application.]

B. An applicant for a construction permit or a certification letter may request a refund of the application fee if the applicant voluntarily withdraws his application before the department issues the requested permit. The application fee will be refunded if the application is withdrawn before the department makes a site visit for the purpose of evaluating the application.

C. An applicant who has paid an application fee for a replacement well shall be refunded the application fee in full upon receipt by the department of a Uniform Water Well Completion Report, pursuant to 12VAC5-630-310, showing that the well that was replaced has been properly and permanently abandoned or decommissioned.

D. All applications for refunds must be made to the department no later than 12 months following the date upon which the applicant receives notification that his application for a construction permit or certification letter has been denied, within 12 months following the date upon which his application was withdrawn, or within 12 months following the date upon which any appeals of the denial of the application have been concluded.

E. All applications for refunds shall be made in writing in a form approved by the department.

F. [Denials of applications may be appealed only when the applicant has a currently active application before the department, including payment of any required application fee. Applications which have been withdrawn are not subject to appeal.]

12VAC5-620-100. Determining eligibility for waiver based on family income.

A. An owner seeking a waiver of an application fee shall request the waiver on the application form. The department will require information as to income, family size, financial status and other related data. The department shall not process the application until final resolution of the eligibility determination for waiver.

B. It is the owner's responsibility to furnish the department with the correct financial data in order to be appropriately classified according to income level and to determine eligibility for a waiver of an application fee. The owner shall be required to provide written verification of [any employment or non-employment] income such as check stubs, written letter from an employer, W-2 forms, [~~etc.~~, or other documentation acceptable to the department] in order to provide documentation for the application.

C. The proof of income must reflect current income ~~which~~ that is expected to be available during the next 12-month period. Proof of income must include [, where applicable,] ~~Name~~ name of employer, amount of gross earnings, and pay period for stated earnings. If no pay stub is submitted, a written statement must include the name, address, telephone number, and title of person certifying the income.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 28, 2014

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services

SUBJECT: *The Alternative Discharging Sewage Treatment Regulations for Single Family Home Dwellings* ("Discharging Regulations," 12VAC5-640-10)

The Board of Health adopted the Discharge Regulations in 1992 and this is the first revision since then. In the fall of 2010, the Virginia Department of Health (VDH) performed a periodic review of the regulations pursuant to Virginia Code Section 2.2-4017 and Executive Order 14 (2010). The periodic review determined a need to revise the regulations to address changes in the sewage treatment industry. On February 28, 2011, VDH published the Notice of Intended Regulatory Action to amend the discharging regulations in the Virginia Register of Regulations. In addition, VDH convened an ad hoc advisory committee to get input from experts as to how the discharging regulations should be modified.

The proposed regulations were published in the Virginia Register for a 60-day comment period on December 16, 2013; and a public hearing was held on January 13, 2014. Twelve comments were received in total (none at the January 13, 2014 public hearing). VDH worked with an internal stakeholder committee of environmental health managers and staff to review the public comments. Changes from the proposed stage were made based on these 12 comments. The draft final regulation provides more flexibility for operation and maintenance and contracts. The changes focus on the outcome of proper operation and maintenance. The regulation reduces the annual health department inspection to once every three years, provided the system fully complies with reporting requirements for at least three years.

This is the final stage in the regulatory process. Following the Board of Health's approval, the final regulations will be subject to executive branch review and approval. Upon executive branch approval, the regulations will be published in the Virginia Register for a 30 day final adoption period.



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-640
Regulation title	Alternative Discharging Sewage Treatment Regulations for Individual Single Family Home Dwellings
Action title	Update and modify the regulations for less than or equal to 1000 gallons per day individual single family home discharging systems to incorporate policy documents and new technology and consider impacts to the Chesapeake Bay Total Maximum Daily Load (TMDL).
Date this document prepared	April 28, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The proposed amendments to the existing regulation provide greater flexibility for the design and use of discharging systems and ensure that these systems protect public health and the environment. The changes include: simplifying the application process, adding requirements to assure that discharging systems are properly operated and maintained, adding requirements to assure reliability of system function, improving and simplifying the process that the Virginia Department of Health (VDH) uses to evaluate treatment units for general approval, addressing discharges to wetlands, amending administrative processes to ensure efficiency, and eliminating inconsistencies with the Code of Virginia and the administrative process act (APA).

Public comments on the proposed regulations resulted in two main changes to the final regulation. First, an allowance to reduce departmental inspections of systems from once a year to once in three years was provided for regulatory compliant systems. Second, modifications were made to address the cost of maintenance contracts. Those modifications included deleting references to terms of contracts and contract requirements; eliminating the requirement to submit a maintenance contract to the department;

and redefining the duties of an operator and owner to focus on outcomes. The proposed amendments had already expanded the classes of operators who can provide operation and maintenance which will increase the available population of operators. These changes should result in more competition and more flexibility for homeowners who are negotiating with operators for operation and maintenance of their system.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The final amendments to the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Home Dwellings were approved by the State Board of Health on June 5, 2014.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The *Code of Virginia* at §§ 32.1-12, 32.1-163 and 32.1-164 provides the statutory authority and mandates that the Board protect public health and the environment. *Code of Virginia* § 32.1-12 authorizes the Board to make, adopt, promulgate and enforce regulations that may be necessary to carry out the provisions of title 32.1 and other laws of the Commonwealth administered by it or the Commissioner. Further, *Code of Virginia* § 32.1-164.A. states that "the Board shall have supervision and control over the safe and sanitary collection, conveyance, transportation, treatment, and disposal of sewage by onsite sewage systems and alternative discharging sewage systems, and treatment works as they affect the public health and welfare." Moreover, *Code of Virginia* § 32.1-164.B mandates that the Board promulgate regulations that govern the collection, conveyance, transportation, treatment and disposal of sewage by onsite sewage systems and alternative discharging sewage systems. *Code of Virginia* § 32.1-164.A mandates that the Board require, and that the Department conduct, regular inspections of alternative discharging sewage systems. The subsection further mandates that the Board establish requirements for maintenance contracts for alternative discharging sewage systems.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Board has not updated the regulations since 1992. Since the regulations became effective, new technologies have emerged that offer more cost effective solutions to homeowners. These new technologies offer a higher degree of protection of public health and the environment. The regulations simplify the application processes, improve the process for conferring general approval on treatment units, and provide greater flexibility for the design and use of discharging systems. Further, the regulations protect the health, safety and welfare of citizens by ensuring that these systems are properly designed, operated and maintained to prevent system failure and to protect Commonwealth citizens from the deleterious effects of raw sewage.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Definitions added include the following: "alternative onsite sewage system," "BOD5," "biological treatment unit," "combined application," "conventional onsite sewage system," "dechlorination," "maintenance," "modify," "operate," "operation," "operation and maintenance contract," "general approval," definitions for reliability and treatment levels, "wetlands," "surface waters," "emergency pump and haul," "post aeration unit," "total residual chlorine" "point source discharge," "NPDES," and "VPDES". A requirement was added so that owners of discharging systems permitted after the effective date of the regulations must have an operation and maintenance manual. The regulation:

1. Expands the onsite options that must be evaluated and found unsatisfactory before a discharge is considered;
2. Eliminates redundancies and inconsistencies with the APA and Title 32.1 of the Code with regard to hearings, orders and enforcement;
3. Increases the length of time that a construction permit is valid and allows for a one time renewal for 18 months under limited circumstances;
4. Provides for the transfer of construction and operation permits under limited circumstances;
5. Modifies the application process in an effort to simplify it;
6. Eliminates any reference to permit suspension;
7. Requires wetland delineation by the U.S. Army Corps of Engineers when the proposed discharge is to a wetland;
8. Simplifies the general approval process for treatment units;
9. Reduces the sampling and monitoring requirements to the homeowner for most systems;
10. Eliminates the requirement to submit a written operation and maintenance contract, and substitutes a certification statement from the owner that the system will be operated, maintained and monitored, and reports will be filed in accordance with the regulation;
11. Requires reliability assurances for discharging systems to protect against the public health and environmental problems associated with component or system failure. VDH added three levels of reliability that are based on the available discharge area and the discharge point;
12. Repeals the prohibition on the use of discharging systems for dwellings subject to intermittent use and allows it under certain circumstances;
13. Requires systems to be designed to accommodate peak flow rates and to protect against adverse weather conditions;
14. Restricts access between humans, animals, and effluent for wetland discharges and provides more design flexibility;

- 15. Adds design requirements for system components to parallel requirements contained in the Sewage Collection and Treatment Regulations (9VAC25-790 et seq.);
- 16. Modifies the informal control testing to more accurately assesses system performance;
- 17. Expands the number of allowed individuals who can perform maintenance, to include Alternative Onsite Sewage System Operators in addition to the existing Class IV or higher wastewater works operator license; and
- 18. Requires electronic reporting of inspection results.

Issues

Please identify the issues associated with the proposed regulatory action, including:
 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
 3) *other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.*

- 1. The regulations provide benefits to the public by: allowing more cost-efficient technologies, simplifying the application process, clarifying the operation and maintenance requirements, expanding the available operator pool, reducing the number of annual departmental inspections for compliant systems, and allowing the transfer of construction and operation permits to new owners under certain circumstances.
- 2. The regulations provide advantages to the agency and Commonwealth by: simplifying the application process, allowing private sector individuals to perform site evaluations, and modifying the general approval process for treatment components to mirror other regulatory programs.
- 3. The regulations provide greater protection to public health and the environment by requiring reliability assurances against component or system failure. The proposed amendments provide system designers and users with greater flexibility by reducing the separation distance between discharge points, by defining requirements for discharges to wetlands, and by allowing these systems for dwellings subject to intermittent use.

There are no known disadvantages to the public or Commonwealth.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
5	No definition of operation and maintenance contract.	Added definition for operation and maintenance contract.	Definition added to address public comments.
5	No definition for total residual chlorine	Added definition for total residual chlorine	Acronym of “TRC” used in text and not defined. Definition added for clarity.
30D	Identified the department, licensed onsite soil	Modified the section to an individual licensed in Virginia to	Change made to address public comment.

	evaluators, and professional engineers as eligible parties to submit a required evaluation.	evaluate and design onsite sewage systems, such as a licensed onsite soil evaluator or professional engineer, and added a reference to 12VAC5-610 and 12VAC5-613, which describe evaluations.	
220B	Defined the lifespan of a construction permit, but did not consider if it could be renewed.	Added a statement that a construction permit may be renewed one time for an additional 18 months if no conditions have changed.	During internal review, it was recognized that an owner could receive a construction permit with a very short expiration date if obtained just before the General Permit expired. As long as the reissued General Permit and the design and site conditions are unchanged, then the construction permit will be eligible for a one time, 18 month renewal.
220D	Defined the lifespan of an operation permit and tied it to having maintenance or monitoring contracts in place.	The section was modified to indicate that if operator reports are being received as required, and the system is in compliance, then the operation permit will be renewed.	Previously, a written contract was required to verify maintenance was being done. Verifying proper maintenance based on operator reports is a better approach. This change will eliminate maintenance contract monitoring. This change was made based on public comments.
220E	Allows for the transfer of a construction or operation permit to a new owner under limited circumstances.	Clarified that the expiration date of the permit does not change with a transfer of ownership.	Eliminates confusion on transfer of permits.
266	Identified required items for issuance of an operation permit.	Deleted requirement to submit maintenance and monitoring contracts.	Change made to address public comments.
270B	Identified that an operation or construction permit could be denied without submission of a valid maintenance or monitoring contract.	Removed the reference to submission of a contract. A certification statement was added to the Combined Application and the Transfer of Ownership Application to ensure the owner is aware that the system must be properly operated and maintained.	Change made to address public comments.
280D.2	A construction or operation permit can be revoked if a maintenance or monitoring contract is not kept in force.	This statement was deleted.	Failure to comply with the operation and maintenance requirements is already covered by the regulations.
460.A.2g	Used term 'sensors' in describing how a	Modified to state 'a sensor'	The intention is to have the unit monitored for operability

	disinfection system is to be monitored.		and not imply that multiple sensors are required. Modification was made for clarity.
470M	Provide a sign at the discharge point with the maintenance provider's name and phone number	Modified sign verbiage to 'licensed operator with oversight of the system'	Reflects the requirement that all maintenance providers must be licensed operators.
490.B	Allowed for suspending a permit.	Modified to remove the term 'suspending' and only allow a revocation of a permit.	Modification made to be consistent with other APA changes.
490 Table 3.3	Uses the acronym 'UV' in right hand side of table without defining the term	UV is defined as 'ultraviolet disinfection' in the left side of column	Modified to provide clarity.
490F	Stated that the department shall conduct annual inspections at a minimum.	Allows for a reduction in department inspections to once every 3 years if compliance for 3 consecutive years is observed.	Public comment objected to the cost of department inspections (\$75). The fee is mandated by Code, but the department allowed that a less frequent inspection schedule could be afforded for those systems that were in compliance.
490G	Described a separate monitoring contract and the conditions under which an existing waiver to the contract could be revoked.	This section was deleted. The discussion on how an existing waiver can be revoked was moved to 500A.	The regulation separated monitoring and maintenance into two separate contractual items. This change provides for a single entity to provide operation and maintenance services that include monitoring.
500	Maintenance.	Operation and Maintenance Requirements.	Modified title to reflect contents.
500A	Set the general requirement to have a maintenance contract.	Modified to require that the owner engage a licensed operator	Change is based on public comment and is related to removing requirements for submission of contracts.
500B	Required that a maintenance contract be in force at all times and that a copy be kept on file with the department.	Deleted and replaced with owner responsibilities.	Public comments indicated confusion on owner responsibilities and operator responsibilities. This clarifies expectations.
500C	Itemized elements of a maintenance contract.	Deleted and replaced with operator responsibilities.	See previous rationale.
500D	Allows for waiver of maintenance and/or monitoring contracts if system is operated by a utility.	Modified to use term operation and maintenance.	Change is consistent with operation and maintenance expectations. Change based on public comment.
Form	Combined application.	Added a certification statement to ensure owner is aware to engage a licensed operator to operate, maintain, monitor, and submit reports.	Change based on public comment.

Form	Permit Transfer	Added a certification statement to ensure owner is aware to engage a licensed operator to operate, maintain, monitor, and submit reports	Change based on public comment.
------	-----------------	--	---------------------------------

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Lisa Quillen	<p>What will happen when sewer is extended to these homes? Will they still be required to pay the high cost of maintaining them?</p> <p>Suggests that there be some kind of program to help with the cost of the maintenance or at least someone local who can do the service.</p>	<p>If the treatment system is taken offline through connection to a public sewer, then the permit would be revoked. The individual treatment system would be abandoned or dismantled and the owner would contract with the utility for the service. The agency has expanded the types of operators who can operate discharging systems. This change will increase the population of operators, which should reduce costs. Any eligible owner may apply for a waiver to fees, such as the inspection fee. There is currently no funding to aid with operation and maintenance.</p>
Douglas Darter	<p>Commenter is an owner who has been maintaining his treatment system for over 20 years and the Health Department has been testing and monitoring during that period. He's been told that the system has tested well and there are no problems. He would prefer to hook to central sewer as it is a 1/2 mile from his home, but no one can tell him when it will be extended to him. He understands that he will now be forced to hire a contractor to do the maintenance and monitoring. He is on a fixed income and cannot afford the cost. He explains that his system is simple to maintain but expensive. He noted costs of \$240/yr for chemicals and bearing replacements and a pumpout every 3 years at \$300. He checks his system every week and adds chlorine as needed. He contacted at least four operators from a list provided by VDH. One contract was \$250 for two years, but no testing was included and the</p>	<p>The requirement to have a maintenance contract is found in the Code of Virginia and is in the regulation. However, the regulation has been modified to allow more flexibility in how an owner contracts with an operator, which should help reduce costs. Evidence of a contract is submission of required reports, or for new or transferred permits, the owner's certification. The agency has expanded the types of operators who can operate discharging systems, which will increase the population of operators available and should reduce costs.</p>

	<p>operator would charge extra to come out. One operator charged \$100 just to visit the site. Others said it was too far and would not offer a price. Availability is an issue for these remote areas. He would like to do the right thing, but needs a cheaper a solution.</p>	
<p>Elaine Sheldon</p>	<p>Commenter had previously maintained the system. They supplied the Health Department with the schedule of aerator cleaning (quarterly) and tablet replacement (every 2-3 weeks), and had the tank pumped every couple of years. Recently, they purchased a maintenance contract at the insistence of VDH. They note that it seems like a lot of money just to say that if something goes wrong, they will call on a contractor. They are questioning the 'new' requirement for a monitoring contract and thought that VDH was doing the monitoring. They also understand that there will be a charge for the VDH inspections of \$75. They question who can sample besides VDH. They note it is expensive enough to purchase tablets, clean the tank, and keep the equipment running, without paying for contracts, as well.</p>	<p>The requirement to have a maintenance contract is found in the Code of Virginia and has been in effect since 1992. However, the regulation has been modified to allow more flexibility in how an owner contracts with an operator. Submission of the contract is no longer required. This flexibility should help reduce costs. Evidence of a contract is submission of required reports, or for new or transferred permits, the owner's certification. The agency has expanded the types of operators who can operate discharging systems. This change will increase the population of operators available, which should reduce costs. A separate monitoring contract has been deleted from the regulation. The intention is that an owner would engage an operator to provide operation, maintenance, monitoring, and reporting of the system. The operator is the one licensed to do routine operation and maintenance visits, monitor the system, and report the results to the agency. The Code of Virginia requires the Agency to charge \$75 for department inspections. Annual inspections have been extremely useful in reducing public health threats. For those systems that are being operated, maintained, monitored, and reported properly, the regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years. In those cases, the department inspection frequency is reduced to once every three years. The owner is still obligated to have an operator complete all required visits and testing in accordance with the regulation and General Permit.</p>
<p>Richard Holland</p>	<p>The commenter is an owner who currently does the routine maintenance on his system. He checks it weekly, adds chemicals (\$150/bucket, cleans the motor, and has it pumped every 2 to 3 years at a cost of \$750). He takes a sample to a lab for analysis (\$65) and sends results to VDH. He keeps a</p>	<p>The requirement to have a maintenance contract is found in the Code of Virginia and has been in this regulation since 1992. However, the regulation has been modified to allow more flexibility in how an owner contracts with an operator and submittal of the contract itself is no longer required. That flexibility should help reduce costs. Evidence of a contract is submission of required reports or, for new or transferred permits, the owner's</p>

	<p>detailed record of everything. The County Health Department comes once a year and also checks the system and he maintains copies of those records as well. He does not see why he must get a maintenance contract when operators charge \$250 to write a letter stating they will do maintenance on the system if called and told what the problem is, which he would do anyway. He will still have to do all of the regular maintenance on it, keep detailed records and pay out \$250 for the contract. No value in a contract. He lives within 1/2 mile of a sewer plant, but no lines on his side of the road. He cannot afford anymore additional costs. He is on a limited budget. Commenter provided additional letters he sent to Congressman Morgan and Delegate Kilgore to describe the same issues.</p>	<p>certification. The intention is that an owner would engage an operator to provide operation, maintenance, monitoring, and reporting of the system. The operator is the one licensed to perform routine operation and maintenance, monitor the system, and report the results to the agency. The agency has expanded the types of operators who can operate discharging systems, which will increase the population of operators available and should reduce costs.</p>
<p>Tim and Brenda Greene</p>	<p>The commenters have been maintaining their system for over 20 years and have been conscientious in maintaining the system. They contact a local company if they need help with maintenance or repairs. They are dismayed to learn that there may be changes in the law which would require them to purchase a maintenance contract in order to continue running their system. First, there are not many companies in the area who service these units. Second, they are still going to have to do the routine maintenance themselves. They will have to pay someone to inspect a couple of times a year but not receive any real service from the contract. The installers told them the contracts are essentially a payment to insure there is someone available to do repairs just in case which they already do now but only have to pay for actual services performed. The goal should be that when system owners whose monitoring doesn't meet criteria (possibly two times in a row) then they would have to purchase this</p>	<p>The requirement to have a maintenance contract is found in the Code of Virginia and has been in effect since 1992. The regulation was modified to allow more flexibility in how an owner contracts with an operator. Submission of the contract is no longer required. This flexibility should help reduce costs. Evidence of a contract is submission of required reports, or for new or transferred permits, the owner's signature on a certification statement. The intention is that an owner would engage an operator to provide operation, maintenance, monitoring, and reporting of the system. The operator is the one licensed to do routine operation and maintenance visits, monitor the system, and report the results to the agency. The agency has expanded the types of operators who can operate discharging systems. This change will increase the population of operators available, which should reduce costs. The Code of Virginia requires the agency to charge \$75 for department inspections. Annual inspections have been extremely useful in reducing public health threats. For those systems that are being operated, maintained, monitored, and reported properly, the regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years. In those cases, the department inspection frequency is reduced to</p>

	<p>service contract. Please do not punish owners who have continually had good inspections and never had problems. They want to run the system correctly and be good stewards of the environment. They object to making the cost of running the system so high that it is not affordable.</p>	<p>once every three years. The owner is still obligated to have the operator complete all required visits and testing in accordance with the regulation and their General Permit.</p>
<p>Stuart Mullins</p>	<p>The commenter is an owner who currently pays around \$500/year to maintain his ATU unit and have it tested. His contractor [operator] is licensed by the state and does an excellent job. He feels the \$75 charge for a VDH inspection is not fair since he is already paying for someone to maintain it. If VDH wants to inspect it, that is great. He respects the fact that VDH wants to ensure that diseases are not being spread. However, he already pays plenty to maintain his unit and this additional fee is a tax. He already pays taxes.</p> <p>Additional information relayed via email from Delegate Ogburn's office. In 2002, he installed a treatment unit as his land did not 'perc'. He contracted with a company to do routine maintenance, provide chlorine and dechlorination tablets, add bacteria, test the discharge, etc. The company that he uses, "does a wonderful job", and he pays around \$500 per year. A couple of years ago, he was surprised to receive a bill for \$75 from the County Health Dept. for inspection of his unit. He investigated and informed that this was a new requirement and that he would have to pay it once per year. He recognizes that \$75 is not an oppressive amount, but he thinks it is unfair especially since he uses a licensed firm to maintain his system and the licensed firm does a more thorough inspection than the health department.</p>	<p>The Code of Virginia requires the agency to charge \$75 for department inspections. Annual inspections have been extremely useful in reducing public health threats. For those systems that are being operated, maintained, monitored, and reported properly, the regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years. In those cases, the department inspection frequency is reduced to once every three years. The owner is still obligated to have an operator complete required visits and testing in accordance with the regulation and General Permit.</p>
<p>Penni Mullins</p>	<p>The Health Department should not be allowed to charge a fee to inspect a system when the owner is</p>	<p>The Code of Virginia requires the agency to charge \$75 for department inspections. Annual inspections have been extremely useful</p>

	<p>already paying a licensed contractor to maintain the unit.</p>	<p>reducing public health threats. For those systems that are being operated, maintained, monitored, and reported properly, the regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years. In those cases, the department inspection frequency is reduced to once every three years. The owner is still obligated to have an operator complete all required visits and testing in accordance with the regulation and General Permit.</p>
<p>Wendell Dingus</p>	<p>Mr. Dingus opposes the maintenance contract. There is no reason for it. The owner has to contract an authorized agency to test the system once a year, then the VDH comes and tests once a year. Why is this needed? Records are kept on the system to record chemical addition so why do you need the VDH inspection? No one wants to contaminate the streams, but EPA regulations are becoming too burdensome for ordinary folks to live with. Before adding more cost to the folks with alternative systems, how about spot checking traditional septic systems to see how long since they have been pumped and if they are working properly. If they do not operate properly, that sewage goes directly into the watershed untreated.</p>	<p>The requirement to have a maintenance contract is found in the Code of Virginia and has been in effect since 1992. The regulation was modified to allow more flexibility in how an owner contracts with an operator. Submission of the contract is no longer required. This flexibility should help reduce costs. Evidence of a contract is submission of required reports, or for new or transferred permits, the owner's certification. The intention is that an owner would engage an operator to provide operation, maintenance, monitoring, and reporting of the system. The operator is licensed to perform routine operation and maintenance visits, monitor the system, and report the results to the agency. The Code of Virginia requires the agency to charge \$75 for department inspections. Annual inspections have been extremely useful in reducing public health threats. For those systems that are being operated, maintained, monitored, and reported properly, the regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years. In those cases, the department inspection frequency is reduced to once every three years. The owner is still obligated to have an operator complete required visits and testing in accordance with the regulation and General Permit.</p>
<p>Regulator (1)</p>	<p>The commenter agrees with those who oppose the \$75 annual inspection fee that VDH charges. He/she believes the annual visit by VDH should be optional, not mandatory. This would be more consistent with the onsite sewage system program requirements under the AOSS Regulations. This program has been turned over to the private sector. Let them have it.</p>	<p>The Code of Virginia requires the Agency to charge \$75 for required department inspections. Annual inspections have been extremely useful in reducing public health threats. The regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years.</p>

<p>Regulator (2)</p>	<p>Alternative Discharging systems that are not operated properly can and do pose a greater risk to public health and the environment since they discharge sewage effluent directly to the surface of state waters and drainways leading to state waters. Humans, pets, insects, etc. can be exposed to this effluent so assurance that these systems are operated and maintained properly is critical. VDH is charged with protecting public health and the environment and does so by inspecting and assuring these systems are in compliance with minimum regulatory requirements, by conducting at least an annual inspection with follow-up inspections when necessary, and by evaluating operation and testing data submitted by operators. The commenter notes that § 32.1-164.E. of the Code of Virginia requires VDH to charge a \$75 fee for an inspection but is out dated and should be rescinded. Legislators amended the Code of Virginia to require civil penalties for violations to VDH's regulations which states: § 32.1-164.E J. <i>"The Board shall establish a uniform schedule of civil penalties for violations of regulations promulgated pursuant to subsection B that are not remedied within 30 days after service of notice from the Department..."</i> Homeowners who operate and maintain their systems in compliance should not be charged fee for an inspection and those who fail to do so should be dealt with in accordance with the law.</p>	<p>Department inspections have been extremely useful in protecting public health. The Code requires the agency to charge \$75 fee for such an inspection. The fees offset the cost to the local health department for conducting the inspections. The fees collected from civil penalties go to a different fund and are not available to offset the cost of the program. The regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years.</p>
<p>Peter Brooks</p>	<p>This program, based on his experience, allowed poor people or people with family owned land with poor soils or oftentimes both, to live on the property which is a good thing. He has also observed few well maintained systems, with disinfection in particular neglected. Lack of o+m [operation and maintenance] is due, in his</p>	<p>The Code of Virginia requires the agency to charge \$75 for department inspections. Annual inspections have been extremely useful in reducing public health threats. For those systems that are being operated, maintained, monitored, and reported properly, the regulation was modified to allow a reduction in department inspections when a system has been in compliance for three consecutive years. The owner must have an operator</p>

	<p>opinion, to two reasons: the owner is not held accountable for compliance with effluent limits and limited dollars to spend on operation and maintenance. Assurance that systems are operating properly must be required or significant public health problems will occur. He suggests VDH allocate resources to local health departments to perform inspection services to make owners accountable for their systems. When problems are observed, VDH will have an opportunity to educate the homeowner on the need to properly operate the system, assist him/her to locate an operator and alternative funding sources for low income owners.</p>	<p>complete required visits and testing in accordance with the regulation and General Permit. Any eligible owner may apply for a waiver to the fee. There is currently no funding source to help with routine operation and maintenance of a system.</p>
Bill Sledjeski	<p>12VAC5-640-20, Add licensed soil scientist as equivalent profession to conduct onsite evaluations. New wording would be "<u>or a licensed onsite soil evaluator, licensed soil scientist or professional engineer</u>"</p>	<p>The correct section reference is 30.D. The agency recognizes that the Department of Professional and Occupational Regulation (DPOR) licenses professionals and determines responsibilities for regulants. The regulation was modified to read that any person licensed in Virginia to evaluate and design onsite systems could submit an evaluation of a site. Licensed soil scientists are not eligible to design onsite systems at this time.</p>

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
10	10	Authority for Regulations.	VDH amended this section to clarify that the flows for these systems are calculated on a monthly, not yearly average.
20	20	Purpose of Regulations.	Stylistic changes made.
30	30	Scope of Regulations. The chapter applies to all discharge systems constructed and operated to serve individual single family homes with flows less than or equal to 1000 gallons per day. Location criteria do not	Amendments made to clarify flow calculation (monthly not yearly), to make sure other regulatory sections are cross-referenced correctly and to clarify the effective date of the applicability of the location criteria contained in this chapter. VDH clarified that those owners who were

		<p>apply to systems installed prior to this chapter. A permit under this chapter will only be issued when no onsite options are available.</p>	<p>permitted prior to July 30, 1992, by DEQ that are exempted from the maintenance requirements are still required to collect and report the annual monitoring data required by the General Permit.</p> <p>VDH also amended this section to establish the requirement for owners to have an operation and maintenance manual; this requirement is to help ensure that these systems are being operated and maintained so as to preclude system failure. However, out of fairness to current system owners, the requirements will not be applied retroactively.</p> <p>VDH amended the requirement that onsite options must be evaluated and found unsatisfactory before a discharge option is to be considered so as to extend the evaluation to reduced footprint options available under 12VAC5-613-10 et seq. The rationale for the change is that more onsite options have become available since the effective date of this regulation.</p> <p>In addition, the amendments clarify that the performance requirements and horizontal setbacks in this chapter also apply to designs submitted under §32.1-163.6 of the Code of Virginia.</p> <p>In response to public comments, a clarification was made that any person licensed in Virginia to evaluate and design onsite systems could submit an evaluation of a site.</p>
40	40	<p>Establishes that this chapter is supplemental to Sewage Handling and Disposal Regulations.</p>	<p>Stylistic amendment.</p>
50	Repealed	<p>Established that this chapter relies on the Sewage Collection and Treatment Regulations for design criteria</p>	<p>Repealed as the pertinent sections were added to this regulation.</p>
60	60	<p>Establishes that this chapter is supplemental to the State Water Control Board's VPDES Regulations.</p>	<p>Amended to clarify that the flows for these systems are calculated on a monthly, not yearly average.</p>
70	70	<p>Establishes the relationship to the uniform building code.</p>	<p>Stylistic amendment.</p>
80	80	<p>Establishes the administration of this chapter and delegations of authority.</p>	<p>The Commissioner may delegate certain authority. Stylistic edits and cross-reference changes to this section were made.</p>

100	05	Definitions.	<p>Definitions for “aerobic treatment unit,” “intermittent sand filter system,” “generic system design,” “proprietary system design,” “onsite sewage disposal,” “pump and haul,” and “recirculating sand media filter system” were deleted because these terms are obsolete and unnecessary. Definitions for “alternative onsite sewage treatment system” and “conventional onsite sewage system” were added. Definition of “Five day biochemical oxygen demand” was changed to make it consistent with 12VAC5-613-10. Definitions of “Board,” “Division,” and “Department” were added. Definition of “reliability” and three reliability classes were added. The definitions achieve consistency with 9VAC25-790. A definition of “combined application” was added for the application process. Definitions of “dechlorination,” “biological treatment unit,” “disinfection unit,” “post aeration unit,” “post filtration unit,” “treatment system,” “TL-2 effluent,” and “TL-3 effluent” were added. Definitions of “operate,” “operation,” “maintenance,” and “modify” were added. A definition of “point source discharge” was added to parallel the definition in the Clean Water Act.</p> <p>Definitions of “family” and “income” were removed because they will be addressed by 12VAC5-620-10. The definition of “failing onsite sewage disposal system” was changed to make it consistent with 12VAC5-610-20. The definition of “failing alternative discharge treatment system” was changed. A definition of “emergency pump and haul” was added. The definition of “pump and haul” was deleted. Emergency pump and haul is specifically used in this regulation alone and has not been previously defined. The definition of “owner” was changed to parallel the definition found in Va. Code §32.1-163. The definitions of “NPDES” and “VPDES” were added to clarify this regulation’s relationship to the Clean Water Act and the State Water Control Board’s regulations. A definition of “surface waters” was added to parallel 9VAC25-31-10. A definition of “wetlands” was added to parallel the definition found in Va. Code §62.1-44.3. Definitions of “sewer,” “subsurface soil absorption,” and “subdivision” were deleted</p>
-----	----	--------------	--

			because there is no statutory or regulatory basis for defining these terms. The definition of “dry ditch” was changed to make it more easily understood. A definition of “operation and maintenance contract” was added to address public comments.
110	110	Establishes compliance with the Administrative Process Act.	This section was changed to be consistent with the Administrative Process Act (APA).
120	120	No change.	No change.
130	None	Established the effective date of the original regulation.	Deleted this section because it is no longer necessary.
140	140	Emergency Orders	Section references were modified to reflect changes in section 150.
150	150	Sets duties and powers of the Commissioner or VDH pertaining to enforcing this chapter.	Amended subsection A to reconcile its content with the APA and the definition of a “case decision” found in §2.2-4001 of the Code. The APA requires that agencies decide cases through informal conference or consultation proceedings, and this subsection, as previously written, was inconsistent with the APA because it purported to authorize the issuance of a “case decision” prior to an informal conference or consultation proceeding. Subsections C through F were deleted as they overlapped and were redundant with Va. Code §32.1.
160	160	No changes proposed.	
170	170	Establishes the requirements for an applicant to obtain a variance and for the Commissioner to grant a variance.	Stylistic changes. Deleted references to a “hearing” when the agency is intending to refer to an informal conference or consultation proceeding pursuant to the APA and Va. Code §2.2-4019. The term “hearing” denotes a legal adjudicatory proceeding, while the APA contemplates informal proceeding. Deleted the requirement for the Commissioner to act on a variance within 60 days of receipt. The rationale is that the Commissioner, in many instances, does not need to act (i.e. grant or deny) a variance as there may be other viable regulatory options available to the applicant that would resolve the matter and would obviate the need for a variance.
180	180	Establishes proceeding and hearing types.	Amended this section to delete many extraneous provisions that either overlapped or conflicted with the APA.
190	None	Request for hearing.	Deleted this section because it is not enforceable. The APA prohibits VDH from denying a hearing request because it was sent to the wrong address; therefore, such a requirement is not enforceable and should not be in regulation.

200	None	Hearing as a matter of right.	Deleted this section because it was inconsistent with the APA.
210	210	Establishes timelines for requesting appeals.	Amended this section to make timelines equal and consistent.
220	220	Establishes the basic need for construction and operation permits and sets conditions for validity.	Stylistic amendments were made for readability and clarity. The construction permit is now valid for up to 60 months instead of 54 months so that it has the same lifespan as the General Permit. Added a one-time renewal option for construction permits of 18 months under certain conditions. This section was modified to state that the operation permit would be renewed if evidence of proper operation and maintenance was received through reporting, and the system was in compliance. This section was amended to allow for the transfer of construction and operation permits under certain conditions. Clarified that the expiration date of a construction or operation permit was unchanged when such a permit is transferred to a new owner.
230	230	The current regulation combined the process for applying for a General Permit with the process of applying for a construction permit. This section also outlined how fees and fee waivers are handled.	The application for a General Permit using the Combined Application was split from the application for a construction permit. This section now only addresses applying for the General Permit with the Combined Application which will clarify the process for the public. Modifications were made to recognize that either VDH or a consultant could conduct the site evaluation for a suitable discharge point. Additional submittal requirements for proposed discharges to wetlands were added. All references to fees and fee waivers were struck as VDH has a separate regulation that addresses fees.
240	240	This section sets the minimum requirements for what must be submitted for receipt of a construction permit.	This section was clarified by adding in detail on what constitutes a proper construction application from the Sewage Handling and Disposal Regulations. Additional submittal requirements for proposed discharges to wetlands were added. Section references were corrected.
250	250	Describes that a construction permit shall be issued when this requirements of this section are met.	Section references were modified to match the general approval process. Minor stylistic edits were made.
260	260	Sites with failing onsite sewage disposal systems that do not meet the siting requirements of this regulation may have those	The section was modified to reflect reference section changes. Adds a requirement that waivers must be requested in writing and that VDH will issue the waiver in writing.

		requirements waived.	
300	262	Sets requirements for a contractor to submit a statement of completion at the end of construction.	This section was moved for clarity. It also added a requirement for an engineer's statement of completion and for the submittal of as-built drawings, if any changes were made during construction. 262.B. incorporates old section 310 which cautions that a system cannot be put into operation except for the purposes of testing without an operation permit.
None	264	None	An operation and maintenance manual has been added for new systems being constructed. This section outlines the basic information that is required. The changes provide consistency with 12VAC5-613.
320	266	Sets the standard for issuing the operation permit as receipt of the contractor's completion statement, maintenance/monitoring contract, and VDH inspection. Also addressed fees for inspections	The new section was relocated for clarity and includes requirements for the operation and maintenance manual; the engineer's completion statement; and as-built drawings. The requirement to submit maintenance and monitoring contracts was deleted due to public comment.
270	270	Sets the requirements for when a construction or operation permit can be denied.	Modified the section for compliance with the APA. Made changes to section references. In response to public comment, the section was modified to eliminate the reference to submittal of a contract. A certification statement from the owner was added to the Combined Application and the Transfer of Ownership
280	280	Sets standards for when a construction or operation permit can be suspended or revoked.	Changes were made to be consistent with the APA. In response to public comments and the removal of the requirement to submit contracts to VDH, failure to submit a contract was deleted as a reason for permit revocation.
290	290	Voidance of construction permits.	Edits made to comply with APA. A construction permit is valid 60 months.
300		See discussion for new Section 266 (old Section 320).	See discussion for Section 266 (old Section 320).
310	None	Requires VDH to inspect a system prior to issuing an operation permit.	This section was repealed as its components were rolled into new Sections 266 and 262.
320		See above under new Section 266.	Repealed. See new Section 266.
330	None	Sets conditions under which VDH may suspend an operation permit.	Repealed as VDH can revoke, but cannot suspend a permit.
340	None	Sets conditions under which VDH may reinstate an operation permit.	Repealed as VDH cannot reinstate an operation permit; VDH can only issue an operation permit.

350	None	Described a process for approval of treatment units that included progressively moving a design through 3 levels of testing. Each level of testing required numerous system installations and took over 5 years to complete.	This section was repealed as VDH has not been implementing this process. Section 432 describes the new process for considering a system generally approved, which is consistent with 12VAC5-613.
360	None	Registration requirements for a product design with VDH	Repealed. No longer needed.
370	None	Described submission of plans for 3 types of treatment units.	Repealed. No longer needed.
380	None	Describes how a product approval achieved under section 350 could be rescinded.	Repealed. No longer needed.
390	390	No change.	No change.
400	400	Identified all weather streams, intermittent streams, and dry ditches as appropriate discharge points and conditions under which they may be used.	Stylistic edits were made for clarity. The intermittent stream/dry ditch requirements were changed to eliminate the maximum slope requirement for the discharge channel, but added a requirement to protect the channel from erosion. Also it was recognized that engineered channels have been used to extend natural swales and drainage ways to improve the discharge channel. Wetlands have been added as a potential discharge point, but a wetlands delineation must be completed and submitted to confirm the presence of wetlands.
410	410	No change.	No change.
420	420	Prohibited discharges within one mile upstream of a drinking water intake and designated swimming areas; set a public notice/comment procedure for VDH to prohibit discharges to certain stream segments; established setback distances to wells, cisterns, limestone outcrops, sinkholes, springs, proximity to other discharge points,	The section was modified for clarity and identifies existing prohibitions; added an option for a VDH health director to increase the treatment level and reliability class if needed for public health protection; established setbacks for the treatment components (tanks, etc.) from wells and cisterns; establishes new setbacks for wetland discharges; adds a recognition that setback distances to other wells (i.e. gas, geothermal) will be established on a case by case basis; modifies the setbacks to sinkholes and limestone outcrops to be less stringent; clarifies the conditions under which the distance between discharges can be reduced for various categories of discharge points; and modified the distance from a Class IV well to the downstream channel of a discharge to be consistent with Class IIIC wells because the risk of contamination is the same.

430	430	Set the basic performance requirements equal to the General Permit.	Modified this section to recognize that the construction and operation standards in this regulation must be met and maintained.
None	432	None.	This section replaces old section 350 and represents the current VDH method for approving treatment unit technology. Additionally, it recognizes that all of the discharging systems are composed of additional treatment components such as disinfection and post aeration. This section establishes methods/procedures by which VDH will consider the whole system generally approved.
None	434	None.	A new concept of reliability was added to address implied levels of reliability for various discharge points that were found in old Table 3.2.
440	440	Special factors that affect design are discussed. Homes that have intermittent usage (less than three months) are prohibited from having a discharge permit. Other factors discussed include flow, organic loading, erosion, and restricted access.	Modified this section to remove the prohibition for a discharge permit on homes with intermittent/seasonal use. Recognizes that intermittent use can be successful if appropriate measures are taken. The specific requirement to record permits with conditional flows was deleted as now all permits will be recorded under section 266. Other minor clarifications were made.
450	450	Requires restricted access for dry ditches and intermittent stream discharge points with easements. Also sets treatment design requirements for these types of discharge points.	Restricted access and easement requirements were added for wetland discharge points. Table 3.2 was modified to reflect a performance standard for the treatment required. Reliability classification (I or II) is being used along with TL-3 to attain a similar level of public health protection.
460	460	Set the design standards for chlorine disinfection and recognized that other methods may be used if approved by VDH.	Design standards from 9VAC25-790 were added to this section to incorporate the more complete design standards for chlorine disinfection, dechlorination, ultraviolet disinfection, post aeration, and post-filtration. Constructed wetlands requirements were adopted from other agency policies.
470	470	Identifies numerous basic construction requirements for discharging systems	Stylistic edits were made; clarified sampling port requirements, and added a requirement to post a permanent sign at the discharge point. Modified signage requirements to reflect an operator rather than a maintenance provider in Section 470M.
480	480	Required VDH to inspect the site and for the engineer to inspect and note any comments/concerns	Repealed and combined into Sections 262 and 266.

490	490	<p>Required homeowners to sample treatment systems (up to quarterly) in excess of the General Permit requirements based on the classification of the system. Also provided for up to monthly visits with informal testing depending on the classification of the system. Allows homeowners to collect their own samples with approval from VDH.</p>	<p>Revised to reflect two categories of systems only: generally approved or not generally approved. If generally approved, then there is a startup sample. If acceptable from testing, then sampling frequency is changed to annual sampling, with two maintenance visits per year at a minimum. If not generally approved, four quarterly samples are required to demonstrate the system can comply with the general permit. If satisfactory, then reverts to same as generally approved. Informal tests (Table 3.3) have been modified to be more system specific and also reference the required operation and maintenance manual. Clarified that when VDH inspects a system, it may or may not collect informal or formal samples. The waiver to allow homeowners to collect their own samples has been deleted. Existing waivers will be recognized, but no new waivers will be issued. In response to public comment, VDH reduced department inspections to once every three years if the system is in compliance for three consecutive years. Section 490G was deleted and the pertinent sections regarding monitoring contract waivers were moved to 500A. This change was based on the modification to merge the operation and maintenance contracts into one document.</p>
500	500	<p>Sets the standards for the maintenance contract and states that only a Class IV wastewater works operator may provide maintenance</p>	<p>In response to public comments, this section was modified to reflect that an owner engages an operator and does not need to submit a contract. Specific maintenance contract items were eliminated and replaced with owner and operator expectations. The individuals who can provide maintenance have been expanded to include any wastewater works operator (Class IV or higher) and Alternative Onsite Sewage System Operators (AOSS) operators.</p>
510	510	<p>Requires owners to submit the results of all testing and activities to VDH.</p>	<p>Modified to require electronic reporting by the 15th of the month following the month in which the activity occurred to be consistent with 12VAC5-613.</p>
520	520	<p>Identifies that failure to conduct or report monitoring results can result in suspension or revocation of the operation permit.</p>	<p>Modified this section to remove suspension from the options and leave just revocation. It also states that VDH will notify DEQ of the revocation of the operation permit.</p>

Project 2735 - Proposed

DEPARTMENT OF HEALTH

Amend Alternative Discharging Sewage Treatment Regulations for Single Family Home Dwellings

Part I

General Provisions

12VAC5-640-5. Definitions.

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

"Agent" means a legally authorized representative of the owner.

"All weather stream" means any stream that will, at all times, dilute point source discharge effluent from a pipe at least 10:1 as measured during a seven consecutive day average of a 10-year low flow (7-Q-10).

"Alternative discharging sewage treatment system" or "discharging system" means any device or system that results in a point source discharge of treated sewage for which the board may issue a permit authorizing construction and operation when such system is regulated by the SWCB pursuant to a general VPDES permit issued for an individual single family dwelling with flows less than or equal to 1,000 gallons per day on a monthly average.

"Alternative onsite sewage treatment system" means a treatment works that is not a conventional onsite sewage system and does not result in a point source discharge.

"Biochemical oxygen demand, five day" or "BOD₅" means the quantitative measure of the amount of oxygen consumed by bacteria while stabilizing, digesting, or treating biodegradable organic matter under aerobic conditions over a five-day incubation period; BOD₅ is expressed in milligrams per liter (mg/l).

"Biological treatment unit" means a method, technique, equipment, or process other than a septic tank or septic tanks that uses biological organisms to treat sewage to produce effluent of a specified quality.

"Board" means the State Board of Health.

"Combined Application" means a Virginia Department of Health Discharging System Application Form for Single Family Dwellings Discharging Sewage Less Than or Equal to 1,000 Gallons Per Day and a 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.

"Commissioner" means the State Health Commissioner or his subordinate who has been delegated powers in accordance with subdivision 2 of 12VAC5-640-80.

"Conventional onsite sewage system" means a treatment works consisting of one or more septic tanks with gravity, pumped, or siphoned conveyance to a gravity distributed subsurface drainfield.

"Dechlorination" means a process that neutralizes chlorine in the final effluent.

"Department" means the district or local health department with jurisdiction over the site or proposed site of the alternative discharging sewage treatment system.

"Disinfection" means a process used to destroy or inactivate pathogenic microorganisms in wastewater to render them noninfectious.

"Disinfection unit" means a separate treatment component that disinfects wastewater.

"District health department" means a consolidation of local health departments as authorized in § 32.1-31 C of the Code of Virginia.

"Division" means the Division of Onsite Sewage, Water Services, Environmental Engineering, and Marina Programs.

"Dry ditch" means a naturally occurring swale or channel that is topographically connected to an all weather stream. In some cases, a dry ditch may have a manmade component that provides a topographical connection to an existing, naturally occurring swale or channel. A dry ditch may have observable flow during or immediately after a storm event or snow melt. For the purposes of this chapter, all dry ditches shall have a well defined natural channel with sides that have at least a 1:10 (rise:run) slope.

"Emergency pump and haul" means an emergency condition to pump out the treatment systems tanks by a licensed sewage handler as needed to not allow a discharge to protect public health and the environment.

"Failing alternative discharging sewage treatment system" means any alternative discharging sewage treatment system that discharges effluent having a BOD₅, total suspended solids, pH, chlorine residual, dissolved oxygen, or bacteria value that is out of compliance with the General Permit or fails to comply with 12VAC5-640-430. The failure to discharge due to exfiltration may indicate system failure.

"Failing onsite sewage disposal system" means an onsite sewage disposal system where the presence of raw or partially treated sewage on the ground's surface or in adjacent ditches or waterways or exposure to insects, animals, or humans is prima facie evidence of a system failure. Pollution of the groundwater or backup of sewage into plumbing fixtures may also indicate system failure.

"General approval" means that a treatment unit has been evaluated and approved for TL-2 effluent or TL-3 effluent in accordance with the requirements of this chapter and 12VAC5-610.

"General Permit" means a Virginia Pollutant Discharge Elimination System (VPDES) General Permit for domestic sewage discharges less than or equal to 1,000 gallons per day on a monthly average issued by the State Water Control Board.

"Intermittent stream" means any stream that will not, at all times, dilute point source discharge effluent at least 10:1 as measured during a seven consecutive day average of a 10-year low flow (7-Q-10). For the purposes of this section, an intermittent stream is identified as a dashed or dotted line on a U.S. Geological Survey 7.5 minute topographic map or an all weather stream that provides less than 10:1 dilution of the effluent based on 7-Q-10 flow.

"Local health department" means the department established in each city and county in accordance with § 32.1-30 of the Code of Virginia.

"Maintenance" means performing adjustments to equipment and controls and in-kind replacement of normal wear and tear parts such as light bulbs, fuses, filters, pumps, motors, or other like components. Maintenance includes pumping the tanks or cleaning the building sewer on a periodic basis.

"Modify" means to alter a treatment works, excluding actions taken to "operate" the treatment works and "maintenance" activities as those terms are defined in § 32.1-163 of the Code of Virginia.

"National Pollutant Discharge Elimination System" or "NPDES" means the national program for (i) issuing, modifying, revoking and reissuing, terminating, monitoring, and enforcing permits and (ii) imposing and enforcing pretreatment requirements under §§ 307, 402, 318, and 405 of the Clean Water Act (§ 33 USC § 1251 et seq.). The term includes an approved program.

"Operate" means the act of making a decision on one's own volition to (i) place into or take out of service a unit process or unit processes or (ii) make or cause adjustments in the operation of a unit process at a treatment works.

"Operation" means the biological, chemical, and mechanical processes of transforming sewage or wastewater to compounds or elements and water that no longer possess an adverse environmental or health impact.

["Operation and maintenance contract" means an agreement between an owner and licensed operator that the operator will provide services to operate, maintain, monitor, repair, and report on the treatment system in accordance with this regulation.]

"Owner" means the Commonwealth or any of its political subdivisions, including sanitary districts, sanitation district commissions and authorities, or any individual, any group of individuals acting individually or as a group, or any public or private institution, corporation, company, partnership, firm, or association that owns or proposes to own a sewerage system or treatment works.

"Person" means any and all persons, including individuals, firms, partnerships, associations, public or private institutions, municipalities or political subdivisions, governmental agencies, or private or public corporations organized under the law of this Commonwealth or any other state or country.

"Point source discharge" means any discernible, confined, and discrete conveyance including, but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, landfill leachate collection system, vessel, or other floating craft from which pollutants are or may be discharged. This term does not include return flows from irrigated agriculture or agricultural stormwater run-off.

"Post-aeration unit" means a treatment component that is designed to add oxygen to an effluent.

"Post-filtration unit" means a treatment component that physically removes total suspended solids.

"Reliability" means a measure of the ability of a component or system to perform its designated function without failure or interruption of service. Overflow criteria, such as an allowable period of a noncompliant discharge, are utilized solely for the establishment of reliability classification for design purposes and are not to be construed as authorization for, or defense of, an unpermitted discharge to state waters. The reliability classification shall be based on the water quality and public health and welfare consequences of a component or system failure.

"Reliability Class I" means a measure of reliability that requires a treatment system design to provide continuous satisfactory operation during power failures, flooding, peak loads, equipment failure, and maintenance shut-down. For the purposes of this chapter, continuous operability shall be defined as restoring proper operation or otherwise eliminating the out-of-compliance discharge within 24 hours. This class includes design features, such as additional electrical power sources, additional flow storage capacity, and additional treatment units that provide operation in accordance with the issued permit requirements.

"Reliability Class II" means a measure of reliability that requires a treatment design that limits out-of-compliance discharges due to power failures, flooding, peak loads, equipment failure, and maintenance shut-down to less than 36 hours. This class includes design features such as alarms with telemetry to the operator, additional treatment units, or additional flow storage capacity that provide operation in accordance with the issued permit requirements.

"Reliability Class III" means a measure of reliability that requires a treatment design that limits out-of-compliance discharges due to power failures, flooding, peak loads, equipment

failure, and maintenance shut-down to less than 48 hours. This class includes design features such as onsite alarms and owner initiated operator notification to address the alarm condition to provide operation in accordance with the issued permit requirements.

"Sanitary survey" means an investigation of any condition that may affect public health.

"Sewage" means water carried and nonwater carried human excrement, kitchen, laundry, shower, bath, or lavatory wastes separately or together with such underground, surface, storm, and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments, or other places.

"Site sketch" means a scale drawing of a proposed site for a discharge system, with pertinent distances shown. The scale shall typically be 1" = 50' for lots of three acres or less and 1" = 100' for larger lots. Site sketches may be made by the homeowner or any agent for the homeowner.

"Surface waters" means:

1. All waters that are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters that are subject to the ebb and flow of the tide;

2. All interstate waters, including interstate wetlands;

3. All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sandflats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds and the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

a. That are or could be used by interstate or foreign travelers for recreational or other purposes;

b. From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or

c. That are used or could be used for industrial purposes by industries in interstate commerce;

4. All impoundments of waters otherwise defined as surface waters under this definition;

5. Tributaries of waters identified in subdivisions 1 through 4 of this definition;

6. The territorial sea; and

7. Wetlands adjacent to waters, other than water that are themselves wetlands, identified in subdivisions 1 through 6 of this definition.

"SWCB" means the State Water Control Board and its designees.

["Total residual chlorine" or "TRC" means a measurement of the combined available chlorine and the free available chlorine available in a sample after a specified contact time.]

"Total suspended solids" or "TSS" means solids in effluent samples that can be removed readily by standard filtering procedures in a laboratory and expressed as mg/l.

"Treatment level 2 effluent" or "TL-2 effluent" means effluent that has been treated to produce BOD₅ and TSS concentrations less than or equal to 30 mg/l each.

"Treatment level 3 effluent" or "TL-3 effluent" means effluent that has been treated to produce BOD₅ and TSS concentrations less than or equal to 10 mg/l each.

"Treatment system" means the combination of treatment components that together produce the required quality of effluent.

"Variance" means a conditional waiver of a specific regulation that is granted to a specific owner relating to a specific situation or facility and may be for a specified time period.

"VPDES permit" means a Virginia Pollutant Discharge Elimination System permit issued by the SWCB under the authority of the federal NPDES program.

"Water well" or "well" means any artificial opening or artificially altered natural opening, however made, by which ground water is sought or through which ground water flows under natural pressure or is intended to be artificially drawn. This definition shall not include wells drilled for the following purposes: (i) exploration or production of oil or gas, (ii) building foundation investigation and construction, (iii) elevator shafts, (iv) grounding of electrical apparatus, or (v) the modification or development of springs.

"Wetlands" means those areas that are inundated or saturated by surface water 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. Wetlands generally include swamps, marshes, bogs, and similar areas.

Part I
General Framework for Regulations
Article 1
General Provisions

12VAC5-640-10. Authority for regulations. (Repealed.)

~~Title 32.1 of the Code of Virginia and specifically §§ 32.1-12, 32.1-163, and 32.1-164 provide that the State Board of Health, hereinafter referred to as the board, has the duty to protect the public health and the environment. In order to discharge this duty, the board is empowered to supervise and regulate the construction, location and operation of alternative discharging sewage treatment systems with flows less than or equal to 1,000 gallons per day on a yearly average for an individual single family dwelling within the Commonwealth when such a system is regulated by the Virginia State Water Control Board pursuant to a Virginia Pollutant Discharge Elimination System General Permit.~~

12VAC5-640-20. Purpose of regulations.

Title 32.1 of the Code of Virginia and specifically §§ 32.1-12, 32.1-163, and 32.1-164 of the Code of Virginia provide that the board has the duty to protect the public health and the environment. In order to discharge this duty, the board is empowered to supervise and regulate the construction, location, and operation of alternative discharging sewage treatment systems with flows less than or equal to 1,000 gallons per day on a monthly average for an individual single family dwelling within the Commonwealth when such a system is regulated by the Virginia State Water Control Board pursuant to a Virginia Pollutant Discharge Elimination System General Permit.

These regulations have been promulgated by the State Board of Health to:

1. Ensure that discharging systems are permitted, constructed, and operated in a manner which protects the environment and protects the public welfare, safety and health;
2. Guide the ~~State Health Commissioner~~ commissioner in his determination of whether a permit for construction and operation of a discharging system should be issued or denied;
3. Guide the owner or his agent in the requirements necessary to secure a permit for construction of a discharging system;
4. Guide the owner or his agent in the requirements necessary to secure an operation permit following construction;
5. Guide the owner or his agent in the requirements necessary to operate and maintain a discharging system;

6. Guide the ~~State Health Commissioner~~ commissioner in his determination of whether a discharging system is being operated in a manner which protects public health and the environment; and
7. Guide the ~~State Health Commissioner~~ commissioner in his determination of what actions are appropriate to correct violations of this chapter.

12VAC5-640-30. Scope of regulations.

A. ~~Systems served.~~ This chapter applies to all alternative discharging sewage treatment systems constructed and operated to serve an individual single family dwelling with flows less than or equal to 1,000 gallons per day on a ~~yearly~~ monthly average. This includes the following systems:

1. ~~New construction.~~ All new discharging systems described above when such ~~system is~~ systems are regulated by the State Water Control Board pursuant to a ~~Virginia Pollutant Discharge Elimination System~~ General Permit.
2. ~~Existing systems with individual VPDES permits.~~ All existing discharging sewage treatment systems, as described above, constructed prior to July 30, 1992, and ~~which were~~ permitted by the State Water Control Board under its individual VPDES permit program shall be governed by this chapter, except ~~as to~~ for the monitoring requirements noted below, effective upon the expiration date of their individual VPDES permit and approval of the owner's registration statement by the SWCB under the General Permit. Upon approval under the General Permit, the owners of such systems need only ~~to~~ comply with the monitoring requirements of the General Permit and the monitoring requirements in 12VAC5-640-510, and not 12VAC5-640-490 and 12VAC5-640-500, until (i) a change in ownership or (ii) the discharging system violates the effluent limitations of the General Permit for two consecutive quarters, whichever occurs first. After either event, the owner shall comply with 12VAC5-640-490 and 12VAC5-640-500.
3. ~~Existing systems without individual VPDES permits.~~ All existing discharging sewage treatment systems as described above ~~which that~~ were operating without a valid VPDES permit on July 30, 1992, shall be governed by this chapter after the owner receives registration statement approval from the SWCB under the General Permit.

B. ~~Upgrading of existing systems.~~ Location criteria contained in this chapter shall not apply to systems legally installed prior to ~~this chapter~~ July 30, 1992. When extensive repairs, modifications, or replacement are required to bring a system into compliance with the discharge requirements of the General Permit, a construction permit and temporary operation permit must be obtained by the system owner. The construction permit and temporary operation permit shall be valid for the time specified on its face, at which time the repairs, modifications, or replacement must be completed.

C. Requirements for an operation and maintenance manual contained in this chapter shall only apply to alternative discharging systems with construction applications filed on or after (insert the effective date of this chapter).

~~G. Evaluation of other options required.~~ D. The department will not [consider issuance of issue] a permit to construct a discharging system, unless all options for conventional and alternative onsite sewage treatment and disposal systems have been evaluated and found unsatisfactory in accordance with this section. For the purposes of this section, the consideration of all options include means site evaluation(s) conducted by [the department] and when appropriate, a report prepared by a person having a special knowledge of soil science as defined in § 54.1-2200 of the Code of Virginia and the methods and principles of soil evaluation as acquired by education or experience in the formation, description and mapping of soils [an individual licensed in Virginia to evaluate and design onsite sewage systems such as an or a licensed] onsite soil evaluator or professional engineer indicating that no sewage

disposal site exists on that property for the site and soil conditions allowed under the Sewage Handling and Disposal Regulations (12VAC5-610) or its successor including the use of TL-2 and TL-3 effluent to reduce footprint area as allowed under 12VAC5-613 or its successor. [All evaluations must be completed in accordance with the methods and requirements of 12VAC5-610 and 12VAC5-613.] ~~Options include a conventional onsite septic system using a pump, low pressure distribution (LPD), or an elevated sand mound or other systems which may be approved by the department under the Sewage Handling and Disposal Regulations, 12VAC5-600-10 et seq.~~

E. Pursuant to § 32.1-163.6 of the Code of Virginia, this chapter establishes performance requirements and horizontal setbacks for alternative discharging systems that are necessary to protect public health and the environment.

12VAC5-640-40. Relationship to the Virginia Sewage Handling and Disposal Regulations.

This chapter is supplemental to the Sewage Handling and Disposal Regulations (~~12VAC5-600-10 et seq.~~) which (12VAC5-610) or its successor that govern the treatment and disposal of sewage utilizing onsite systems. The Sewage Handling and Disposal Regulations shall govern the materials and construction practices used to install alternative discharging sewage treatment systems and all appurtenances associated with systems including but not limited to pipes and fittings whenever specifications are not contained in this chapter.

~~12VAC5-640-50. Relationship to the proposed Sewage Collection and Treatment Regulations. (Repealed.)~~

~~The proposed Sewage Collection and Treatment Regulations, upon final adoption, shall be used to establish design and construction criteria for systems, and portions of systems, not otherwise explicitly regulated within this chapter or the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq. Prior to the adoption of the Sewage Collection and Treatment Regulations, the Sewerage Regulations, 12VAC5-580-10 et seq., shall be used in their place.~~

12VAC5-640-60. Relationship to the State Water Control Board.

This chapter contains administrative procedures and construction, location, monitoring and maintenance requirements which are supplementary to the State Water Control Board's VPDES General Permit Regulation for domestic sewage discharges less than or equal to 1,000 gallons per day. This chapter applies only to individual single family dwellings with flows less than or equal to 1,000 gallons per day on a yearly monthly average registered under this General Permit. Single family dwellings are a subset of the systems regulated by the State Water Control Board under this General Permit.

12VAC5-640-70. Relationship to the Uniform Statewide Building Code.

This chapter is independent of, and in addition to, the requirements of the Uniform Statewide Building Code (13VAC5-63). All persons having obtained a construction permit under this chapter shall furnish a copy of the permit to the local building official, upon request, when making application for a building permit. Prior to obtaining an occupancy permit, an applicant shall furnish the local building official with a copy of the operation permit demonstrating the system has been inspected and approved by the ~~district or local health~~ department.

12VAC5-640-80. Administration of regulations.

This chapter is administered by the following:

1. The State Board of Health has the responsibility to promulgate, amend, and repeal regulations necessary to ensure the proper construction, location, and operation of alternative discharging systems.
2. ~~The State Health Commissioner, hereinafter referred to as the commissioner,~~ is the chief executive officer of the State Department of Health. The commissioner has the

authority to act, within the scope of regulations promulgated by the board, and for the board when it is not in session. The commissioner may delegate his powers under this chapter ~~in writing~~ to any subordinate, with the exception of (i) his power to issue variances under § 32.1-12 of the Code of Virginia and 12VAC5-640-170; and (ii) his power to issue orders under § 32.1-26 of the Code of Virginia and 12VAC5-640-140 and 12VAC5-640-150; ~~and (iii) the power to suspend or revoke construction and operation permits under 12VAC5-640-280, which may only be delegated pursuant to 12VAC5-640-330.~~ The commissioner has final authority to adjudicate contested case decisions of subordinates delegated powers under this section prior to appeal of such case decisions to the circuit court.

3. The State Department of Health, ~~hereinafter referred to as the department,~~ is designated as the primary agent of the commissioner for the purpose of administering this chapter.

4. The district or local health departments are responsible for implementing and enforcing the ~~regulatory activities required by~~ requirements of this chapter.

Article 2
Definitions

12VAC5-640-100. Definitions. (Repealed.)

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

"Aerobic treatment unit" or "ATU" means ~~any mechanical sewage treatment plant, designed to treat sewage from a single family dwelling utilizing the process of extended aeration with or without a means to return sludge to the aeration chamber.~~

~~"Agent" means a legally authorized representative of the owner.~~

~~"All weather stream" means any stream which will, at all times, dilute point source discharge effluent (from a pipe) at least 10:1 as measured during a 7 consecutive day average of a 10 year low flow (7-Q-10).~~

~~"Alternative discharging sewage treatment system" or "discharging system" means any device or system which results in a point source discharge of treated sewage for which the Department of Health may issue a permit authorizing construction and operation when such system is regulated by the SWCB pursuant to a general VPDES permit issued for an individual single family dwelling with flows less than or equal to 1,000 gallons per day on a yearly average. Such a system is designed to treat sewage from a residential source and dispose of the effluent by discharging it to an all weather stream, an intermittent stream, a dry ditch, or other location approved by the department.~~

~~"Commissioner" means the State Health Commissioner or his subordinate who has been delegated powers in accordance with 12VAC5-640-80-2 of this chapter.~~

~~"Disinfection" means the reduction of pathogenic organisms to a level that complies with the discharge limits of the general permit.~~

~~"District health department" means a consolidation of local health departments as authorized in § 32.1-31 C of the Code of Virginia.~~

~~"Division" means the Division of Sanitarian Services.~~

~~"Dry ditch" means a naturally occurring (i.e., not man made) swale or channel which ultimately leads to an all weather stream. A dry ditch may have observable flow during or immediately after a storm event or snow melt. For the purposes of this chapter all dry ditches shall have a well defined natural channel with sides that have at least a 1:10 (rise:run) slope.~~

~~"Family" means the economic unit which shall include the owner, the spouse of the owner, and any other person actually and properly dependent upon or contributing to the family's income for subsistence.~~

~~A husband and wife who have been separated and are not living together, and who are not dependent on each other for support, shall be considered separate family units.~~

~~The family unit which is based on cohabitation is considered to be a separate family unit for determining if an application fee is waiverable. The cohabitating partners and any children shall be considered a family unit.~~

~~"Failing alternative discharging sewage treatment system" means any alternative discharging sewage treatment system which either fails to discharge due to exfiltration or discharges effluent having a BOD₅, suspended solids, pH, chlorine residual, dissolved oxygen or fecal coliform greater than allowed by the General Permit as measured at the outfall. However, chlorine residual and dissolved oxygen content shall not be used for the purposes of determining whether a particular class of discharging systems complies with the requirements of 12VAC5-640-380.~~

~~"Failing onsite sewage disposal system" means an onsite sewage disposal system that is backing up in a house, or is discharging untreated or partially treated effluent on the ground surface, into surface waters, or into ground water.~~

~~"Five-day biochemical oxygen demand (BOD₅)" means the quantity of oxygen used in the biochemical oxidation of organic matter in five days at 20°C under specified conditions and expressed as milligrams per liter (mg/l).~~

~~"General Permit" means a Virginia Pollutant Discharge Elimination System ("VPDES") General Permit for domestic sewage discharges less than or equal to 1,000 gallons per day on a yearly average issued by the State Water Control Board.~~

~~"Generic system design" means nonsite specific plans and specifications for a system designed to treat sewage flows of 1,000 GPD or less, or an equivalent BOD₅ loading rate, which have been reviewed and approved by the division for uses governed by this chapter.~~

~~"Income" means total cash receipts of the family before taxes from all sources. These include money wages and salaries before any deductions, but do not include food or rent in lieu of wages. These receipts include not receipts from nonfarm or farm self-employment (e.g., receipts from own business or farm after deductions for business or farm expenses). They include regular payments from public assistance (including Supplemental Security Income), social security or railroad retirement, unemployment and worker's compensation, strike benefits from union funds, veterans' benefits, training stipends, alimony, child support, and military family allotments or other regular support from an absent family member or someone not living in the household; private pensions, government employee pensions, and regular insurance or annuity payment; and income from dividends, interest, rents, royalties, or periodic receipts from estates or trusts. These receipts further include funds obtained through college work study programs, scholarships, and grants to the extent said funds are used for current living costs. Income does not include the value of food stamps, WIC checks, fuel assistance, money borrowed, tax refunds, gifts, lump sum settlements, inheritances or insurance payments, withdrawal of bank deposits, earnings of minor children, or money received from the sale of property. Income also does not include funds derived from college work study programs, scholarships, loans, or grants to the extent such funds are not used for current living costs.~~

~~"Intermittent sand filter system" means a system designed to treat sewage by causing the sewage to be dosed through a properly designed bed of graded sand media.~~

~~"Intermittent stream" means any stream which cannot, at all times, dilute point source discharge effluent (from a pipe) at least 10:1 as measured during a 7 consecutive day average of a 10 year low flow (7-Q-10).~~

~~"Local health department" means the department established in each city and county in accordance with § 32.1-30 of the Code of Virginia.~~

~~"Onsite sewage disposal system" means a sewerage system or treatment works designed not to result in a point source discharge.~~

~~"Owner" means any person, who owns, leases, or proposes to own or lease an alternative discharging sewage treatment system.~~

~~"Person" means any and all persons, including individuals, firms, partnerships, associations, public or private institutions, municipalities or political subdivisions, governmental agencies, or private or public corporations organized under the law of this Commonwealth or any other state or country.~~

~~"Proprietary system design" means any group of discharging sewage treatment systems manufactured and installed following substantially similar engineering plans and specifications designed to treat a specific volume of sewage or BOD₅ loading rate as determined by the division.~~

~~"Pump and haul" means the temporary (less than one year) disposal of sewage conducted under a valid pump and haul permit issued in accordance with the Sewage Handling and Disposal Regulations.~~

~~"Recirculating sand filter system" means a system which treats sewage effluent by repeatedly passing the sewage through a pump chamber and sand filter to achieve alternating wetting and drying cycles.~~

~~"Sanitary survey" means an investigation of any condition that may effect public health.~~

~~"Settleable solids" means solids which settle after 30 minutes and expressed as milligrams per liter (mg/l).~~

~~"Sewage" means water carried and nonwater carried human excrement, kitchen, laundry, shower, bath, or lavatory wastes separately or together with such underground, surface, storm and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments or other places.~~

~~"Sewer" means any sanitary or combined sewer used to convey sewage or municipal or industrial wastes.~~

~~"Site sketch" means a scale drawing of a proposed site for a discharge system, with pertinent distances shown. The scale shall typically be 1" = 50' for lots of three acres or less and 1" = 100' for larger lots. Site sketches may be made by the homeowner or any agent for the homeowner.~~

~~"Subdivision" means multiple building lots derived from a parcel(s) of land in conformance with local zoning or subdivision requirements.~~

~~"Subsurface soil absorption" means a process which utilizes the soil to treat and dispose of sewage effluent.~~

~~"SWCB" means the State Water Control Board and its designees.~~

~~"Total suspended solids" means solids in effluent samples which can be removed readily by standard filtering procedures in a laboratory and expressed as mg/l.~~

~~"Variance" means a conditional waiver of a specific regulation which is granted to a specific owner relating to a specific situation or facility and may be for a specified time period.~~

~~"VPDES permit" means a Virginia Pollutant Discharge Elimination System permit issued by the SWCB under the authority of the federal NPDES program.~~

~~"Well" means any artificial opening or artificially altered natural opening, however made, by which ground water is sought or through which ground water flows under natural pressure or is intended to be artificially drawn; provided this definition shall not include wells drilled for the following purposes: (i) exploration or production of oil or gas, (ii) building foundation investigation and construction, (iii) elevator shafts, (iv) grounding of electrical apparatus, or (v) the modification or development of springs.~~

Part II
Procedural Regulations
Article 1
Procedures

12VAC5-640-110. Compliance with the Administrative Process Act.

The provisions of the Virginia Administrative Process Act (§ ~~9-6.14:1~~ 2.2-4000 et seq. of the Code of Virginia) shall govern the promulgation and administration of this chapter and shall be applicable to the appeal of any case decision based upon this chapter govern the procedures pertaining to the decisions of cases under this chapter.

12VAC5-640-130. Effective date of regulations. (Repealed.)

~~The effective date of these regulations is July 30, 1992. Those permits issued under the emergency regulation VR355-34-400 are hereby recognized as modified, valid and covered by these regulations.~~

12VAC5-640-140. Emergency order.

If an emergency exists the commissioner may issue an emergency order as is necessary for preservation of public health, safety, and welfare or to protect environmental resources. The emergency order shall state the reasons and precise factual basis upon which the emergency order is issued. The emergency order shall state the time period for which it is effective. Emergency orders will be publicized in a manner deemed appropriate by the commissioner. The provisions of 12VAC5-640-150 ~~C and D~~ shall not apply to emergency orders issued pursuant to this section.

12VAC5-640-150. Enforcement of regulations.

~~A. Notice. Subject to the exceptions below, whenever Whenever the commissioner or the district or local health department has reason to believe a violation of any of this chapter has occurred or is occurring, the alleged violator shall be notified. Such notice shall be made in writing, shall be delivered personally or sent by certified mail, shall cite the regulation or regulations that are allegedly being violated, shall state the facts which form the basis for believing the violation has occurred or is occurring, shall include a request for a specific action by the recipient by a specified time and shall state the penalties associated with such violation. notifies a named party of an alleged violation of this chapter, the procedures and content of such notice shall be as follows:~~

1. Any notice of alleged violation shall be made in writing and shall be delivered personally or sent by certified mail to the named party.
2. The notice shall cite the regulation or regulations that are applicable to the situation.
3. The notice shall state the factual basis for the issuance of the notice.
4. The notice shall include a request for a specific action by the recipient by a specified time.

5. The notice shall include information on the process for obtaining an informal fact finding conference to determine whether or not a violation has occurred.

The issuance of a notice of alleged violation by the commissioner or the department shall not be considered a case decision as defined in § 2.2-4001 of the Code of Virginia. When the commissioner deems it necessary, he may initiate criminal prosecution or seek civil relief through mandamus or injunction prior to giving notice.

~~B. Orders. Pursuant to the authority granted in § 32.1-26 of the Code of Virginia, the~~ The commissioner may issue orders in accordance with Title 32.1 (§ 32.1-1 et seq.) of the Code of Virginia to require any owner, or other person, to comply with the provisions of this chapter. The order shall be signed by the commissioner and may require:

1. The immediate cessation and correction of the violation;
2. Appropriate remedial action to ensure that the violation does not recur;
3. The submission of a plan to prevent future violation to the commissioner for review and approval;
4. The submission of an application for a variance; or
5. Any other corrective action deemed necessary for proper compliance with the chapter.

~~C. Hearing before the issuance of an order. Before the issuance of an order described in 12VAC5-640-150 B, a hearing must be held, with at least 30 days notice by certified mail to the affected owner or other person of the time, place and purpose thereof, for the purpose of adjudicating the alleged violation or violations of this chapter. The procedures at the hearing shall be in accordance with 12VAC5-640-180 A and B and with §§ 9-6.14:11 through 9-6.14:14 of the Code of Virginia.~~

~~D. Order – when effective. All orders issued pursuant to 12VAC5-640-150 B shall become effective not less than 15 days after mailing a copy thereof by certified mail to the last known address of the owner or person violating this chapter. Violation of an order is a Class 1 misdemeanor. See § 32.1-27 of the Code of Virginia.~~

~~E. Compliance with effective orders. The commissioner may enforce all orders. Should any owner or other person fail to comply with any order, the commissioner may:~~

1. Apply to an appropriate court for an injunction or other legal process to prevent or stop any practice in violation of the order;
2. Commence administrative proceedings to suspend or revoke the applicable permit;
3. Request the Attorney General to bring an action for civil penalty, injunction, or other appropriate remedy; or
4. Request the commonwealth attorney to bring a criminal action.

~~F. Not exclusive means of enforcement. Nothing contained in 12VAC5-640-140 or 12VAC5-640-150 shall be interpreted to require the commissioner to issue an order prior to commencing administrative proceedings or seeking enforcement of any regulations or statute through an injunction, mandamus or criminal prosecution.~~

12VAC5-640-170. Variances.

Only the commissioner or the deputy commissioners may grant a variance to this chapter. (See §§ 32.1-12 and 32.1-22 of the Code of Virginia and 12VAC5-640-80 2.) The commissioner or the deputy commissioners shall follow the appropriate procedures set forth in this subsection section in granting a variance.

~~A. Requirements for a variance. 1.~~ 1. The commissioner may grant a variance if a thorough investigation reveals that the hardship imposed by this chapter outweighs the benefits

that may be received by the public. Further, the granting of such a variance shall not subject the public to unreasonable health risks or jeopardize environmental resources.

~~B. Application for a variance. 2.~~ Any owner who seeks a variance shall apply in writing within the time period specified in 12VAC5-640-210 ~~B C~~. The application shall be signed by the owner, ~~addressed and sent to the commissioner at the State Department of Health in Richmond.~~ The application shall include:

1. ~~a.~~ A citation to the regulation from which a variance is requested;
2. ~~b.~~ The nature and duration of the variance requested;
3. ~~c.~~ Any relevant analytical results including results of relevant tests conducted pursuant to the requirements of this chapter;
4. ~~d.~~ Statements or evidence why the public health and welfare and environmental resources would not be degraded if the variance were granted;
5. ~~e.~~ Suggested conditions that might be imposed on the granting of a variance that would limit the detrimental impact on the public health and welfare or environmental resources;
6. ~~f.~~ Other information, if any, believed pertinent by the applicant; and
7. ~~g.~~ Such other information as the ~~district or local health~~ department or commissioner may require.

~~C. Evaluation of a variance application.~~

1. ~~The commissioner shall act on any variance request submitted pursuant to 12VAC5-640-170 B within 60 calendar days of receipt of the request.~~

2. ~~3.~~ In the evaluation of a variance application, the commissioner shall consider the following factors:

- a. The effect that such a variance would have on the construction, location, or operation of the discharging system;
- b. The cost and other economic considerations imposed by this requirement;
- c. The effect that such a variance would have on protection of the public health;
- d. The effect that such a variance would have on protection of environmental resources; and
- e. Such other factors as the commissioner may deem appropriate.

~~D. Disposition of a variance request. 4.~~ The commissioner may grant or deny a variance request in accordance with the requirements of this subdivision.

1. ~~a.~~ The commissioner may deny any application for a variance by sending a denial notice to the applicant by certified mail. The notice shall be in writing and shall state the reasons for the denial.

2. ~~b.~~ If the commissioner proposes to grant a variance request submitted pursuant to ~~12VAC5-640-170 B~~ subdivision 2 of this section, the applicant shall be notified in writing of this decision. Such notice shall identify the variance, and the discharging system covered, and shall specify the period of time for which the variance will be effective. The effective date of a variance shall be as stated in the variance.

3. ~~c.~~ No owner may challenge the terms or conditions set forth in the variance after 30 calendar days have elapsed from the effective date of the variance.

~~E. Posting of variances. 5.~~ All variances granted to any discharging sewage treatment system are transferable from owner to owner unless otherwise stated. Each variance shall be attached to the permit to which it is granted. Each variance is revoked when the permit to which it is attached is revoked.

~~F. Hearings on disposition of variances. 6. Subject to the time limitations specified in 12VAC5-640-210, informal conference or consultation proceedings or hearings on denials of an application for a variance or on challenges to the terms and conditions of a granted variance may be held pursuant to 12VAC5-640-180 A or B, except that informal hearings conference or consultation proceedings under 12VAC5-640-180 A shall be held before the commissioner or his designee.~~

12VAC5-640-180. Hearing types Informal conferences and hearings.

~~Hearings before the commissioner or the commissioner's designees shall include any of the following forms depending on the nature of the controversy and the interests of the parties involved.~~

~~A. Informal hearings. An informal hearing conference or consultation proceeding is a meeting with a district or local health department with the district or local health director presiding and held in conformance with § 9-6.14:14 2.2-4019 of the Code of Virginia. The department shall ascertain the fact basis for its decisions of cases through informal conference or consultation proceedings unless the named party and the department consent to waive such a conference or proceeding to go directly to a formal hearing. The district or local health department shall consider all evidence presented at the meeting which is relevant to the issue in controversy. Presentation of evidence, however, is entirely voluntary. The district or local health department shall have no subpoena power. No verbatim record need be taken at the informal hearing. The local or district health director shall review the facts presented and based on those facts render a decision. A written copy of the decision and the basis for the decision shall be sent to the appellant within 15 work days of the hearing, unless the parties mutually agree to a later date in order to allow the department to evaluate additional evidence. If the decision is adverse to the interests of the appellant, an aggrieved appellant may request an adjudicatory hearing pursuant to 12VAC5-640-180 B.~~

~~B. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory proceeding before the commissioner, or a designated hearing officer, and held in conformance with § 9-6.14:12 2.2-4020 of the Code of Virginia. The commissioner may afford opportunity for an adjudicatory hearing in any case to the extent that informal procedures under § 2.2-4019 and subsection A of this section have not been had or have failed to dispose of a case by consent. An adjudicatory hearing includes the following features:~~

- ~~1. Notice. Notice which states the time and place and the issues involved in the prospective hearing shall be sent to the owner or other person who is the subject of the hearing. Notice shall be sent by certified mail at least 15 calendar days before the hearing is to take place.~~
- ~~2. Record. A record of the hearing shall be made by a court reporter. A copy of the transcript of the hearing, if transcribed, will be provided within a reasonable time to any person upon written request and payment of the cost.~~
- ~~3. Evidence. All interested parties may attend the hearing and submit oral and documentary evidence and rebuttal proofs, expert or otherwise, that are material and relevant to the issues in controversy. The admissibility of evidence shall be determined in accordance with § 9-6.14:12 of the Code of Virginia.~~
- ~~4. Counsel. All parties may be accompanied by and represented by counsel and are entitled to conduct such cross-examination as may elicit a full and fair disclosure of the facts.~~
- ~~5. Subpoena. Pursuant to § 9-6.14:13 of the Code of Virginia, the commissioner or hearing officer may issue subpoenas on behalf of himself or any person or owner for the attendance of witnesses and the production of books, papers or maps. Failure to~~

~~appear or to testify or to produce documents without adequate excuse may be reported by the commissioner to the appropriate circuit court for enforcement.~~

~~6. Judgment and final order. The commissioner may designate a hearing officer or subordinate to conduct the hearing as provided in § 9-6.14:12 of the Code of Virginia, and to make written recommended findings of fact and conclusions of law to be submitted for review and final decision by the commissioner. The final decision of the commissioner shall be reduced to writing and will contain the explicit findings of fact upon which his decision is based. Certified copies of the decision shall be delivered to the owner affected by it. Notice of a decision will be served upon the parties and become a part of the record. Service may be by personal service or certified mail return receipt requested.~~

12VAC5-640-190. Request for hearing. (Repealed.)

~~A request for an informal hearing shall be made by sending the request in writing to the district or local health department. A request for an adjudicatory hearing shall be made in writing and directed to the commissioner at the State Department of Health in Richmond. Requests for hearings shall cite the reason(s) for the hearing request and shall cite the section(s) of this chapter involved.~~

12VAC5-640-200. Hearing as a matter of right. (Repealed.)

~~Except as provided in 12VAC5-640-330, any owner or other person whose rights, duties, or privileges have been, or may be affected by any decision of the board or its subordinates in the administration of this chapter shall have a right to both informal and adjudicatory hearings. The commissioner may require participation in an informal hearing before granting the request for a full adjudicatory hearing. Exception: No person other than an owner shall have the right to an adjudicatory hearing to challenge the issuance of either a construction permit or operation permit unless the person can demonstrate at an informal hearing that the minimum standards contained in this chapter have not been applied and that he will be injured in some manner by the issuance of the permit.~~

12VAC5-640-210. Appeals.

~~A. Any appeal from a denial of a construction or operation permit for a discharging system must be made in writing and received by the department within 60 30 days of the date of the denial.~~

~~A. B. Any request for hearing on appeal from the denial of an application for a variance pursuant to subdivision 4 a of 12VAC5-640-170 D-4 must be made in writing and received within 60 30 days of receipt of the denial notice.~~

~~B. C. Any request for a variance must be made in writing and received by the department prior to the denial of the discharging system permit, or within 60 30 days after such denial.~~

~~C. D. In the event a person applies for a variance within the 60-day 30-day period provided by subsection B above C of this section, the date for appealing the denial of the permit, pursuant to subsection A of this section, shall commence from the date on which the department acts on the request for a variance.~~

~~D. E. Pursuant to the Administrative Process Act (§ 9-6.14:1 2.2-4000 et seq. of the Code of Virginia) an aggrieved owner may appeal a final decision of the commissioner to an appropriate circuit court.~~

12VAC5-640-220. Permits; general.

~~A. Construction permit required. After July 30, 1992, no No person shall construct, alter, rehabilitate, modify, or extend a discharging system or allow the construction, alteration, rehabilitation, or extension of a discharging system, without a written construction permit from the commissioner or the department. Furthermore, except as provided in 12VAC5-640-30 A-2~~

~~and 12VAC5-640-220 B, no person or owner shall cause or permit any discharging system to be operated without a written operation permit issued by the commissioner which authorizes the operation of the discharging system. Conditions may be imposed on the issuance of any construction or operation permit and no discharging system shall be constructed or operated in violation of those conditions.~~

B. Except as provided in 12VAC5-640-30, 12VAC5-640-280, and 12VAC5-640-290, construction permits for a discharging system shall be deemed valid for a period of 60 months from the date of issuance or until the expiration of the General Permit, whichever comes first. [The permit to construct may be renewed one time for an additional 18 months if the building permit has been obtained or building construction commenced, the General Permit is reissued and the effluent requirements of the General Permit are unchanged.]

~~B. Operation permit required. C. Except as provided in 12VAC5-640-310 12VAC5-640-30 A 2 and 12VAC5-640-266, no person shall place a discharging system in operation, or cause or allow a discharging system to be placed in operation, without obtaining a written operation permit. Conditions may be imposed on the issuance of any operation permit, and no discharging system shall be operated in violation of those conditions.~~

~~C. Construction permits validity. Except as provided in 12VAC5-640-30, 12VAC5-640-280 and 12VAC5-640-290, construction permits for a discharging system with general or preliminary system approval shall be deemed valid for a period of 54 months from the date of issuance. Construction permits for discharging systems with experimental approval shall be valid for 30 days except as provided in 12VAC5-640-30, 12VAC5-640-280 and 12VAC5-640-290.~~

~~D. Operation permit validity. Except as provided for in 12VAC5-640-280 and 12VAC5-640-290, operation permits shall be valid for a period of time not longer than the General Permit [and the maintenance contract required pursuant to 12VAC5-640-500 B or the monitoring contract required pursuant to 12VAC5-640-490 F G, whichever expires first.] The operation permit may be renewed shall remain valid [upon written proof of a new or renewed maintenance contract or monitoring contract when continued reporting of operation, maintenance and monitoring occurs in accordance with 12VAC5-640-490, 12VAC5-640-500, and 12VAC5-640-510] provided they are all valid for not less than 24 months the facility is otherwise in compliance with this chapter. [The period of renewal shall coincide with the expiration date of the document with the shortest period of validity.]~~

~~E. Permits not transferable. Construction and operation permits for discharging systems shall not be transferable from one person to another or from one location to another. Each new owner shall make a written application for a permit. Application forms are available at all local health departments except as provided below:~~

1. A construction permit for a specific discharging system will be issued to a new owner if the new owner (i) applies for the permit transfer on a form approved by the department, (ii) pays the applicable fee, (iii) provides the department with change of ownership documentation in accordance with the General Permit, and (iv) provides written certification that there are no new site conditions that will adversely impact the existing approved construction permit and documents or the original construction application.

2. An operation permit for a specific discharging system will be issued to a new owner if the new owner (i) applies for the permit transfer on a form approved by the department, (ii) pays the applicable fee, [and] (iii) provides the department with change of ownership documentation in accordance with the General Permit [, and (iv) provides a copy of a valid maintenance and monitoring contract as required.

3. The expiration date of the transferred operation or construction permit shall not change.]

12VAC5-640-230. Procedures Application process for obtaining a construction permit Department of Environmental Quality General Permit using the Combined Application.

~~The process for obtaining a construction permit for a discharging system consists of two steps. These are filing an application with fee to determine the suitability of a site and filing plans for the type of system being proposed.~~

~~A. Application fees. A fee of \$50 shall be charged to the owner for filing an application for an alternative discharging sewage treatment system permit with the department. The fee shall be paid to the Virginia Department of Health by the owner or his agent at the time of filing the application and the application shall not be processed until the fee has been collected. Applications shall be limited to one site specific proposal. When site conditions change, or the needs of an applicant change, or the applicant proposes and requests another site be evaluated, and a new site evaluation is conducted, a new application and fee are required.~~

~~1. Waiver of fees. An owner whose income of his family is at or below the 1988 Poverty Income Guidelines For All States (Except Alaska and Hawaii) And The District of Columbia established by the Department of Health and Human Services, 53 FR 4213 (1988), or any successor guidelines, shall not be charged a fee for filing an application for an alternative discharging sewage treatment system permit.~~

~~2. Determining eligibility.~~

~~a. An owner seeking a waiver of an application fee shall request the waiver on the application form. The department will require information as to income, family size, financial status and other related data. The department shall not process the application until final resolution of the eligibility determination for waiver.~~

~~b. It is the owner's responsibility to furnish the department with the correct financial data in order to be appropriately classified according to income level and to determine eligibility for a waiver of an application fee. The owner shall be required to provide written verification of income such as check stubs, written letter from an employer, W-2 forms, etc., in order to provide documentation for the application.~~

~~c. The proof of income must reflect current income which is expected to be available during the next 12-month period. Proof of income must include: name of employer, amount of gross earnings, pay period for stated earnings. If no pay stub, a written statement must include the name, address, telephone number and title of person certifying the income.~~

~~A. The process for obtaining a General Permit consists of (i) filing a Combined Application with fee to determine the suitability of a discharge point, (ii) obtaining confirmation of a suitable discharge point from the department, and (iii) obtaining coverage under the Department of Environmental Quality's General Permit. Once a General Permit registration has been received, the owner shall file an application for a construction permit as described in 12VAC5-640-240 and shall apply for an operation permit in accordance with 12VAC5-640-266 before a discharge is authorized.~~

~~B. Written application required. Construction permits are issued by the authority of the commissioner. All requests for construction permits review of a suitable discharge point for discharging systems shall be by written application on the Combined Application, signed by the owner or his agent, and shall be directed to the district or local health department. All applications shall be made on the application form (Virginia Department of Health Discharging System Application Form for Single Family Dwellings Discharging Sewage Treatment Systems with Flows 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 Discharge Less Than or Equal to 1,000 Gallons Per Day).~~

C. ~~Application completeness.~~ An application shall be deemed complete upon receipt by the ~~district or local health~~ department of a signed and dated application, ~~together with~~ and the appropriate fee, containing the following information:

1. The property owner's name, address, and telephone number;
2. The applicant's name, address, and phone number (if different from subdivision 1 of this subsection);
3. A statement signed by the property owner, or his agent, granting the ~~Health Department~~ department access to the site for the purposes of evaluating the suitability of the site for a discharging system and allowing the department access to inspect the construction, maintenance and operation of the discharging system after it is installed. The applicant must secure and produce written permission for the department to enter on any property necessary to evaluate the application;
4. A site sketch on a survey plat showing the ~~location of existing or proposed houses, property boundaries, existing and proposed wells, actual or proposed discharging systems within 600 feet of the discharge point, recorded easements, the slope and side slope of any proposed dry ditch channels, setback distances of proposed system components (such as ATU's, sandfilters, and dry ditches) to property lines, wells and other discharging systems public water supply intakes, and swimming or recreational water use areas within five miles. The drawing should be approximately to scale (plus or minus 10%) or drawn on a United States Geological Survey 7.5 minute topographic map; locations of and setback distances from the proposed discharge point and discharging system components to the following:~~
 - a. Location of existing or proposed houses and other structures;
 - b. Property boundaries;
 - c. Location of proposed discharge point;
 - d. Existing and proposed wells, springs, cisterns, or other sources of potable water within 200 feet upslope or 1,600 feet downslope of the proposed discharge point;
 - e. Actual or proposed discharging systems within 600 feet of the proposed discharge point;
 - f. Recorded and proposed easements;
 - g. Existing and proposed overhead and buried utilities such as water lines, electrical lines, phone lines, gas lines, etc;
 - h. Sink holes located within 1,600 feet downslope of the proposed discharge point;
 - i. Other topographical features such as wetlands, lakes, ponds, rivers, streams, drainage ways, and swales, within 200 feet upslope and 600 feet downslope of the proposed discharge point;
 - j. Slope and side slope of any proposed dry ditch channels;
 - k. Public water supply intakes; and
 - l. Swimming or recreational water use areas within one mile upstream or five miles downstream of the proposed discharge point shown on a United States Geological Survey 7.5 minute topographic map or surveyed plat.

The site sketch should be to scale and accompanied by a United States Geological Survey 7.5 minute topographic map to provide information relevant to offsite setbacks.

5. ~~A written statement from the SWCB that the owner's registration statement has been approved under the General Permit regulation;~~

~~6. 5. Copies of all easements required by subdivision 2 of 12VAC5-640-450 B; however, at the discretion of the department district health director or the district sanitarian, the submission of easements may be postponed until submission of the construction plan if the property owner submits the name, address, and property location of each person that must grant an easement to the owner; and~~

~~6. If the discharge is to a wetlands, the application must contain a wetland delineation map of the geographic area for wetlands, stream, and open water on site and any other correspondence, approval, or certifications from the U.S. Army Corps of Engineers or the Department of Environmental Quality that wetlands were properly identified and delineated;~~

~~7. A letter of denial from the department or a certified site and soil evaluation report from a qualified person showing that the requirements of 12VAC5-640-30 D have been satisfied; and~~

~~7. 8. Other information which that the department deems necessary to comply with the intent of this chapter.~~

~~D. Application assistance. It is the policy of the department to assist persons applying for a discharging system permit by maintaining a supply of all appropriate forms in each local office. Department personnel will assist individuals in understanding how to fill out the form and provide information on the administrative process and technical requirements involved in obtaining a permit.~~

~~E. Site review. D. Upon receipt of a completed Combined Application application the department will conduct a site review to determine if the site meets the minimum siting criteria contained in Part III (12VAC5-640-390 et seq.) of this chapter. The owner may opt to have a licensed professional engineer conduct the site review and submit appropriate documentation with the application for review by the department. The department may opt to conduct a site review to verify an application submitted by a licensed professional engineer. Upon completing conducting the site evaluation or upon reviewing the site evaluation conducted by a licensed professional engineer, the department will advise the owner in writing of the results of the evaluation.~~

~~1. Satisfactory site found. When a satisfactory site is found for a discharging system, the written notice to the applicant shall include the type of discharge point found (i.e., wetland, all weather stream, intermittent stream, or dry ditch). The completed Combined Application and a copy of the documentation pursuant to 12VAC5-640-30 D shall be forwarded to the Department of Environmental Quality to complete the application process for a General Permit.~~

~~2. No satisfactory site found. When no satisfactory discharge point site is found the department shall deny the application in accordance with 12VAC5-640-270 owner shall be notified of all limiting factors restricting the use of a discharging system. Further, the applicant shall be notified of his right to appeal and what steps are necessary to initiate the process. The department shall send a copy of the denial to the Department of Environmental Quality.~~

12VAC5-640-240. Construction plan Application for a construction permit.

~~A. After a satisfactory site for a discharging system has been found and a General Permit has been obtained from the Department of Environmental Quality, the applicant shall submit a construction plan an application, the appropriate fee, construction plans, specifications, design criteria and calculations, and documentation that coverage under the General Permit has been obtained. The documentation shall include the cover letter and copy of the General Permit issued by the Department of Environmental Quality. If the discharge is to a wetland, the construction submittal must include documentation that a Virginia Water Protection Permit from~~

the Department of Environmental Quality or a permit under the U.S. Army Corps of Engineers has been obtained as needed. The purpose of the construction plan submittal is to demonstrate how the effluent limitations established by the SWCB and the remaining criteria construction, location, and performance requirements of this chapter can be met. At a minimum the construction plan must show the following:

B. All plans for alternative discharging systems shall bear a suitable title showing the name of the owner and shall show the scale in feet, a graphical scale, the north point, date, revision dates (when applicable), and the name of the licensed professional engineer by or under whom prepared. The cover sheet and each plan sheet shall bear the same general title identifying the overall sewage disposal project and each shall be numbered. Appropriate subtitles shall be included on the individual sheets.

The plans shall be clear and legible. Plans shall be drawn to a scale that permits all necessary information to be plainly shown. The size of the plans shall be no larger than 30 inches by 48 inches. Data used should be indicated. The precise location of the proposed system shall be shown on the plans. Detailed plans shall consist of plan views, elevations, sections, and supplementary views that together with the specifications and general layouts provide the working information for the contract and construction of the work, including dimensions and relative elevations of structures, the location and outline form of equipment and components to be installed, the location and size of piping, water levels, ground elevations, and erosion control abatement facilities.

C. Complete technical specifications for the construction of the alternative discharging system and all appurtenances shall accompany the plans. The specifications accompanying construction drawings shall include, but not be limited to, all construction information not shown on the drawings, necessary to provide the installer with all detail of the design requirements as to the quality of material workmanship and fabrication of the project; type, size, strength, operating characteristics, and rating of equipment; allowable infiltration, machinery, valves, piping, and jointing of pipe; electrical apparatus, wiring, and meters; operating tools and construction materials; special filter materials such as stone, sand, gravel, or slag; miscellaneous appurtenances; chemicals when used; instructions for testing materials and equipment deemed necessary to meet design standards; and operational testing for the complete works and component units.

D. At a minimum, the construction submittal must show the following:

1. Information gathered in the site review evaluation:

1. Type of system. The 2. For each system component, the plan shall note the type of system component and, where applicable, the manufacturer, model number, NSF approval and, status in accordance with 12VAC5-640-432, hydraulic capacity, and capacity in pounds of BOD₅ per day treatment capacity;

2. Location 3. The specific location of the property including the county tax map number (where available), a copy of the United States Geological Survey 7.5 minute topographic map showing the discharge point and down stream downstream for one mile, and directions to the property;

3. Grades 4. The elevation of the house sewer line where it exits the house and the elevation of the inlet and outlet ports or tees on all treatment units. Where discharges are to dry ditches or intermittent streams the site plan shall show the elevation of the discharge point, the point 500' downgrade from the discharge point and points every 50 feet between the discharge point and 500' downstream. This requirement may be met by drawing a flow diagram showing all elements listed above;

4. Distances. 5. The distance between all elevation points required by 12VAC5-640-240 3 D 4 so that the grade and setback distances can be established;

~~5. Pump specifications~~ 6. If a pump is proposed, specifications must be provided which that include the manufacturer, model number, and a pump curve with a system curve overlain on the pump curve;

~~6. Flood plain~~ 7. The location of the 100-year flood plain. All portions of a discharging system, except for the discharge pipe and step type post aeration, if required, shall be located above the 100-year flood plain;

~~7. Plans and specifications. Plans and specifications showing compliance~~ 8. Compliance with subsections B through N (inclusive) of 12VAC5-640-470 12VAC5-640-430 through 12VAC5-640-470; and

9. Other information as deemed appropriate by the department to verify the design.

12VAC5-640-250. Issuance of the construction permit.

A construction permit shall be issued to the owner by the commissioner or the department after receipt and review of a complete application submitted under ~~12VAC5-640-230 and 12VAC5-640-240~~, a satisfactory site and construction plan review, and approval under ~~12VAC5-640-240~~ verification of issuance of a General Permit from the Department of Environmental Quality. The construction permit shall note whether the permitted system has ~~experimental, preliminary, or general approval or is not in accordance with 12VAC5-640-432~~. Further, the construction permit will indicate that the operation and maintenance of the system is the owner's responsibility and that discharges in excess of the limits established by the General Permit, now or in the future, may cause the department to mandate the repair, expansion or replacement of the discharging system.

12VAC5-640-260. Exception for failing onsite sewage disposal systems.

~~When a failing onsite sewage disposal system is identified, and the site location criteria in this chapter cannot be met, the site location criteria in Article 1 of Part III and 12VAC5-640-240 F, 12VAC5-640-470 H and the dimensions of the easement specified in 12VAC5-640-450 B of this chapter may be waived, provided the following conditions are met.~~

When a failing onsite sewage disposal system is identified and the site location criteria in 12VAC5-640-400, 12VAC5-640-410, 12VAC5-640-420, and 12VAC5-640-470 H, and the dimensions of the easement specified in subdivision 2 of 12VAC5-640-450 cannot be met, the department may issue a written waiver that specifies the criteria that are being waived and the rationale for the waiver. In order to obtain this waiver, the owner must provide a written request for the waiver that includes justification and specifies any mitigating measures used to offset the reduced site conditions. The following conditions must apply in order for the waiver to be considered:

A. Reduce health hazard or environmental impact.

1. The issuance of a discharging system permit will reduce an existing health hazard or will improve or negate environmental impacts associated with the existing discharge. This determination shall be made by the ~~district health director or the district sanitarian manager~~ department.

B. No increase in waste load.

2. There will be no increase in the waste load generated by any additions to the dwelling except when necessary to provide for minimum facilities necessary for good sanitation. The minimum facilities for a single family dwelling are: a water closet, a bathroom sink, a bathtub or shower or both, and a kitchen sink. More than one bathroom may be added to a dwelling provided the potential occupancy of the structure is not increased.

C. Minimum facilities.

3. Where a failing onsite sewage disposal system already has more than the minimum facilities described above, the discharging system may be designed and permitted to accommodate the entire existing sewage flow. In no event shall the system designed and permitted exceed the existing sewage flow unless all conditions and criteria of this chapter are met.

12VAC5-640-262. Statements required upon completion of construction.

A. Upon completion of the construction, alteration, or rehabilitation of a discharging system, the owner or agent shall submit to the department a completion statement signed by the contractor responsible for the construction and a completion statement signed by the licensed professional engineer responsible for the design, upon forms approved by the department, that the system was installed and constructed in accordance with the construction permit and complies with all applicable state and local regulations, ordinances, and laws. These completion statements shall be based upon inspections of the treatment works during and after construction or modification that are adequate to ensure the truth of the statements. Should the treatment works be modified from the approved construction plan, the licensed professional engineer shall submit as built drawings documenting the changes. The licensed professional engineer's completion statement shall certify that the treatment works as modified will comply with all applicable state and local regulations, ordinances, and laws.

B. No discharging system shall be placed in operation, except for the purposes of testing the mechanical soundness of the system, until an operation permit is issued by the department in accordance with 12VAC5-640-266.

12VAC5-640-264. Operation and maintenance manual.

A. Prior to issuance of the operation permit, the owner shall submit an operation and maintenance (O&M) manual for the discharging system. The general purpose of the manual is to present both technical guidance and regulatory requirements to facilitate operation and maintenance of the discharging system for both normal conditions and generally anticipated adverse conditions. The manual shall be designed as a reference document, being as brief as possible while presenting the information in a readily accessible manner. The manual shall be tailored to the specific system. The manual must state the minimum required frequencies for routine maintenance, operation, sampling, and monitoring frequencies in this chapter, but additional maintenance visits, sampling, and monitoring may be added as needed, depending on the design of the system. The manual should reflect the minimum operation and maintenance activities required to properly maintain the system and ensure compliance with the General Permit requirements.

B. The manual shall include the following minimum items:

1. Basic information relevant to the discharging system design including treatment unit capacities, pump operating conditions, a list of the components comprising the discharging system, a dimensioned site drawing, sampling locations, and contact information for replacement parts and chemicals for each unit process;
2. Safety considerations;
3. A list of all control functions and how to use them;
4. All operation, maintenance, sampling, and inspection schedules for the discharging system including any requirements that exceed the minimum requirements of this chapter;
6. The General Permit effluent sampling and reporting schedule;
7. The sampling location for each of the required General Permit parameters and for informal (process control) testing parameters;
8. The expected ranges of any recommended informal (process control) tests;

9. The limits of the discharging system and how to operate the system within those design limits; and

10. Other information deemed necessary or appropriate by the designer.

12VAC5-640-266. Issuance of the operation permit.

A. Prior to issuance of the operation permit, the department may inspect the discharging system to determine if the installation is in substantial compliance with the construction permit and the requirements of this chapter. Minor deviations from the permit or proposed plans and specifications, excluding the manufacturer's design and installation specification, that do not affect the quality of the sewage treatment process or endanger public health or the environment may be approved by the department.

B. Before receipt of an operation permit, the owner shall:

1. Submit the completion statements and as built drawings as required under 12VAC5-640-262; [and]

2. Submit the operation and maintenance manual as required under 12VAC5-640-264 [~~and~~

~~3. Submit the maintenance and monitoring contracts as required under 12VAC5-640-490 G and 12VAC5-640-500 B.]~~

C. Upon the owner's satisfactory completion of the requirements in subsection B of this section, the commissioner or department shall issue an operation permit to the owner. The issuance of an operation permit does not denote or imply any warranty or guarantee by the commissioner or department that the discharging system will function for any specified period of time. The operation permit shall note whether the permitted system has general or nongeneral approval.

12VAC5-640-270. Denial of a construction or operation permit.

A. ~~Construction permit.~~ If the commissioner or department determines ~~it is determined~~ that the proposed site does not comply with this chapter or that the design of the system would preclude the safe and proper operation of a discharging system, ~~or that the installation and operation of the system would create an actual or potential health hazard or nuisance,~~ or the proposed design would adversely impact the environment, the permit shall be denied and the owner shall be notified in writing, by certified mail, of the basis for the denial, and a copy shall be sent to the Department of Environmental Quality. ~~The notification shall also state that the owner has the right to appeal the denial.~~

B. ~~Operation permit.~~ In addition to the grounds set forth in 12VAC5-640-270 subsection A of this section, the operation permit shall be denied if the discharging system is not constructed in accordance with the construction permit or the owner has failed to provide the completion ~~statement~~ statements required by 12VAC5-640-300 ~~12VAC5-640-262,~~ ~~or [or] the operation and maintenance manual required by 12VAC5-640-264 [~~and~~ a copy of a valid maintenance contract required by 12VAC5-640-500 or a valid monitoring contract as required in 12VAC5-640-490 F ~~G~~] .~~ The owner shall be notified in writing, by certified mail, of the basis for the denial, and a copy of the denial shall be sent to the Department of Environmental Quality. ~~The notification shall also state that the owner has the right to appeal the denial.~~

12VAC5-640-280. ~~Suspension or revocation~~ Revocation of construction permits and operation permits.

The ~~After providing the owner with the notice and the opportunity to participate in an informal conference or consultation proceeding in accordance with § 2.2-4019 of the Code of Virginia and 12VAC5-640-180,~~ the commissioner may ~~suspend or revoke~~ a construction permit or operation permit for any of the following reasons:

1. Failure to comply with the conditions of the permit including, but not limited to, the monitoring and maintenance requirements in Article 4 (12VAC5-640-490 et seq.) of Part III of this chapter and the payment of the inspection fee under 12VAC5-640-320;

~~[2. Failure to keep a maintenance contract in force in accordance with 12VAC5-640-500, or keep a monitoring contract in force in accordance with 12VAC5-640-490 F G;]~~

~~[3.2.]~~ Violation of any requirement of this chapter for which no variance has been issued;

~~[4.3.]~~ Facts become known which reveal that an actual or potential health hazard has been or would be created or that the environmental resources may be adversely affected by allowing the proposed discharging system to be installed or operated; or

~~[5.4.]~~ Failure to comply with the effluent limitations set forth by the SWCB in the General Permit as determined by the monitoring required by Article 4 of Part III.

12VAC5-640-290. Voidance of construction or operation permits.

A. Null and void.

~~All~~ After providing the owner with the notice and the opportunity to participate in an informal conference or consultation proceeding in accordance with § 2.2-4019 of the Code of Virginia and 12VAC5-640-180, the commissioner or the department may declare a discharging system system's construction permits are or operation permit null and void when any of the following conditions occur:

1. Conditions such as house location, well location, discharging system location, discharge point, discharge system design, topography, drainage ways, or other site conditions are changed from those shown on the application or site plan;

2. Conditions are changed from those shown on the construction permit;

3. More than ~~54~~ 60 months elapse from the date the permit was issued; or

4. The ~~suspension~~, revocation or expiration of the General Permit or of the owner's approved registration by the SWCB.

B. Reapplication.

~~Reapplication for the purposes of having an expired construction permit reissued shall be the responsibility of the owner, and such reapplication shall be handled as an initial application and comply fully with 12VAC5-640-230.~~

12VAC5-640-300. Statement required upon completion of construction. (Repealed.)

~~Upon completion of the construction, alteration, or rehabilitation of a discharging system, the owner or agent shall submit to the district or local health department a statement, signed by the contractor, upon the form set out in Appendix II, that the system was installed and constructed in accordance with the permit, and further that the system complies with all applicable state and local regulations, ordinances and laws.~~

12VAC5-640-310. Inspection and correction. (Repealed.)

~~No discharging system shall be placed in operation, except for the purposes of testing the mechanical soundness of the system, until inspected by the district or local health department, corrections made if necessary, and the owner has been issued an operation permit by the district or local health department.~~

12VAC5-640-320. Issuance of the operation permit. (Repealed.)

~~Upon satisfactory completion of the requirements of 12VAC5-640-300, 12VAC5-640-310, 12VAC5-640-490 F and 12VAC5-640-500 B, the commissioner shall issue an operation permit to the owner. The issuance of an operation permit does not denote or imply any warranty or guarantee by the department that the discharging system will function for any specified period of time. The operation permit shall note whether the permitted system has experimental,~~

preliminary, or general approval. Further, the operation permit will indicate that the operation and maintenance of the system is the owner's responsibility and that discharges in excess of the limits established by the General Permit, now or in the future, may cause the department to mandate the repair, expansion or replacement of the discharging system.

A. ~~Inspection fees. A fee of \$50 shall be charged to the owner for each mandatory monitoring inspection of an alternative discharging sewage treatment system conducted by the department in accordance with 12VAC5-640-490 C, D, or E. The fee shall be paid to the Virginia Department of Health by the owner or his agent prior to receipt of the inspection results from the department. Each inspection fee shall apply to one site specific inspection of only one discharging system.~~

B. ~~Waiver of fees. An owner whose income of his family is at or below the 1988 Poverty Income Guidelines For All States (Except Alaska and Hawaii) And The District of Columbia established by the Department of Health and Human Services, 53 Fed. Reg. 4213 (1988), or any successor guidelines, shall not be charged a fee for mandatory monitoring inspection of an alternative discharging sewage treatment system conducted by the Department of Health in accordance with 12VAC5-640-490 C, D, or E.~~

C. ~~Determining eligibility.~~

1. ~~An owner seeking a waiver of an inspection fee shall request the waiver in writing. The department will require information as to income, family size, financial status and other related data.~~

2. ~~It is the owner's responsibility to furnish the department with the correct financial data in order to be appropriately classified according to income level and to determine eligibility for a waiver of an inspection fee. The owner shall be required to provide written verification of income such as check stubs, written letter from an employer, W-2 forms, etc., in order to provide documentation for the file.~~

3. ~~The proof of income must reflect current income which is expected to be available during the next 12-month period. Proof of income must include: name of employer, amount of gross earnings, pay period for stated earnings. If no pay stub, a written statement must include the name, address, telephone number and title of person certifying the income.~~

12VAC5-640-330. Suspension of an operation permit. (Repealed.)

A. ~~Suspension. The district health director or district sanitarian manager may suspend the operation permit held by the owner of any discharging system which discharges effluent in violation of the effluent limitations set forth in the General Permit provided the following conditions have been met:~~

1. ~~The owner has received written notification, either in person or by certified mail, of the violation at least seven working days prior to the suspension;~~

2. ~~The owner has been advised of the nature of the violation and, if known, what actions are necessary to correct the violation;~~

3. ~~The owner has been advised of his right to a hearing pursuant to 12VAC5-640-180 B to appeal the suspension of the operation permit;~~

4. ~~The owner has taken no significant demonstrable action to identify and correct the problem causing the system to fail; and~~

5. ~~The owner has been issued an emergency pump and haul permit, or given another alternative method of sewage disposal, at least 24 hours prior to the suspension of the operation permit.~~

~~B. Discharge suspended. Upon suspension of an operation permit the owner shall immediately cease discharging effluent until corrections have been made to the discharging system which may be expected to bring the system into compliance with this chapter. The owner shall demonstrate to the health department that interim sewage disposal methods are in compliance with all federal, state and local laws governing public health and the environment. When pump and haul is utilized to prevent a discharge from occurring, the owner shall comply with the emergency pump and haul requirements found in the Sewage Handling and Disposal Regulations (12VAC5-640-10 et seq.) and provide the local health department with the name, address and phone number of the hauler and the frequency of pumping prior to initiating the emergency pump and haul process.~~

~~C. Modifications, alterations, or extensions. In addition to the remedies under 12VAC5-640-330 A and B, when any individual discharging system has exceeded its permitted discharge limitations three times in any one year or five times in any two consecutive years, the district health director or district sanitarian manager may require modifications, alterations or extensions to the system in order to improve the effectiveness of the system.~~

12VAC5-640-340. Reinstatement of an operation permit. (Repealed.)

~~Upon completion of repairs, modifications, alterations, or extensions to the discharging system, which may be reasonably expected to correct the cause of the violation, the department shall reinstate the operation permit. Upon reinstating the operation permit, the pump and haul permit shall be rescinded. The notice of reinstatement of the operation permit and rescinding of the pump and haul permit shall be made in writing and delivered in person or by certified mail.~~

12VAC5-640-350. System approval. (Repealed.)

~~Discharging systems will be classified by the division according to the data available to indicate the performance limits and reliability of various discharging systems. Systems may be classified as having an experimental system approval, a preliminary system approval, or a general system approval. The type and frequency of testing for each class of approval is designed to reflect the certainty with which the system has demonstrated its ability to meet the limits of the General Permit. Approval of generic system designs or of individual proprietary systems will be made by the division.~~

~~A. Experimental system approval. Experimental system approval indicates that a system, process, technology, or design has not been rigorously tested and proven capable of meeting either the discharge limits of the General Permit or the standards for Class 1 systems as defined by ANSI/NSF (American National Standards Institute/National Sanitation Foundation) International Standard 40, revised July 1990 ("Standard 40") hereby incorporated by reference. Products which have not been field tested or demonstrated in use as described in 12VAC5-640-350 B or C shall be considered experimental.~~

~~1. Notification of owner. All owners proposing experimental discharging systems shall sign a waiver of liability relieving, and agreeing to indemnify, the Department of Health and its employees for all liability associated with the design, operation, and performance of the system. Further, the owner shall agree to replace the experimental system with a system that has either general approval or preliminary approval in the event the experimental system fails and cannot be repaired. The cost of all repairs to, or replacement of, any experimental system shall be the responsibility of the system owner and shall not lie with the department.~~

~~2. Limit of 25 systems. A maximum of 25 experimental discharging systems of any one type or design may be installed at any one time in the Commonwealth.~~

~~3. Time limit for experimental system status. Experimental approval shall not extend for more than 18 months after the 15th experimental system of one type or design has been installed. After 18 months the experimental process, technology or design~~

~~shall be reviewed by the division and either granted preliminary system approval or the experimental approval shall be revoked. Preliminary system approval shall be granted if the system complies with the requirements of 12VAC5-640-350 B 1 c.~~

~~B. Preliminary system approval. Preliminary approval of a particular model of a discharging system indicates that the specific model uses a method, technology, process or combination of methods, technologies or processes that has been demonstrated in full scale systems under controlled test conditions. The results of these tests indicate that the system may have the potential to treat residential sewage under actual residential conditions to the level required by the General Permit. Demonstrated in situ performance, to the level of treatment required by the General Permit, is necessary to maintain system approval.~~

~~1. A discharging system may receive preliminary system approval by one of three methods:~~

~~a. ANSI/NSF testing. A system may be tested by an entity accredited by the American National Standards Institute and demonstrated to comply with Standard 40; or~~

~~b. Accepted engineering practice. System designs such as intermittent dosed sand filters, recirculating sand filters, and other system concepts which use design concepts and loading rates proven in accordance with accepted industry standards and practices and which have been routinely used and have associated test results meeting or exceeding those required for experimental systems to receive preliminary approval, may be granted preliminary approval by the division; or~~

~~c. Successful experimental system testing. A system may receive preliminary system approval by successfully demonstrating as an experimental system it can meet the following requirements:~~

~~(1) Replicates. At a minimum 15 systems of the same type or design shall be tested under residential conditions for a minimum period of one year each (i.e., no individual system shall be tested for less than one year);~~

~~(2) Data collection. Data shall be collected and reported to the Division for each system in accordance with the requirements of 12VAC5-640-490; and~~

~~(3) Results. The data shall demonstrate that during the previous year, not less than 95% of all systems of any one type or design were functioning properly during any quarter. That is, during the previous one year there were no data indicating the need to suspend the preliminary system approval.~~

~~2. Time limit for preliminary system approval. Preliminary system approval shall not extend for more than 60 months after the 25th preliminary system of one type or design has been installed. After 60 months the preliminary system approval status shall be reviewed by the division and the system either granted general system approval or the preliminary system approval shall be revoked. General system approval shall be granted if the system complies with the requirements of 12VAC5-640-350.~~

~~C. General system approval. Systems that have demonstrated in actual residential use that they can consistently meet the limits of the General Permit shall be eligible for general system approval. To meet the intent of this section the system shall meet the following requirements:~~

~~1. Replicates. At a minimum 25 systems shall be tested under residential conditions for a minimum period of five years each (i.e., no individual system shall be tested for less than five years);~~

~~2. Data collection. Data shall be collected and reported to the district health department for each system in accordance with the requirements of 12VAC5-640-490; and~~

~~3. Results. The data shall demonstrate that during the previous five years, not less than 95% of all systems of any one type or design were functioning properly during any quarter. That is, during the previous five years there were no data indicating the need to suspend the preliminary system approval. All systems installed and tested at the time of evaluation shall be included in the review. Nothing shall limit the department to basing its evaluation only on the first 25 systems installed.~~

12VAC5-640-360. Product registration. (Repealed.)

~~All aerobic treatment units shall be registered with the Division of Sanitarian Services in order to receive preliminary approval. In order to register a product, the manufacturer shall submit documentation showing the results of the Standard 40 testing and detailed plans and specifications of the product. Detailed plans and specifications shall include at a minimum a plan view of the ATU, a cross section of the ATU and any supplementary views which together with the specification and general installation guidelines will provide sufficient information for sanitarians to issue permits.~~

~~A. Health department review. The Division of Sanitarian Services will review requests for preliminary approval within 30 work days of receipt and respond to the applicant in writing. The department may approve, deny, conditionally approve, or request additional information on any request. When additional information is requested the division shall respond to the additional information within 30 days of receipt.~~

~~B. Certification mark or seal. All Class I ATU's in compliance with ANSI/NSF International Standard 40 shall have a registered certification mark or seal which must be affixed in a conspicuous location on the unit.~~

12VAC5-640-370. Submission of plans. (Repealed.)

~~A. Intermittent sand filter. All plans for an intermittent sand filter must use a design prepared by a professional engineer licensed to practice in Virginia, except for generic system designs which have been approved by the division. All plans and specifications shall bear the name, address, and occupation of the author and date of design.~~

~~B. Recirculating sand filter. All recirculating sand filters must use a design prepared by a professional engineer licensed to practice in Virginia, except for generic system designs which have been approved by the division. All plans and specifications shall bear the name, address, and occupation of the author and date of design.~~

~~C. Constructed wetlands. Constructed wetlands are considered experimental and will be considered on a case by case basis by the department. All constructed wetland systems shall be designed to meet or exceed 10 mg/l BOD₅ and 10 mg/l suspended solids.~~

12VAC5-640-380. Suspension and revocation of system approval. (Repealed.)

~~A. General. The experimental and preliminary approval of systems cited in 12VAC5-640-350 is based on the capability, or theoretical capability, of a particular method, technology or design to treat sewage under controlled conditions. Designs having general system approval have demonstrated their ability to meet the discharge limits of the General Permit; however, these systems still require routine maintenance and attention to their proper use such that they operate in a safe and sanitary manner. In order to protect public health and the environment, these systems must also be capable working properly under normal field conditions.~~

~~B. Suspension of approval. Anytime more than 5.0%, as measured statewide, of the discharging systems of any approved generic system or of any approved proprietary system design are found to be failing for two consecutive quarters, the approval of that design or model~~

shall be suspended. Failure for the purposes of this section means the discharge of effluent that does not meet the effluent limitations set forth in the State Water Control Board's General Permit for all constituents except residual chlorine and dissolved oxygen.

1. When less than 100 systems of a single design have been installed, Table 2.1 shall be used to determine the maximum acceptable failure rate. The 5.0% rule shall not apply because a small number of failures, or even a single failure, may violate this percentage without unduly endangering public health or the environment.

2. When the approval of a system has been suspended, no additional systems of that design or model shall be installed or approved unless construction or installation is already in progress and the system or materials to construct the system are already on the job site.

TABLE 2.1

Number of systems Installed in VA	No. not to exceed for suspension	No. not to exceed for revocation
0-10	4	3
11-25	2	6
26-50	3	9
51-75	4	12
76-99	5	15

C. Reinstatement of approval for a suspended system. The approval of a system under suspension may be reinstated by the division after the following conditions have been met:

1. Repairs have been made to all failing systems, and

2. Follow-up testing, performed in accordance with 12VAC5-640-490 D 1, reveals that less than 2.0% of the systems are failing. When less than 100 systems have been installed, approval may be reinstated when repairs and testing as described above has been completed on all failing systems and the number of failures is less than that shown in Table 2.1.

D. Revocation of approval. Anytime more than 15%, as measured statewide, of the discharging systems of any approved generic system or of any approved proprietary system design are found to be failing for two consecutive quarters, the approval of that design shall be revoked. Failure for the purposes of this section means the discharge of effluent that does not meet the effluent limitations set forth in the State Water Control Board's General Permit for all constituents except residual chlorine and dissolved oxygen. Further, the division shall revoke the approval of any Class I ATU which fails to meet Standard 40 upon retesting for continued certification, when such testing has been performed by NSF or other third party which has been accredited by the American National Standards Institute.

1. When less than 100 systems of a single design have been installed, Table 2.1 shall be used to determine the maximum acceptable failure rate. The 15% rule shall not apply because a small number of failures, or even a single failure, may violate this percentage without unduly endangering public health or the environment.

2. When the approval of a system has been revoked, no additional systems of that type shall be installed or approved.

E. Reinstatement of a revoked system. The approval of a system that has had its approval revoked may be reinstated by the division after the following conditions have been met:

1. Design flaws which led to the excessive failure rate have been corrected;

~~2. Repairs have been made to all systems to correct the design flaws;~~

~~3. Follow-up testing, performed in accordance with 12VAC5-640-490 D 1 reveals that less than 2.0% of the systems are failing. When less than 100 systems have been installed, approval may be reinstated when repairs and testing as described above has been completed on all failing systems and the number of failures is less than that shown in Table 2.1; and~~

~~4. Retesting and recertification of any Class I ATU under Standard 40.~~

~~F. Notification by the department. When the approval for a system is suspended, or is revoked, the department will send notice of the suspension to all regional and district offices of the Health Department, the manufacturer (if applicable), and other interested parties who have notified the department in writing that they wish to be notified. The notice shall include the system name, failure rate, location of failing systems and what actions are necessary to return to an approved status.~~

12VAC5-640-400. Classifications of discharge point points.

~~The nature of the discharge point will determine what precautions must be taken to protect public health and environmental resources. These regulations identify two classifications of discharge points.~~

~~A. All 1. Where an all weather stream required if possible is available, it shall be used rather than discharging to an intermittent stream, dry ditch, or wetland. The preferred point of discharge is an An all weather stream where effluent can be readily diluted dilute the effluent at least 10:1 as measured during a 7 at the seven consecutive day average of a 10-year 10-year low flow (7-Q-10) and thereby minimize public health and water quality impacts. Where an all weather stream is available for use it shall be used rather than discharging to an intermittent stream or dry ditch.~~

~~B. Stream type identification on USGS maps. 2. An all weather stream may generally be identified is represented by a solid blue line on the most recently published 7.5 minute United States Geologic Survey (U.S.G.S.) topographic map and has a 7-Q-10 flow that can provide 10:1 dilution of the effluent. The site evaluation shall include a review to verify that the stream is flowing at the time of the site evaluation. The USGS map shall not be the sole and final factor used to determine if a stream is an all weather stream when the department observes otherwise. Intermittent streams may be identified are represented by a dotted and dashed blue line on the most recently published 7.5 minute United States Geologic Survey topographic map. An all weather stream that provides less than 10:1 dilution of the effluent based on 7-Q-10 flow shall be considered an intermittent stream. Intermittent streams and dry ditches have an assigned stream flow 7-Q-10 of zero.~~

~~C. Other means of determining stream flow. 3. An owner may submit to the division additional hydrologic data, including but not limited to stream records and anecdotal evidence of long time residents, to support that a stream can provide a dilution ratio of 10:1. When in the opinion of the division, the evidence warrants a change, the division may determine that a stream is an all weather stream for the purposes of this chapter. The owner may also request site specific stream flow determinations from the Department of Environmental Quality.~~

~~D. Intermittent streams or dry ditches. 4. Discharges into intermittent streams or dry ditches which that do not have the dilution capability cited in 12VAC5-640-400 A subdivision 1 of this section shall be located entirely within the owner's property, or within a recorded easement as described in subdivision 2 of 12VAC5-640-450 B or a combination of the two.~~

~~1. Average slope. a.~~ The average slope for any intermittent stream or dry ditch discharge receiving effluent from a discharging system shall be between a minimum of 2.0% and 30% for the first 500 feet from the point of discharge. The intermittent stream or dry ditch shall be protected from erosion by the discharge as needed.

~~2. Minimum slope. b.~~ In order to prevent ponding, the minimum slope shall not be less than 1.0% at any point.

~~3. Grading of slopes. c.~~ All slope measurements described in subdivisions 1 and 2 of this subsection shall be made prior to initiating any grading and are intended to reflect naturally occurring swales and drainage ways. Nothing contained herein however, is intended to prohibit a property owner from making minor grading improvements to prevent ponding in areas with minimal slopes. Naturally occurring swales and drainage ways may be extended with an engineered channel on a case-by-case basis, but any engineered channel must tie into the existing natural swale or drainage.

5. Wetlands shall be confirmed by the U.S. Army Corps of Engineers or the Department of Environmental Quality, as appropriate, based on the type of wetland. Confirmation of delineated wetlands shall be provided, and include a wetland delineation map, wetland field data sheets, and any other documentation from the U.S. Army Corps of Engineers or the Department of Environmental Quality indicating their approval of the wetland boundary. 7-Q-10 flows cannot be calculated for wetlands and therefore the assigned 7-Q-10 flow value is zero. Discharges to wetlands shall be located entirely within the owner's property, or within a recorded easement as described in subdivision 2 of 12VAC5-640-450.

12VAC5-640-420. Setback distances from discharge points and downstream channels for the protection of public health.

~~A. Water supply intakes and recreational uses.~~ Discharges proposed within one mile (upstream or up channel) of any public water intake ~~or one mile (upstream or up channel) of any area explicitly designated for public swimming~~ shall not be permitted.

B. Discharges proposed within one mile upstream or up channel of any area explicitly designated for public swimming shall not be permitted.

C. When any river, stream, or other potential discharge area appears to receive significant primary contact use, such as, but not limited to, swimming, water skiing, tubing, or wet-wading, so that the discharge will pose a significant threat to public health ~~or create a nuisance~~, the district health director may require a higher level of treatment and reliability class for the permitted discharge facility.

D. The district health director, in consultation with the local governing authority and the department, may prohibit discharges into specified portions of the river, stream, or other potential discharge area. Prior to taking such action, the health director shall take the following steps:

1. Publish a notice announcing the department's intention to consider areas for restricting the use of discharging systems, establishing the date, time and location(s) of the public meeting(s), and soliciting public comment on the proposed area or areas being reviewed;
2. Request the opinion of the local governing body and other appropriate government agencies concerning proposed restrictions to be submitted before the close of the public comment period;
3. Have a public comment period on the proposal of not less than 30 days;

4. Hold at least one public meeting, 30 days or more after publication of the notice specified in subdivision 1 of this section; and
5. Evaluate the public comments received and staff evaluations regarding the use of the proposed area or areas for primary contact uses.

When in the best professional opinion of the health director the area or areas under consideration receives, for 30 days or more per year, significant primary contact uses, such that the discharge will pose a significant threat to public health ~~or create a nuisance~~, the director may designate areas where discharge systems are prohibited. Prohibited discharge areas may include areas upstream in the main channel and tributaries, from the area under review, for distances up to one mile if warranted by the evidence. Prohibited discharge areas shall be clearly defined in writing and delineated on a United States Geological Survey 7.5 minute topographic map. The prohibition on discharges, if any are found necessary, shall be effective upon notice after completion of the elements contained in this section.

~~B. Private and public water supplies.~~ E. The wastewater treatment system (ATU, sandfilter etc.) (tankage and components), shall be a minimum of 50 feet from private and public water wells and private cisterns. The discharge point and the channel of treated effluent flow shall be located in accordance with the distances given in Table 3.1 from private and public water supplies wells and cisterns. Where the bottom elevation of a cistern is located above the elevation of the discharge point, the setback distances shall not apply. The set back distances between the water supply well or cistern and the downstream channel established in Table 3.1 shall apply for 50 feet downstream of the discharge point for all weather streams and 500 feet downstream for intermittent stream or dry ditch discharges. For wetlands where the flow path can be established, generally where the slope is 10% or greater, the setback distances between the water well or the cistern and the "downstream channel" shall apply for 250 feet downstream of the discharge point. For wetlands where the flow path cannot be established, generally where the slope is less than 10%, then the distance shall be measured radially for 250 feet from the point of discharge.

F. Setback distances to other wells not covered in Table 3.1 of this section, such as geothermal and gas wells, will be determined on a case-by-case basis.

~~C. Springs.~~ G. No discharging system nor or any portion of the channel carrying the treated effluent flow shall be within 100 feet of a spring. Further, no discharging system shall discharge within 1,500 feet upstream or 100 feet downstream of any spring used for human consumption.

~~D. Sink holes.~~ H. Discharging systems are prohibited from discharging directly into sink holes or into dry ditches, intermittent streams, wetlands, streams, or other waterways that flow into sink holes within 1,500 feet from the point of discharge, and dry ditches that flow into sink holes within one mile from the point of discharge.

~~E. Limestone outcrops.~~ I. Dry ditch discharges to swales or drainage ways which have shall not have limestone outcrops within 25 feet of the dry ditch channel bottom are prohibited. This provision shall apply for the entire distance required for ownership or easement in 12VAC5-640-450-B a distance of 50 feet along the channel.

~~F. Proximity to other discharge points.~~ The J. Except as noted below, the department will not approve discharging systems except where discharge points will be at least 500 feet apart. If the proposed system utilizes aerobic biological treatment followed by sand filtration this distance may be reduced to 250 feet apart. The separation distance may be reduced to 250 feet between discharge points in accordance with the following:

1. For discharges to an all weather stream, the distance may be reduced to 250 feet by providing a Reliability Class II facility.

2. For discharges to a dry ditch or intermittent stream, the distance may be reduced to 250 feet by providing a Reliability Class I system that produces a TL-3 effluent and a fecal coliform concentration of 100 col/100 ml or less.

3. No reduction in the distance between discharge points is allowed for discharges to wetlands.

~~G. Shellfish waters.~~ K. No discharge shall be permitted under this chapter which will result in the condemnation of shellfish waters or the continued condemnation of shellfish waters closed only because of inadequate water quality.

TABLE 3.1 SETBACK DISTANCES FROM PRIVATE AND PUBLIC WATER SUPPLIES
WELLS AND CISTERNS
 (All distances are in feet)

Type of Water Channel Supply Stream	Distance from Point of Discharge	Distance from Downstream Channel	
		Downstream Channel With 7-Q-10 Discharge to All Weather Stream	<u>Downstream Discharge to Wetland², Intermittent Stream, or Dry Ditch</u>
Class I and II ¹ Wells	100	100	100
Class IIIA Well	50	50	50
Class IIIB Well	50	50	50
Class IIIC Well	100	50	100
Class IV Well	100	25 <u>50</u>	50 <u>100</u>
Cistern	100	50	100

¹Class I and II well specifications are found in the Waterworks Regulations (12VAC5-590). All other well specifications may be found in the Private Well Regulations (12VAC5-630).

²The downstream 'channel' of a wetland where the flow path can be established shall be a minimum of 25 feet wide and approximately centered on the flow path. Where the flow path cannot be established in a wetland, then the distance shall be measured radially from the point of discharge.

Article 2

Design Requirements

12VAC5-640-430. Performance requirements.

A. ~~Discharge limits.~~ All systems operated under this chapter shall meet the effluent limitations set forth by the State Water Control Board in the General Permit. All systems operated under this chapter shall maintain the treatment system in accordance with the approved construction permit or as modified by the final construction permit in accordance with the operation permit, "as built" plans, and the operation and maintenance manual.

B. ~~Bypass flow.~~ No system shall be approved for use which provides a bypass pipe, or otherwise allows untreated or partially treated effluent to discharge in the event of a system failure.

12VAC5-640-432. Treatment unit and additional system component classifications.

A. Biological treatment units will be classified by the division according to the data available to demonstrate the performance limits and reliability of those treatment units. The division may

classify treatment units as generally approved or not generally approved. The type and frequency of testing for each approval class is designed to reflect the certainty with which the system has demonstrated its ability to meet the limits of the General Permit or the performance requirements of this chapter.

1. General approval may be issued by the division for both TL-2 and TL-3 treatment units in accordance with the current policies of the division. Generally approved units shall be listed on the division's website.

2. Nongenerally approved biological treatment unit designs shall be properly supported with design calculations and one or more of the following:

a. Documentation from applicable engineering standards, texts, or other publications;

b. Relevant peer-reviewed research;

c. Technical guidance from other states (may be considered on a case-by-case basis); or

d. Technical guidance from the U.S. Environmental Protection Agency.

Scale drawings of the treatment unit, appropriate design calculations, and control system details shall be provided that demonstrate the ability of the unit to meet the required effluent limits and reliability standards at the proposed design flow.

B. Additional system components for discharging systems will be classified by the division as generally approved or not generally approved.

1. The division shall consider additional system components such as post-filtration, disinfection, dechlorination, and post-aeration to be generally approved if the unit has been tested and approved under a National Sanitation Foundation (NSF) or other recognized protocol for the proposed wastewater use or if the design complies with the design standards in 12VAC5-640-460.

2. Nongenerally approved system component designs shall be properly supported with design calculations and one or more of the following:

a. Documentation from applicable engineering standards, texts, or other publications;

b. Relevant peer-reviewed research;

c. Technical guidance from other states (may be considered on a case-by-case basis); or

d. Technical guidance from the U.S. Environmental Protection Agency.

Scale drawings of the treatment unit, appropriate design calculations, and control system details shall be provided that demonstrate the ability of the unit to meet the required effluent limits and reliability standards at the proposed design flow.

C. Discharging systems that are comprised entirely of generally approved treatment biological treatment units and system components as described in this section are considered generally approved treatment systems.

12VAC5-640-434. Reliability.

A. Reliability is a measure of the ability of a component or system to perform its designated function without failure or interruption of service. Overflow criteria, such as the allowable period of noncompliant discharge, are utilized solely for the establishment of reliability classification for design purposes and are not to be construed as authorization for, or defense of, an unpermitted discharge to state waters. The reliability classification shall be based on the water quality and public health and welfare consequences of a component or system failure.

B. Reliability Class I is required for dry ditch and intermittent stream discharges with 250 feet of easement available and wetland discharges with 100 feet of easement available.

1. For biological treatment processes, Reliability Class I shall be met by providing one of the following:

- a. A passive, backup biological treatment system (e.g., an intermittent sand, peat, or media filter or a constructed wetlands);
- b. A generator for the treatment system with automatic transfer switch;
- c. A 24-hour holding tank for raw wastewater with telemetry system to immediately notify the operator of system failure; or
- d. Any alternative means that limits the discharge of a noncompliant effluent to a maximum of 24 hours.

2. For disinfection, a Reliability Class I design shall ensure that the effluent is continually disinfected by providing electronic or mechanical means of monitoring the process such that failure of disinfection systems may be corrected within 24 hours.

C. Reliability Class II is required for dry ditch and intermittent stream discharges with 500 feet of easement available and wetland discharges with 250 feet of easement available. Reliability Class II is also required for the reduction of the distance between discharge points to 250 feet on an all weather stream.

1. For biological treatment processes, Reliability Class II shall be met by providing:

- a. A fixed film biological treatment process such as an intermittent sand filter, recirculating media filter, or a peat filter;
- b. A suspended growth biological system followed by post-filtration;
- c. Telemetry to relay alarm conditions to the operator; or
- d. Any alternative means that limits the discharge of a noncompliant effluent to a maximum of 36 hours.

2. For disinfection, a Reliability Class II design shall ensure that the effluent is continually disinfected by providing electronic or mechanical means of monitoring the process such that failure of disinfection systems may be corrected within 36 hours.

D. Reliability Class III is required for all weather stream discharges with a separation distance between discharge points of 500 feet or greater. For the purposes of this chapter, noncompliant discharges must be limited to a maximum of 48 hours in accordance with 12VAC5-640-500 C.

12VAC5-640-440. Factors Special factors affecting system design.

Each type of discharging system has its own unique advantages and disadvantages. These unique characteristics define the situations where a system may be used to advantage. The design of the system must be appropriate for the intended use and the site conditions where it is placed. the system is to be installed. Subdivisions 1 through 6 of this section contain a list of factors that will require special design consideration. This list should not be considered all encompassing. There may be other design factors that require special consideration. A preliminary engineering conference may be scheduled with the department to discuss such factors prior to submitting designs for department review.

A. Discharge to a dry ditch or intermittent stream. 1. When a discharge is proposed to a wetland, dry ditch, or intermittent stream, the department shall require restricted access to the wetland, dry ditch, or intermittent stream in accordance with 12VAC5-640-450 to protect public health.

B. Intermittent use. 2. Intermittent use for the purposes of this chapter constitutes use of the system for less than three consecutive months. Systems serving weekend cottages, or other intermittent uses will not reliably treat effluent prior to discharge. Therefore, the

~~use of discharging systems for dwellings subject to intermittent use is prohibited~~ require special design, operation, and maintenance consideration.

~~C. Infiltration.~~ 3. When a discharging system is proposed to be located in an area subject to infiltration by surface water or shallow ground water, the department may require additional protection from infiltration, inflow, and flotation, including placement of the system above natural grade.

~~D. Erosion.~~ 4. Erosion must be controlled by the owner of the discharging system in accordance with any local erosion control ordinances ~~or the Soil Conservation Services recommendations.~~

~~E. Sewage design flows.~~ 5. All systems shall normally be designed to treat the BOD₅ loading rate of 0.4 lbs/day per bedroom and a flow of 150 gallons per day per bedroom for systems up to three bedrooms. Systems serving single family dwellings having more than three bedrooms shall be permitted and designed to treat the anticipated loading rate based on BOD₅ and be capable of handling anticipated peak loading and flow rates. All systems shall be designed to operate over the range of anticipated flow and loading rates. When a system is permitted with a design less than the maximum capacity of the dwelling, the owner shall have the construction permit recorded and indexed in the grantor index under the owner's name in the land records of the clerk of the circuit court having jurisdiction over the site of the discharging system.

6. All system designs must include protection of the components from freezing or other adverse weather conditions and ensure that the system will function properly year round.

12VAC5-640-450. Criteria Design criteria for the use of intermittent streams ~~or~~, dry ditches, or wetlands.

All owners of systems discharging to an intermittent stream, ~~or~~ dry ditch, or wetland shall ensure the following conditions are met:

1. ~~Restricted access.~~ Direct contact between minimally diluted effluent and insects, animals, and humans must be restricted for the life of the system. This will be achieved by reducing the chance of ponding and run-off and limiting access to the effluent. The department shall require fencing, rip-rap, or other barriers to restrict access to effluent discharging to a dry ditch, ~~or~~ intermittent stream, or wetland as deemed necessary to protect public health. This determination shall be made by the ~~district health director or district sanitarian~~ department on a case by case basis.

The a. For dry ditch and intermittent stream discharges, the restricted access area shall begin at the point where the effluent is discharged and continue for 500 feet, or until the effluent discharges into an all weather stream or is no longer visible during the wet season. The design shall provide justification for the length of the restricted access channel if less than 500 feet.

b. For wetland discharges, the restricted access shall extend for a distance of 250 feet along the flow path of the discharge unless a 10:1 dilution with the wetland can be achieved. If the flow path cannot be established and a 10:1 dilution cannot be obtained, then access shall be restricted for 100 feet radially from the point of discharge. For wetland discharges, the access barrier may be a subsurface discharge point, but in no case shall the discharge point and diffuser be greater than 18 inches below the natural wetland surface.

2. ~~Ownership and easements.~~ When effluent is discharged to a dry ditch, ~~or~~ intermittent stream, or wetland, the owner shall ~~either own the land or have~~ acquire an easement from the downstream or downgradient land owner to discharge on all land below the point of discharge for the distance shown in Table 3.2. To allow for system construction

and repair of within the restricted access area, ~~as well as~~ and to facilitate maintenance and monitoring, the ~~width of the~~ width of the easement shall be a minimum of 25 feet wide and approximately centered on either side of the low point of the dry ditch or intermittent stream for the entire length of the restricted access area. For wetlands, the easement shall be measured radially from the point of discharge unless flow direction can be established. In those cases where flow direction can be established, the easement shall be a minimum of 25 feet wide and approximately centered on the discharge path and extend for a distance along the flow path as described in Table 3.2. If the slope across the discharge site is equal to or greater than 10%, the flow direction can be determined by observation. For slopes less than 10%, a site specific study must be conducted to document the direction of flow. All easements must be in perpetuity and shall be recorded by the owner with the clerk of the circuit court having jurisdiction over the property prior to issuance of the construction permit. For the purposes of complying with this chapter, ~~a CE-7 permit issued~~ written approval to utilize an easement owned by the Virginia Department of Transportation shall be considered as equivalent to an easement in perpetuity recorded by the owner with the clerk of the circuit court office having jurisdiction over the property.

TABLE 3.2
REQUIREMENTS FOR OWNERSHIP OR EASEMENTS DOWNSTREAM FROM
DISCHARGING SYSTEMS

Process	Downstream or Down Channel Distance (feet)	
	No spring below	Spring below
Sandfilter, aerobic system (w/post filtration), constructed wetland, or other single process system	500'	1,500'
Aerobic system w/sand filter, or other combination process with equal treatment	250'	1,500'

3. ~~Public health and environmental impact reduction and nuisance abatement.~~ Each discharging system which that discharges to a dry ditch, ~~or~~ intermittent stream, or wetland must receive additional treatment beyond that required by the General Permit in order to reduce the increased potential for public health ~~and nuisance~~ problems which may result when partially treated effluent is not diluted. Such additional treatment shall be capable of producing an effluent with a quality of 10 mg/l of BOD₅, 10 mg/l of suspended solids and a fecal coliform level of less than or equal to 100 colonies per 100 ml. Treatment units approved as TL-3 are recognized as having the ability to meet this BOD₅ and TSS standard, but have not been tested for compliance with the fecal coliform standard. Therefore, the following reliability classifications in Table 3.2 must be met when designing discharge systems intended to discharge into dry ditches, intermittent streams, or wetlands.

TABLE 3.2
REQUIREMENTS FOR RELIABILITY CLASSIFICATION AND OWNERSHIP OR
EASEMENTS DOWNSTREAM FROM SYSTEMS THAT DISCHARGE TO DRY DITCHES,
INTERMITTENT STREAMS, OR WETLANDS

Reliability Class	Downstream or Down Channel	Wetlands from Discharge Point
-------------------	----------------------------	-------------------------------

	<u>Distance for Dry Ditches or Intermittent Streams (feet)</u>		<u>along Flow Path or Radially from Discharge Point</u>
	<u>No spring below</u>	<u>Spring below</u>	
<u>Reliability Class I</u>	<u>250 ft</u>	<u>1,500 ft</u>	<u>100 ft</u>
<u>Reliability Class II</u>	<u>500 ft</u>	<u>1,500 ft</u>	<u>250 ft</u>

12VAC5-640-460. Disinfection Design requirements for system components.

A. All discharging systems shall be equipped with a means of disinfecting the effluent which is acceptable to the division and meets the performance requirements of this chapter.

A. 1. All discharging systems utilizing chlorine as a disinfectant shall be equipped with a chlorinator and contact chamber. Dechlorination is to be supplied if required by the General Permit.

a. Chlorinator capacity shall be based on the degree of treatment, flow variations, and other variables in the treatment processes. For disinfection, the capacity shall be adequate to maintain a total chlorine residual between 1.0 mg/l and 3.0 mg/l in the effluent after the required contact period. All chlorinators shall be designed to provide the appropriate dose of chlorine and mix the chlorine with the effluent. All chlorine products used to disinfect effluent from a discharging system shall be approved by the U.S. Environmental Protection Agency for use as a sewage disinfectant; products unapproved for wastewater disinfection are not acceptable. Use of unapproved products shall constitute a violation of this chapter.

b. The chlorine contact chamber shall have a length to width ratio of 20:1 and shall be capable of maintaining a total chlorine residual between 1.0 mg/l and 3.0 mg/l in the effluent within the chlorine contact chamber for provide a contact time of 30 minutes based on peak hourly flow, or 60 minutes based on peak daily flow. The length to width ratio may be reduced on a case by case basis when increased chlorine contact times are utilized.

c. When required by the General Permit, dechlorination capacity shall be adequate to dechlorinate the maximum chlorine residual anticipated and achieve the required General Permit effluent limits for total residual chlorine by providing at least 1-1/2 parts sulfite salt to one part chlorine. Provisions shall be made to thoroughly mix the dechlorinating agent with the contact tank effluent within a period of approximately one minute.

d. To meet Reliability Class I or Class II, all chlorination and dechlorination units shall be alarmed to notify the operator when tablets are not present in the dosing chamber or equipped with duplicate units that automatically switch over to the redundant unit if the primary unit is not operating.

2. Disinfection can be achieved through exposure of microorganisms to a sufficient level of ultraviolet light (UV) irradiation at the germicidal wavelength for an adequate period of time.

a. UV disinfection equipment shall be capable of providing a minimum average calculated dose of 50,000 microwatt-seconds per square centimeter after the UV lamps have been in operation for 7,500 hours or more and at a 65% transmissivity.

The dosage may be reduced on a case-by-case basis when sufficient information is provided to demonstrate that the required level of disinfection can be obtained at a lower dose level through test data.

b. UV lamps shall produce 90% or more of their emitted light output at the germicidal wavelength of 253.7 nanometers.

c. UV lamp assemblies shall be so located as to provide convenient access for lamp maintenance and removal.

d. UV lamps should not be viewed in the ambient air without proper eye protection as required by VOSH and other applicable regulations. The system design should prevent exposure of bare skin to UV lamp emission for durations exceeding several minutes.

e. An elapsed time meter shall be provided to indicate the total operating time of the UV lamps.

f. UV systems are sensitive to color and suspended solids. Precautions should be taken to protect the UV system from both color and excessive suspended solids.

g. To meet Reliability Class I or Class II, all UV units shall be equipped with [~~sensors~~ a sensor] to detect bulb failure with an alarm or equipped with duplicate units that automatically switchover if the primary unit is not operating.

~~B. All chlorine used to disinfect effluent from a discharging system shall be approved by the Environmental Protection Agency for use as a sewage disinfectant.~~

~~C. Other methods of disinfection for the removal of bacteria and viruses, which have been demonstrated effective under field use, may be approved by the division.~~

B. Post-aeration as required by the General Permit shall be provided to ensure that the final effluent complies with the dissolved oxygen effluent limits in the General Permit. Post-aeration may involve diffused aeration or cascade type aeration. All post-aeration designs shall assume a zero dissolved oxygen concentration in the influent wastewater to the post-aeration unit.

1. Effluent post-aeration may be achieved by the introduction of diffused air into the effluent.

a. Diffused aeration basins shall be designed to eliminate short-circuiting and the occurrence of dead spaces. For maximum efficiencies, sufficient detention time shall be provided to allow the air bubbles to rise to the surface of the wastewater prior to discharge from the basin.

b. When the detention time in the aeration basin exceeds 30 minutes, consideration shall be given to the oxygen requirements resulting from biological activity in the aeration unit.

c. Diffused air aeration systems shall be designed utilizing Fick's Law (the rate of molecular diffusion of a dissolved gas in a liquid) in the determination of oxygen requirements. Supporting experimental data shall be included with the submission of any proposal for the use of diffusers that are considered nonconventional. Such proposals will be evaluated on a case-by-case basis by the division.

d. Alternatively, an airflow of one cubic foot per minute at a diffuser submergence of one foot is sufficient to increase the dissolved oxygen of 1000 gallons per day of effluent to greater than five mg/l dissolved oxygen at 25°C.

e. If airflow is to be siphoned off the blower for the biological treatment unit, calculations shall be submitted to verify that there is sufficient air for both uses.

2. Effluent post-aeration may be achieved through a turbulent liquid-air interface established by passing the effluent downstream over either a series of constructed steps

that produces a similar opportunity for transfer of dissolved oxygen to the effluent, otherwise known as cascade or step aeration.

a. The following equation shall be used in the design of cascade/step type aerators:

$$r^n = (C_s - C_a) / (C_s - C_b)$$

where: r ≡ Deficit ratio

C_s ≡ Dissolved oxygen saturation (mg/l)

C_a ≡ Dissolved oxygen concentration above the weir, assumed to be 0.0 mg/l

C_b ≡ Dissolved oxygen concentration in the effluent from the last or preceding step

n ≡ The number of equal size steps

r ≡ 1 + (0.11) (ab) (1 + 0.046 T) (h)

where: T ≡ Water temperature (°C)

h

≡ Height of one step (ft)

a

≡ 1.0 for effluents (BOD₅ of less than 15 mg/l) or

0.8 for effluents (BOD₅ of 15 mg/l to 30 mg/l)

b

≡ 1.0 for free fall and 1.3 for step weirs

b. The equation for determining the number of steps is dependent upon equidistant steps, and if unequal steps are used, transfer efficiencies must be determined for each separate step.

c. The effluent discharge to a cascade type aerator shall be over a sharp weir to provide for a thin sheet of wastewater. Consideration shall be given to prevention of freezing.

d. The final step of the cascade type aerator shall be above normal stream flow elevation and the cascade aerator shall be protected from erosion damage due to storm water drainage or flood/wave action.

e. When pumping is necessary prior to discharge over the cascade aerator, the range of the flow rate to the post-aeration unit must be accounted for in the design.

f. A step aerator with multiple steps each less than or equal to one foot and a total drop of five feet is sufficient to increase the dissolved oxygen in an effluent at 25°C to greater than five mg/l.

C. Post-filtration may be used to ensure compliance with the reliability standards in 12VAC5-640-434 and generally follow the biological treatment unit and are prior to disinfection in the treatment process. For granular media filters, the media depth shall not be less than 30 inches. Sand media for intermittently dosed and recirculated effluent, shall have an effective size of 0.30 mm to 1.0 mm and 0.8 mm to 1.5 mm, respectively. The uniformity coefficient should not exceed 4.0. No more than 2.0% shall be finer than 0.177 mm (80 mesh sieve) and not more than 1.0% shall be finer than 0.149 mm. No more than 2.0% shall be larger than 4.76 mm (4 mesh sieve). Larger granular media up to five mm in effective size may be considered on a case-by-case basis. The filter shall be equipped with an underdrain. The surface of the filter shall be accessible for maintenance. For the purposes of a filtration unit, the maximum surface hydraulic loading rate is 15 gpd/sf.

D. Constructed wetlands that are used as a passive backup biological treatment unit for the purposes of meeting Reliability Class I requirements of 12VAC5-640-350 shall be lined with a minimum surface area of 100 square feet, a depth of 18 inches, a length to width ratio of about 4 to 1, and shall have subsurface flow. Wastewater shall be disinfected prior to entering the constructed wetlands and sampling ports shall be provided to allow monitoring of the influent to the wetlands. Effluent dechlorination prior to entering the wetlands may be necessary to protect the plants from toxic levels of chlorine.

Article 3
Construction Requirements

12VAC5-640-470. ~~Installation review~~ General construction requirements.

A. ~~General.~~ No portion of any system may be covered or used until inspected, corrections made if necessary, and approved, by the ~~local health~~ department or unless expressly authorized in writing by the ~~local health~~ department. All applicable sections contained in the Sewage Handling and Disposal Regulations, ~~12VAC5-610-10 et seq.~~ 12VAC5-610, shall be used to establish design and construction criteria not contained in this chapter.

B. ~~Slope.~~ Gravity sewer lines and lines between components of the system shall be schedule 40 pipe and shall have a minimum grade of ~~4.35"~~ 1.25 inches per ~~40'~~ ten feet for ~~3"~~ three-inch and ~~4"~~ four-inch sewer lines. Discharge lines after primary or secondary treatment units shall have a minimum grade of ~~6"~~ six inches per ~~100'~~ 100 feet. Where minimum grades cannot be maintained, detailed pump specifications shall be shown on the site plan in accordance with Article 4 (12VAC5-610-598 et seq.) of Part IV of the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.

C. ~~Location.~~ The treatment unit and all piping and appurtenances shall be located in conformance with the approved plans. All changes in location shall be approved by the local department prior to the installation of the system.

D. ~~Pumps.~~ All pumps and appurtenances to the pump shall be installed according to the plans and specifications approved by the department and referenced in the permit.

E. ~~Electrical.~~ All wiring shall be approved by the local building official and shall be weather tight and permanent in nature (hard wired).

F. ~~Controls.~~ The control panel for the system shall be located within 15 feet of the treatment unit and shall be provided with a manual override switch. Each pumping station shall be provided with controls for automatically starting and stopping the pumps based on water level. When float type controls are utilized they shall be placed so as to be unaffected by the flow entering the wet well.

G. ~~Alarm.~~ All mechanical treatment units shall be provided with an alarm system on a separate electrical circuit from the remainder of the treatment unit. The alarm shall be both audio and visual and shall be located in an inhabited portion of the dwelling. Examples of alarm conditions to be monitored include aerator failure, blower failure, and high water level.

~~All ATU's shall be equipped with an alarm that detects aerator failure and a high water alarm to warn against the back-up or overflow of sewage.~~

H. ~~Flood plain.~~ Except for the discharge pipe, and step type post aeration if ~~required~~ used for post-aeration, no portion of the discharging system may be located in the 100-year flood plain.

I. ~~Sampling ports.~~ All discharging systems shall be equipped with a six-inch (or larger) sampling port connected to an approved effluent collection box at the chlorine contact chamber after the 30- or 60-minute contact time (i.e., the sampling port shall be located at the outlet end of the chamber. Additionally, a separate sampling port shall be required after the dechlorination

~~unit. Other sampling ports may be required elsewhere on a case by case basis as required by the system design.~~

I. The design must allow for sampling to confirm the efficacy of the treatment process. Sampling ports shall be identified on the construction documents and shall meet the following minimum requirements:

1. All discharging systems utilizing chlorine as a disinfectant shall be equipped with a four inch or larger sampling port connected to an approved effluent collection box at the chlorine contact chamber after the 30-minute or 60-minute contact time (i.e., the sampling port shall be located at the outlet end of the chamber).

2. A separate sampling port shall be required after the dechlorination unit.

3. The sampling location is to be identified and a port provided if needed for sampling the final effluent prior to the effluent entering the discharge channel.

4. Other sampling ports may be required on a case-by-case basis due to the system design.

~~J. Clean out port. All discharging systems shall have a clean out port, accessible from the surface of the ground within 40' 10 feet of the influent invert of the treatment unit.~~

~~K. Ventilation. Positive ventilation shall be provided at pumping stations when personnel are required to enter the station for routine maintenance.~~

~~L. Filter liners. Sand filter liners shall be constructed of clay having a permeability of 10^{-6} cm/sec. or less, a 28 mil vinyl or PVC plastic liner, concrete, or other material approved by the division. A watertight seal shall be provided where underdrain piping exits the filter.~~

~~M. Filter materials. Sandfilter materials shall meet the specifications described in 12VAC5-580-760 B of the Sewerage Regulations, or as amended.~~

~~N. Posting of discharge pipe. M. The owner of each discharging system that discharges to state waters, including either an all-weather stream or an intermittent stream, shall post a permanent sign at the point of discharge with the following notice:~~

~~This pipe carries treated sewage effluent and is not suitable for human consumption. This system is owned by (FULL NAME OF PERMIT HOLDER) and is maintained by (NAME AND PHONE NUMBER OF [LICENSED OPERATOR WITH OVERSIGHT OF THE SYSTEM MAINTENANCE PROVIDER IN MAINTENANCE CONTRACT]).~~

~~The sign shall be posted within three feet of the discharge pipe, and shall be plainly visible to the public, and shall be constructed of durable material. All lettering shall be at least one-inch high and shall be clearly legible. The sign shall have black letters on a white background (or be painted in other contrasting colors) and be plainly visible at a distance of 25 feet to a person with normal vision. Failure to maintain this sign shall be grounds for suspending the owner's operation permit.~~

~~12VAC5-640-480. Compliance with plans. (Repealed.)~~

~~Prior to the issuance of an operation permit all discharging systems must be inspected by the health department and found to substantially comply with the intent of the chapter. Minor deviations from the permit or proposed plans and specifications (excluding the manufacturer's design and installation specifications) that do not affect the quality of the sewage treatment process or endanger public health or the environment may be approved. Where engineering plans were submitted and were incorporated in the construction permit, the design engineer, or other professional engineer designated by the design engineer, shall inspect the installation and submit written comments concerning the compliance of the installation with the design specifications prior to the issuance of the operation permit.~~

Article 4

Monitoring [,Operation,] and Maintenance Requirements

12VAC5-640-490. Monitoring.

A. ~~General.~~ Discharging systems that discharge improperly treated effluent can endanger public health and threaten environmental resources. All discharging systems shall be routinely inspected and the effluent sampled to determine compliance with the effluent limitations set forth by the State Water Control Board in the General Permit and in accordance with 12VAC5-640-430 and 12VAC5-640-510. All testing requirements contained in this chapter are the responsibility of the system owner to have collected, analyzed, and reported to the department.

B. ~~Types of testing.~~ There are two types of testing recognized by this chapter: formal compliance testing and informal (process control) testing. Formal testing is conducted to determine either compliance or noncompliance with ~~this chapter~~ the General Permit. Informal testing is conducted to assess the treatment system's performance ~~determine compliance with this chapter~~ and to determine when additional formal compliance testing is necessary. Informal testing may support but shall not be the sole basis for ~~suspending an operation permit pursuant to 12VAC5-640-330 or to suspend or revoke [suspending or]~~ revoking the approval of the system pursuant to 12VAC5-640-380 of this chapter 12VAC5-640-280.

1. ~~Formal compliance testing.~~ Effluent from all discharging systems shall be tested for the following parameters at a frequency specified in Table 3.4: Five-day biochemical oxygen demand (BOD₅), total suspended solids, fecal coliform bacteria, dissolved oxygen and total chlorine residual (measured at the outfall and in the chlorine contact chamber if dechlorination is required). The tests shall be analyzed by a laboratory certified by the E.P.A. or the SWCB to conduct self-monitoring analysis to determine compliance limits for VPDES permit discharge limits. Samples shall be collected, stored, transported and analyzed in accordance with requirements set forth in Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act as published in 40 CFR Part 136 (July 1, 1991).

2. ~~Informal testing.~~ The following tests will be conducted on the effluent, except as noted, at a frequency specified in Table 3.4; 30 minute settleable solids (conducted on the mixed liquor suspended solids), odor, color, pH, and chlorine (after the chlorine contact chamber). In addition, systems requiring effluent dechlorination shall be tested for dechlorination at the point of discharge. These tests shall be run in the field during routine monitoring inspections. The criteria for satisfactory informal testing are contained in Table 3.3.

TABLE 3.3
INFORMAL TESTING CRITERIA
(FOR ALL CLASSES OF DISCHARGING SYSTEMS)

Settleable solids	less than 65% (mixed liquor suspended solids)
Odor	Slight musky odor (MLSS not septic)
Color	less than 15 units (measured at outfall - no solids present)
pH	Same as formal compliance test limits
Chlorine	1.0 mg/l 3.0 mg/l (measured after chlorinator) None detected (measured at the outfall)

C. Frequency of mandatory testing.

~~1. Formal compliance testing. Formal compliance testing as described in 12VAC5-640-490 B 1, shall be conducted at the frequency listed in Table 3.4 for all discharging systems for all constituents listed under 12VAC5-640-490 B 1. Additionally, formal compliance testing may be required anytime informal testing indicates a discharging system appears to be discharging effluent that exceeds the effluent limitations set forth in the State Water Control Board's General Permit. Compliance monitoring conducted pursuant to the SWCB General Permit requirements may be submitted for one of the mandatory tests to comply with this chapter.~~

~~2. Informal testing. Informal testing, as described in 12VAC5-640-490 B 2, shall be used as an inexpensive screening method to identify systems that are potentially in violation of the effluent limitations set forth in the State Water Control Board's General Permit. Informal testing shall be conducted monthly for at least six consecutive months beginning the second full month after the issuance of the operation permit. After a discharging system has met the permit limits for six consecutive months the testing shall be conducted at the frequency listed in Table 3.4.~~

TABLE 3.4
FREQUENCY OF MANDATORY TESTING BEGINNING SIX MONTHS
AFTER SYSTEM START-UP

System Approval Testing	Formal Testing	Informal Testing
Experimental ¹	Quarterly ²	Monthly
Preliminary	Semi-Annually ²	Quarterly
General	Annually ²	Semi-Annually

¹Testing on systems with experimental approval shall begin 3 months after installation and continue for 12 or more consecutive months. The initial sample testing at three months shall be formal testing and the formal testing shall continue quarterly from that time forward.

²Also see 12VAC5-640-490 D 1.

C. All treatment systems shall undergo startup testing to assess the ability of the system to comply with the established performance requirements.

1. Treatment systems are considered generally approved for the purposes of establishing startup testing requirements only when all treatment components (i.e., biological treatment unit, disinfection, dechlorination, post-aeration, etc.) of the system are considered generally approved as described in 12VAC5-640-432.

2. All new discharging systems shall undergo formal startup compliance testing for parameters limited by the General Permit. The collection, storage, transportation, and analysis of all formal compliance samples shall be in accordance with the requirements of the General Permit.

a. For generally approved systems, the first formal compliance testing event shall occur 45 to 90 days after the system begins discharging. If the formal compliance test data indicate the system is in compliance with the General Permit, then the system will revert to annual formal compliance sampling in accordance with the General Permit. The initial sample may be used to comply with the first annual sampling requirement. If the testing data indicates that any parameter is out of compliance, subsection E of this section shall apply.

b. For nongenerally approved systems, the first formal compliance testing event shall occur 45 to 90 days after the system begins discharging. Three additional formal compliance testing events are to occur quarterly and at least 60 days apart. If the four startup compliance test data indicate the system is in compliance with the General Permit, then the system will revert to annual formal compliance sampling in accordance with the General Permit. If the testing data indicates that any parameter is out of compliance, subsection E of this section shall apply.

3. Informal (process control) testing shall be conducted monthly for at least six consecutive months beginning the second full month after the issuance of the operation permit. After successful startup of the treatment system, informal testing shall be conducted semiannually at a minimum and any time formal testing is conducted. Informal testing shall be in accordance with the approved operation and maintenance manual, which shall include at a minimum the tests listed in Table 3.3. The specific test, sample location, and frequency shall be itemized in the operation and maintenance manual for the treatment system.

D. Both formal and informal routine monitoring is required after a system successfully completes startup testing.

1. After a system successfully completes startup testing, the system formal testing reverts to the General Permit monitoring frequency for the parameters limited by the General Permit. The collection, storage, transportation, and analysis of all formal testing shall be in accordance with the requirements of the General Permit.

2. Informal (process control) testing shall be conducted during routine maintenance visits. The specific test, sample location, and frequency shall be itemized in the operation and maintenance manual for the treatment system. When an operation and maintenance manual is not available, informal testing shall be sufficient to assess the treatment system's performance. Table 3.3 contains the minimum informal testing that must be conducted as appropriate for a given system.

TABLE 3.3
INFORMAL (PROCESS CONTROL) TESTING

<u>Treatment Unit</u>	<u>Informal Tests</u>
<u>Septic tank/trash tank</u>	<u>Sludge depth</u>
<u>Suspended growth biological treatment unit</u>	<u>Dissolved oxygen, settleability, pH, odor</u>
<u>Fixed film biological treatment unit</u>	<u>Dissolved oxygen (effluent from unit), pH, odor</u>
<u>Chlorine disinfection/dechlorination</u>	<u>TRC at end of contact tank (>1.0 mg/l), TRC after dechlorination</u>
<u>Ultraviolet disinfection [UV]</u>	<u>Turbidity prior to UV</u>
<u>Final effluent</u>	<u>Dissolved oxygen, pH, odor, color</u>

~~D. Nonroutine mandatory testing and inspection.~~ E. The district health director or district sanitarian manager department may require additional formal compliance testing or informal testing, or both, as necessary to protect public health and the environment. Additional testing shall be based on observed problems and shall not be implemented routinely on all discharging systems.

1. Anytime a discharging system is found to ~~exceed~~ be out of compliance with the effluent limitations of the General Permit, follow-up formal compliance testing shall be repeated between 45 and 90 days after the original samples were collected and the results reported to the local health department. This follow-up formal compliance testing shall constitute a subsequent consecutive quarter for the purposes of determining compliance with 12VAC5-640-380 B and D. Prior to resampling, the operator should attempt to determine the reason for the noncompliance and take corrective actions.
2. Anytime an informal test reveals an apparent a potential problem, additional formal or informal testing may be conducted to review the effectiveness of any repairs or adjustments.
3. Anytime the results of two consecutive formal compliance tests as specified in ~~12VAC5-640-490 B-4~~ subdivision C 2 or D 1 of this section result in a ~~violation~~ violation of the effluent limitations of the General Permit, informal testing shall revert to monthly frequency until satisfactory results are obtained for six consecutive months. Nothing in this section shall preclude requiring the collection of samples for formal compliance testing as described in ~~12VAC5-640-490 B-4~~ subdivisions C 2 and D 1 of this section to determine compliance with the effluent limitations set forth in the General Permit.

~~E. Responsibility for testing. E.~~ The owner of each system is responsible for ensuring that the collection, analysis, and reporting of all effluent sample tests are completed in a timely fashion and in accordance with ~~12VAC5-640-490~~ this section and 12VAC5-640-510. ~~In addition to the mandated testing requirements contained in this chapter, the~~ The department shall conduct, at a minimum, an annual inspection, which may include formal or informal testing at the option of the department and may conduct additional inspections at its discretion. Furthermore, the department may conduct or mandate formal or informal testing as deemed appropriate [by the department] . Nothing contained herein shall be construed to prohibit the department from mandating additional formal and informal testing as deemed appropriate by the department. Further, the department at its discretion may require split samples be collected at any time (i.e., for routine or nonroutine testing). [If a system is in compliance three consecutive years, the department may reduce the department inspection frequency to a three year cycle .Annual inspections by the department will resume if the department receives evidence that the system is out of compliance. Compliance for the purposes of this section is compliance with the testing, inspection, effluent limits, and reporting requirements of this regulation. Inspection by the department does not substitute for the required operation, maintenance, testing and reporting requirements in 12VAC5-640-490, 12VAC5-640-500, and 12VAC5-640-510.]

~~F. Monitoring contract. [G.~~ In order to assure that monitoring is performed in a timely and competent fashion, the owner of each system shall have a contract for the performance of all mandated sampling with a person capable of performing the sampling and analysis of the samples. This requirement may be met by including the performance of all testing and monitoring as part of the maintenance contract in accordance with 12VAC5-640-500 C 1. Failure to obtain or renew a monitoring contract shall result in the suspension or revocation of the operation permit as described in 12VAC5-640-280. When the district health director or the sanitarian manager find that the homeowner is capable of collecting and transporting samples to an approved laboratory in compliance with this chapter, the requirement for having a valid monitoring contract may be waived. Waiving of this requirement shall be done only on an individual basis and shall reflect the competency of the individual based on profession, training or other educational experience. ~~Owners with existing waivers to the monitoring contract as of the effective date of the amendment to the regulations may be extended, but no new waivers shall be issued. In the event the individual for whom this section is waived fails to collect three or more of any of the required samples in any five-year period, the district sanitarian or the health director~~ department may reinstate the requirement for a monitoring contract.]

12VAC5-640-500. [Maintenance Operation and Maintenance Requirements] .

A. ~~General~~. Due to the potential for degrading surface water and ground water quality or jeopardizing the public health, or both, routine [operation and] maintenance of discharging systems is required. In order to assure [maintenance is performed in a timely manner a maintenance contract between the treatment system is operated, maintained, monitored, and reported properly,] the permit holder [and a person capable of performing maintenance shall engage a licensed operator] as defined in subsection E of this section [.is required. Reporting in accordance with 12VAC5-640-490 and 12VAC5-640-510 is sufficient evidence of an ongoing contract. Owners with existing monitoring waivers that allow the owner to collect formal compliance samples as of [the effective date of the amendment to the regulations (insert effective date of this chapter)] may be extended, but, no new waivers shall be issued. In the event the individual fails to collect three or more of any of the required samples in any five-year period, the department will void the waiver and require evidence of an operation and maintenance contract that includes monitoring.]

B. ~~Maintenance contract~~. [A maintenance contract shall be kept in force at all times. Failure to obtain or renew a maintenance contract shall result in the suspension or revocation of the operation permit as described in 12VAC5-640-280. The operation permit holder shall be responsible for ensuring that the local health department has a current copy of a valid maintenance agreement. When a maintenance contract expires or is canceled or voided, by any party to the contract, the owner and maintenance provider shall report the occurrence to the local health department within 10 work days. It is the owner's responsibility to do the following:

1. Have the system operated and maintained by a licensed operator;
2. Have an operator visit the system at the frequency required by this chapter (at least semi-annually);
3. Have an operator collect and analyze any samples required by this chapter;
4. Provide prompt maintenance and repair of the treatment works. If an owner is notified by the operator of a repair or maintenance need pursuant to 12VAC5-640-500C.4. and the discharge does not comply with the effluent requirements of the General Permit, then the owner shall begin pump and haul of the sewage and take other actions as may be directed by the local health department until the treatment works returns to normal function;
5. Keep a copy of the log provided by the operator on the property where the system is located in electronic or hardcopy form, make the log available to the department upon request, and make a reasonable effort to transfer the log to any future owner;
6. Follow the O&M manual (where available) and keep a copy of the O&M manual in electronic or hard copy form for the system on the property where the system is located, make the O&M manual available to the department upon request, and make a reasonable effort to transfer the O&M manual to any future owner; and
7. Comply with the VPDES permit requirements contained in 9VAC25-110.]

C. ~~Elements of a maintenance contract~~. [At a minimum each maintenance contract shall provide for the following:

1. Performance of all testing required in 12VAC5-640-490 B either Part I A or Part I B of the General Permit, as appropriate, and in this chapter, unless the owner maintains a separate monitoring contract in accordance with 12VAC5-640-490 F G. 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 formal sample, but the informal sampling should be used to identify any operational problems;

~~2. Full and complete repairs to the system within 48 hours of notification that repairs are needed. Any deductible provision in a maintenance agreement shall not exceed \$500 in any given year for repairs (including parts and labor). Periodic (at least semiannual) inspections of the treatment works or as needed to keep the treatment system functional and in compliance;~~

~~3. Twenty-four months of consecutive coverage shall be the minimum time period a maintenance contract may be valid. 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~~

~~4. Electronic reporting to the department in accordance with 12VAC 640-510.~~

The operator has the following responsibilities:

1. Perform all testing required in either Part I A or Part I B of the General Permit, as appropriate, and in this chapter, unless the owner maintains a [separate monitoring contract waiver] in accordance with 12VAC5-640-500A. Note: The treatment works will be sampled during normal discharging operations or normal discharging conditions (i.e., operations that are normal for that facility). The operator should not force a discharge in order to collect a formal sample, but the informal sampling should be used to identify any operational problems;

2. Whenever an operator performs a visit that is required by this chapter, he shall do so in such a manner as to accomplish the various responsibilities and assessments required by this chapter through visual or other observations and through laboratory and field tests that are required by this chapter or that he deems appropriate;

3. When performing activities pursuant to a visit that is required by this chapter, the operator is responsible for the entire system and, where applicable, the operator shall follow the approved O&M manual;

4. Provide a written or electronic notification to the owner within 24 hours whenever the operator becomes aware that maintenance or repair of the owner's treatment works is necessary; and

5 Document the results of each site visit in the log and report in accordance with 12VAC5-640-510. Each operator shall keep an electronic or hard copy log for each system for which he is responsible. The operator shall provide a copy of the log to the owner. In addition, the operator shall make the log available to the department upon request. At a minimum, the operator shall record the following items in the log:

a. Results of all testing and sampling;

b. A copy of the Discharge Monitoring Report required by the General Permit;

c. Maintenance, corrective actions, and repair activities that are performed;

d. Recommendations for repair and replacement of system components;

e. Sludge or solids removal; and

f. The date reports were given to the owner.]

D. Public utility. In localities where a public service authority, sanitary district, or other public utility exists which [monitors or operates and] maintains the systems, or monitors and maintains the systems, permitted under this chapter, the requirements for the [monitoring or operation and] maintenance contract [or both] may be waived by the division provided the

owner of the system subscribes to the service and the utility meets the minimum elements described in 12VAC5-640-490 [~~, and~~] 12VAC5-640-500 [~~and 12VAC5-640-510~~] .

~~E. Qualifications to perform maintenance.~~ In order to competently evaluate system performance, collect samples, and interpret sample results, ~~as well as~~ and repair and maintain discharging systems, an individual must be knowledgeable in sewage treatment processes. ~~Therefore, after July 1, 1994, all~~ All individuals who perform maintenance on discharging systems pursuant to 12VAC5-640-500, are required to hold a valid Class IV or higher wastewater works operator license or an alternative onsite sewage system operator license issued by the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals. ~~Until July 1, 1994, individuals that can demonstrate two years of practical experience with discharging systems, with flows under 1,000 GPD, may conduct maintenance on all systems.~~

12VAC5-640-510. Information to be reported electronically.

~~A. Who is responsible for reporting.~~ All owners Every owner issued an operation permit for a discharging system ~~are~~ is responsible for ~~reporting~~ having the results of all mandated testing and inspections submitted to the department in the form and format acceptable to the department.

~~B. What must be reported.~~ All formal compliance testing, informal testing, repairs, modifications, alterations, expansions and routine maintenance must be reported.

~~C. When reports are due.~~ All reports and test results must be submitted ~~within 15 working days of the sample collection~~ by the 15th of the month following the month in which the activity occurred.

~~D. Where to report results.~~ All reports and test results shall be submitted ~~to the local or district office of the health department~~ electronically. When formal testing indicates that a discharge limit established in the General Permit is being exceeded or when informal testing indicates a discharging system may be in violation of the General Permit requirements, the owner shall notify the maintenance provider and the department ~~shall be notified by the owner~~ within 24 hours.

12VAC5-640-520. Failure to submit information.

Failure to conduct mandatory monitoring or to report monitoring results as required in 12VAC5-640-490 and 12VAC5-640-510 may result in the ~~suspension or~~ revocation of the owner's operation permit. The department shall notify the Department of Environmental Quality of the revocation of the operation permit.

FORMS (12VAC5-640)

~~Appendix I-Combined Application Virginia Department of Health Discharging System Application Form for Single Family Dwellings Discharging Sewage Treatment Systems With Flows 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.~~

~~Appendix II-Completion Statement.~~

[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 \(rev. 9/11\)](#)

[Permit Transfer under 12 VAC 5-640-220 E \(undated\)](#)

[Completion Statement \(undated\)](#)

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

PART A. General Information

Types of Application: _____ New, _____ Repair, _____ Modification, _____ Expansion
_____ County or City Health Department Date: _____, 20____

Name of Facility/Residence: _____ Owner(s) of Facility/Residence: _____
Street Address _____ Street Address _____
City, State, Zip _____ City, State, Zip _____
Day Phone: _____ Cell: _____ Day Phone: _____ Cell: _____
Email Address: _____

Agent (if applicable): _____
Street Address _____
City, State, Zip _____
Day Phone: _____ Cell: _____

Tax Map#: _____ Subdivision: _____ Sect/Block: _____ Lot #: _____
Size of Parcel: _____ Acres. _____ Proposed Use (# of bedrooms): _____
Proposed volume of discharge (gallons per day): _____ gpd _____

If the discharge is to a wetland, attach the statement from the Army Corps of Engineers confirming the wetland delineation.

- | | YES | NO |
|--|-------|-------|
| 1. Are central sewage facilities available to this site/facility?
If yes, explain: _____ | _____ | _____ |
| 2. Does the residence/facility (existing or proposed) currently have an existing VPDES permit?
If yes, please provide the VPDES permit number: _____ | _____ | _____ |
| 3. Will any pollutants other than domestic sewage be treated or discharged?
If yes, please indicate what: _____ | _____ | _____ |
| 4. Is this application for a system to replace a failing septic system? _____ | _____ | _____ |
| 5. Discharge permits can only be issued to sites with no onsite solution in accordance with 12VAC5-640
Attach a copy of the onsite sewage permit denial.
OSE/PE: _____ Date of Denial: _____ PE/OSE License #: _____ | | |

I hereby give permission to the Health Department to enter onto the above referenced property for the purpose of processing this application. I certify that the property lines and the proposed location of the treatment system, discharge point, proposed structures, water supplies, utilities, easements, are clearly marked and the property is sufficiently clear to see the topography.

Signature of Property Owner Date

PART B. Site Evaluation

	YES	NO	N/A
6. Will discharge be directly to a year-round, all-weather stream? If so Name of Proposed Receiving Stream: _____	_____	_____	_____
7. If discharge is to an intermittent stream or to a dry ditch, how far will discharge flow before leaving this property? _____ ft.			
8. If discharge is to an intermittent stream, a dry ditch, or a wetland, and discharge will flow less than 500 feet on this property, can an easement be obtained in accordance with 12 VAC 5-640-370?	_____	_____	_____
		YES	NO
9. If discharge is to an intermittent stream or to a dry ditch, is the slope \geq 1% for all of the fifty foot segments?		_____	_____
10. Is the average slope \geq 2%?		_____	_____
11. In the first 500 feet will the path of wastewater flow within 100 feet of any well or domestic water supply?		_____	_____
12. Are there any springs used for human consumption within 1500 feet downstream, or 100 feet upstream of the discharge point?		_____	_____
13. Is there any public water supply intake within one mile downstream of the proposed discharge point?		_____	_____
14. Are there any public swimming areas designated for public use or prohibited discharge areas within one mile downstream from the proposed discharge point?		_____	_____
15. Is the receiving stream classified as, or does it discharge to, shellfish waters?		_____	_____
16. Are there any other existing or proposed VPDES discharges within 500 feet of this proposed discharge point along the flow path?		_____	_____
17. Will any part of the proposed treatment system (excluding the discharge pipe and any aeration steps) be located within the 100 year flood plain?		_____	_____
18. Will any part of the proposed treatment system (excluding the discharge pipe and any aeration steps) be located in a topographically low, wet, or swampy area?		_____	_____
19. Will the building served by this system be used intermittently, or be subject to frequent electrical power interruptions?		_____	_____
20. Provide verification that this proposed activity is consistent with all local ordinances adopted pursuant to Title 15.2 of the Code of Virginia including wetlands.		_____	_____
21. How will the discharge be disinfected? Circle one: Chlorine; Ultraviolet radiation; Other _____			

PART C. Site Sketch

PLEASE ATTACH A SITE SKETCH TO THIS APPLICATION SHOWING:

- 1) A survey plat with topographic contour, and the location of existing structures, easements, utilities, water supplies, and springs should be provided by the owner. Other information referenced in this application is to be plotted on the survey plat.
- 2) Directions to and boundaries of the property.
- 3) The specific location of the property including the county tax map number (where available), a copy of the United States Geological Survey 7.5 minute topographic map showing the discharge point and downstream for five miles.
- 4) The location and distance to any existing or proposed buildings, wells, sewage treatment systems, VPDES discharges, water sources, water lines, easements, or utilities within 600 feet of any part of the proposed sewage disposal system. Indicate the discharge point, property boundaries, limestone outcrops and wells within 500 feet.
- 5) The important topographic features of the site (drainways, sinkholes, ponds, lakes, streams) including the limits of the 100-year flood plain.
- 6) The path of wastewater flow to the receiving year-round stream.
- 7) A diagram of the existing or proposed sewage treatment system, including the location of the residence/facility and the individual sewage treatment units.
- 8) The elevation of the discharge point and the elevation and slope every 50 feet for 500 feet downstream along the discharge path. Also include the slope of the channel sides every 50 feet for 500 feet downstream along the discharge path.
- 9) The latitude and longitude of the proposed discharge point in degrees, minutes, and seconds.

Certification:

To the best of my knowledge the information provided on the site sketch and the site evaluation are accurate.

Site Summary: Discharge Point Type: _____
Easement Required? _____

Site Evaluation and Site Sketch prepared by: _____ Date: _____

VDH Site Evaluation Concurrence by: _____ Date: _____

PART C. Permissions

As the applicant for a construction permit on the above referenced property, I certify that, to the best of my knowledge, the above information and the attached site sketch and topographic map are true, correct, and complete. I understand that if the department finds a satisfactory site in response to this application that I will be required to submit construction permit application and plans and specifications for the treatment system prepared by an engineer and, certified copies of any necessary easements

Signature of Applicant

Date

As the applicant for an alternative discharging system construction and operations permit on the above referenced property, I hereby give permission to the Health Department, or their authorized agent, to enter onto the above referenced property for the purpose of inspecting the construction of and monitoring the operation and quality of effluent from my sewage treatment plant.

Signature of Applicant

Date

Department of Environmental Quality 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.

Signature of Applicant

Date

PART D. CERTIFICATION

I understand that I am responsible for contracting with a licensed operator to conduct all operation, maintenance, monitoring, and reporting for this permitted wastewater treatment system in accordance with 12VAC5-640. I certify that this system will be maintained by a licensed operator in accordance with 12VAC5-640.

Signature of Applicant

Date

PERMIT TRANSFER UNDER 12 VAC 5-640-220.E

Commonwealth of Virginia
Virginia Department of Health

_____ Health Department

General Permit Number VAG _____

Name of New Owner: _____

Signature of New Owner: _____

Address New Owner: _____

New Owner Phone Number: _____

Discharging System Address: _____

Certification Statement:

I understand that I am responsible for contracting with a licensed operator to conduct all operation, maintenance, monitoring, and reporting for this permitted wastewater treatment system in accordance with 12VAC5-640. I certify that this system will be maintained by a licensed operator in accordance with 12VAC5-640.

New Owner Signature

Date

Request for Transfer of Construction Permit:

- Attach: 1. Copy of Transfer of Ownership Form for VPDES Permit from Department of Environmental Quality
2. Written certification that there are no new site conditions that will adversely impact the existing approved construction permit and documents or the original construction application.

Request for Transfer of Operation Permit:

Attach: Copy of Transfer of Ownership Form for VPDES Permit from Department of Environmental Quality



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: May 7, 2014

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services

SUBJECT: *The Regulations for the Repacking of Crab Meat for Human Consumption*
(12VAC5-165)

The Office of Environmental Health Services, Division of Shellfish Sanitation has completed the periodic review of the Regulations for the Repacking of Crab Meat for Human Consumption 12VAC5-165 (Regulations). The Regulations are being presented to the Board in their final stage as part of the regulatory review process. The Board of Health approved the proposed regulations in 2011. The proposed Regulations were published in the Virginia Register for a 60-day comment period on December 16, 2013. Three comments were received during the comment period, and those recommendations were incorporated into the final stage of the Regulations.

The Regulations pertain to the practice of transferring crab meat from one processor's container into the container of a different processor, primarily for marketing purposes. When these regulations were adopted in 2000, they were developed to address the sanitation, product traceability, and labeling concerns associated with the situation where one processor would purchase crab meat packed by another certified crab meat processor, whether of a domestic or foreign origin, and repack the meat into a different container to market the product as their own. The amended Regulations provide requirements that Virginia processors can reasonably meet and will address the existing risks of the importation and repacking of foreign crab meat.

This is the final stage in the regulatory process. Following the Board of Health's approval, the final Regulations will be subject to executive branch review and approval. Upon executive branch approval, the Regulations will be published in the Virginia Register for a final 30 day notice of adoption.



Virginia

Regulatory
Town Hall
townhall.virginia.gov
V

Final Regulation Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-165
Regulation title	Regulations for the Repacking of Crab Meat for Human Consumption
Action title	Final amendments following periodic review
Date this document prepared	May 7, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The regulations under 12VAC5-165 et seq. pertain to the practice of transferring crab meat from one processor's container into the container of a different processor, primarily for marketing purposes. When these regulations were adopted in 2000, they were developed to address the sanitation, product traceability, and labeling concerns associated with the situation where one processor would purchase crab meat packed by another certified crab meat processor, whether of a domestic or foreign origin, and repack the meat into the new processor's container.

Currently, crab meat shipped into the United States originates from nearly thirty or more different processing facilities in foreign countries, even though it may be shipped by a single exporter to the U.S. Under this multi-source practice, the one-on-one relationship between the original processor and the Virginia crab meat processor can no longer exist. As such, several of the requirements that depended upon this relationship cannot be reliably met, and new processes for assuring the safety of this crab meat have been developed.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The final amendments to the Regulations for the Repacking of Crab Meat for Human Consumption (12VAC5-165) were approved by the State Board of Health on June 5, 2014.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The legal authority to promulgate the regulations is § 28.2-801 of the Code of Virginia. The promulgating entity is the State Board of Health.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Some of the provisions of 12VAC5-165 either cannot be met by certified Virginia repacking establishments because of changes in the way that crab meat is being imported from foreign countries and shipped into the U.S., or are no longer necessary and have no relevance to public health. The amended regulations are essential to protect public health in that they provide requirements that Virginia processors can reasonably meet and will address the existing risks of the importation of crab meat and the repacking of foreign crab meat and labeling it as domestic crab meat.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The Department proposes repealing 12VAC5-165-70 which states that the Division of Shellfish Sanitation (Division) should be contacted when any condition that may compromise the safety of the product exists. This provision is unnecessary and burdensome to both industry and the Division. Pursuant to existing federal regulations, the repacker is responsible to decide the appropriate disposition of product they are processing without the approval or disapproval of the Division.

The Department proposes modifying 12VAC5-165-90 which addresses the verification of shipping temperatures of imported crab meat. The modification is to include all crab meat and to clarify the verification.

The Department proposes modifying 12VAC5-165-100.A which addresses sampling requirements for imported crab meat to be repacked. The current U. S. Food and Drug Administration import requirements in the Code of Federal Regulations: 21 CFR 123.12 'Special requirements for imported products" have specific requirements for fish and fishery products which preclude the end product sampling requirement currently in place

The Department proposes modifying 12VAC5-165-100.B, which addresses organoleptic sensing. There is a lack of local capacity to train persons in organoleptic sensing to the level of being certified in seafood decomposition, which has made this regulation impractical. In its place, repacking establishments may organoleptically sense, to the best of the individual's capability, each container when opened and keep records attesting to this practice. Unsatisfactory containers would be discarded and a record kept of this process.

The Department proposes repealing 12VAC5-200, which requires the repacker to pasteurize all imported crab meat that has not been pasteurized. A review of national illness data from the Centers for Disease Control indicates that unpasteurized foreign crab meat does not pose the elevated public health risk originally believed to exist; therefore this requirement is no longer necessary.

The Department proposes modifying 12VAC5-165-220.B which requires that the lot number indicate the original source firm that picked the crab meat. Since a reliable indication of the establishment that picked the meat may be unrealistic, some other means of identifying lot numbers may be used by the repacker.

The Department proposes repealing 12VAC5-165-280 which requires that records must be kept separate from other production records. This requirement is unnecessary since the method and type of records being kept are dictated by the repacker's Hazard Analysis Critical Control Point (HACCP) plan. Other sections of this regulation may be addressed during this process.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*
If there are no disadvantages to the public or the Commonwealth, please indicate.

The proposed amendments will serve to protect the public's health by clarifying requirements for repacking crab meat. The proposed amendments eliminate or modify certain regulatory requirements that are unnecessary, burdensome or no longer practical. For example, the proposed amendment to 12VAC5-165-100 will eliminate burdensome and unnecessary sampling requirements. In addition, the repeal of 12VAC5-165-280 will eliminate unnecessary recordkeeping requirements.

There are no disadvantages to the public or the Commonwealth.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-165-150 and 12VAC5-165-180	Containers of pasteurized crab meat destined for repacking shall be stored at a temperature of 36°F or less.	US FDA guidance for the cold holding temperature of pasteurized crab meat was changed from 36°F to 40°F	4 th Edition of FDA Seafood Hazards Guide allows for the cold holding temperature for pasteurized crab meat to be 40°F or less. Public comments addressed this issue.
12VAC5-165-230	Imported crabmeat is required to be packed into containers which bear a declaration of the country of origin. At the proposed stage the regulation was amended to require a pre-printed container with the country of origin on the principal display panel.	A permanent pre-printed label on the container will not be required.	Based on public comment the proposed regulation was changed. Permanent demarcation on containers will not be required. Labels will be allowed to be placed on containers identifying the country of origin. The requirement for pre printed containers will cause businesses to purchase containers that may not be used and therefore cause an upfront expense which may not be easily recouped based on the supplier at the time of repacking crab meat.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Mike Jahncke, Director, Virginia Tech Seafood Extension	Suggested the refrigeration temperature for pasteurized crabmeat be changed from 36° F to 40° F or less.	Agree with temperature change. 40°F temperature will enable processors to meet HACCP guidelines.
Kelly Minor, Little River Seafood	Request refrigeration temperature for pasteurized crabmeat be changed from 36° F to 40°, and indicated that pg 252 of 4 th edition of FDA Hazards Guide; Fish and Fishery Products. If we do not change the temperature, she would not know how to report on HACCP documents when product was over 36°F but 40°F or less.	Agree with temperature change. 40°F temperature will enable processors to meet HACCP guidelines.
Kevin Wade	Production of preprinted cups poses an economic burden and prohibits business model	Proposed regulation has been changed to allow for the addition of a label after the container has been purchased as long as the requirement for labeling for country of origin is met.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current Section Number	Proposed new section number if applicable	Current requirement	Proposed change and rationale
12VAC5-165-10	N/A	Importer not defined.	Importer means either the owner or consignee at the time of entry into the United States, or the agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.
12VAC5-165-10	N/A	Processor is defined as a person who operates as establishment that cooks, picks, packs, repacks, or pasteurizes crab meat.	Processor means any person engaged in commercial, custom, or institutional processing of crab meat, either in the United States or in a foreign country.
12VAC5-165-70	N/A	Oversight of safety of product. Any condition that may compromise the safety of the final product shall be identified by the repacker and the Division shall be contacted for appropriate disposition of the product.	Repealed. The processor is responsible for the safety of the product and may decide the appropriate disposition independently from the Division in consult with VA Tech Seafood Extension or using the U. S. FDA Seafood Hazards Guide.
12VAC5-165-80	N/A	Crab meat for repacking from a foreign government shall be picked and packed by a crab processing establishment which is currently licensed, permitted or certified and inspected by a foreign government public health authority and shall operate under a HACCP plan approved by a foreign government public health authority.	Added the FDA imports requirement that imported crab meat shall meet the requirements of the Code of Federal Regulations: 21 CFR 123.12 "Special requirements for imported products."
12VAC5-165-90	N/A	Imported crab meat must be received with transport temperature conditions. The measuring device must be approved by the	The regulation will be amended to include transport temperature receiving conditions for all crab meat whether domestic or foreign in line with the FDA requirements for pasteurized crab meat. The Division does not

		Division.	need to approve the temperature measuring device. The device used must meet the requirements of the FDA Seafood Hazards Guide for its intended use.
12VAC5-165-100	N/A	Sampling and analysis of imported crab meat is currently required prior to repacking.	All imported crab meat must meet the FDA Code of Federal Regulations: 21 CFR 123.12 in order to be imported into the United States. The import requirements help to ensure that the crab meat is processed in a facility that is comparable to a U.S regulated facility, follows good manufacturing practices and Seafood Hazard Analysis and Critical Control Points (HACCP). The regulation is amended to allow for sampling prior to repacking and gives action levels for both aerobic plate counts and fecal coliform.
12VAC5-165-120	N/A	Verification of container integrity for imported, pasteurized crab meat.	Amended regulation for all pasteurized crab meat to have a container integrity check and the records be kept on file for a minimum of one year.
12VAC5-165-150	N/A	Containers of pasteurized crab meat destined for repacking shall be stored at a temperature of 36°F or less. Transportation is included.	Amended regulation to require all pasteurized crab meat to be stored at 40°F or less as a result of the public comment period. Transportation requirement removed since it is responsibility of the receiving company to ensure temperature requirements.
12VAC5-165-180	N/A	Cooling of crab meat after repacking.	Remove “or both”, requirement is unnecessary. Amend regulation to require refrigeration not to exceed to 40°F.
12VAC5-165-200	N/A	Imported crab meat to be pasteurized is currently required to meet the National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards.	Amended regulation to remove requirement. The FDA Seafood Hazards Guide and in plant validation studies conducted by VA Tech Seafood Extension serves to control hazards in pasteurization.
12VAC5-220	N/A	Lot number requirements on containers referred to the source firm.	Amended regulation to change source firm to original processor for consistency.
12VAC5 - 165-230	N/A	Imported crab meat is required to be packed into containers which bear a declaration of the country of origin.	For the proposed stage it was noted that stickers are often placed onto containers with the country of origin. These stickers are easily removed from the container so that consumer believes the crab meat is domestic, which demands a higher price. The regulation was amended in the proposed stage to require a preprinted container with country of origin on the principal display panel. During the public comment period it was expressed that having to preorder containers printed with the country of origin may cause unnecessary expense to a firm due to the possibility of sources of crabmeat. A change in suppliers could render the firm with a large quantity of containers that could

			not be used due to the demarcation on the container.
12VAC5-165-260	N/A	The individual crab meat shall be easily traceable.	The current regulation does not define the scope of what must be traceable. The regulation is amended to require lots of crab meat to be traceable.
12VAC5-165-270	N/A	The minimum records to be kept are listed.	The regulation is amended to better clarify and be consistent with the type of records and length of time they must be kept.
12VAC5-165-290	N/A	Decertification of certified facilities.	The regulation is repealed since the penalty for not labeling the repacked crab meat with the country of origin is a Class 1 misdemeanor.
12VAC5-165-310	N/A	Persons guilty of a Class 1 misdemeanor if found to be packing or repacking foreign crab meat into a container without the country of origin indicated on the principal display panel.	Persons are clarified. The owner of a facility and the supervisory employees of that facility may be guilty of a Class 1 misdemeanor. It is not the intent of VDH to charge a subordinate employee who is found repacking foreign crab meat as domestic crab meat. The persons in charge such as the owner and/or supervisor are responsible to assure compliance with the regulations, and would be the named parties in an enforcement action.

Project 2705 - Proposed

DEPARTMENT OF HEALTH

Modify regulations for repacking of crabmeat as result of periodic review

Part I

General Provisions

12VAC5-165-10. Definitions.

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

"Action level" means the limit established for a deleterious substance present in a product or the environment, above which level prescribed actions by the division may be required to protect public health.

~~"Agency" means the Virginia Department of Health.~~

"Certificate of Inspection" means a numbered certificate issued by the division to a shipper after an inspection confirms compliance with applicable regulations and standards.

"Certification number" means a unique number assigned to each shipper upon issuance of a Certificate of Inspection.

"Certified laboratory" means a laboratory certified by the U.S. Food and Drug Administration for analysis of food products.

"Critical Control Point ~~(CCP)~~" or "CCP" means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can, as a result, be prevented, eliminated or reduced to acceptable numbers.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

~~"Decertification" means the revocation of a Certificate of Inspection.~~

~~"Department" means the Virginia Department of Health.~~

"Division" means the Division of Shellfish Sanitation of the Virginia Department of Health.

"Establishment" means any vehicle, vessel, property, or premises where crustacea, finfish or shellfish are transported, held, stored, processed, packed, repacked or pasteurized in preparation for marketing.

"HACCP plan" means a written document that delineates the formal procedures that a dealer follows to implement a Hazard Analysis Critical Control Point methodology to assure food safety.

"Hazard analysis" means a process used to determine whether there are food safety hazards that are reasonably likely to occur while repacking crab meat and to identify the preventive measures that the repacker can apply to control those hazards.

"Importer" means either the owner or consignee at the time of entry of the crab meat into the United States, or the agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.

"Lot" means repacked crab meat that bears the same repack date and source code.

"Preventive measure" means actions taken to prevent or control a food safety hazard.

"Principal display panel" means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

"Processing" means cooking, picking, packing, repacking or pasteurizing crab meat.

"Processor" means ~~a person who operates an establishment that cooks, picks, packs, repacks or pasteurizes crab meat~~ any person engaged in commercial, custom, or institutional processing of crab meat, either in the United States or in a foreign country.

"Repacker" means a person who operates an establishment that transfers crab meat from a container originally packed by another establishment to another container.

"Repacking operation" means a process of transferring crab meat from the original shipper's packing container to a different packing container, including all steps beginning with the removal of the original containers of meat from the repacker's refrigeration and ending with the repacked crab meat in properly identified containers placed into refrigeration.

"Shipper" means a person who operates an establishment for the cooking, picking, repacking or pasteurizing of crab meat.

"Source code" means a code designated by the repacker which represents the crab processing facility where crab meat was obtained.

12VAC5-165-70. Oversight for safety of product. (Repealed.)

~~Any condition that may compromise the safety of the final product shall be identified by the repacker and the division shall be contacted for appropriate disposition of the product.~~

Part II

Sources of Crab Meat for Repacking

12VAC5-165-80. Source facility requirements.

Crab meat for repacking shall be picked and packed by a crab processing establishment which is currently licensed, permitted or certified and inspected by either a state public health authority or by a foreign government public health authority, and shall operate under a HACCP plan approved by the state or a foreign government public health authority, or the U.S. Food and Drug Administration. Imported crab meat shall meet the requirements for imported products set forth in 21 CFR 123.12 (60 FR 65197, December 18, 1995).

12VAC5-165-90. Verification of shipping temperatures for imported crab meat.

~~When imported crab meat is used as a source for repacking, the~~ The repacker shall provide a record of international transport temperature receiving conditions for each shipment, or other information sufficient to verify that the product was not temperature abused of crab meat. Temperature recording may be by maximum temperature recording, continuous temperature recording, or by other device approved by the Division of Shellfish Sanitation such as adequate amount of ice or adequate quantity of chemical cooling media. ~~The processor repacker shall include the transport receiving temperature conditions as a part of the receiving CCP in its the HACCP plan.~~

12VAC5-165-100. Sampling and analysis requirements for imported crab meat.

A. ~~When imported crab meat is used as a source for repacking, the repacker shall take a minimum of five samples from the first two shipments prior to any processing to be analyzed by a certified laboratory. If all samples from both initial shipments meet the specified action levels, then the sampling interval may be reduced to once every three months (quarterly) for each shipper. If any quarterly samples exceed the action levels, then sampling will be required on all successive shipments until all samples from two successive shipments meet the action levels as follows: importer or repacker may take samples from each lot prior to processing to be analyzed by a certified laboratory and maintain on file a copy of the sampling results for a minimum of one year. The action levels for the crab meat sampled are as follows:~~

1. Pasteurized crab meat.
 - a. Aerobic plate count; action level of >3,000/g.

- b. Fecal coliforms; action level of >20/100g.
- 2. All other crab meat.
 - a. Aerobic plate count; action level of >100,000/g.
 - b. Fecal coliforms; action level of >93/100g.

B. When imported crab meat is used as a source for repacking, the importer or repacker shall may take a minimum of five samples from every shipment to be tested for decomposition by organoleptic sensing technique and maintain a copy of the results on file for a minimum of one year. ~~These analyses shall be conducted only by a designated person trained in organoleptic sensing technique either by Virginia Polytechnic Institute and State University (Virginia Tech), the United States Food and Drug Administration (FDA), or by another source approved by the division. The repacker shall submit to the division a copy of the certificate of training or other documentation denoting successful completion of the training from the trainer for each individual conducting the analysis, and shall maintain a copy in his records.~~

C. If any sample is found to exceed an action level or guideline, or is found to show evidence of decomposition, the repacker shall stop processing the lot sampled and ~~contact the division before proceeding with processing to determine the disposition of that lot.~~

D. All records of sample analyses ~~shall be kept on file at the repacker and~~ repacker's establishment shall be made available for review by the division. These records shall be maintained for a period of one year from the date of processing for products packaged for fresh distribution, and two years for products packaged for frozen or pasteurized distribution.

12VAC5-165-120. Verification of container integrity for imported, pasteurized crab meat.

The repacker shall evaluate the container integrity of all imported, pasteurized crab meat products. These evaluations shall also be conducted after any pasteurization by the repacker. This evaluation shall at a minimum include visual inspection of all containers for evidence of leaks. A record of inspection shall be maintained on file by the repacker for a minimum of one year.

12VAC5-165-150. Pasteurized crab meat storage temperature.

Containers of pasteurized crab meat ~~destined for repacking~~ shall be stored and transported in a refrigerated room ~~or vehicle~~ at a temperature of [~~36°F~~ 40°F] or less.

12VAC5-165-180. Cooling of crab meat after repacking.

Immediately after repacking, the repacker shall place containers of repacked crab meat ~~shall be either placed into crushed or flaked ice or placed into refrigeration not to exceed [36°F 40°F] , or both.~~

12VAC5-165-200. Imported crab meat to be pasteurized. (Repealed.)

~~Prior to or after repacking, the repacker shall pasteurize all imported crab meat which has not been pasteurized in the country of origin. Pasteurization shall meet the National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards, revised November 8, 1993, with records of pasteurization to be kept as required in Article 3 (12VAC5-165-240 et seq.) of this part. The heat penetration in the crab meat during the pasteurization process for all container sizes and types shall be confirmed in writing by Virginia Tech or other authority approved by the division as meeting the aforementioned minimum requirements.~~

12VAC5-165-220. Lot numbers.

A. Containers of repacked crab meat shall be stamped or embossed with the lot number.

B. Lot numbers shall consist of a repack date and a code indicating the original ~~source firm that picked the crab meat~~. All codes for lot numbers shall be logged in the processor records. Records shall be maintained by the repacker for a minimum of one year with an explanation of the code.

12VAC5-165-230. Country of origin for imported crab meat.

Imported crab meat shall be packed by the repacker into containers ~~which that~~ bear a declaration of the country of origin of the repacked crab meat ~~on the [using a preprinted principal display panel]-~~ of the container.

Article 3

Records and Recordkeeping

12VAC5-165-240. Accessibility of records.

All required records shall be ~~(i) kept in logical order, (ii) maintained by the repacker, and (iii) readily accessible by~~ shall be made available to the Division of Shellfish Sanitation staff division for inspection.

12VAC5-165-270. Minimum records to be kept.

The repacker shall, ~~at a minimum,~~ maintain the following information on each lot of repacked crab meat ~~the source plant, quantity received from source, type of meat, date of repacking, buyers, and quantities of repacked lots sold. Additional clarifying records may be required if individual lots of product cannot easily be traced~~ for a minimum of one year: (i) the original processor information, (ii) verification records of shipping temperature conditions, (iii) records required by the repacker's HACCP plan, and (iv) repacked crab meat sales records. Additional clarifying records may be required by the division to identify lot codes on containers.

12VAC5-165-280. Records to be kept separate. (Repealed.)

~~Records for repacked imported crab meat shall be kept separate from other production records.~~

Article 4

Penalties

12VAC5-165-290. Decertification of certified facilities. (Repealed.)

~~Any certified crab meat processor found to be packing or repacking foreign crab meat into a container without the country of origin on the principal display panel will be decertified for 30 days, effective immediately upon the finding by the Director of the Division of Shellfish Sanitation.~~

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-165)

~~National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards, National Blue Crab Industry Association Grades and Cooking Standards Committee, revised November 8, 1993.~~