

**State of Board of Health
Agenda - REVISED
September 12, 2013 – 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	Mr. Edwards
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of June 6, 2013 Minutes	Mr. Edwards
Commissioner’s Report	Cynthia C. Romero, MD, FAAFP State Health Commissioner
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Informed Consent for Abortion Statute – Overview of VDH Statutory Responsibilities	Lauri Kalanges, MD, MPH Acting Director, Office of Family Health Services
Break	
Regulatory Action Update	Mr. Hilbert
Public Comment Period	
<u>Action Items</u>	
Statewide Trauma Registry Minimum Data Set (§ 32.1-116.1 of the Code of Virginia)	Gary Brown, Director Office of Emergency Medical Services
Guidelines for Cleanup of Residential Property Used to Manufacture Methamphetamine (HB796 of 2012, HB1615 of 2013)	Allen Knapp, Director Office of Environmental Health Services
Lunch	

Lunch Speaker – Ms. Beth Bortz, Executive Director, Virginia Center for Health Innovation

Regulatory Action Items

Sewage Handling and Disposal Regulations
12VAC5-610
(Emergency Regulations – Gravelless Material
and Drip Dispersal)

Mr. Knapp

Regulations for Disease Reporting and Control
12VAC5-90
(Proposed Amendments)

David Trump, MD, MPH
Director, Office of Epidemiology

Regulations Prohibiting the Taking of Fish
for Human Consumption from the North Fork
of the Holston River
12VAC5-170
(Repeal)

Dr. Trump

Regulations for the Licensure of Nursing Facilities
12VAC5-371
(Fast Track Amendments – Electronic Monitoring)

Mr. Bodin

Regulations for the Licensure of Hospitals in Virginia
12VAC5-410
(Notice of Intended Regulatory Action)

Mr. Bodin

Regulations for the Licensure of Nursing Facilities
12VAC5-371
(Notice of Intended Regulatory Action)

Mr. Bodin

Break

Rules and Regulations for Identification of
Medically Underserved Areas in Virginia
12VAC5-540
(Final Amendments)

Karen Reed
Acting Director of Administration
Office of Minority Health and Health Equity

2014 Board Proposed Meeting Schedule

Mr. Edwards

Member Reports

Other Business

Adjourn

August 7, 2013

MEMORANDUM

TO: Virginia State Board of Health

FROM: Gary R. Brown
Director, Office of Emergency Medical Services

SUBJECT: Statewide Trauma Center Designation Manual Revisions

Section 32.1-116.1 of the Code of Virginia requires the Board of Health to prescribe the minimum dataset and technical format used by the Virginia Statewide Trauma Registry (VSTR). Section 32.1-116.1 states all licensed hospitals which render emergency medical services shall participate in the VSTR by making available to the State Health Commissioner or his designees abstracts of the records of all patients admitted to the institution with a diagnosis related to trauma. The abstracts shall be submitted in the format prescribed by the Department and shall include the minimum data set prescribed by the Board.

The Virginia Department of Health's Office of Emergency Medical Services (VDH/OEMS) has not revised its trauma registry minimum dataset or technical format since 2004. VDH/OEMS has attempted to be conservative in the number of data elements it collects with the goals of moving closer to the national trauma data standard, meet its mandates for trauma triage monitoring, trauma center designation, performance improvement, and allow for linkage to other applicable databases.

The proposed Virginia Statewide Trauma Registry Minimum Dataset version 3 (VSTRv3) was distributed to Virginia hospitals, trauma centers, third party trauma registry software vendors serving Virginia hospitals, the Department of Rehabilitative Services, and the general public. Approximately 25 notices have been sent to these entities using U.S. Mail, e-mail list serves, during standing committee meetings, Web site postings, and other venues.

Public comment occurred via a Wiki page dedicated to this project. Google Analytics was used to monitor the Wiki page to assure that the target audience was being reached. Two public comment periods were held with a moderate amount of input received. Public comment for each comment period was compiled and distributed. Most comments led to the requested changes being made or by adding additional information to the resource materials that are being developed to support the program.

The Trauma System Oversight and Management Committee of the Emergency Medical Services Advisory Board endorsed the revised minimum dataset at its June 5, 2013 meeting and the Emergency Medical Services endorsed the dataset on August 9, 2013.

OEMS requests the State Board of Health approve the revised VSTRv3 minimum dataset and technical format. If the Board of Health adopts the revised Designation Manual, these criteria will become effective January 1, 2014.

Code of Virginia § 32.1-116.1 The Prehospital patient care reporting procedure: trauma registry; confidentiality

In order to collect data on the incidence, severity and cause of trauma, integrate the information available from other state agencies on trauma and improve the delivery of prehospital and hospital emergency medical services, there is hereby established the Emergency Medical Services Patient Care Information System. The Emergency Medical Services Patient Care Information System shall include the Virginia Emergency Medical Services (EMS) Registry and the Virginia Statewide Trauma Registry.

All licensed hospitals which render emergency medical services shall participate in the Virginia Statewide Trauma Registry by making available to the Commissioner or his designees abstracts of the records of all patients admitted to the institutions' with diagnoses related to trauma. The abstracts shall be submitted in the technical format prescribed by the Department and shall include the minimum data set prescribed by the Board.

VDH/OEMS has not revised its trauma registry minimum dataset or technical format since 2004. VDH/OEMS has attempted to be conservative in the number of data elements it collects with the goals of moving closer to the national trauma standard, meet its mandates for trauma triage monitoring, trauma center designation, performance improvement, and allow for linkage to other applicable databases.

The proposed Virginia Statewide Trauma Registry Minimum Dataset version 3 (VSTRv3) was distributed to Virginia hospitals, trauma centers, third party trauma registry software vendors serving Virginia hospitals, the Department of Rehabilitative Services, and the general public. Approximately 25 notices have been sent to these entities using U.S. Mail, e-mail list serves, during standing committee meetings, Web site postings, and other venues.

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The Trauma System Oversight and Management Committee of the EMS Advisory Board endorsed the revised minimum dataset at its June 5, 2013 meeting and the State Emergency Medical Services Advisory Board endorsed the dataset on August 9, 2013.

Table 1 below exhibits the proposed revised Virginia Statewide Trauma Registry minimum dataset and if the element is a national element and if it will be collected by designated trauma centers, acute cares hospitals, or both.

Table 1 Proposed Trauma Registry Minimum Dataset

New Element?	Proposed Trauma Registry Data Element Number and Name (VSTRv3)	NTDS*	Trauma Centers*	Hospitals*
No	Demographic_01 – Patient’s Home ZIP Code	Y	Y	Y
No	Demographic_02 – Patient’s Home Country	Y	Y	Y
No	Demographic_03 – Patient’s Home State	Y	Y	Y
No	Demographic_04 – Patient’s Home County/City	Y	Y	Y
No	Demographic_05 – Patient’s Home Town	Y	Y	Y
No	Demographic_06 – Alternate Home Address	Y	Y	Y
No	Demographic_07 – Patient’s Date of Birth	Y	Y	Y
No	Demographic_08 - Age	Y	Y	Y
No	Demographic_09 – Age Units	Y	Y	Y
No	Demographic_10 - Race	Y	Y	Y
Yes	Demographic_11 – Ethnicity	Y	Y	Y
No	Demographic_12 - Gender	Y	Y	Y
No	Demographic_13 - Medical Record Number (MRN)	N	Y	Y
No	Demographic_14 - Last Name	N	Y	Y
No	Demographic_15 - First Name	N	Y	Y
No	Demographic_16 - Patient's Street Address	N	Y	Y
Yes	Diagnosis_01 - Co-Morbid Conditions	Y	Y	N
No	Diagnosis_02 – Injury Diagnosis	Y	Y	Y
No	ED/Hospital_01 – ED/Hospital Arrival Date	Y	Y	Y
No	ED/Hospital_02 – ED/Hospital Arrival Time	Y	Y	Y
No	ED/Hospital_03 – Initial ED/Hospital SBP (Systolic Blood Pressure)	Y	Y	Y
Yes	ED/Hospital_04 – Initial ED/Hospital Heart Rate	Y	Y	Y
Yes	ED/Hospital_05 – Initial ED/Hospital Temperature	Y	Y	Y
No	ED/Hospital_06 – Initial ED/Hospital Respiratory Rate	Y	Y	Y
Yes	ED/Hospital_07 – Initial ED/Hospital Respiratory Assistance	Y	Y	Y
Yes	ED/Hospital_08 – Initial ED/Hospital Pulse Oximetry	Y	Y	Y
Yes	ED/Hospital_09 – Initial ED/Hospital Supplemental Oxygen	Y	Y	Y
No	ED/Hospital_10 – Initial ED/Hospital Glasgow Coma Score - Eye	Y	Y	Y
No	ED/Hospital_11 – Initial ED/Hospital Glasgow Coma Score - Verbal	Y	Y	Y
No	ED/Hospital_12 – Initial ED/Hospital Glasgow Coma Score - Motor	Y	Y	Y
No	ED/Hospital_13 – Initial ED/Hospital Total Glasgow Coma Score	Y	Y	Y
Yes	ED/Hospital_14 – Initial ED/Hospital Glasgow Coma Score - Qualifier	Y	Y	Y
No	ED/Hospital_15 – Alcohol Use Indicator	Y	Y	Y
Yes	ED/Hospital_16 – Drug Use Indicator	Y	Y	Y

New Element?	Proposed Trauma Registry Data Element Number and Name (VSTRv3)	NTDS*	Trauma Centers*	Hospitals*
No	ED/Hospital_17 – ED Discharge Disposition	Y	Y	Y
Yes	ED/Hospital_19 – ED Discharge Date	Y	Y	Y
Yes	ED/Hospital_20 – ED Discharge Time	Y	Y	Y
No	Financial_01 – Primary Method of Payment	Y	Y	Y
No	Injury_01 – Injury Incident Date	Y	Y	Y
No	Injury_02 – Injury Incident Time	Y	Y	Y
No	Injury_03 – Work-Related	Y	Y	Y
Yes	Injury_04 – Patient’s Occupational Industry	Y	Y	Y
Yes	Injury_05 – Patient’s Occupation	Y	Y	Y
No	Injury_06 – Primary E-Code Type	Y	Y	Y
No	Injury_07 – Injury E-Code Place	Y	Y	Y
Yes	Injury_08 – Additional E-Code	Y	Y	Y
No	Injury_09 - Incident Location ZIP Code	Y	Y	Y
No	Injury_11 - Incident State	Y	Y	Y
No	Injury_12 - Incident County or City	Y	Y	Y
No	Injury_13 - Incident Town (if applicable)	Y	Y	Y
No	Injury_14 - Use of Protective Devices/Safety Equipment	Y	Y	Y
No	Injury_16 - Airbag Deployment	Y	Y	Y
No	Organ_01 - Organs Donated	N	Y	Y
No	Outcome_01 – Total ICU Length of Stay	Y	Y	Y
Yes	Outcome_02 – Total Ventilator Days	Y	Y	Y
No	Outcome_03 – Hospital Discharge Date	Y	Y	Y
No	Outcome_04 – Hospital Discharge Time	Y	Y	Y
No	Outcome_05 – Hospital Discharge Disposition	Y	Y	Y
No	Outcome_06 - Name of Facility Transferred To Code	N	Y	Y
Yes	Prehospital_01 – EMS Dispatch Date	Y	Y	N
Yes	Prehospital_02 – EMS Dispatch Time	Y	Y	N
Yes	Prehospital_03 – EMS Unit Arrival Date at Scene or Transferring Facility	Y	Y	N
Yes	Prehospital_04 – EMS Unit Arrival Time at Scene or Transferring Facility	Y	Y	N
Yes	Prehospital_05 – EMS Unit Departure Date From Scene or Transferring Facility	Y	Y	N
Yes	Prehospital_06 – EMS Unit Departure Time From Scene or Transferring Facility	Y	Y	N
No	Prehospital_07 - Transport Method to Hospital	Y	Y	Y
Yes	Prehospital_08 – Other/Additional Transport Methods to Hospital	Y	Y	Y
Yes	Prehospital_09 – Initial Field SBP (Systolic Blood Pressure)	Y	Y	N
Yes	Prehospital_10 – Initial Field Heart Rate	Y	Y	N
Yes	Prehospital_11 – Initial Field Respiratory Rate	Y	Y	N
Yes	Prehospital_12 – Initial Field Pulse Oximetry	Y	Y	N

New Element?	Proposed Trauma Registry Data Element Number and Name (VSTRv3)	NTDS*	Trauma Centers*	Hospitals*
Yes	Prehospital_13 – Initial Field Glasgow Coma Score - Eye	Y	Y	N
Yes	Prehospital_14 – Initial Field Glasgow Coma Score - Verbal	Y	Y	N
Yes	Prehospital_15 – Initial Field Glasgow Coma Score - Motor	Y	Y	N
Yes	Prehospital_16 – Initial Field Total Glasgow Coma Score	Y	Y	N
No	Prehospital_17 – Interfacility Transfer	Y	Y	Y
No	Prehospital_18 - Name of Facility Transferred From	N	Y	Y
No	Prehospital_19 - Name of EMS Agency Received From	N	Y	Y
Yes	Procedures_01 – Hospital Procedures	Y	Y	Y
Yes	Procedures_02 – Hospital Procedure Start Date	Y	Y	N
Yes	Procedures_03 – Hospital Procedure Start Time	Y	Y	N
Yes	Quality_01 – Hospital Complications	Y	Y	N
Yes	Severity_01 – AIS Code	Y	Y	N
Yes	Severity_02 – AIS Severity	Y	Y	N
No	Severity_03 – ISS Score	Y	Y	N
Yes	Severity_04 – AIS Version	Y	Y	N
No	Severity_05 – Locally Calculated ISS	Y	Y	N

* Legend

NTDB = National Trauma Data Standard.

Trauma Centers = Hospitals that are designated as a Level I, II, or III trauma center.

Hospitals = Hospitals that do not hold trauma center designation

Data elements that have been retired:

Patient_ID (SSN, AIN)
Middle Name
Suffix
Personal Identification
Personal Identification Type
Address Line 1
Address Line 2
USA Phone
Extension
International Phone
Prehospital Care (level)



COMMONWEALTH of VIRGINIA

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Cynthia C. Romero, MD, FAAFP
State Health Commissioner

MEMORANDUM

DATE: July 26, 2013

TO: Virginia Board of Health

FROM: Allen Knapp
Director, Office of Environmental Health Services

SUBJECT: Proposed Guidelines for Cleanup of Residential Property Used to Manufacture Methamphetamine

Enclosed for your review are the proposed Guidelines for Cleanup of Residential Property Used to Manufacture Methamphetamine ("Guidelines"). The Guidelines will take effect upon adoption by the Virginia State Board of Health (Board).

On April 18, 2012, Governor McDonnell approved legislation, introduced as House Bill 796, which required the Board to establish guidelines for the cleanup of residential property formerly used as clandestine methamphetamine laboratories. On March 20, 2013, the Governor approved additional legislation, introduced as House Bill 1615, which expanded the scope of the guidelines to all residential properties where methamphetamine was manufactured. The statutory mandate for the Board to establish the Guidelines is codified in § 32.1-11.7 of the Code of Virginia.

In developing the proposed Guidelines, the agency convened a stakeholder working group which included representatives from the Department of Environmental Quality, the Virginia State Police, the Department of Emergency Management, the Department of Housing and Community Development, the Town of Christiansburg, ServPro, and the Virginia Association of Realtors. The proposed Guidelines were developed based on input from the stakeholder working group, nationally recognized cleanup standards and relevant peer reviewed literature. The agency believes that adherence to the cleanup procedures and standards in the proposed Guidelines should provide reasonable assurances that methamphetamine contamination in residential properties has been remediated to a level that poses a negligible threat to human health and the environment.

Thank you for your consideration. I look forward to discussing the proposed Guidelines with you at the September meeting.

**Guidelines for Cleanup of Residential Property
Used to Manufacture Methamphetamine**

August 6, 2013

Virginia Department of Health

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I. Background

On April 18, 2012, Governor McDonnell approved legislation, introduced as House Bill 796 by Delegate Nick Rush, which required the Virginia Board of Health (Board) to establish guidelines for the cleanup of residential property formerly used as clandestine methamphetamine laboratories. After the law became effective on July 1, 2012, the Virginia Department of Health (VDH) convened a working group to develop a set of draft guidelines for review and approval by the Board. Along with staff from VDH, this workgroup included representatives from the Department of Environmental Quality, the Virginia State Police, the Department of Emergency Management, the Department of Housing and Community Development, the Town of Christiansburg, ServPro, and the Virginia Association of Realtors. On March 20, 2013, Governor McDonnell approved additional legislation, House Bill 1615, which expanded the scope of the guidelines to all residential properties where methamphetamine was manufactured as well as establishing residential property disclosure notifications. House Bill 1615 has a delayed effective date of July 1, 2014 to allow time for the Board's Guidelines to be established. The guidelines offered here represent the consensus of the participating members and their best efforts to assure the cleanup guidelines meet nationally recognized models put forth to prevent further contamination of residential property and to protect public health.

In the Southeastern United States, methamphetamine production by illicit or clandestine laboratories has been on the rise in recent years (Office of National Drug Control Policy, 2010). Methamphetamine manufacturing operations have been discovered in various settings including, but not limited to, occupied and abandoned houses, apartments, motel rooms, sheds, and motor vehicles. For the purposes of these guidelines, the cleanup recommendations are limited to residential properties.

The Board developed these guidelines based on nationally recognized standards, relevant peer reviewed literature and input from industry and governmental stakeholders and subject matter experts. It is important to emphasize that the standards and procedures contained in these documents are guidelines; guidelines do not have the force of law and adherence is voluntary. At the same time, the purpose of the Guidelines are to provide clean-up procedures and standards determined by the Board to be "best practices" reasonably calculated to assure that current and future property owners and occupants who follow the Guidelines can remediate methamphetamine contamination to a level that does not pose a threat to persons occupying residential dwelling units in Virginia. Nothing in these Guidelines shall be construed to establish a factual or proximate causal relationship between the risks associated with the manufacture of methamphetamine and any exposure or other injury sustained by current or future owners, occupants or inhabitants of residential dwelling units. In addition, the Board and its designees do not conduct inspections of residential properties to document or enforce compliance with these Guidelines.

II. Definitions

Methamphetamine means any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers; methamphetamine is a schedule II central nervous system stimulant (base formula C₁₀ H₁₅ N).

Residential property or residential dwelling unit means a structure or part of a structure that is used as a home or residence by one or more persons who maintain a household including, but not limited to, a manufactured home.

III. Health Concerns Related to Manufacture of Methamphetamine

Several processes and many different combinations of chemicals made as ‘recipes’ are used to manufacture or ‘cook’ methamphetamine (See Appendix A). The release of these vapors presents a potential exposure hazard for occupants of the premises where the methamphetamine was manufactured. Each process uses and produces gases or vapors at some point during the cooking operation. The distribution of gases and vapors may be extended or spread by a building’s heating, ventilation and air-conditioning (HVAC) system.

Both acute (short-term) and chronic (long-term) health hazards may result from the manufacturing of methamphetamine. Acute exposure hazards come from direct contact with product or waste and inhalation of product or waste. Burns, tissue irritation, and rashes can result from chemical spills, explosion, and direct skin contact with chemicals. Headaches, dizziness, nausea and other health effects can result from inhalation of vapors.

The potential for exposure to methamphetamine residues on surfaces and porous articles depends on accessibility of residues to surfaces and frequency of direct contact. The likely use of a contaminated area is an important factor in estimating frequency of contact. For example, residues in a kitchen or bathroom of a house will likely be contacted more frequently than residues in outdoor buildings such as unattached garages and sheds. Methamphetamine exposures may occur via dermal, ingestion or inhalation pathways. Methamphetamine residues may directly irritate the skin, or may be absorbed into the body through the skin, which may result in dermal exposure. If hand to mouth behavior occurs when hands have been in contact with toxic chemicals, the chemicals may be ingested into the body which may result in ingestion exposure. Hand to eye behavior may also introduce toxic materials to the eyes. Lastly, inhalation exposure may occur if vapors or associated chemical particles are breathed in.

IV. Methamphetamine Contaminants

The two primary methods generally used to manufacture methamphetamine are the One-pot/Ammonia reduction method (Table 1) and, to a lesser extent, the Red Phosphorous method (Table 2). Each method uses commonly found household products that, when used for household purposes, are generally considered safe. However, someone with a basic chemistry background and a good teacher can mix household products to make methamphetamine. In addition to making methamphetamine, hazardous chemicals that are produced in the manufacturing process may be corrosive, flammable, explosive, and toxic. Each pound of methamphetamine made can produce nine to eleven pounds of toxic waste. Methamphetamine “cooks” may dispose of toxic waste without any consideration to the environment or human health. Chemicals are commonly dumped in the sink, bath tubs, and outdoors and have the potential to pollute surface or groundwater supplies. Chemical spills and chemicals found in unmarked containers or stored improperly can put humans at risk of exposure.

Common chemicals used or produced by the One-pot/Ammonia reduction method and the associated health hazard include:

Table 1. Chemicals and hazards associated with the One-pot/Ammonia reduction method

Chemical	Potential Hazard*
Ammonia	Corrosive, toxic, flammable
Lithium	Reacts violently with water to produce hydrogen gas (explosive)
Pseudoephedrine/ephedrine	
Hydrochloric acid	Corrosive, toxic
Sodium hydroxide	Corrosive, toxic
Solvents (methanol, petroleum distillates)	Flammable, toxic
Sulfuric acid (salting process)	Corrosive, toxic

* These potential hazards identified are for the concentrated chemical and may not be applicable to the concentration of the chemical found in the source.

Common chemicals used or produced by the Red Phosphorus method and the associated health hazard include:

Table 2. Chemicals and hazards associated with the Red Phosphorus method

Chemical	Potential Hazard*
Red Phosphorous	Decomposes to phosphine gas in presence of moisture and oxygen, explosive when mixed with organic material
Iodine	Corrosive, reactive, toxic
Hydriodic acid	Corrosive, toxic
Hydrogen Peroxide	Supports combustion, reactive, explosive, toxic
Pseudoephedrine/ephedrine	
Sodium hydroxide	Corrosive, toxic
Hydrochloric acid	Corrosive, toxic
Solvents (methanol)	Flammable, toxic
Sulfuric acid (salting process)	Corrosive, toxic

*The potential hazards identified are for the concentrated chemical and may not be applicable to the concentration of the chemical found in the source.

After law enforcement seizes methamphetamine, there remains some low risk of exposure to chemical residues, particularly when the Red Phosphorus method is used. Chemical residues or gross contamination can often be identified by chemical odors, spills, staining, and opened containers of chemicals; however, residual contamination may remain on surfaces even after bulk chemicals and odors have been removed. Depending on the levels of any remaining contamination in the household and the method used to make methamphetamine, the property

owners should consider whether to allow persons inside the dwelling unit before a preliminary assessment has been made and any necessary clean-up has been completed in accordance with these Guidelines.

V. Methamphetamine Site Cleanup

A. General

The toxicity of methamphetamine residues depend upon the amount of the residue and the chemicals that make up the residue. The amount of residues depend upon the quantity of the methamphetamine manufactured, the period of time over which it was produced, the methods of chemical storage and disposal, the occurrence of chemicals, and the physical characteristics of the structure in which the methamphetamine was manufactured. The chemicals in the residue will vary with the method of methamphetamine manufacture (Appendix A).

The level and extent of contamination, and the type of contaminant material determines the necessary cleaning methods, and the likelihood that cleaning activities will be successful. For example, single cleaning events consisting of wash-rinse cycles may not be sufficient to remove contamination from household items; generally three wash-rinse cycles are recommended (USEPA, 2009). In some instances, it may often be more cost effective to discard porous furnishings (e.g. upholstery, carpet, draperies) rather than trying to clean them.

Cleaning of a residential dwelling unit should occur after the complete removal of bulk chemicals and hazardous materials has been made and law enforcement has removed any defensive measures (e.g. anti-personnel devices or “booby traps”). The Board recommends review of recommended cleaning procedures for specific items in the US Environmental Protection Agency *Voluntary Guidelines for Methamphetamine Laboratory Cleanup* (“EPA Guidelines”) (USEPA, 2009).

B. Homeowner and Worker Safety

The Board recommends that no assessment or clean-up commence until law enforcement has secured the dwelling unit. A methamphetamine manufacturing operation may create health hazards, including the potential for explosion; some of these risks will be reduced by the law enforcement seizure activity

Once seizure is complete, however, residents and other individuals should consider using Personal Protective Equipment (PPE) when initially re-entering the site, as chemical residue or other bulk materials used in the production process may still be present. Long sleeves, pants, and boots can be worn to minimize direct contact with remaining contaminants on site. A respirator (mask) can be used to minimize inhalation risks.

Adequate safety precautions should be taken by everyone who enters the structure before remediation is complete. In addition, persons conducting cleanup activities should wear appropriate PPEs to include protective clothing, gloves, eye protection, and respiratory protection. While these Guidelines only address assessment and clean-up related to

methamphetamine manufacturing operations, asbestos and lead may be present, particularly in older structures, and persons undertaking remediation activities should consider whether additional hazards may exist in the dwelling unit. Consultation with a professional who is trained to determine the risks and to recommend appropriate clean-up practices, policies and procedures is recommended.

Law enforcement personnel should follow the Virginia State Police *2005 Best Practices Protocol For Use by Law Enforcement and Emergency Response Agencies Regarding the Clean-up of Abandoned and Deactivated Methamphetamine Production Sites and the Retention and Handling of the Byproducts of Methamphetamine Production*.

C. Interior Remediation

This section provides a general overview of a typical remediation sequence. The sequence outlined here assumes that law enforcement has already removed any bulk chemicals and manufacturing equipment. Removal of any bulk chemicals or manufacturing equipment should be coordinated with the responsible law enforcement agency, and transportation and disposal of chemicals must follow all applicable regulations.

Overview of the remediation sequence

1. Thoroughly ventilate the structure.
2. Perform a preliminary assessment.
3. Conduct any pre-remediation sampling determined to be necessary.
4. Develop a work plan based on the preliminary assessment and any sampling results.
5. Remove all contaminated materials that will be permanently discarded.
6. Thoroughly vacuum interior surfaces using a high-efficiency particulate air (HEPA) vacuum.
7. Complete an initial washing of interior surfaces.
8. Clean and seal the HVAC system. Do not operate the HVAC system again until all further remediation activities are completed.
9. Flush plumbing traps.
10. Use a detergent and water solution to wash ceilings, walls, floors and other non-porous items that will be kept.
11. Conduct any post-remediation sampling determined to be necessary.
12. Encapsulate ceilings, walls and floors.
13. Develop a final report.

1. Ventilation

Thorough ventilation of the structure should be done before, during and after remediation activities. Open all doors and windows and use fans, blowers or a negative air machine equipped with a HEPA filter. Do not use the HVAC system for ventilation—doing so may spread contamination to previously uncontaminated areas of the structure. Take precautions to avoid discharging exhaust air to air intakes of adjacent structures. After

the initial airing, ventilation must be continued throughout the decontamination activity. The property should be protected from adverse weather effects during this time period (e.g., rain, freezing temperatures, etc.). Venting will not remove methamphetamine residues and is not a cleanup method.

a. Pre-Remediation Ventilation

The site should be ventilated prior to the entry of cleanup personnel. In some cases, law enforcement personnel will have already ventilated the site before completing criminal investigation activities or the removal of bulk chemicals or manufacturing equipment. If the dwelling unit was sealed after these activities, the dwelling unit should be ventilated again before remediation occurs. Ventilation should be performed for a minimum of twenty-four hours and preferably forty-eight hours prior to undertaking further remediation activities.

b. Continued Ventilation

It is important to continue ventilation throughout the remediation process (except when it would interfere with air monitoring). To protect assessment or clean-up workers and to limit cross-contamination, leave windows open and use fans, blowers, or a negative air unit with a HEPA filtration system during the cleanup. A negative air unit equipped with a HEPA filtration system will limit or prevent the transfer of airborne contamination from dirty to clean areas.

c. Post-Remediation Ventilation

Ventilate the property for a minimum of two days after cleanup is completed. After cleaning and ventilating the property, recheck for new staining and odor (the presence of which would indicate that additional cleaning is necessary).

2. Preliminary Assessment

The purpose of a preliminary assessment is to obtain and document the information required to plan and carry out a remediation process for the specific dwelling unit. The preliminary assessment should include a review of records related to the methamphetamine manufacturing operation and a physical examination of the site to identify actual and potential hazards.

All available records related to the methamphetamine manufacturing operation should be reviewed. These records may include law enforcement reports and any waste removal documents. Relevant information acquired through this record review may include the duration of the methamphetamine manufacturing operation; the manufacturing process; the chemicals found on site; the location of “cooking”, storage, and disposal areas; and sites of observed contamination.

After reviewing any available records relating to the methamphetamine manufacturing operation, the dwelling unit should be inspected to determine and document the actual

conditions inside the dwelling unit and to conduct any pre-remediation sampling. The site survey should:

- a. Describe the layout and construction of the dwelling unit , including the location and size of rooms, location of doors and windows, the ventilation system, appliances, and any furnishings that remain in the dwelling unit ;
 - b. Document the areas of heaviest contamination based on staining or other visual or olfactory evidence;
 - c. Examine the ventilation system for visual signs of contamination;
 - d. Examine the plumbing system for visual signs of contamination such as staining and etching;
 - e. Identify the type of wastewater disposal (e.g., septic system or public sewer) serving the site;
 - f. Identify potential sources of cross-contamination to adjacent structures or other units; and
 - g. Identify evidence of outside contamination such as disposal of chemicals by burning or dumping.
3. Pre-remediation Sampling

The decision to conduct sampling prior to remediation should be weighed against the cost and potential benefits of the sampling results. Sampling is not inexpensive and, if it is likely that extensive remediation will be necessary regardless of sampling results, then the owner of the dwelling unit and contractor may reasonably elect to avoid those costs and simply begin remediation without sampling. On the other hand, if there is evidence that contamination is limited to specific areas of the structure, or the contamination may not be extensive, sampling may show that remediation of a more limited scope is appropriate under these Guidelines. The decision as to the necessity of pre-remediation sampling should be made by the clean-up contractor or other qualified professional on a case-by-case basis. If pre-remediation sampling is performed, it should be done in accordance with Table 4.

4. Work Plan

These Guidelines anticipate that the information from the preliminary assessment and the results of any pre-remediation sampling should be used to develop a remediation work plan. The work plan is a guide for accomplishing remediation in accordance with these Guidelines.

The work plan should summarize the information obtained during the preliminary assessment, describe worker protections to be taken, describe the cleanup methods that

will be implemented, and describe any post-remediation sampling to be conducted. The description of the cleaning methods should include:

- a. A list of the items that will be removed from the structure;
- b. A list of the surfaces to be cleaned on-site;
- c. Procedures for cleaning;
- d. Areas to be encapsulated and the methods and materials of encapsulation;
- e. Location and procedures for on-site decontamination; and
- f. Methods to be used to prevent the off-site contamination.

The EPA Guidelines list additional items that are recommended for inclusion in the work plan.

5. Removal of Materials to be Permanently Discarded

The first remediation step following ventilation should be removal and disposal of all materials that will be permanently discarded. Visibly stained materials, chemical odor-emitting materials or materials that are visibly damaged by contamination should be discarded. The EPA Guidelines offer the following considerations to help determine whether to discard or clean other materials and items:

- a. **Potential for Contact.** Consider whether inhabitants of the structure are likely to come into contact with the item regularly (such as bedding). Discard contaminated items with a high potential for human contact (e.g., children's toys and bottles) more readily than items with a low potential for human contact.
- b. **Intrinsic or Emotional Value.** Weigh the intrinsic or emotional value of the item with how much it would cost to effectively clean the item. If sampling will be conducted, the cost of cleanup includes the cost of sampling to ensure the item is cleaned. In many cases it is more cost-effective to dispose of an item and replace it than it is to clean it. In some circumstances however, items of great emotional value, such as wedding albums, may be salvaged.
- c. **Porosity.** Consider the porosity of the item or material. In general, porous items and materials are easily penetrated or permeated by hazardous gases, liquids or residues. Non-porous surfaces are more resistant to this type of contamination. As a result, contamination is often located in porous items and on the surface of non-porous items. Thus, it is generally more difficult to eliminate contamination from porous items and materials.

For example, carpeting is highly porous and therefore likely to be contaminated, is difficult to thoroughly clean, typically has a relatively low intrinsic or emotional value, and has a high potential for contact by children crawling or playing on the floor. Therefore, carpet should typically be discarded.

Minnesota (Minnesota Department of Health, 2010) offers the following 2x2 table to illustrate the process for deciding to clean or discard materials:

Table 3. Decision aid for determining whether to salvage or discard an item.

<p>High Value – High Contact Items E.g., Mattresses, carpeting, large upholstered items should almost always be discarded.</p>	<p>High Value – Low Contact Items E.g., In some circumstances, photographs may be salvaged without cleaning, or large appliances may be cleaned and saved.</p>
<p>Low Value – High Contact Items E.g., clothing, plastic toys and toothbrush should always be discarded.</p>	<p>Low Value – Low Contact Items E.g., A screw driver, garden rake or other metal or hard material item may be cleaned in some circumstances.</p>

All materials that are discarded should be disposed of in a manner that will prevent salvage and reuse by other persons.

6. HEPA Vacuum the Interior

After removal of materials to be permanently discarded, thoroughly vacuum all surfaces with a vacuum equipped with a HEPA filter. Household vacuums are not recommended since they lack adequate filtration and may simply further spread contaminants. Vacuuming with a HEPA filter will effectively remove particulate contamination as well as dust and cobwebs that may interfere with washing. HEPA vacuuming alone is not sufficient to decontaminate most surfaces.

7. Initial Washing

Perform an initial washing of walls and floors with a detergent-water solution to reduce contamination and thereby help prevent exposure of workers and reduce recontamination of cleaned areas. A household detergent or soap product should be used for all washing solutions. The water does not have to be hot. *Bleach is not recommended* because it may react with some chemical pre-cursors or by-products of methamphetamine production to produce other toxic compounds.

8. Clean and Seal HVAC System

In structures with an HVAC or other forced air system, including kitchen and bathroom vents, fumes and other contaminants from methamphetamine production are likely to accumulate in the vents, ductwork, and filters and on the walls and ceilings near the ventilation ducts. The systems may also spread contamination to any area served by the

system, including other rooms and sometimes other dwellings. To limit the further spread of contamination, the HVAC system should be shut down and remain out of operation until all remediation activities are completed.

Adequate cleaning of HVAC systems requires special tools and training. HVAC systems should be cleaned by contractors who specialize in cleaning these systems or who have experience cleaning ventilation systems in former methamphetamine manufacturing sites. Some ductwork cannot be properly cleaned of contamination; it is recommended that insulation-lined ducts and flexible ductwork be discarded and later replaced after the rest of the system is cleaned.

After cleaning, the HVAC should be sealed at all openings. The system should remain sealed until all remediation activity is complete.

9. Flush Plumbing Traps

Methamphetamine chemicals may be poured down the waste drains while manufacturing is active and the traps of sinks, bathtubs, and showers may contain concentrations of these chemicals. In addition, the plumbing fixtures themselves may be compromised by the chemicals. If visible or other tangible evidence of dumping is detected, the clean-up contractor may want to consider having the system tested for the presence of VOCs, which present a flammability hazard, with a photoionization detector (PID) prior to taking remediation steps related to the plumbing system. The outfall of the wastewater system should be verified as well. Different steps may be required for the plumbing system of a structure served by an onsite sewage disposal system than for one served by a public sewerage system. In addition, some structures may have an illegal “straight pipe” that discharges sewage to the ground or to surface water. In instances where the structure is served by an onsite sewage disposal system or a straight pipe is encountered, the local health department should be contacted for instructions prior to flushing traps or disposing of any liquid into the plumbing system.

Plumbing fixtures with visible signs of contamination such as etching or staining should be removed and permanently discarded as they will be difficult to clean. Porcelain and stainless steel fixtures in which the surface is not pitted or damaged may be cleaned using the procedures outlined herein. When staining is noted around plumbing fixtures or if a strong chemical odor is emitted by the plumbing system, the drain system should be flushed using a generous amount of water to reduce the concentration of chemicals in the system. The entire system should be flushed at the same time. Flushing of the system should not be done until there is verification that waste will be properly disposed of. Additionally, if the wash and rinse water from the cleanup will be disposed of via the household plumbing system, flushing should be delayed until that part of the remediation is completed.

10. Detergent Wash

Ceilings, walls, floors and all household items that will not be discarded should be washed using a solution of household detergent and water. Use the manufacturer’s instructions for mixing the solution. The water does not have to be hot. *Bleach is not*

recommended because it may react with some chemical pre-cursors or by-products of methamphetamine production to produce other toxic compounds.

It is important that the washing be thorough. The entire surface, and not just spots, must be covered by the cleaning step. The typical procedure is to start with the ceiling, then from the top to the bottom of the walls and finally the floor. Follow the wash with a thorough rinse using clean water and clean rags. Change the wash solution, the rinse solution and rags frequently. Allow the surfaces to thoroughly dry and then repeat the wash and rinse steps at least two additional times.

Wash and rinse water typically may be disposed of via the structure's plumbing system, provided that the structure is connected to a public sewer system. The concentration of cleaning solutions may upset the functioning of an onsite sewage disposal system (septic system). If the structure is not served by public sewerage, the wash and rinse water can be collected for proper off-site disposal; one possible method is to have a licensed sewage handler empty the septic tank before remediation begins to provide storage capacity in the tank and then pump the tank again before the liquid reaches the effluent port on the tank.

It is important to prevent recontamination of cleaned areas and items. Once a room has been adequately cleaned (at least three wash-rinse cycles), seal the room using 6.0 mm plastic sheeting and do not re-enter the room. Similarly, household items that are cleaned onsite should be bagged or wrapped in plastic after they have been cleaned. Items may be stored offsite after they have been sufficiently cleaned. Do not return these items until remediation of the structure is completed.

11. Encapsulation

Encapsulation of surfaces with primers, paint and other sealants may provide additional protection against the migration of contaminants to the surface of the material. Encapsulation is recommended for all porous surfaces that are suspected of contamination and that are not removed from the unit. However, encapsulation is ***not a substitute for cleaning***. Encapsulation should be done after surfaces have been cleaned in accordance with these guidelines and allowed to dry thoroughly. If post-remediation sampling is to be conducted, encapsulation should be performed only after sampling shows that washing has reduced contamination to the recommended level.

Oil-based paint, epoxy coatings, and polyurethane should be used to encapsulate surfaces. Surfaces should be primed with a high quality, non-latex primer that will be durable over time and meets the recommendations of the finish-coat manufacturer. Follow the manufacturer's recommendations for application methods, thickness, and drying or curing time between coats. Complete coverage of the surface is important and may require multiple applications of finish.

Spray application may provide more thorough coverage than hand-rolling and is therefore recommended in many remediation guidelines, particularly for textured plaster and drywall surfaces that may be damaged by hand-rolling.

12. Post-remediation Sampling

The Board recommends sampling of the dwelling unit following the completion of all remediation activity. Such sampling provides evidence that the remediation activity was done in accordance with these Guidelines and that the dwelling unit has been successfully decontaminated. The health based standard for residual methamphetamine contamination on surfaces in dwelling units is 1.5 micrograms per centimeter squared ($\mu\text{g}/100\text{cm}^2$). This level is based on peer-reviewed scientific literature recommending a health-based exposure standard from California (Salocks, 2009) (See Also Appendix B); the literature indicates that a residual level of $1.5\mu\text{g}/100\text{cm}^2$ or less of methamphetamine contamination protects humans from negative health effects. As such, a residual level of $1.5\mu\text{g}/100\text{cm}^2$ or less of methamphetamine contamination meets the recommended safe level under these Guidelines.

Sampling should be done by a qualified professional and analyzed by a properly certified laboratory. Table 4 below contains recommended standards and possible locations for testing for volatile organic compounds (VOCs), metals (lead and mercury), corrosives (as a measure of pH) and residual methamphetamine. At a minimum, the Board recommends sampling for residual methamphetamine contamination in accordance with Table 4 at indoor locations where human contact with methamphetamine vapor or other chemicals may be likely to occur, including in any common areas of a multi-family community. Sampling in accordance with Table 4 may also be conducted on a case by case basis at locations identified in the site assessment as demonstrating visual signs or other evidence of methamphetamine contamination.

Table 4. Tests, chemicals, locations and guidelines for sampling.

Test	Chemical(s)	Sampling Location	Guideline
VOCs	Benzene, Coleman fuel, naphtha, petroleum distillates	Indoor air, outdoor over contaminated soil, drains, septic systems	Less than 1 parts per million (ppm)
pH	Acids and bases	Food preparation areas, visible contamination, septic system, areas where chemicals stored	pH 6 to 8
Metals*	Mercury and Lead	Contact VDH	Contact VDH
Wipe sample	Methamphetamine	Case by case	1.5 micrograms per centimeter square ($\mu\text{g}/100\text{cm}^2$)
Visual	Iodine and red phosphorous	Stained area	Remove stained surfaces and appliances

*Two methods commonly used to make methamphetamine in Virginia do not require mercury or lead. If mercury and lead are identified, please contact the Virginia Department of Health.

For manufacturing operations utilizing the Red Phosphorous method, please consult the Virginia Department of Health for sampling guidance. In addition, consult the table in Appendix A for a list of some of the common contaminants associated with methamphetamine manufacturing using two of the most common methods.

13. Final Report

A final report documenting that the dwelling unit has been remediated according to applicable guidelines should be prepared by the clean-up contractor or other qualified professional. The final report should document all assessments, remediation activity, and post-remediation sampling completed at the dwelling unit, including the dates and the names of the persons who were in charge of each activity. A copy of the final report should be provided to the property owner.

The following items are suggested for inclusion in the final report:

- a. Physical address of the residential property and a description of the structures on the property;
- b. A summary of the pre-remediation site assessment, including any known information about chemicals that were present and removed from the site both before and during the remediation process, the methamphetamine production method, and any areas where contamination was observed;
- c. The names and qualifications of the clean-up contractor or other qualified professional and the laboratory that analyzed any samples;
- d. The cleanup plan and documentation that the cleanup was completed, including a description of the areas that were decontaminated and the methods used;
- e. The waste management procedures, including handling and final disposition of waste; and
- f. The sampling plan, a description of the sampling methods, a list of the areas sampled and the results of all laboratory analysis.

D. Recommendations for Specific Items and Materials

1. Walls

Remove and replace wall absorbent materials (e.g., drywall, plaster, wallpaper) that are visibly stained or are emitting chemical odors. Other smooth, painted surfaces should be washed as outlined above and should be encapsulated. Textured walls, especially those that were installed prior to 1980, may contain asbestos and should be tested for asbestos presence before cleaning or removal. Asbestos-containing materials should be addressed according to applicable guidelines.

2. Ceilings

Ceilings typically have some of the highest contamination levels. Although ceilings have a low potential for human contact, they should be cleaned in accordance with these guidelines and should be encapsulated. As with walls, any absorbent materials that are stained or emit chemical odors should be removed and replaced.

Textured ceilings (e.g. “popcorn” or spray-on finishes) and tiled ceilings should be sampled for asbestos and methamphetamine contamination. Ceiling tiles in areas of heavy contamination that do not contain asbestos should be removed and replaced. When no asbestos contamination is present, ceiling tiles in areas of low potential contamination and textured ceilings may be encapsulated after vacuuming with a HEPA vacuum. Any asbestos-containing materials should be addressed according to applicable guidelines.

3. Floors

Resilient floors (e.g., vinyl) should be removed and replaced if stained or damaged. Porous and absorbent materials such as cork, unfinished wood and carpet (including any carpet pad) should be removed and replaced. Simply covering a contaminated floor with new materials is not a suitable remediation method, since the contaminants may still migrate to the surface of the new material.

After finish-flooring materials are removed, HEPA vacuum the subfloor to remove any contaminated dust and debris and then wash with a detergent solution before installing the new finish flooring materials.

Floors that will not be removed should be washed with a detergent solution in accordance with these guidelines and should be encapsulated with a suitable product (e.g., polyurethane for wood floors). Any ceramic or stone tile floors that will remain should be washed and, if porous, re-glazed. Grout should be ground-down and the tile or stone re-grouted and sealed.

4. Kitchen Countertops

Kitchen countertops have a high potential to transfer contamination, both through direct human contact and through food preparation activities. Consideration should be given to simply replacing any countertops likely to be highly contaminated. All countertops with visible or olfactory signs of contamination such as staining, etching, or chemical odor-emission and countertops constructed of porous materials (wood, granite) should be discarded.

Some countertops built of solid, man-made materials may be effectively decontaminated by sanding to remove some of the material and washing with detergent. Stainless steel can be decontaminated by washing with a detergent solution. It is recommended that stone and ceramic tile countertops in high contact areas be discarded. If not discarded, the grout should be removed and new grout placed and sealed.

5. Concrete, Cement and Brick

Exposed concrete, cement and brick are problematic because the materials are absorbent and difficult to thoroughly clean and because the materials are often structural elements that are expensive to remove and replace. Exposed masonry surfaces should be washed with a detergent solution. Power-washing, using a wet vacuum to remove excess water, or steam cleaning with extraction is recommended by some authorities (EPA, Minnesota). Masonry surfaces that will remain exposed should be encapsulated after cleaning.

6. Appliances

All appliances that have been used directly in the production or storage of methamphetamine and any appliances or electronics that show visible signs of contamination should be discarded. To prevent contamination of workers who may handle these items at disposal or recycling facilities, the exterior of appliances that will be discarded should be washed.

For any appliances that will be kept, thoroughly wash and rinse both the interior and exterior surfaces. Repeat at least once. Sampling of potential contact surfaces of appliances is highly recommended to assure that they have been adequately decontaminated.

7. Wood

All removeable wood surfaces with visible signs of contamination should be discarded. Any wooden items that will not be discarded should be triple washed with a detergent solution, allowed to dry thoroughly and then encapsulated with a properly applied non-water based sealant.

8. Windows

Window glass should be cleaned at the same time as the surrounding wall surfaces. Triple clean with a standard household window washing solution, and, as with other surfaces, replace the cleaning cloths for each round of cleaning. Window trim should be cleaned or discarded in the same manner as other wall surfaces.

9. Electrical fixtures, outlet and switch plates

Switch plates and electrical plates should be discarded; these items tend to be high-contact and low cost. It is recommended that switches, receptacles and light fixtures should also be discarded, since they will be difficult to clean and, again, are typically low cost items. Any electrical fixtures that will not be discarded should be temporarily removed, washed, and thoroughly dried before re-installation.

NOTE: Be sure to take adequate safety precautions when working with any electrical items. Do not attempt to wet-clean electrical items in place or to remove electrical fixtures before ensuring that electricity to the fixture is turned off.

10. Non-porous household goods

All household goods such as dishes and flatware should be discarded if there is any indication that they have been used in the methamphetamine manufacturing process. Other ceramic, metal, hard plastic and glass items that were not used in the methamphetamine production process may be cleaned using a detergent solution.

11. Toys and other children's items

Children have a greater risk for health effects if exposed to methamphetamine and other chemicals. Children's items are typically highly absorbent and present. Therefore, the Board recommends that all children's items be discarded. Any toys that have the potential to be placed in the mouth and any toys that show signs of contamination should be discarded. Plastic baby bottles and nipples, as well as infant/toddler eating utensils should be discarded. Stuffed toys and other toys made of porous materials are difficult to adequately clean and discarding is recommended.

12. Personal items and medical devices

Personal items such as eye glasses and other medical devices that are made of hard plastic or metal and which would be expensive to replace may be decontaminated by triple washing with detergent.

13. Machine washable fabrics, bed coverings, clothing or draperies

Absorbent materials can accumulate vapors that are dispersed during the cooking process or can collect dust and powder from chemicals used in drug manufacture. Machine-washable porous materials such as draperies, bed coverings, and clothing should be washed three times with detergent and water or disposed of in accordance with the waste disposal plan if such materials were found in rooms assessed as contaminated or rooms serviced by the same HVAC system as the room where methamphetamine was manufactured. When washing, *do not use detergents with bleach*, oxidizing detergents, or fabric softener and do not dry between washings.

14. Upholstered furniture, mattresses, carpet or other non-machine washable fabrics

Non-machine washable porous materials such as upholstered furniture, mattresses, and carpeting will be difficult or impossible to decontaminate economically. In rooms assessed as contaminated and rooms serviced by the same HVAC as the room where methamphetamine was manufactured, these non-machine washable porous materials should be disposed of. It may be possible to strip the existing upholstery from furniture, clean, and seal any wooden parts and install new upholstery.

15. Sewerage & Septic Systems

As previously stated, most liquid chemical by-products are dumped into bathtubs, sinks, drains, and toilets. This waste is flushed from the plumbing where it enters the

wastewater system serving the property, typically either a sewerage system or onsite septic system.

Discarded chemicals are typically flushed within minutes or hours when connected to a sewerage system. Chemicals may remain in the system longer if connections are on a line of very low flow.

Microorganisms in septic systems are capable of breaking down much of the waste associated with the production of methamphetamine. However, large scale methamphetamine manufacturing operations or sites in operation for an extended period of time may generate a voluminous amount of chemicals which can affect pH, sludge buildup, and bacterial die-off if disposed of into the septic system. The EPA recommends field screening of the septic tank if there is evidence that methamphetamine waste may have been disposed of in the septic system. Several states recommend that remediation procedures for septic systems be based on the level of VOC found in effluent samples.

An assessment of the septic system should be conducted to determine if evidence suggests that chemicals have been disposed of in the septic system. Evidence of waste disposal may include, but is not limited to: witness statements; stained or etched sinks bathtubs, or toilets; chemical odors coming from plumbing or septic tank; visual observations of unusual conditions within the septic tank; or stressed or dead vegetation over the drain-field (Minnesota Department of Health, 2010). If no evidence of waste disposal is found then no further action may be necessary.

If evidence of disposal in the septic system is found then the septic tank should be pumped and the contents taken to an approved sewerage disposal facility. The disposal facility should be contacted prior to pumping to determine if additional actions, such as sampling of waste, will be required prior to disposal. Though sampling of waste may not be necessary, disposal of waste should comply with all local, state and federal disposal requirements and proper precautions should be taken during pumping and disposal.

16. Soils

The site assessment should also include an outdoor evaluation of the ground to determine if it is visibly stained or otherwise affected (e.g. odors, burn piles, dead vegetation or remnants of reaction waste). If burn or trash pits, discolored soil or dead vegetation are found, affected soil should be removed and disposed of in accordance with applicable state and federal solid waste laws and regulations.

17. Wells

Private wells constructed pursuant to the Virginia Department of Health's Private Well Regulations are located and constructed to protect from potential sources of contamination known at the time of permitting. Disposal of chemicals in onsite septic systems, on the ground surface, or in burn pits could be considered a potential source of contamination for private wells. If visible evidence suggests that chemical byproducts of methamphetamine manufacturing were disposed of in a dumpsite, burn pit or trash pit

adjacent to a private well, the cleanup contractor should consider consulting with the Virginia Department of Health, Office of Environmental Health Services, for recommended testing and remediation actions.

18. Surface Water

The potential release of by-product chemicals to surface water should be evaluated during the site assessment when applicable. If evidence suggests chemicals may have been disposed directly into or adjacent to surface waters, contact the Virginia Department of Environmental Quality.

VI. Methamphetamine Testing

It is cost prohibitive to test households for every chemical that could be used for the production of methamphetamine or that is generated as part of the cooking process. Also, many of these chemicals are present in commonly used household products. Because the long-term health effects of exposure to methamphetamine residue have not been firmly established, many states have adopted clean-up standards that are based on analytical detection limits. It is assumed that the cleaning method used to reduce a methamphetamine residues will also reduce other potential chemical contamination caused by methamphetamine production. In 2007, the California Department of Toxic Substances Control was the first government agency to develop a health-based remediation standard. The residual amount of methamphetamine allowed on surfaces in homes formerly used to manufacture methamphetamine is 1.5µg/100cm².

While the Virginia Department of Health cannot recommend, endorse, license, or otherwise approve methamphetamine cleanup companies, the Virginia Department of Health does maintain a list of contractors that have indicated their ability to perform methamphetamine cleanup activities in Virginia.

VII. Re-Entry into the Residential Dwelling Unit and Property Owner Notification

It is recommended that the property not be rented, sold, or occupied until the assessment and cleanup following these Guidelines have been completed. It is further recommended that local building departments be contacted prior to remediation activity to ensure compliance with applicable provisions of the Uniform State Building Code (USBC) and any local ordinances such as public health nuisance ordinances. Additionally, §15.2-1716.2 of the Code of Virginia authorizes localities to adopt an ordinance providing that persons convicted for manufacture of methamphetamine pursuant to §§18.2-248 or 18.2-248.03 of the Code of Virginia are liable at time of conviction or in a separate civil action to the locality or any other law enforcement entity for the cost of cleanup.

Effective July 1, 2014, if landlords of single-family or multi-family residential properties have actual knowledge that the dwelling unit was previously used to manufacture methamphetamine and has not been cleaned up according to these guidelines, the landlord must provide the prospective tenant a written disclosure with this information pursuant to §§55-225.17 and 55-248.12:3 of the Code of Virginia. In the case of the sale of a residential dwelling unit, if the owner of such property has actual knowledge that the residential property was used for the manufacture of methamphetamine and has not been cleaned up according to these guidelines, the

owner must provide the prospective purchaser a written disclosure with this information pursuant to §55-519.4 of the Code of Virginia. This information will be provided to the purchaser on a form provided by the Virginia Real Estate Board, effective July 1, 2014.

For more information or clarification, please refer to the points of contact listed below.

Table 5. Important contacts.

Topic	Agency		
Methamphetamine Site Seizure and First Response	Virginia State Police	Appomattox Chesapeake Culpeper Fairfax Richmond Salem Wytheville	(800) 552-0962 (800) 582-8350 (800) 572-2260 (800) 572-4510 (800) 552-9965 (800) 542-5959 (800) 542-8716
Health Hazards and Concerns			
Health hazards, exposure routes, exposure risk	Virginia Department of Health Office of Epidemiology, Toxicology		(804) 864-8182
Cleanup			
Developing a cleanup plan, sampling and remediation	Virginia Department of Health Office of Epidemiology, Toxicology		(804) 864-8182
Contractor cleanup list	Virginia Department of Health Office of Environmental Health		(804) 864-7400
Environmental Contamination, Waste Disposal			
Outdoor contamination and remediation (soil, water); waste disposal	Virginia Department of Environmental Quality	Abingdon Glen Allen Harrisonburg Lynchburg Richmond Roanoke Woodbridge VA Beach	(276) 676-4800 (804) 527-5020 (540) 574-7800 (434) 582-5120 (804) 698-4000 (540) 562-6700 (703) 583-3800 (757) 518-2000

VIII. References

1. Integrated Risk Assessment Branch. Office of Environmental Health Hazard Assessment. California Environmental Protection Agency. C. B. Salocks. Assessment of children's exposure to surface methamphetamine residues in former clandestine methamphetamine labs, and identification of a risk-based cleanup standard for surface methamphetamine contamination. February 2009.
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7. Tennessee Department of Environmental and Conservation Reasonable, Appropriate, Protective (RAP) Cleanup Response and Documentation Guidance for Properties Quarantined Because of Clandestine Methamphetamine Laboratory (CML) Activities, June 1, 2006. Retrieved from http://www.state.tn.us/environment/dor/pdf/Meth_RAP_Guidance.pdf
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9. Virginia Department of Health Private Well Regulations, 12 VAC 5-630-10 et. seq., August 16, 2012. Retrieved from <http://www.vdh.virginia.gov/EnvironmentalHealth/ONSITE/regulations/documents/2012/pdf/12%20VAC%205%20630.pdf>
10. Virginia State Police. (2005). Best Practices Protocol For Use by Law Enforcement and Emergency Response Agencies Regarding the Clean-up of Abandoned and Deactivated Methamphetamine Production Sites and the Retention and Handling of the Byproducts of Methamphetamine Production.

Appendix A. Methods of Methamphetamine Production.

Current methods for methamphetamine production and toxic byproducts.

Method	Chemical Reaction	Chemical Contaminants	Hazard Category	Health Hazard Potential
Iodine/Red Phosphorus	Reduction of ephedrine	Phosphine Gas	Toxic Gas	<p>Acute: May cause lung irritation, cough, and chest tightness. Persons acutely exposed to phosphine may exhibit agitated, psychotic behavior. Signs and symptoms of acute phosphine toxicity may include rapid and/or irregular heart rate, low blood pressure, shock, nausea, abdominal pain, vomiting, diarrhea, and cardiac arrest.</p> <p>Chronic: May cause anemia, bronchitis, gastrointestinal symptoms (nausea, vomiting, abdominal pain, and diarrhea), and neurological effects (tremors, double vision, impaired gait, and difficulty speaking). Liver damage and jaundice, as well as renal failure are also potential consequences of long-term exposure to phosphine gas.</p>
	Reduction of ephedrine	Red Phosphorus	Flammable Solid	<p>Acute: May cause irritation of the skin, eyes, upper respiratory tract, gastrointestinal tract, and mucous membranes. Inhalation of red phosphorus dust may cause bronchitis. Ingestion of red phosphorus may also cause stomach pains, vomiting, and diarrhea.</p> <p>Chronic: Chronic exposure may cause kidney and liver damage, anemia, stomach pains, vomiting, diarrhea, blood disorders, and cardiovascular effects. Chronic ingestion or inhalation may induce systemic phosphorus poisoning.</p>

Method	Chemical Reaction	Chemical Contaminants	Hazard Category	Health Hazard Potential
	Production of Hydrogen Iodide	Iodine	Irritant Vapor	<p>Acute: Iodine vapor may cause eye, skin, nose and throat irritation, coughing, wheezing, and laryngitis. Exposure to high concentrations may result in airway spasm, chest tightness, breathing difficulty, severe inflammation, and fluid accumulation in the voice box, upper airways, and lungs. Some people develop allergic hypersensitivity to iodine vapor.</p> <p>Chronic: Studies of the effects of long-term inhalation of iodine vapors by humans are not conclusive. Studies in laboratory animals indicate that long-term inhalation of iodine vapor may disrupt thyroid function and reduces the ability of the lungs to take up oxygen. Adverse changes in the lungs of exposed animals may include edema, scaling of bronchial epithelium, and bleeding.</p>
	Production of Hydrogen Iodide	Hydrogen Sulfide	Toxic Gas	Exposure to low concentrations of hydrogen sulfide may cause irritation to the eyes, nose, or throat. It may also cause difficulty in breathing for some asthmatics. Brief exposures to high concentrations of hydrogen sulfide (greater than 500ppm) may cause a loss of consciousness.
	Pseudoephedrine Extraction	Polar solvents (methanol or denatured alcohols)	Fire Hazard	
	Product Isolation	Strong Base	Corrosive Compound	

Method	Chemical Reaction	Chemical Contaminants	Hazard Category	Health Hazard Potential
	Methamphetamine Extraction	Coleman fuel, naphtha, lighter fluid, Freon, carbon tetrachloride, etc	Flammable (except freons or heavily chlorinated solvents—which are asphyxiants)	
	Methamphetamine Salting from Solvent Phase	Hydrochloric acid gas (HCl)	Corrosive compound	Acute: May cause irritation of the respiratory tract with burning, choking, coughing, eye irritation and severe burns. Ulceration of nose and throat may also occur.
One-pot/Ammonia Reduction	Reduction of ephedrine	Dry Lithium (from batteries)	Corrosive, Flammable and Water-Reactive Solid	May cause burns and pulmonary edema.
	Reduction of ephedrine	Ammonia	Corrosive Compound	Exposure to high levels of ammonia in air may irritate skin, eyes, throat, and lungs and may cause coughing and burns. Lung damage may occur after exposure to very high concentrations. Some people with asthma may be more sensitive to breathing ammonia than others. Swallowing concentrated solutions of ammonia may cause burns in the mouth, throat, and stomach.
All Methods		Methamphetamine Residuals	Controlled Substance	May cause chemical addiction, personality and behavior pattern changes

Appendix B. State Methamphetamine Cleanup Guidelines and Standards

A search for required and recommended sampling results to confirm successful remediation of methamphetamine manufacturing operations was completed using multiple Internet search engines. The search revealed twenty-two states with mandatory residual standards for methamphetamine and one, North Carolina, with a recommended level. The results of these mandatory state cleanup guidelines and standards are listed below in Table 5. Seventeen states set required maximum residual levels for one or more precursors typically used for the illegal manufacture of methamphetamine, also found below.

Seven other states including Illinois, Iowa, Missouri, North Dakota, Ohio, Oklahoma and Wisconsin recommended that post-remediation testing in some circumstances. However none of these states provide sampling guidance and only one, Illinois, suggests a maximum post-remediation standard.

Cleanup Guidelines and Standards by State.

State	Chemical Test & Standard ¹									
	Methamphetamine ($\mu\text{g}/100\text{cm}^2$ unless otherwise specified)	VOCs ²	Lead	Mercury	Corrosives	Ephedrine; pseudo- ephedrine	Red Phosphorus	Iodine Flakes, Crystal	Tincture of Iodine	Amphetamine
Alaska	0.1	1ppm total hydrocarbons & VOCs	2mg/100cm ²	5ng/m ³ in air	NV	NV	NV	NV	NV	NV
Arizona	0.1	NV	4.3 $\mu\text{g}/100\text{cm}^2$	3.0 $\mu\text{g}/\text{m}^3$ in air	6-8 pH	0.1 $\mu/100\text{cm}^2$	Removal of stained material or cleaned pursuant to standards		NV	NV
Arkansas	0.05	NV	3.21 $\mu\text{g}/100\text{cm}^2$	0.667 $\mu\text{g}/100\text{cm}^2$	NV	1860 $\mu\text{g}/100\text{cm}^2$	6190 $\mu\text{g}/100\text{cm}^2$	NV	NV	NV
California	1.5	NV	NV	NV	NV	NV	NV	NV	NV	NV
Colorado	0.5	NV	40 $\mu\text{g}/\text{ft}^2$	1 $\mu\text{g}/\text{ft}^2$	NV	NV	NV		22 $\mu\text{g}/100\text{cm}^2$ (if not removed)	NV
Connecticut	<0.1	<1ppm total VOCs in air	<40 $\mu\text{g}/\text{ft}^2$	<1 $\mu\text{g}/\text{ft}^2$	NV	<0.1 $\mu/100\text{cm}^2$	Removal of stained material	22 $\mu\text{g}/100\text{cm}^2$	Removal of stained material	NV
Hawaii	0.1	1ppm total hydrocarbon and VOCs in air	2 $\mu\text{g}/100\text{cm}^2$	50ng/m ³ in air	NV	NV	NV	NV	NV	NV
Kansas	1.5	NV	NV	NV	NV	NV	NV	NV	NV	NV
Idaho	0.1	NV	NV	NV	NV	NV	NV	NV	NV	0.5 $\mu\text{g}/100\text{cm}^2$
Indiana	0.5	NV	NV	NV	NV	0.5 $\mu\text{g}/100\text{cm}^2$	NV	NV	NV	NV
Kentucky	0.1	<1ppm total VOCs in air	NV	NV	6-8 pH		Removal of stained material			NV
Michigan	0.5	NV	40 $\mu\text{g}/\text{ft}^2$	1 $\mu\text{g}/\text{m}^3$	NV	NV	NV	NV	NV	NV
Minnesota	1.5	<1ppm total VOCs in air	40 $\mu\text{g}/\text{ft}^2$	<0.3 $\mu\text{g}/\text{m}^3$	NV	NV	NV	NV	NV	NV

State	Chemical Test & Standard ¹									
	Methamphetamine ($\mu\text{g}/100\text{cm}^2$ unless otherwise specified)	VOCs ²	Lead	Mercury	Corrosives	Ephedrine; pseudo- ephedrine	Red Phosphorus	Iodine Flakes, Crystal	Tincture of Iodine	Amphetamine
Montana	0.1	1ppm total VOCs in air	$20\mu\text{g}/\text{ft}^2$	$50\text{ng}/\text{m}^3$ in air	NV	NV	NV	NV	NV	NV
Nebraska	≤ 0.1	$\leq 1\text{ppm}$	$\leq 40\mu\text{g}/\text{ft}^2$	$\leq 300\text{ng}/\text{m}^3$	NV	NV	NV	NV	NV	NV
New Hampshire	0.1	1ppm total VOCs in air	$40\mu\text{g}/\text{ft}^2$	$1\mu\text{g}/\text{m}^3$	6-8 pH	$0.1\mu\text{g}/100\text{cm}^2$	Removal of stained material	Removal of stained material; $22\mu\text{g}/100\text{cm}^2$		NV
New Mexico	$1.0\mu\text{g}/\text{ft}^2$ (including precursors)	$\leq 1\text{ppm}$	$\leq 40\mu\text{g}/\text{ft}^2$	$< 0.3\mu\text{g}/\text{m}^3$	6-8 pH	NV	Discard stained material	Discard stained material	NV	NV
North Carolina	< 0.1 (recommended level)	NV	$4.3\mu\text{g}/100\text{cm}^2$	$0.3\mu\text{g}/\text{m}^3$	NV	NV	NV	NV	NV	NV
Oregon	$0.5\mu\text{g}/\text{ft}^2$ (composite samples)	NV	NV	NV	NV	NV	NV	NV	NV	NV
South Dakota	0.1	$< 1\text{ppm}$	NV	NV	6-8 pH	NV	Removal of stained material			NV
Tennessee	0.1 (on hard surfaces)	1ppm in air, measured under normal inhabitable conditions	$40\mu\text{g}/\text{ft}^2$	$50\text{ng}/\text{m}^3$ in air	NV	NV	NV	NV	NV	NV
Utah	≤ 1.0	$\leq 1\text{ppm}$	$\leq 4.3\mu\text{g}/100\text{cm}^2$	$\leq 0.3\mu\text{g}/\text{m}^3$	6-8 pH	$\leq 0.1\mu\text{g}/100\text{cm}^2$	No visible residue	No visible residue	NV	NV
Washington	< 0.1	1ppm total hydrocarbon & VOCs in air	$\leq 20\mu\text{g}/\text{ft}^2$	$\leq 50\text{ng}/\text{m}^3$ in air	NV	NV	NV	NV	NV	NV
West Virginia	0.1	NV	NV	NV	NV	NV	NV	NV	NV	NV

1. Where indicated by the standard, a value is provided. If no value is provided, then 'NV' is indicated denoting its absence.

2. VOCs means *volatile organic compounds*.

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Appendix C: Fate and Transport of Chemicals Associated with Methamphetamine

Environmental Fate and Transport of Methamphetamine Manufacturing Chemicals

Chemical	Form	Source	Hazard	Fate and Transport
Ammonia	Colorless gas with pungent odor, anhydrous form is liquid under pressure	Cold Packs	Corrosive, toxic	Lighter than air gas, likely to dissipate into atmosphere
Hydriodic acid	Clear colorless liquid with pungent odor		Corrosive, toxic	Miscible with water and slightly heavier. What does not react with soil may leach to shallow groundwater.
Hydrochloric acid	Clean colorless liquid with pungent odor	Muriatic acid	Corrosive, toxic	Miscible with water and slightly heavier. What does not react with soil may leach to shallow groundwater.
Iodine	Solid purple crystal or flakes, dark red solution (mixture of ethanol, iodine crystals and sodium iodide)	Tincture	Corrosive, reactive, toxic	Crystal or flakes, slightly soluble in water.
Lithium	Soft silvery-white metal	Batteries	Reacts violently with water to produce hydrogen gas (explosive)	Metal will transform to LiOH and Li ₂ O. LiOH may be mobile in soil.
Methanol	Clear colorless liquid	Coleman fuel, lighter fluid	Flammable	Methanol is miscible in and lighter than water. When released to the ground in sufficient quantities to get into the subsurface it will leach into percolating water and may reach the groundwater. Methanol is biodegradable.
Petroleum distillates (Naphtha)	Clear colorless liquid with a hydrocarbon odor	Coleman fuel, lighter fluid	Flammable	Naphthas are hydrophobic and lighter than water. In sufficient volume, they will move through the subsurface until they encounter a low permeability soil or groundwater. Naphthas slowly biodegrade.
Pseudoephedrine/ephedrine	White crystalline powder	Medicines		Completely soluble in water. As a crystal may be transported by wind. Dissolved in water or subject to water will leach through soil. Moderately biodegradable.
Red Phosphorous	Odorless red to violet solid	Striker strips/matchboxes	Decomposes to phosphine gas in presence of moisture and oxygen, explosive when mixed with organic material	Harmful to aquatic organisms. Insoluble in water. Will remain on ground surface if released.

Appendix D. Cleanup Checklist

List of steps for documenting cleanup activities

	Task (Refer to Guidelines for specific information)	Yes	No	Not Applicable
1	Pre-remediation ventilation completed.			
2	Preliminary assessment completed.			
3	Pre-remediation sampling conducted.			
4	Work plan based on the preliminary assessment and any sampling results provided			
5	Contaminated materials that will be permanently discarded removed and properly disposed of			
6	Interior surfaces vacuumed using a HEPA vacuum			
7	Initial washing of interior surfaces			
8	HVAC system cleaned			
9	Flush plumbing traps			
10	Ceilings, walls, floors and other non-porous items that will be kept washed three times with detergent solution (not bleach)			
11	Ceilings, walls and floors encapsulated			
12	Post-remediation sampling conducted			
13	Septic tank pumped (if applicable)			
14	Develop a final report			
15	Property owner provided with copies of all documentation, including sample results, work plan, and final report			

Appendix E. Code of Virginia Excerpts Related to Methamphetamine Cleanup and Notification.

§ 15.2-1716.2. Methamphetamine lab cleanup costs; localities may charge for reimbursement.

Any locality may provide by ordinance that any person who is convicted of an offense for manufacture of methamphetamine pursuant to § [18.2-248](#) or [18.2-248.03](#) shall be liable at the time of sentencing or in a separate civil action to the locality or to any other law-enforcement entity for the expense in cleaning up any methamphetamine lab related to the conviction. The amount charged shall not exceed the actual expenses associated with cleanup, removal, or repair of the affected property or the replacement cost of personal protective equipment used. (2012, cc. [517](#), [616](#).)

§ 18.2-248.04. Methamphetamine Cleanup Fund established.

There is hereby created in the state treasury a special nonreverting fund to be known as the Methamphetamine Cleanup Fund, hereafter referred to as "the Fund." The Fund shall be established on the books of the Comptroller. All moneys assessed against a person convicted of manufacture of methamphetamine as methamphetamine cleanup funds pursuant to subsection C1 of § [18.2-248](#) shall be paid into the state treasury and credited to the Fund. Interest earned on moneys in the Fund shall remain in the Fund and be credited to it. Any moneys remaining in the Fund, including interest thereon, at the end of each fiscal year shall not revert to the general fund but shall remain in the Fund. Moneys in the Fund shall be used solely for the purposes of restoration to an environmentally sound state sites used for the criminal manufacture of methamphetamine. Expenditures and disbursements from the Fund shall be made by the State Treasurer on warrants issued by the Comptroller upon written request signed by any agency of the Commonwealth, law-enforcement agency, or locality with the responsibility for and engaged in a specific methamphetamine site cleanup. (2012, c. [219](#).)

§ 32.1-11.7. Guidelines for cleanup of residential property used to manufacture methamphetamine.

The Board, in consultation with the Department of Environmental Quality and other relevant entities, shall establish guidelines for the cleanup of residential property formerly used to manufacture methamphetamine. (2012, c. [778](#); 2013, c. [557](#).)

§ 55-225.17. (Effective July 1, 2014) Required disclosures for property previously used to manufacture methamphetamine; remedy for nondisclosure.

A. If the landlord of a residential dwelling unit has actual knowledge that the dwelling unit was previously used to manufacture methamphetamine and has not been cleaned up in accordance with the guidelines established pursuant to § [32.1-11.7](#), the landlord shall provide to a prospective tenant a written disclosure that so states. Such disclosure shall be provided prior to the execution by the tenant of a written lease agreement or, in the case of an oral lease agreement, prior to occupancy by the tenant.

B. Any tenant who is not provided the disclosure required by subsection A may terminate the lease agreement at any time within 60 days of discovery that the property was previously used to manufacture methamphetamine and has not been cleaned up in accordance with the guidelines established pursuant to § [32.1-11.7](#) by providing written notice to the landlord in accordance with the lease or as required by law. Such termination shall be effective as of (i) 15 days after the date of the mailing of the notice or (ii) the date through which rent has been paid, whichever is

later. In no event, however, shall the effective date of the termination exceed one month from the date of mailing. Termination of the lease agreement shall be the exclusive remedy for the failure to comply with the disclosure provisions required by this section and shall not affect any rights or duties of the landlord or tenant arising under this chapter, other applicable law, or the rental agreement. (2013, c. [557](#).)

§ 55-248.12:3. (Effective July 1, 2014) Required disclosures for property previously used to manufacture methamphetamine; remedy for nondisclosure.

A. If the landlord of a residential dwelling unit has actual knowledge that the dwelling unit was previously used to manufacture methamphetamine and has not been cleaned up in accordance with the guidelines established pursuant to § [32.1-11.7](#), the landlord shall provide to a prospective tenant a written disclosure that so states. Such disclosure shall be provided prior to the execution by the tenant of a written lease agreement or, in the case of an oral lease agreement, prior to occupancy by the tenant.

B. Any tenant who is not provided the disclosure required by subsection A may terminate the lease agreement at any time within 60 days of discovery that the property was previously used to manufacture methamphetamine and has not been cleaned up in accordance with the guidelines established pursuant to § [32.1-11.7](#) by providing written notice to the landlord in accordance with the lease or as required by law. Such termination shall be effective as of (i) 15 days after the date of the mailing of the notice or (ii) the date through which rent has been paid, whichever is later. In no event, however, shall the effective date of the termination exceed one month from the date of mailing. Termination of the lease agreement shall be the exclusive remedy for the failure to comply with the disclosure provisions required by this section and shall not affect any rights or duties of the landlord or tenant arising under this chapter, other applicable law, or the rental agreement. (2013, c. [557](#).)

§ 55-519.4. (Effective July 1, 2014) Required disclosures; property previously used to manufacture methamphetamine.

Notwithstanding the exemptions in § [55-518](#), if the owner of a residential dwelling unit has actual knowledge that such residential property was previously used to manufacture methamphetamine and has not been cleaned up in accordance with the guidelines established pursuant to § [32.1-11.7](#), the owner shall provide to a prospective purchaser a written disclosure that so states. Such disclosure shall be provided to the purchaser on a form provided by the Virginia Real Estate Board and otherwise in accordance with this chapter. (2013, c. [557](#).)

Appendix F. Administration Review

This guideline will be reviewed by the Virginia Department of Health Chief Deputy Commissioner for Public Health and recommendations made to the Virginia Board of Health, in consideration of the Code of Virginia Title 32.1-11.7 and other available sources of information, as needed but no less frequently than every two years after initial date of approval.

Approver: _____
Cynthia C. Romero, MD, FAAFP
State Health Commissioner

Date: _____



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 12, 2013

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services 

SUBJECT: The Emergency Regulations for Gravelless Material and Drip Dispersal

Chapter 202 of the 2013 Acts of Assembly (HB 1726) mandates the Board of Health to promulgate regulations for chamber and bundled expanded polystyrene systems. The Board can also promulgate regulations for other technologies as deemed necessary. The emergency regulations must be promulgated within 280 days from enactment, on or before December 12, 2013. Karri Atwood, Assistant Attorney General, reviewed the draft emergency regulations.

The draft emergency regulations amend 12VAC5-610 (the Sewage Handling and Disposal Regulations) by establishing requirements for gravelless material and drip dispersal technology. Health department staff convened two technical advisory committees to develop the draft emergency regulations. The advisory committee held five meetings and reviewed existing guidance documents for gravelless material and drip dispersal technology before making recommendations. The draft emergency regulations were discussed with the Sewage Handling and Disposal Advisory Committee following the technical committees' work. The draft emergency regulations contain a number of similar provisions that were found in agency guidance documents, which will no longer be needed upon promulgation of the emergency regulations.

Upon approval by the Board of Health, the emergency regulations will undergo executive branch review and approval before publication. Following executive review, the emergency regulations will be filed with the Registrar of Regulations, at which time they will be effective for 18 months, and published in the Virginia Register of Regulations.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-610
Regulation title	Sewage Handling and Disposal Regulations
Action title	Amend the regulations to establish requirements for the physical construction, design, and installation of gravelless material including chambers and bundled expanded polystyrene; and establish requirements for the physical construction, design, and installation of drip dispersal.
Date this document prepared	July 24, 2013

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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*.

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

- 1) Please explain why this is an emergency situation as described above.*
- 2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.*

Chapter 202 of the 2013 Acts of Assembly (HB 1726) requires the Board of Health to promulgate regulations for chamber and bundled expanded polystyrene effluent systems. The Board may promulgate regulations for other distribution technologies. HB1726 specifies that

regulations must be effective within 280 days of enactment (on or before December 12, 2013). The Board is using the emergency rulemaking process authorized by the Administrative Process Act to promulgate regulations within 280 days.

The Sewage Handling and Disposal Regulations (12 VAC 5-610-20 et. seq., the Regulations) contain construction, design, and installation requirements for gravel and pipe effluent absorption trench, low pressure distribution, elevated sand mound, and sand-on-sand systems. The Regulations, as amended, will establish construction, design, and installation requirements for gravelless material and drip dispersal 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.

HB 1726 mandates the Board promulgate regulations for chamber and bundled expanded polystyrene systems, and other effluent distribution system technologies for onsite sewage systems as deemed necessary by the Board.

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 and required to exercise due diligence to protect the quality of both surface water and ground water.

Title 2.2-4011 of the Code states that agencies may adopt emergency regulations when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from enactment and the regulation is not exempt under the provisions of subdivision A. 4. of Title 2.2-4006.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The amended Regulations establish the following:

- 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 wastewater.

- 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 need for the regulations is to address HB 1726 and incorporate requirements for technology not presently included in the regulations. The Sewage Handling and Disposal Regulations do not include construction, design, and installation requirements for gravelless material or drip dispersal systems. Since 2002, VDH has recognized through policies that gravelless material is an acceptable means of dispersing wastewater. Since 1995, VDH has also recognized through policies that drip dispersal is an acceptable means of transmitting wastewater. The goal of the amended Regulations is to move the construction, design, and installation standards for gravelless material and drip dispersal from VDH policies into the Regulations.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

This regulatory action is mandated by HB1726. The Regulations were initially intended to establish construction and location requirements primarily for gravel and pipe effluent absorption trenches, low pressure distribution, elevated sand mound, and sand-on-sand systems. The Regulations allow the use of experimental or provisionally approved sewage treatment and disposal methods and provide a mechanism for provisionally approved systems to receive general approval. However, the Regulations have not been extensively updated since 2000.

The Regulations lack construction, design, and installation requirements for gravelless material, including chamber and bundled expanded polystyrene, and drip dispersal systems. To keep up with emerging technologies VDH has issued four GMPs for gravelless materials and five GMPs for drip dispersal to set physical construction, design, and installation standards. With the growing number of gravelless materials approved under these policies, and the increasing use of gravelless material and drip dispersal in Virginia, amendments to the Regulations are necessary.

Regulatory requirements for gravelless material in other states were considered. Health department staff conducted a review of regulations for gravelless material and drip dispersal systems from other states as part of this regulatory action. Potential issues may develop with how the emergency regulations are similar or different to requirements in other states or how the regulations might impact the work of licensed professionals in the Commonwealth of Virginia.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

No substantive changes were made to existing requirements of the Regulations. However, the term “soil gravel or sand interface” used in section 920 and 950(A) of the Regulations was modified to ensure inclusion of gravelless material and drip dispersal within these sections.

The new requirements contained in sections 930(F), 940(D), 950(D), Table 5.4, and 955 of the emergency regulations address the mandates of HB1726. HB1726 requires the regulations to include the following:

- 1) Specifications for the physical construction of chamber and bundled expanded polystyrene effluent distribution systems including:
 - a. Minimum exterior width.
 - b. Minimum height.
 - c. Minimum effluent storage capacity.
 - d. Minimum structural capacity.
- 2) Requirements for a permeable interface between chamber and bundled expanded polystyrene effluent distribution systems and trench sidewall soil surfaces for the absorption of wastewater.
- 3) Specifications for the installation of chamber and bundled expanded polystyrene effluent distribution system trenches including:
 - a. Allowable slope of a trench.
 - b. Maximum length of a trench.
 - c. Minimum sidewall depth of a trench.
 - d. Minimum lateral separation of trenches.
- 4) Criteria for substituting chamber and bundled expanded polystyrene effluent distribution systems for gravity percolation trenches and gravel and crushed stone low pressure systems.
- 5) Criteria for determining the minimum area requirements for chamber and bundled expanded polystyrene effluent distribution system absorption trenches.
- 6) Regulations for other effluent distribution system technologies for onsite sewage systems as may be deemed necessary by the Board.

To meet these requirements, the emergency regulations contain the following provisions, which are new:

A definition of gravelless material, which means:

“A product specifically manufactured to disperse effluent within the absorption trench of an onsite sewage system without the use of gravel. Gravelless material may include chambers, bundled expanded polystyrene, and multi-pipe systems.”

A definition of drip dispersal, which means:

“[A system that] applies wastewater in an even and controlled manner over an absorption area. Drip 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.”

This definition uses language currently found in GMP 107 and is intended to cover all components essential to the proper design and operation of drip dispersal systems.

Section 930(F)(1) creates a process that allows gravelless material currently approved under Guidance, Memoranda, and Policy (GMP) 116, 127, and 135 to retain general approval status. The regulations provide a process for future technologies to apply for general approval. Although the regulations currently provide a means for receiving general approval (Experimental or Provisional Approval), the Board has created a separate approval process for gravelless materials similar to the current approval process under GMP 116, 127, and 135.

Section 930(F)(2)(a) creates a minimum exterior width requirement for gravelless material based on current requirements contained in GMP 127. This is intended to meet minimum exterior width as required by Part 1(i) of HB 1726.

Section 930(F)(2)(b) creates a minimum height requirement for gravelless material based on current requirements contained in GMP 127. This is intended to meet minimum height as required by Part 1(i) of HB 1726.

Section 930(F)(2)(c) creates a requirement for a permeable interface between gravelless material and the trench sidewall as required by Part 1(ii) of HB 1726.

Section 930(F)(2)(d) creates a minimum storage capacity for gravelless material based on current requirements used to approve products under GMP 116, GMP 127, and GMP 135. The required storage capacity is equivalent to the storage capacity below the pipe in a gravel trench. This is intended to meet minimum storage capacity as required by Part 1(i) of HB 1726.

Section 930(F)(2)(e) and 930(F)(2)(f) create minimum structural capacity requirements for gravelless material based on current requirements contained in GMP 127. This is intended to meet minimum structural capacity as required by Part 1(i) of HB 1726.

Section 930(F)(3) requires that effluent be dispersed evenly throughout a gravelless system and that the trench bottom be protected from erosion. These requirements are based on current requirements in the Regulations and comments received from the Chamber and Bundled Expanded Polystyrene Technical Advisory Committee (CBEP TAC). The Board deems these requirements necessary in accordance with Part 1(vi) of HB 1726.

Section 930(F)(4) requires gravelless material be designed and installed in compliance with existing requirements contained in the Regulations, including current requirements for minimum installation depth, allowable slope, maximum length, minimum sidewall depth, and minimum lateral separation of absorption trenches. This proposed section also provides a provision for gravelless material installations to deviate from the requirements of the Regulations if approved by the Division as part of the general approval or if granted an exception pursuant to 12 VAC 5-610-660. This is intended to meet the requirements of Part 1(iii) of HB 1726.

Section 930(F)(5) and 940(D) set minimum requirements for low pressure distribution systems which use gravelless material to bed the pressure percolation lines. These minimums are based on current requirements from GMP 127 and recommendations from the CBEP TAC. This is intended to meet requirements of Part 1(iv) of HB 1726.

Section 930(F)(6) and 930(F)(7) set minimum requirements for pump-to-gravity, open-bottom gravelless material such as chambers. These requirements are intended to assure that effluent velocity is reduced prior to entering the absorption trench to prevent erosion of the trench bottom and assure proper distribution when enhanced flow distribution is utilized. Dosing volume requirements are based on the current requirements for gravel trench systems contained in 12VAC5-610-890(C). The requirement for percolation piping in open bottom gravelless systems is based on requirements contained in the "Comparison of Gravelless Absorption System GMPs" chart under GMP 116, 127, and 135 and comments from CBEP TAC members. The Board deems these requirements necessary in accordance with Part 1(vi) of HB 1726.

Section 930(F)(8) sets criteria for the substitution of gravelless material for gravel when gravelless material is not specified as part of the system design. The intent of section 930(F)(8) is to reference section 310 and 330; substitution of gravelless material does not require a new permit and requires approval by the certifying professional engineer or onsite soil evaluator that substitution is completed in accordance with the approved evaluation and design, and the Regulations. This is intended to meet criteria for substitution required by Part 1(iv) of HB 1726.

Revisions to section 950(D)(2) and Table 5.4 set criteria for determining the minimum area requirements for gravelless material. The revisions are based on minimum area requirements contained in GMP 127 and discussion among CBEP TAC members. This is intended to meet criteria for minimum area requirements required by Part 1(v) of HB 1726.

Section 955 sets minimum physical construction, design, and installation requirements for drip dispersal components and systems as a whole. Requirements include:

1. Standards for physical construction of drip tubing.
2. Minimum linear feet of tubing in the system.
3. Minimum installation depth and cover of drip systems.
4. Minimum soil absorption area and maximum loading rate requirements for drip dispersal.
5. Consideration of landscape linear loading rates.
6. Air/vacuum release valve location.
7. Minimum emergency storage and equalization volume requirements.
8. Minimum dosing volume requirements and prohibition on the use of demand dosing.

9. Minimum filtration and forward flushing requirements.
10. Electrical component requirements.
11. Minimum start up inspection requirements.

These requirements were based on GMP 107 and commentary from the Drip Dispersal Technical Advisory Committee (DD TAC). The Board deems these requirements necessary in accordance with Part 1(vi) of HB 1726.

Additionally the Department of Environmental Quality requested language be modified and added in section 30 to clarify areas of responsibilities between the two agencies.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

HB1726 mandates the Board promulgate these regulations; therefore there are no alternatives to this regulatory action.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

Please also indicate, pursuant to your Public Participation Guidelines, whether a panel has been used in the development of the emergency regulation and whether it will also be used in the development of the proposed regulation.

In response to HB 1726, the Office of Environmental Health Services (OEHS) convened two technical advisory committees to identify stakeholder concerns and to provide input on development of the emergency regulations. Members of the committees included manufacturers of currently approved gravelless material, manufacturers of drip dispersal components, representatives from the Virginia Onsite Wastewater Recycling Association (VOWRA), representatives from the Virginia Association of Professional Soil Scientist (VAPSS), Virginia Society of Professional Engineers (VSPE), American Council of Engineering Companies of Virginia (ACECVA), Alternative Onsite Sewage System Operators, Onsite Sewage System Installers, and VDH district staff.

The committees advised and assisted in the development of the emergency regulations. OEHS held a series of five meetings. Meeting summaries can be found on the Townhall website at:

<http://www.townhall.virginia.gov/L/Viewmeeting.cfm?meetingid=19782> (April 16th CBEP TAC)

<http://www.townhall.virginia.gov/L/Viewmeeting.cfm?meetingid=19834> (April 23rd CBEP TAC)

<http://www.townhall.virginia.gov/L/Viewmeeting.cfm?meetingid=19835> (May 8th CBEP TAC)

<http://www.townhall.virginia.gov/L/Viewmeeting.cfm?meetingid=19781> (April 16th DD TAC)

<http://www.townhall.virginia.gov/L/Viewmeeting.cfm?meetingid=19863> (May 10th DD TAC)

Documents reviewed by the technical advisory committees included the following: [HB 1726](#), VDH [GMP #116](#), VDH [GMP #127](#), VDH [GMP #135](#), list of [approved non-gravel manufacturers and products](#), and VDH [GMP #107](#).

The agency is seeking comments on the regulation that will permanently replace this emergency regulation, including but not limited to 1) ideas to be considered in the development of the permanent replacement regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in Title 2.2-4007.1. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to **Dwayne Roadcap, Acting Director of the Division of Onsite Sewage and Water Services, 109 Governor Street, Richmond, VA 23218, (804) 864-7462 (phone), (804) 864-7476 (fax)** or email dwayne.roadcap@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 day of the public comment period.

A public hearing will not be held following the publication of this regulatory action.

Family impact

Assess the potential 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.

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

Project 3665 - none

DEPARTMENT OF HEALTH

CH 0610 HB 1726

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~~ point of effluent application 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 required 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.

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 the 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 8 inches to provide a continuous exchange of air through a permeable interface.

c. Gravelless material shall have a permeable interface which 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 sewage.

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 minimum specified depth of compacted 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. 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 required by this chapter, 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. 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 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 = Ft²/100 Gals

x = 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 width of the trench excavation 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>124</u>	165
10	120	<u>90</u>	120	180	<u>135</u>	180
15	132	<u>99</u>	132	198	<u>149</u>	198
20	146	<u>110</u>	146	218	<u>164</u>	218
25	158	<u>119</u>	158	237	<u>178</u>	237
30	174	<u>131</u>	164	260	<u>195</u>	255
35	191	<u>143</u>	170	286	<u>215</u>	260
40	209	<u>157</u>	176	314	<u>236</u>	264
45	229	<u>172</u>	185	344	<u>258</u>	279
50	251	<u>188</u>	193	376	<u>282</u>	293
55	275	<u>206</u>	206	412	<u>309</u>	309
60	302	<u>227</u>	217	452	<u>339</u>	325
65	331	<u>248</u>	228	496	<u>372</u>	342
70	363	<u>272</u>	240	544	<u>408</u>	359
75	398	<u>299</u>	251	596	<u>447</u>	375
80	437	<u>328</u>	262	656	<u>492</u>	394
85	479	<u>359</u>	273	718	<u>539</u>	409
90	525	<u>394</u>	284	786	<u>590</u>	424
95	575	<u>489</u>	288	862	<u>733</u>	431
100	631	<u>536</u>	316	946	<u>804</u>	473
105	692	<u>588</u>	346	1038	<u>882</u>	519
110	759	<u>645</u>	379	1138	<u>967</u>	569
115	832	<u>707</u>	416	1248	<u>1061</u>	624
120	912	<u>775</u>	456	1368	<u>1163</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 piping, 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% 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.

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 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/feet).

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 6 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 conduct a start up inspection that verifies 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.

FORMS (12VAC5-610)

Application for a Sewage Disposal System Construction Permit, C.H.S. 200 (rev. 4/83).

Sewage Disposal System Construction Permit, C.H.S. 202A (rev. 6/84).

Schematic Drawing of Sewage Disposal System and Topographic, C.H.S. 202B (rev. 6/84).

Application for Sewage Handling Permit, B.W.E. 23-1.

Application for Pump and Haul, B.W.E. 25-1.

Pump and Haul Storage Facility Construction Permit, B.W.E. 26-1.

Soil Evaluation Form, C.H.S. 201 (rev. 4/83).

Soils Evaluation Percolation Test Data.

Record of Inspection —Non-Public Drinking Water Supply System.

Completion Statement, C.H.S. 204 (rev. 4/83).

Gravelless Material – Application for General Approval

**Gravelless Material
Application for General Approval**

Company Name: _____
Company Address: _____
City/State/Zip: _____

Company Owner: _____

Virginia Representative: _____

Telephone Number: _____
Secondary Number: _____
Fax Number: _____
E-mail Address: _____
Secondary E-mail: _____

1. Name of Product(s) Submitted for Approval: _____

2. Other States where product(s) are approved for use: _____

3. In order to complete the review please provide the following with your application:

A. The exterior dimensions (width) of the products. If the product is not considered chamber, bundled expanded polystyrene, or multipipe please include the manufacturer's method for determining external width in accordance with 12 VAC 5-610-950.F.1.

B. The physical height of product and the method for continuous exchange of air and effluent.

C. The product's calculated effluent storage capacity.

D. A description of the mechanism used to reduce the velocity of incoming effluent to prevent scouring of soils at the trench bottom.

E. Results from the American Association of State Highway and Transportation Officials H-10 and H-20 load rating (as applicable), or equivalent testing results.

F. A copy of the product installation manual including a sizing chart in accordance with Table 5.4 or listing any requested deviation from that requirement.

G. The product's material safety data sheet, as applicable.

H. Provide data to address the chemical stability of the product. Data may include results of leachate study.

I. A list of any requested deviations from the requirements of 12 VAC5-610 and the basis for the request.

4. I, _____ (owner/representative name) _____, hereby certify that the product(s) being submitted for approval by _____ (company name) _____ meet all requirements listed in the Sewage Handling and Disposal Regulations, 12 VAC 5-610-20 et. seq., for gravelless material (see 12 VAC 5-610-930.F).

Signature

Date

Print



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 2, 2013

TO: Virginia State Board of Health

FROM: David H. Trump, MD, MPH, MPA
State Epidemiologist & Director, Office of Epidemiology

SUBJECT: Proposed Amendment to the Regulations for Disease Reporting and Control

The proposed amendments to the Regulations for Disease Reporting and Control include many minor modifications to ensure consistency within the document and to bring the language into alignment with current usage. An example of the former is to specify that reporting 'by the most rapid means available' means 'immediately' in each section where rapid reporting is mentioned. Another example of internal consistency is changing some sections that had numbered subsections to have lettered subsections instead. An example of a change to reflect current usage is proposing to use 'Shiga toxin-producing' E. coli infections in place of referring to E. coli O157:H7. In addition, many new laboratory tests are included in the list of conditions reportable by laboratory directors. This change reflects the adoption of available scientific methods by laboratories as well as the provision of information necessary for public health surveillance.

More substantive changes include the following:

- Lowering the blood lead level at which laboratories report and physicians educate patients from 10 ug/dL to 5 ug/dL for children and from 25 ug/dL to 10 ug/dL in persons 15 years of age and older. This is consistent with CDC recommendations.
- Adding babesiosis and leptospirosis to the reportable disease list. These are on the nationally notifiable disease list and the Council of State and Territorial Epidemiologists has recommended that states make these conditions reportable. Both conditions may be acquired from environmental sources (ticks and water, respectively).
- Removing monkeypox and laboratory reporting of invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infections from reporting requirements. Monkeypox would still be reportable under the 'unusual conditions of public health concern' provision. Data on MRSA infections would be available to health department staff

through other means if proposed amendments to the healthcare-associated infections section of these regulations were approved.

- Defining severe acute respiratory syndrome (SARS) to include SARS-associated coronavirus disease, Middle East respiratory syndrome-associated coronavirus disease, or another coronavirus causing a severe acute illness.
- Asking laboratory directors to provide additional information on antimicrobial susceptibility for gonorrhea, details of hepatitis test results, and to submit remnant HIV diagnostic serum to DCLS for HIV recency testing and HIV genetic sequence data from HIV drug resistance tests. Labs are also asked to report all hepatitis B test results for children under 2 years of age and HIV test results for children under 4 years of age.
- Updating the immunization section to reflect licensed professionals permitted to administer immunizations.
- Updating the section on dangerous microbes and pathogens to comply with federal regulations and to specify that the information is protected regardless of what entity provides the information to the department.

These changes will improve the department's ability to detect and control conditions of public health concern that are affecting the residents of Virginia.

Following approval of the proposed amendments by the Board, the department intends to submit the regulatory packet for Executive Branch review.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation	12 VAC5-90
Regulation title	Regulations for Disease Reporting and Control
Action title	Amendment to comply with changes in public health practice
Date this document prepared	August 2, 2013

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 disease control and emergency preparedness that are needed to protect the health of the residents of Virginia.

The specific changes being proposed are necessary to ensure the regulations comply with recent changes in the practice of public health pertaining to the reporting of diseases in humans that are potentially transmitted from environmental sources (e.g., babesiosis and leptospirosis) as well as to update the list of laboratory tests that can be used to identify reportable disease findings and of specimens needing further testing to reflect advances in laboratory technology. Further amendments are necessary to clarify definitions and ensure consistency of the regulatory language, such as to standardize the reporting requirements for those who are required to report. Minor changes are also proposed to the section on the reporting of dangerous microbes to align the regulatory requirements with federal requirements. Renumbering is proposed for internal consistency and to ensure relevant sections are maintained as a whole.

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. Further, § 32.1-42 of the *Code of Virginia* authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. 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 in order to ensure that the regulations comply with changes in the *Code of Virginia* 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, including outbreaks and emergencies that could be caused by naturally occurring disease or acts of bioterrorism. 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.)

- Update definitions to align them with current usage;
- Update the reportable disease list to reflect current national recommendations and language;

- Update the list of conditions reportable by laboratory directors to reflect current laboratory technology and public health standards;
- Increase the information reported by laboratory directors for hepatitis B and human immunodeficiency virus testing, especially for children, and the specimens to be submitted to the Division of Consolidated Laboratory Services for advanced laboratory testing;
- Update language to ensure consistency between sections;
- Clarify agency role in inter-state and national notifications;
- Clarify level of information that may be shared with the agency by schools and other facilities;
- Renumber sections to increase internal consistency within the regulations;
- Update reporting of dangerous microbes and pathogens sections to reflect federal code section numbering changes and other requirements.

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 amendments will improve the ability of the Virginia Department of Health to detect and control diseases of public health importance. Most of the changes being proposed are updates to terminology to reflect current usage or to clarify requirements. Some formatting changes have also been proposed.

The addition of laboratory testing methods to the list of conditions that laboratory directors must report reflects advances in laboratory science, but would mean that laboratories conducting business in Virginia will have to report additional positive laboratory findings to the health department. To reflect current Centers for Disease Control and Prevention recommendations, the reportable blood lead level is changed from 10 to 5 µg/dL for children and from 25 to 10 µg/dL for adults. Many of the proposed changes are already being reported by laboratories who offer those testing options.

The proposed amendments would require laboratory directors to provide additional information on antimicrobial susceptibility for gonorrhea, details of hepatitis test results, and to submit remnant HIV diagnostic serum to DCLS for HIV recency testing and HIV genetic sequence data from HIV drug resistance tests. They would also report all hepatitis B test results for children under 2 years of age and HIV test results for children under 4 years of age.

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.

<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 regulations pertain to physicians, laboratory directors, medical facility directors and directors of other settings where disease outbreaks may occur. The proposed amendments are anticipated to have minimal impact on these entities because the changes are minimal additions to existing disease reporting requirements. The two diseases being added to the reportable disease list, babesiosis and leptospirosis, occur at low frequencies and will not add appreciable volume to those required to submit disease reports to the health department. The largest impact is that laboratories will need to report additional positive laboratory findings and forward</p>
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	additional specimens to the Division of Consolidated Laboratory Services.
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.	Up to 100 laboratories may be affected by the changes proposed in laboratory reporting requirements; however, not all will offer the types of testing that must be reported. These laboratories are already reporting disease information to the health department, and the additions should have minimal impact. Some of the affected laboratories, including those in hospitals, would meet the definition of a small business.
Benefits expected as a result of this regulatory proposal.	Benefits include more complete reporting of diseases of public health importance to the health department so that actions can be taken to minimize the spread of diseases in Virginia’s communities and a better understanding of the magnitude of these health problems in Virginia will be gained.
Projected cost to the <u>state</u> to implement and enforce this regulatory proposal.	No costs are anticipated.
Projected cost to <u>localities</u> to implement and enforce this regulatory proposal.	No costs are anticipated.
All projected costs of this regulatory proposal for <u>affected individuals, businesses, or other entities</u>. 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 additional laboratory tests that must be reported will increase the volume of reports that must be submitted by laboratories to the health department, which will result in incremental increases in the cost of submitting reports. Laboratories would also be required to submit additional specimens to the Division of Consolidated Laboratory Services for additional testing, which means they would incur costs for shipping of such materials.

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 reporting schedules is advisable given the health department’s need to detect health problems in the community and respond quickly to the information reported under the requirements of these regulations in order to protect the health of the public. The schedules and requirements are as necessary and as simple as possible to achieve the goals of the regulations. 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
12VAC5-90-10		Definitions	<ul style="list-style-type: none"> • Defines Centers for Disease Control and Prevention (CDC) and changes its usage upon later referral. • Corrects definition of 'central line device' to say 'great' vessels instead of 'greater'. • Changes capitalization on 'Ehrlichiosis/Anaplasmosis for consistency. • Updates definition of 'lead, elevated blood levels' to reflect current definition based on CDC reference value. • Updates definition of severe acute respiratory syndrome to include other novel coronavirus infections.
12VAC5-90-50	Repeal	Applicability Section	<ul style="list-style-type: none"> • This section stated that the regulations apply throughout the Commonwealth and are governed by the Administrative Process Act. Legislative Services advised that it is not necessary and is redundant with Code requirements.
12VAC5-90-80.A		Reportable disease list	<ul style="list-style-type: none"> • Additions to the reportable disease list will include babesiosis and leptospirosis. • Deletions will include monkeypox. The Department has other means of receiving data on the occurrence of this disease.
12VAC5-90-80.B		Conditions reportable by directors of laboratories	<ul style="list-style-type: none"> • Additions include babesiosis, hepatitis-other acute viral, and leptospirosis. • Deletions include monkeypox and methicillin-resistant <i>Staphylococcus aureus</i> infections. • Changes are proposed to the reportable results for botulism, Campylobacter infection, <i>E. coli</i> infection, giardiasis, gonorrhea, hepatitis B, hepatitis C, HIV, lead, salmonellosis, shigellosis, Staphylococcal infection, and

			<p>Vibrio infection to incorporate current laboratory methods.</p> <ul style="list-style-type: none"> • Laboratories would report all hepatitis B findings for children under 2 years of age and all HIV results for children under 4 years of age. • Laboratories would submit all remnant HIV sera to the Division of Consolidated Laboratory Services (DCLS) or other designated laboratory for HIV recency testing and would report all HIV genetic sequence data associated with HIV drug resistance testing.
12VAC5-90-80.C-F		Rapidly reportable conditions, toxic substances, outbreaks, and unusual diseases	<ul style="list-style-type: none"> • Deletes monkeypox. • Clarifies that rapid reporting means immediately by the most rapid means, using consistent language between sections.
12VAC5-90-90		Those required to report	<ul style="list-style-type: none"> • Changes are proposed in wording for consistency between all the subsections, including clarification of rapid reporting. • The term 'broth' is clarified and Vibrio is added to the list of isolates that must be submitted to the Division of Consolidated Laboratory Services (DCLS) for further testing. • Laboratories suspecting a diagnosis of a select agent would submit an isolate to DCLS for confirmation. • Clarifications are added that local health departments can report to the state using the electronic surveillance system and that the state is responsible for notifying other states and the Centers for Disease Control and Prevention. • Clarification of what information may be released to the health department by schools, camps, and facilities on individuals has also been added.
12VAC5-90-100		Methods of disease control	<ul style="list-style-type: none"> • Proposes to update language to refer to the 19th edition (2008) of the Control of Communicable Diseases Manual.
12VAC5-90-110		Immunization	<ul style="list-style-type: none"> • States that required immunizations may be obtained from physicians, registered nurses, or other licensed professionals authorized to administer immunizations.

<p>12VAC5-90-280 through 12VAC5-90-360</p>		<p>Reporting of dangerous microbes and pathogens</p>	<ul style="list-style-type: none"> • Strikes section numbers and changes them to letters for consistency within the regulations; • Proposes to update references to the Code of Federal Regulations to reflect changes in federal code section changes for select agent reporting; • Proposes to add language to clarify that select agent information is protected from release regardless of whether the information is submitted directly by laboratories or by federal agencies also holding the information. This is needed to ensure that terrorism-sensitive information is protected from access by potential terrorists seeking access to the materials.
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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
None added			

Project 3366 - NOIRA

DEPARTMENT OF HEALTH

Amendment to comply with changes in public health practice

Part I

Definitions

12VAC5-90-10. Definitions.

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

"Acute care hospital" means a hospital as defined in § 32.1-123 of the Code of Virginia that provides medical treatment for patients having an acute illness or injury or recovering from surgery.

"Adult intensive care unit" means a nursing care area that provides intensive observation, diagnosis, and therapeutic procedures for persons 18 years of age or more who are critically ill. Such units may also provide intensive care to pediatric patients. An intensive care unit excludes nursing areas that provide step-down, intermediate care, or telemetry only.

"Affected area" means any part or the whole of the Commonwealth, which has been identified as where persons reside, or may be located, who are known to have been exposed to or infected with, or who are reasonably suspected to have been exposed to or infected with, a communicable disease of public health threat. "Affected area" shall include, but not be limited to, cities, counties, towns, and subsections of such areas, public and private property, buildings, and other structures.

"Arboviral infection" means a viral illness that is transmitted by a mosquito, tick, or other arthropod. This includes, but is not limited to, chikungunya, dengue, eastern equine encephalitis

(EEE), LaCrosse encephalitis (LAC), St. Louis encephalitis (SLE), and West Nile virus (WNV) infection.

"Board" means the State Board of Health.

"Cancer" means all carcinomas, sarcomas, melanomas, leukemias, and lymphomas excluding localized basal and squamous cell carcinomas of the skin, except for lesions of the mucous membranes.

"CDC" means the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"Central line-associated bloodstream infection" means a primary bloodstream infection identified by laboratory tests, with or without clinical signs or symptoms, in a patient with a central line device, and meeting the current ~~Centers for Disease Control and Prevention (CDC)~~ CDC surveillance definition for laboratory-confirmed primary bloodstream infection.

"Central line device" means a vascular infusion device that terminates at or close to the heart or in one of the ~~greater~~ great vessels. The following are considered great vessels for the purpose of reporting central line infections and counting central line days: aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, and common femoral veins.

"Child care center" means a child day center, child day program, family day home, family day system, or registered family day home as defined by § 63.2-100 of the Code of Virginia, or a similar place providing day care of children by such other name as may be applied.

"Clinic" means any facility, freestanding or associated with a hospital, that provides preventive, diagnostic, therapeutic, rehabilitative, or palliative care or services to outpatients.

"Commissioner" means the State Health Commissioner or his duly designated officer or agent, unless stated in a provision of these regulations that it applies to the State Health Commissioner in his sole discretion.

"Communicable disease" means an illness due to an infectious agent or its toxic products which is transmitted, directly or indirectly, to a susceptible host from an infected person, animal, or arthropod or through the agency of an intermediate host or a vector or through the inanimate environment.

"Communicable disease of public health significance" means an illness caused by a specific or suspected infectious agent that may be transmitted directly or indirectly from one individual to another. This includes but is not limited to infections caused by human immunodeficiency viruses, bloodborne pathogens, and tubercle bacillus. The State Health Commissioner may determine that diseases caused by other pathogens constitute communicable diseases of public health significance.

"Communicable disease of public health threat" means an illness of public health significance, as determined by the State Health Commissioner in accordance with these regulations, caused by a specific or suspected infectious agent that may be reasonably expected or is known to be readily transmitted directly or indirectly from one individual to another and has been found to create a risk of death or significant injury or impairment; this definition shall not, however, be construed to include human immunodeficiency viruses or the tubercle bacilli, unless used as a bioterrorism weapon.

"Companion animal" means any domestic or feral dog, domestic or feral cat, nonhuman primate, guinea pig, hamster, rabbit not raised for human food or fiber, exotic or native animal, reptile, exotic or native bird, or any feral animal or any animal under the care, custody, or ownership of a person or any animal that is bought, sold, traded, or bartered by any person. Agricultural animals, game species, or any animals regulated under federal law as research animals shall not be considered companion animals for the purpose of this regulation.

"Condition" means any adverse health event, such as a disease, an infection, a syndrome, or as indicated by a procedure (including but not limited to the results of a physical exam,

laboratory test, or imaging interpretation) suggesting that an exposure of public health importance has occurred.

"Contact" means a person or animal known to have been in such association with an infected person or animal as to have had an opportunity of acquiring the infection.

"Contact services" means a broad array of services that are offered to persons with infectious diseases and their contacts. Contact services include contact tracing, providing information about current infections, developing risk reduction plans to reduce the chances of future infections, and connecting to appropriate medical care and other services.

"Contact tracing" means the process by which an infected person or health department employee notifies others that they may have been exposed to the infected person in a manner known to transmit the infectious agent in question.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy hazardous substances or organisms from a person, surface, or item to the point that such substances or organisms are no longer capable of causing adverse health effects and the surface or item is rendered safe for handling, use, or disposal.

"Department" means the State Department of Health.

"Designee" or "designated officer or agent" means any person, or group of persons, designated by the State Health Commissioner, to act on behalf of the commissioner or the board.

~~"Ehrlichiosis/anaplasmosis"~~ "Ehrlichiosis/Anaplasmosis" means human infections caused by *Ehrlichia chaffeensis* (formerly included in the category "human monocytic ehrlichiosis" or "HME"), *Ehrlichia ewingii* or *Anaplasma phagocytophilum* (formerly included in the category "human granulocytic ehrlichiosis" or "HGE").

"Epidemic" means the occurrence in a community or region of cases of an illness clearly in excess of normal expectancy.

"Essential needs" means basic human needs for sustenance including but not limited to food, water, and health care, e.g., medications, therapies, testing, and durable medical equipment.

"Exceptional circumstances" means the presence, as determined by the commissioner in his sole discretion, of one or more factors that may affect the ability of the department to effectively control a communicable disease of public health threat. Factors to be considered include but are not limited to: (i) characteristics or suspected characteristics of the disease-causing organism or suspected disease-causing organism such as virulence, routes of transmission, minimum infectious dose, rapidity of disease spread, the potential for extensive disease spread, and the existence and availability of demonstrated effective treatment; (ii) known or suspected risk factors for infection; (iii) the potential magnitude of the effect of the disease on the health and welfare of the public; and (iv) the extent of voluntary compliance with public health recommendations. The determination of exceptional circumstances by the commissioner may take into account the experience or results of investigation in Virginia, another state, or another country.

"Foodborne outbreak" means two or more cases of a similar illness acquired through the consumption of food contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include but are not limited to heavy metal intoxication, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, *Clostridium perfringens* food poisoning, hepatitis A, and Shiga toxin-producing Escherichia coli O157:H7 infection.

"Healthcare-associated infection" (also known as nosocomial infection) means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent or agents or its toxin or toxins that (i) occurs in a patient in a healthcare setting (e.g., a hospital or outpatient clinic), (ii) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting, and (iii) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC.

"Hepatitis C, acute" means the following clinical characteristics are met: (i) discrete onset of symptoms indicative of viral hepatitis and (ii) jaundice or elevated serum aminotransferase levels and the following laboratory criteria are met: (a) serum alanine aminotransferase levels (ALT) greater than 400 IU/L; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc negative (if done); and (d) hepatitis C virus antibody (anti-HCV) screening test positive with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay as defined by CDC, HCV antibody positive by immunoblot (RIBA), or HCV RNA positive by nucleic acid test.

"Hepatitis C, chronic" means that the laboratory criteria specified in clauses (b), (c) and (d) listed above for an acute case are met but clinical signs or symptoms of acute viral hepatitis are not present and serum alanine aminotransferase (ALT) levels do not exceed 400 IU/L. This category will include cases that may be acutely infected but not symptomatic.

"Immunization" means a procedure that increases the protective response of an individual's immune system to specified pathogens.

"Independent pathology laboratory" means a nonhospital or a hospital laboratory performing surgical pathology, including fine needle aspiration biopsy and bone marrow specimen examination services, which reports the results of such tests directly to physician offices, without reporting to a hospital or accessioning the information into a hospital tumor registry.

"Individual" means a person or companion animal. When the context requires it, "person or persons" shall be deemed to include any individual.

"Infection" means the entry and multiplication or persistence of a disease-causing organism (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory means) or manifest (clinically apparent).

"Influenza A, novel virus" means infection of a human with an influenza A virus subtype that is different from currently circulating human influenza H1 and H3 viruses. Novel subtypes

include H2, H5, H7, and H9 subtypes or influenza H1 and H3 subtypes originating from a nonhuman species.

"Invasive" means the organism is affecting a normally sterile site, including but not limited to blood or cerebrospinal fluid.

"Investigation" means an inquiry into the incidence, prevalence, extent, source, mode of transmission, causation of, and other information pertinent to a disease occurrence.

"Isolation" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are infected with, or are reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, complete" means the full-time confinement or restriction of movement of an individual or individuals infected with, or reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, modified" means a selective, partial limitation of freedom of movement or actions of an individual or individuals infected with, or reasonably suspected to be infected with, a communicable disease. Modified isolation is designed to meet particular situations and includes but is not limited to the exclusion of children from school, the prohibition or restriction from engaging in a particular occupation or using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Isolation, protective" means the physical separation of a susceptible individual or individuals not infected with, or not reasonably suspected to be infected with, a communicable disease from an environment where transmission is occurring, or is reasonably suspected to be occurring, in order to prevent the individual or individuals from acquiring the communicable disease.

"Laboratory" as used herein means a clinical laboratory that examines materials derived from the human body for the purpose of providing information on the diagnosis, prevention, or treatment of disease.

"Laboratory director" means any person in charge of supervising a laboratory conducting business in the Commonwealth of Virginia.

"Law-enforcement agency" means any sheriff's office, police department, adult or youth correctional officer, or other agency or department that employs persons who have law-enforcement authority that is under the direction and control of the Commonwealth or any local governing body. "Law-enforcement agency" shall include, by order of the Governor, the Virginia National Guard.

"Lead, elevated blood levels" means a confirmed blood level greater than or equal to ~~40 micrograms of lead per deciliter ($\mu\text{g}/\text{dL}$) of whole blood in a child or children 15 years of age and younger, a venous blood lead level greater than or equal to 25 $\mu\text{g}/\text{dL}$ in a person older than 15 years of age, or such lower blood lead level as may be recommended for individual intervention by the department or the Centers for Disease Control and Prevention~~ the reference value established by the CDC. In 2012, the reference value was 5 $\mu\text{g}/\text{dL}$ in children and 10 $\mu\text{g}/\text{dL}$ for persons older than 15 years of age.

"Least restrictive" means the minimal limitation of the freedom of movement and communication of an individual while under an order of isolation or an order of quarantine that also effectively protects unexposed and susceptible individuals from disease transmission.

"Medical care facility" means any hospital or nursing home licensed in the Commonwealth, or any hospital operated by or contracted to operate by an entity of the United States government or the Commonwealth of Virginia.

"Midwife" means any person who is licensed as a nurse midwife by the Virginia Boards of Nursing and Medicine or who is licensed by the Board of Medicine as a certified professional midwife.

"National Healthcare Safety Network (NHSN)" means a surveillance system created by the CDC for accumulating, exchanging, and integrating relevant information on infectious adverse events associated with healthcare delivery.

"Nucleic acid detection" means laboratory testing of a clinical specimen to determine the presence of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) specific for an infectious agent using any method, including hybridization, sequencing, or amplification such as polymerase chain reaction.

"Nurse" means any person licensed as a professional nurse or as a licensed practical nurse by the Virginia Board of Nursing.

"Occupational outbreak" means a cluster of illness or disease that is indicative of a work-related exposure. Such conditions include but are not limited to silicosis, asbestosis, byssinosis, pneumoconiosis, and tuberculosis.

"Outbreak" means the occurrence of more cases of a disease than expected.

"Period of communicability" means the time or times during which the etiologic agent may be transferred directly or indirectly from an infected person to another person, or from an infected animal to a person.

"Physician" means any person licensed to practice medicine or osteopathy by the Virginia Board of Medicine.

"Quarantine" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are present within an affected area or who are known to have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease and who do not yet show signs or symptoms of infection with the

communicable disease in order to prevent or limit the transmission of the communicable disease of public health threat to unexposed and uninfected individuals.

"Quarantine, complete" means the full-time confinement or restriction of movement of an individual or individuals who do not have signs or symptoms of infection but may have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease of public health threat in order to prevent the transmission of the communicable disease of public health threat to uninfected individuals.

"Quarantine, modified" means a selective, partial limitation of freedom of movement or actions of an individual or individuals who do not have signs or symptoms of the infection but have been exposed to, or are reasonably suspected to have been exposed to, a communicable disease of public health threat. Modified quarantine may be designed to meet particular situations and includes but is not limited to limiting movement to the home, work, and/or one or more other locations, the prohibition or restriction from using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Reportable disease" means an illness due to a specific toxic substance, occupational exposure, or infectious agent, which affects a susceptible individual, either directly, as from an infected animal or person, or indirectly through an intermediate host, vector, or the environment, as determined by the board.

"SARS" means severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-CoV) disease, Middle East respiratory syndrome (MERS)-associated coronavirus (MERS-CoV) disease, or another coronavirus causing a severe acute illness.

"School" means (i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth; (ii) any private or parochial school that offers instruction at any level or grade from kindergarten through grade 12; (iii) any private or parochial

nursery school or preschool, or any private or parochial child care center licensed by the Commonwealth; and (iv) any preschool handicap classes or Head Start classes.

"Serology" means the testing of blood, serum, or other body fluids for the presence of antibodies or other markers of an infection or disease process.

"Surveillance" means the ongoing systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice. A surveillance system includes the functional capacity for data analysis as well as the timely dissemination of these data to persons who can undertake effective prevention and control activities.

"Susceptible individual" means a person or animal who is vulnerable to or potentially able to contract a disease or condition. Factors that affect an individual's susceptibility include but are not limited to physical characteristics, genetics, previous or chronic exposures, chronic conditions or infections, immunization history, or use of medications.

"Toxic substance" means any substance, including any raw materials, intermediate products, catalysts, final products, or by-products of any manufacturing operation conducted in a commercial establishment, that has the capacity, through its physical, chemical or biological properties, to pose a substantial risk of death or impairment either immediately or over time, to the normal functions of humans, aquatic organisms, or any other animal but not including any pharmaceutical preparation which deliberately or inadvertently is consumed in such a way as to result in a drug overdose.

"Tubercle bacilli" means disease-causing organisms belonging to the Mycobacterium tuberculosis complex and includes Mycobacterium tuberculosis, Mycobacterium bovis, and Mycobacterium africanum or other members as may be established by the commissioner.

"Tuberculin skin test (TST)" means a test for demonstrating infection with tubercle bacilli, performed according to the Mantoux method, in which 0.1 ml of 5 TU strength tuberculin purified

protein derivative (PPD) is injected intradermally on the volar surface of the arm. Any reaction is observed 48-72 hours after placement and palpable induration is measured across the diameter transverse to the long axis of the arm. The measurement of the indurated area is recorded in millimeters and the significance of the measured induration is based on existing national and department guidelines.

"Tuberculosis" means a disease caused by tubercle bacilli.

"Tuberculosis, active disease" (also "active tuberculosis disease" and "active TB disease"), as defined by § 32.1-49.1 of the Code of Virginia, means a disease caused by an airborne microorganism and characterized by the presence of either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or nucleic acid amplification, including preliminary identification by rapid methodologies; (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear, and where sufficient clinical and radiographic evidence of active tuberculosis disease is present as determined by a physician licensed to practice medicine in Virginia; or (iii) sufficient clinical and radiographic evidence of active tuberculosis disease as determined by the commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing, or suspected of containing, tubercle bacilli is unobtainable.

"Tuberculosis infection in children age less than 4 years" means a significant reaction resulting from a tuberculin skin test (TST) or other approved test for latent infection without clinical or radiographic evidence of active tuberculosis disease, in children from birth up to their fourth birthday.

"Vaccinia, disease or adverse event" means vaccinia infection or serious or unexpected events in persons who received the smallpox vaccine or their contacts, including but not limited to bacterial infections, eczema vaccinatum, erythema multiforme, generalized vaccinia, progressive vaccinia, inadvertent inoculation, post-vaccinial encephalopathy or encephalomyelitis, ocular vaccinia, and fetal vaccinia.

"Waterborne outbreak" means two or more cases of a similar illness acquired through the ingestion of or other exposure to water contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include but are not limited to giardiasis, viral gastroenteritis, cryptosporidiosis, hepatitis A, cholera, and shigellosis. A single case of laboratory-confirmed primary amebic meningoencephalitis or of waterborne chemical poisoning is considered an outbreak.

12VAC5-90-50. Applicability. (Repealed.)

~~A. This chapter has general application throughout the Commonwealth.~~

~~B. The provisions of the Virginia Administrative Process Act, which is codified as Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code of Virginia shall govern the adoption, amendment, modification, and revision of this chapter, and the conduct of all proceedings and appeals hereunder. All hearings on such regulations shall be conducted in accordance with § 2.2-4007.01 of the Code of Virginia.~~

Part III

Reporting of Disease

12VAC5-90-80. ~~Reportable disease list~~ Lists of diseases that shall be reported.

A. Reportable disease list. The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the persons enumerated in 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Acquired immunodeficiency syndrome (AIDS)

Amebiasis

*Anthrax

Arboviral infections (e.g., dengue, EEE, LAC, SLE, WNV)

Babesiosis

*Botulism

*Brucellosis

Campylobacteriosis

Chancroid

Chickenpox (Varicella)

Chlamydia trachomatis infection

*Cholera

Creutzfeldt-Jakob disease if <55 years of age

Cryptosporidiosis

Cyclosporiasis

*Diphtheria

*Disease caused by an agent that may have been used as a weapon

Ehrlichiosis/Anaplasmosis

Escherichia coli infection, Shiga toxin-producing

Giardiasis

Gonorrhea

Granuloma inguinale

*Haemophilus influenzae infection, invasive

Hantavirus pulmonary syndrome

Hemolytic uremic syndrome (HUS)

*Hepatitis A

Hepatitis B (acute and chronic)

Hepatitis C (acute and chronic)

Hepatitis, other acute viral

Human immunodeficiency virus (HIV) infection

Influenza

*Influenza-associated deaths in children <18 years of age

Lead, elevated blood levels

Legionellosis

Leprosy (~~Hansen~~ Hansen's disease)

Leptospirosis

Listeriosis

Lyme disease

Lymphogranuloma venereum

Malaria

*Measles (Rubeola)

*Meningococcal disease

~~*Monkeypox~~

Mumps

Ophthalmia neonatorum

*Outbreaks, all (including but not limited to foodborne, healthcare-associated, occupational, toxic substance-related, and waterborne)

*Pertussis

*Plague

*Poliovirus infection, including poliomyelitis

*Psittacosis

*Q fever

*Rabies, human and animal

Rabies treatment, post-exposure

*Rubella, including congenital rubella syndrome

Salmonellosis

*Severe acute respiratory syndrome (SARS), including any coronavirus causing a severe acute illness

Shigellosis

*Smallpox (Variola)

Spotted fever rickettsiosis

Staphylococcus aureus infection, vancomycin-intermediate or vancomycin-resistant

Streptococcal disease, Group A, invasive or toxic shock

Streptococcus pneumoniae infection, invasive, in children <5 years of age

Syphilis (report *primary and *secondary syphilis by rapid means)

Tetanus

Toxic substance-related illness

Trichinosis (Trichinellosis)

*Tuberculosis, active disease

Tuberculosis infection in children <4 years of age

*Tularemia

*Typhoid/Paratyphoid fever

*Unusual occurrence of disease of public health concern

*Vaccinia, disease or adverse event

*Vibrio infection

*Viral hemorrhagic fever

*Yellow fever

Yersiniosis

B. Conditions reportable by directors of laboratories.

Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Amebiasis - by microscopic examination, culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Anthrax - by culture, antigen detection or nucleic acid detection

Arboviral infection - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Babesiosis – by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Botulism - by culture, nucleic acid detection, or identification of ~~toxin~~ neurotoxin in a clinical specimen

*Brucellosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Campylobacteriosis - by culture, antigen detection, or nucleic acid detection

Chancroid - by culture, antigen detection, or nucleic acid detection

Chickenpox (~~varicella~~) (Varicella) - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Chlamydia trachomatis infection - by culture, antigen detection, nucleic acid detection or, for lymphogranuloma venereum, serologic results consistent with recent infection

*Cholera - by culture or serologic results consistent with recent infection

Creutzfeldt-Jakob disease if <55 years of age by histopathology in patients under the age of 55 years

Cryptosporidiosis - by microscopic examination, antigen detection, or nucleic acid detection

Cyclosporiasis - by microscopic examination or nucleic acid detection

*Diphtheria - by culture or histopathology

Ehrlichiosis/Anaplasmosis - by culture, nucleic acid detection, or serologic results consistent with recent infection

Escherichia coli infection, Shiga toxin-producing - by culture of ~~E. coli O157 or other Shiga toxin-producing E. coli~~, Shiga toxin detection (e.g., by EIA), or nucleic acid detection

Giardiasis - by microscopic examination, ~~or~~ antigen detection, or nucleic acid detection

Gonorrhea - by microscopic examination of a urethral smear specimen (males only), culture, antigen detection, or nucleic acid detection. Include available antimicrobial susceptibility findings in report.

*Haemophilus influenzae infection, invasive - by culture, antigen detection, or nucleic acid detection from a normally sterile site

Hantavirus pulmonary syndrome - by antigen detection (immunohistochemistry), nucleic acid detection, or serologic results consistent with recent infection

*Hepatitis A - by detection of IgM antibodies

Hepatitis B (acute and chronic) - by detection of HBsAg, HBeAg, or IgM antibodies or nucleic acid detection. For any reportable hepatitis finding, submit all available results from the hepatitis panel. Submit all findings for hepatitis B testing in children under 2 years of age.

Hepatitis C (acute and chronic) - by hepatitis C virus antibody (anti-HCV) screening test positive with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay as defined by CDC, HCV antibody positive by immunoblot (RIBA), or HCV RNA positive by nucleic acid test. For all hepatitis C patients, also report available results of serum alanine aminotransferase (ALT), anti-HAV IgM, anti-HBc IgM, and HBsAg. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Hepatitis, other acute viral – any finding indicative of acute infection with hepatitis D, E, or other cause of viral hepatitis. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Human immunodeficiency virus infection - by culture, antigen detection, nucleic acid detection, or detection of antibody ~~confirmed with a supplemental test~~. For HIV-infected patients, report all results of CD4 and HIV viral load tests and all HIV genetic sequence

data associated with HIV drug resistance tests. For children from birth to three years of age, report all tests regardless of the test findings (e.g., negative or positive).

Influenza - by culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid detection

Lead, elevated blood levels - by blood lead level greater than or equal to ~~10 µg/dL in children ages 0-15 years, or greater than or equal to 25 µg/dL in persons older than 15 years of age~~ the reference value established by CDC. The reference value established in 2012 was 5 µg/dL in children and 10 µg/dL in persons older than 15 years of age.

Legionellosis - by culture, antigen detection (including urinary antigen), nucleic acid detection, or serologic results consistent with recent infection

Leptospirosis – by culture, microscopic examination by dark field microscopy, nucleic acid detection, or serologic results consistent with recent infection

Listeriosis - by culture

Lyme disease - by culture, antigen detection, or detection of antibody confirmed with a supplemental test

Malaria - by microscopic examination, antigen detection, or nucleic acid detection

*Measles (~~rubeola~~) (Rubeola) - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Meningococcal disease - by culture or antigen detection from a normally sterile site

~~*Monkeypox – by culture or nucleic acid detection~~

Mumps - by culture, nucleic acid detection, or serologic results consistent with recent infection

*Mycobacterial diseases - (See 12VAC5-90-225 B) Report any of the following:

1. Acid fast bacilli by microscopic examination;
2. Mycobacterial identification - preliminary and final identification by culture or nucleic acid detection;
3. Drug susceptibility test results for M. tuberculosis.

*Pertussis - by culture, antigen detection, or nucleic acid detection

*Plague - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Poliovirus infection - by culture

*Psittacosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Q fever - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Rabies, human and animal - by culture, antigen detection by direct fluorescent antibody test, nucleic acid detection, or, for humans only, serologic results consistent with recent infection

*Rubella - by culture, nucleic acid detection, or serologic results consistent with recent infection

Salmonellosis - by culture or antigen detection

*Severe acute respiratory syndrome, including any coronavirus causing a severe acute illness - by culture, nucleic acid detection, or serologic results consistent with recent infection

Shigellosis - by culture or antigen detection

*Smallpox (~~variola~~) (Variola) - by culture or nucleic acid detection

Spotted fever rickettsiosis - by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection

Staphylococcus aureus infection, resistant, as defined below.

~~1. Methicillin resistant - by antimicrobial susceptibility testing of a Staphylococcus aureus isolate, with a susceptibility result indicating methicillin resistance, cultured from a normally sterile site~~

2. Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection - by antimicrobial susceptibility testing of a Staphylococcus aureus isolate, with a vancomycin susceptibility result of intermediate or resistant, cultured from a clinical specimen. Include available antimicrobial susceptibility findings in report.

Streptococcal disease, Group A, invasive or toxic shock - by culture from a normally sterile site

Streptococcus pneumoniae infection, invasive, in children <5 years of age - by culture from a normally sterile site in a child under the age of five years

*Syphilis - by microscopic examination (including dark field), antigen detection (including direct fluorescent antibody), or serology by either treponemal or nontreponemal methods

Toxic substance-related illness - by blood or urine laboratory findings above the normal range, including but not limited to heavy metals, pesticides, and industrial-type solvents and gases. When applicable and available, report speciation of metals when blood or urine levels are elevated in order to differentiate the chemical species (elemental, organic, or inorganic).

Trichinosis (~~trichinellosis~~) (Trichinellosis) - by microscopic examination of a muscle biopsy or serologic results consistent with recent infection

*Tularemia - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Typhoid/Paratyphoid fever - by culture

*Vaccinia, disease or adverse event - by culture or nucleic acid detection

*Vibrio infection - by culture. Include Photobacterium damsela and Grimontia hollisae as well as Vibrio species.

*Viral hemorrhagic fever - by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection

*Yellow fever - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Yersiniosis - by culture, nucleic acid detection, or serologic results consistent with recent infection

C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of reportable diseases, because of their extremely contagious nature or their potential for greater harm, or both, require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed below, shall be made immediately by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, pagers, etc.) to the local health director ~~or other professional employee of the~~ department. (These same diseases are also identified by an asterisk (*) in subsection A and subsection B, where applicable, of this section.)

Anthrax

Botulism

Brucellosis

Cholera

Diphtheria

Disease caused by an agent that may have been used as a weapon

Haemophilus influenzae infection, invasive

Hepatitis A

Influenza-associated deaths in children <18 years of age

Influenza A, novel virus

Measles (Rubeola)

Meningococcal disease

~~Monkeypox~~

Outbreaks, all

Pertussis

Plague

Poliovirus infection, including poliomyelitis

Psittacosis

Q fever

Rabies, human and animal

Rubella, including congenital rubella syndrome

Severe acute respiratory syndrome (SARS), including any coronavirus causing a severe acute illness

Smallpox (Variola)

Syphilis, primary and secondary

Tuberculosis, active disease

Tularemia

~~*Typhoid/Paratyphoid~~ Typhoid/Paratyphoid fever

Unusual occurrence of disease of public health concern

Vaccinia, disease or adverse event

Vibrio infection

Viral hemorrhagic fever

Yellow fever

D. Toxic substance-related illnesses. All toxic substance-related illnesses, including pesticide and heavy metal poisoning or illness resulting from exposure to an occupational dust or fiber or radioactive substance, shall be reported.

If such illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such illness shall be ~~by rapid communication as in subsection C of this section~~ immediately by the most rapid means available.

E. Outbreaks. The occurrence of outbreaks or clusters of any illness which may represent a group expression of an illness which may be of public health concern shall be reported to the local health department immediately by the most rapid means available.

F. Unusual or ill-defined diseases or emerging or reemerging pathogens. Unusual or emerging conditions of public health concern shall be reported to the local health department immediately by the most rapid means available. In addition, the commissioner or his designee may establish surveillance systems for diseases or conditions that are not on the list of reportable diseases. Such surveillance may be established to identify cases (delineate the magnitude of the situation), to identify the mode of transmission and risk factors for the disease, and to identify and implement appropriate action to protect public health. Any person reporting

information at the request of the department for special surveillance or other epidemiological studies shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

12VAC5-90-90. Those required to report.

A. Physicians. Each physician who treats or examines any person who is suffering from or who is suspected of having a reportable disease or condition shall report that person's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease diagnosed or suspected; the date of onset of illness; and the name, address, and telephone number of the physician and medical facility where the examination was made, except that influenza should be reported by number of cases only (and type of influenza, if available). Reports are to be made to the local health department serving the jurisdiction where the physician practices. A physician may designate someone to report on his behalf, but the physician remains responsible for ensuring that the appropriate report is made. Any physician, designee, or organization making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

Such reports shall be made on a ~~form to be provided by the department~~ (Form Epi-1), a computer generated printout containing the data items requested on Form Epi-1, or a ~~Centers for Disease Control and Prevention (CDC)~~ surveillance form that provides the same information and shall be made within three days of the suspicion or confirmation of disease ~~unless the disease in question requires rapid reporting under 12VAC5-90-80 C~~ except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available to the local health department serving the jurisdiction in which the facility is located. Reporting may be done by means of secure electronic transmission upon agreement of the physician and the department.

Pursuant to § 32.1-49.1 of the Code of Virginia, additional elements are required to be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to Part X for details on these requirements.

B. Directors of laboratories. Any person ~~who is~~ in charge of a laboratory conducting business in the Commonwealth shall report any laboratory examination of any clinical specimen, whether performed in-house or referred to an out-of-state laboratory, which yields evidence, by the laboratory method(s) indicated or any other confirmatory test, of a disease listed in 12VAC5-90-80 B.

Each report shall give the source of the specimen and the laboratory method and result; the name, address, age, date of birth, race, sex, and pregnancy status for females (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician and medical facility for whom the examination was made. When the influenza virus is isolated, the type should be reported, if available. Reports shall be made within three days of identification of evidence of disease, except that those identified ~~by an asterisk in~~ 12VAC5-90-80 C shall be reported immediately by the most rapid means available, to the local health department serving the jurisdiction in which the laboratory is located. Reports shall be made on Form Epi-1 or on the laboratory's own form if it includes the required information. Computer generated reports containing the required information may be submitted. Reporting may be done by means of secure electronic transmission upon agreement of the laboratory director and the department. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

A laboratory identifying evidence of any of the following conditions shall notify the local health department of the positive culture or other positive test result within the timeframes specified in 12VAC5-90-80 and submit the initial isolate or other initial specimen to the Virginia Division of Consolidated Laboratory Services (~~DCLS~~) within 7 days of identification. All specimens must be identified with the patient and physician information required in this subsection.

Anthrax

Brucellosis

Cholera

Diphtheria

E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA methodology but do not perform simultaneous culture for Shiga toxin-producing E. coli should forward all positive stool specimens or positive ~~broth cultures~~ enrichment broths to ~~DCLS~~ the Division of Consolidated Laboratory Services for confirmation and further characterization.)

Haemophilus influenzae infection, invasive

Human immunodeficiency virus (Submit all remnant HIV diagnostic sera to the Division of Consolidated Laboratory Services or to other laboratory designated by the department for HIV recency testing.)

Influenza A, novel virus

Listeriosis

Meningococcal disease

Pertussis

Plague

Poliovirus infection

Q fever

Salmonellosis

Shigellosis

Streptococcal disease, Group A, invasive

Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to

~~DCLS~~ the Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.)

Typhoid/Paratyphoid fever

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

Vibrio infection, including infections due to Photobacterium damsela and Grimontia hollisae

Yersiniosis

Other diseases as may be requested by the health department

When a clinical specimen yields evidence indicating the presence of a select agent or toxin as defined by federal regulations in 42 CFR Part 73, the person in charge of the laboratory shall contact the Division of Consolidated Laboratory Services and arrange to forward an isolate for confirmation. If a select agent or toxin has been confirmed in a clinical specimen, the laboratory director shall consult with DCLS or CDC regarding isolate transport or destruction.

Laboratories operating within a medical care facility shall be considered to be in compliance with the requirement to notify the health department when the director of that medical care facility assumes the reporting responsibility; however, laboratories are still required to submit isolates to ~~DCLS~~ the Division of Consolidated Laboratory Services or other designated laboratory as noted above.

C. Persons in charge of a medical care facility. Any person in charge of a medical care facility shall make a report to the local health department serving the jurisdiction where the facility is located of the occurrence in or admission to the facility of a patient with a reportable disease listed in 12VAC5-90-80 A unless he has evidence that the occurrence has been reported by a physician. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. The requirement to report shall

include all inpatient, outpatient and emergency care departments within the medical care facility. Such report shall contain the patient's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease being reported; the date of admission; hospital chart number; date expired (when applicable); and attending physician. Influenza should be reported by number of cases only (and type of influenza, if available). Reports shall be made within three days of the suspicion or confirmation of disease ~~unless the disease in question requires rapid reporting under 12VAC5-90-80 C and~~ except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available to the local health department serving the jurisdiction in which the facility is located. Reports shall be made on Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a ~~Centers for Disease Control and Prevention (CDC)~~ surveillance form that provides the same information. Reporting may be done by means of secure electronic transmission upon agreement of the medical care facility and the department.

A person in charge of a medical care facility may assume the reporting responsibility on behalf of the director of the laboratory operating within the facility.

D. Persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp. Any person in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp as defined in § 35.1-1 of the Code of Virginia shall report immediately to the local health department the presence or suspected presence in his program, service, facility, school, child care center, or summer camp of persons who have common symptoms suggesting an outbreak situation. Such persons may report additional information, including identifying and contact information for individual cases of individuals with communicable diseases of public health concern or individuals who are involved in outbreaks that occur in their facilities, as necessary to facilitate

public health investigation and disease control. Any person so reporting shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

E. Local health directors. The local health director shall forward any report of a disease or report of evidence of a disease which has been made on a resident of his jurisdiction to the Office of Epidemiology within three days of receipt. This report shall be submitted immediately by the most rapid means available if the disease is one requiring rapid communication, as required in 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office of Epidemiology, by either a paper report or entry into a shared secure electronic disease surveillance system, within three days. Furthermore, the local health director shall immediately forward to the appropriate local health director any disease reports on individuals residing in the latter's jurisdiction or to the Office of Epidemiology on individuals residing outside Virginia. The Office of Epidemiology shall be responsible for notifying other state health departments of reported illnesses in their residents and of notifying CDC as necessary and appropriate.

F. Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities. In accordance with § 32.1-37.1 of the Code of Virginia, any person in charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional facility shall, at the time of transferring custody of any dead body to any person practicing funeral services, notify the person practicing funeral services or his agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids. These include any of the following infectious diseases:

Creutzfeldt-Jakob disease

Human immunodeficiency virus infection

Hepatitis B

Hepatitis C

Monkeypox

Rabies

Smallpox

Syphilis, infectious

Tuberculosis, active disease

Vaccinia, disease or adverse event

Viral hemorrhagic fever

G. Employees, applicants, and persons in charge of food establishments. 12VAC5-421-80 of the Food Regulations requires a food employee or applicant to notify the person in charge of the food establishment when diagnosed with certain diseases that are transmissible through food. ~~12VAC5-421-120~~ and requires the person in charge of the food establishment to notify the health department. Refer to the appropriate sections of the Virginia Administrative Code for further guidance and clarification regarding these reporting requirements.

Part IV

Control of Disease

12VAC5-90-100. Methods.

The board and commissioner shall use appropriate disease control measures to manage the diseases listed in 12VAC5-90-80 A, including but not limited to those described in the "Methods of Control" sections of the ~~18th~~ 19th Edition of the Control of Communicable Diseases Manual (~~2004~~) (2008) published by the American Public Health Association. The board and commissioner reserve the right to use any legal means to control any disease which is a threat to the public health.

When notified about a disease specified in 12VAC5-90-80, the local health director or his designee shall have the authority and responsibility to perform contact tracing/contact services for HIV infection, infectious syphilis, and active tuberculosis disease and may perform contact services for the other diseases if deemed necessary to protect the public health. All contacts of HIV infection shall be afforded the opportunity for appropriate counseling, testing, and individual face-to-face disclosure of their test results. In no case shall names of informants or infected individuals be revealed to contacts by the health department. All information obtained shall be kept strictly confidential.

The local health director or his designee shall review reports of diseases received from his jurisdiction and follow up such reports, when indicated, with an appropriate investigation in order to evaluate the severity of the problem. The local health director or his designee may recommend to any individual or group of individuals appropriate public health control measures, including but not limited to quarantine, isolation, immunization, decontamination, or treatment. He shall determine in consultation with the Office of Epidemiology and the commissioner if further investigation is required and if one or more forms of quarantine and/or isolation will be necessary.

Complete isolation shall apply to situations where an individual is infected with a communicable disease of public health significance (including but not limited to active tuberculosis disease or HIV infection) and is engaging in behavior that places others at risk for infection with the communicable disease of public health significance, in accordance with the provisions of Article 3.01 (§ 32.1-48.02 et seq.) of the Code of Virginia.

Modified isolation shall apply to situations in which the local health director determines that modifications of activity are necessary to prevent disease transmission. Such situations shall include but are not limited to the temporary exclusion of a child with a communicable disease from school, the temporary exclusion of an individual with a communicable disease from food handling or patient care, the temporary prohibition or restriction of an individual with a

communicable disease from using public transportation, the requirement that a person with a communicable disease use certain personal protective equipment, or restrictions of other activities that may pose a risk to the health of others.

Protective isolation shall apply to situations such as the exclusion, under § 32.1-47 of the Code of Virginia, of any unimmunized child from a school in which an outbreak, potential epidemic, or epidemic of a vaccine preventable disease has been identified.

To the extent permitted by the Code of Virginia, the local health director may be authorized as the commissioner's designee to implement the forms of isolation described in this section. When these forms of isolation are deemed to be insufficient, the local health director may use the provisions of Article 3.01 (§ 32.1-48.01 et seq.) of the Code of Virginia for the control of communicable diseases of public health significance or, in consultation with the Office of Epidemiology, shall provide sufficient information to enable the commissioner to prepare an order or orders of isolation and/or quarantine under Article 3.02 (§ 32.1-48.05 et seq.) of the Code of Virginia for the control of communicable diseases of public health threat.

Part V

Immunization of Persons Less Than 18 Years of Age

12VAC5-90-110. Dosage and age requirements for immunizations; obtaining immunizations.

A. Every person in Virginia less than 18 years of age shall be immunized in accordance with the most recent Immunization Schedule developed and published by the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). Requirements for school and day care attendance are addressed in 12VAC5-110.

B. The required immunizations may be obtained from a physician ~~licensed to practice medicine or from the local health department, registered nurse, or other licensed professional~~

authorized by the Code of Virginia to administer immunizations at locations to include private settings or local health departments.

Part XII

Reporting of Dangerous Microbes and Pathogens

12VAC5-90-280. Definitions. Reporting of Dangerous Microbes and Pathogens

A. Definitions. The following words and terms when used in this part shall have the following meanings unless the context clearly indicates otherwise:

"Biologic agent" means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or other living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

"CDC" means the Centers for Disease Control and Prevention of the Department of Health and Human Services.

"Diagnosis" means the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety.

"Proficiency testing" means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

"Responsible official" means any person in charge of directing or supervising a laboratory conducting business in the Commonwealth of Virginia. At colleges and universities, the responsible official shall be the president of the college or university or his designee. At private,

state or federal organizations, the responsible official shall be the laboratory director or a chief officer of the organization or his designee.

"Select agent or toxin" or "select agent and toxin" means all those biological agents or toxins as defined by federal regulations in 42 CFR Part 73, including:

- ~~1. Health and Human Services (HHS) select agents and toxins, as outlined in 42 CFR 73.4.~~
- ~~2. HHS overlap select agents and toxins, as outlined in 42 CFR 73.5.~~ Health and Human Services select agents and toxins and overlap select agents and toxins.

"Toxin" means the toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa); or infectious substances; or a recombinant or synthesized molecule, whatever the origin and method of production; and includes any poisonous substance or biological product that may be engineered as a result of biotechnology or produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

"Verification" means the process required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

12VAC5-90-290. Authority. (Repealed.)

~~Chapter 2 (§ 32.1-35 et seq.) of Title 32.1 of the Code of Virginia authorizes the reporting of dangerous microbes and pathogens to the department. Specifically, § 32.1-35 directs the board to promulgate regulations specifying which dangerous microbes and pathogens are to be reportable and the method and timeframe by which they are to be reported by laboratories.~~

~~12VAC5-90-300. Administration.~~

B. Administration. The dangerous microbes and pathogens will be known as "select agents and toxins." The select agent and toxin registry will be maintained by the Virginia Department of Health, Office of Epidemiology, Division of Surveillance and Investigation.

~~12VAC5-90-310. Reportable agents.~~

C. Reportable agents. The board declares the select agents and toxins and overlap select agents and toxins outlined in 42 CFR 73.4 and ~~42 CFR 73.5~~ Part 73 to be reportable, and adopts it herein by reference including subsequent amendments and editions. The select agents and toxins are to be reportable by the persons enumerated in ~~12VAC5-90-340~~ subsection F of this section.

~~12VAC5-90-320. Items to report.~~

D. Items to report. Each report shall be made on a form determined by the department and shall contain the following: name, source and characterization information on select agents and toxins and quantities held; objectives of the work with the agent; location (including building and room) where each select agent or toxin is stored or used; identification information of persons with access to each agent; identification information of the person in charge of each of the agents; and the name, position and identification information of one responsible official as a single point of contact for the organization. The report shall also indicate whether the laboratory is registered with the CDC Select Agent Program and may contain additional information as required by 42 CFR Part 73 or the department.

~~12VAC5-90-330. Timing of reports.~~

E. Timing of reports. ~~Initial reports shall be made by October 26, 2004. Thereafter, reports~~ Reports shall be made to the department within seven calendar days of submission of an application to the CDC Select Agent Program. By January 31 of every year, laboratories shall

provide a written update to the department, which shall include a copy of the federal registration certificate received through the CDC Select Agent Program.

In the event that a select agent or toxin that has previously been reported to the department is destroyed, a copy of federal forms addressing the destruction of the select agent or toxin must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

In the event that a select agent or toxin, or a specimen or isolate from a specimen containing a select agent or toxin, has previously been reported to the department and is subsequently transferred to a facility eligible for receiving the items, a copy of federal forms addressing the transfer of the select agent or toxin must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

In the event of a suspected release, loss or theft of any select agent or toxin, the responsible official at a laboratory shall make a report to the department ~~within 24 hours~~ immediately by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, pagers, etc.) The rapid report shall be followed up by a written report within seven calendar days and shall include the following information:

1. The name of the biologic agent and any identifying information (e.g., strain or other characterization information);
2. An estimate of the quantity released, lost or stolen;
3. An estimate of the time during which the release, loss or theft occurred; and
4. The location (building, room) from or in which the release, loss or theft occurred. The report may contain additional information as required by 42 CFR Part 73 or the department.

The department must be notified in writing of any changes to information previously submitted to the department. If a new application or an amendment to an existing application is

filed with the CDC Select Agent Program, a copy of the application or amendment must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

~~12VAC5-90-340. Those required to report.~~

F. Those required to report. The responsible official in charge of a laboratory conducting business in the Commonwealth shall be responsible for annual reporting of select agents and toxins to the Virginia Department of Health and for the reporting of any changes within the time periods as specified within these regulations. Such reports shall be made on forms to be determined by the department. Any person making such reports as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

~~12VAC5-90-350. Exemption from reporting.~~

G. Exemption from reporting. A person who detects a select agent or toxin for the purpose of diagnosing a disease, verification, or proficiency testing and either transfers the specimens or isolates containing the select agent or toxin to a facility eligible for receiving them or destroys them onsite is not required to make a report except as required by 12VAC5-90-80 and 12VAC5-90-90. Proper destruction of the agent must take place through autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation. The transfer or destruction must occur within seven calendar days after identification of a select agent or toxin used for diagnosis or testing and within 90 calendar days after receipt for proficiency testing.

Any additional exemptions from reporting under 42 CFR ~~73.6~~ Part 73, including subsequent amendments and editions, are also exempt from reporting under this regulation; however, the department must be notified of the exemption by submitting a copy of federal forms addressing the exemption within seven calendar days of submission to the CDC Select Agent Program.

~~12VAC5-90-360. Release of reported information.~~

H. Release of reported information. Reports submitted to the select agent and toxin registry shall be confidential and shall not be a public record pursuant to the Freedom of Information Act, regardless of submitter. Release of information on select agents or toxins shall be made only by order of the State Health Commissioner to the CDC and state and federal law-enforcement agencies in any investigation involving the release, theft, or loss of a select agent or toxin required to be reported to the department under this regulation.



COMMONWEALTH of VIRGINIA

Department of Health

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RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: Tuesday August 13, 2013

TO: Virginia State Board of Health

FROM: David Trump, MD, MPH, Director of the Office of Epidemiology

SUBJECT: Prohibiting the Taking of Fish for Human Consumption from the North Fork of the Holston River (12VAC5-170)

Enclosed for your review is an Exempt Final Action for the Prohibiting the Taking of Fish for Human Consumption from the North Fork of the Holston River (12VAC5-170).

To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Department conducted a periodic review of the Prohibiting the Taking of Fish for Human Consumption From the North Fork of the Holston River (12VAC5-170) pursuant to Executive Order 14. As a result of that review, the Department determined that these regulations are no longer necessary. The current process used to inform the public of health risks associated with fish consumption is through fish consumption advisories. In addition, a "Do Not Eat" fish consumption advisory already exists for fish caught in the North Fork of the Holston River. This Final Exempt Action intends to repeal these regulations through the authority provided to the Department pursuant to Code of Virginia §32.1-248.

The Board of Health is requested to approve the Final Exempt Action. Should the Board of Health approve the Final Exempt Action, it shall be published in the Virginia Register of Regulations and become effective. Exempt Actions do not need Executive Branch review and are exempt from the process specified in the Administrative Process Act.



Exempt Action Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-170
Regulation title	Prohibiting the Taking of Fish for Human Consumption From the North Fork of the Holston River
Action title	Repeal of 12VAC5-170
Final agency action date	September 12, 2013
Document preparation date	July 31, 2013

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The existing regulation prohibits consumption of fish caught from the North Fork of the Holston River due to historically elevated mercury levels in fish caught from this area. The regulation does not prohibit catch and release.

In 2013, VDH reviewed this regulation, after soliciting public comment, and recommends that the regulation be repealed. Upon review of the current regulations, VDH determined that:

- The current process VDH uses to inform the public of health risks associated with fish consumption is through a fish consumption advisory.
- VDH already has a "Do Not Eat" fish consumption advisory for fish caught in the North Fork of the Holston River from Saltville, Virginia to the Virginia-Tennessee State Line.
- Public signs with "Do Not Eat" will still remain in effect if the current regulation is repealed.
- No public comments were received that suggested the regulation should remain in effect.
- VDH has the authority to repeal these regulations pursuant to Code of Virginia § 32.1-248.

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 Virginia Board of Health approved the repeal of these regulations on September 12, 2013.

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

The repeal of the regulation will have no impact on the institution of the family and family stability.

Periodic review

If this final regulation is not the result of a periodic review of the regulation, please delete this entire section. If this final regulation is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

No comments were received during the periodic review.

Project 3785 - none

DEPARTMENT OF HEALTH
Exempt Action to Repeal Chapter 170

CHAPTER 170
PROHIBITING THE TAKING OF FISH FOR HUMAN CONSUMPTION FROM THE NORTH
FORK OF THE HOLSTON RIVER

12VAC5-170-10. FDA findings. (Repealed.)

~~The Food and Drug Administration of the Department of Health, Education and Welfare has established that mercury levels in fish in excess of 0.5 milligrams per kilogram may be hazardous to the public health and fish containing amounts in excess of this level are seized in interstate commerce by the Food and Drug Administration.~~

12VAC5-170-20. Laboratory analyses of fish collected. (Repealed.)

~~Laboratory analysis by the Federal Water Quality Administration, Tennessee Valley Authority, Virginia Polytechnic Institute and State University, and the State Water Control Board on 90% of the fish collected from the North Fork of the Holston River showed mercury levels in excess of 0.5 milligrams per kilogram with some fish containing in excess of eight times the 0.5 milligrams per kilogram level.~~

~~Additional laboratory analysis by the Department of Health, Division of Consolidated Laboratory Services, on 226 fish collected from the North Fork of the Holston showed a mercury level in excess of 0.5 milligrams per kilogram in 88% of the fish collected, and in 14% of the fish collected the mercury level was four times the 0.5 milligrams per kilogram level. In the desirable species such as rock bass, smallmouth bass and redbreast sunfish the mean value of mercury exceeded the 0.5 milligrams per kilogram by more than two to three times this value.~~

12VAC5-170-30. Finding of hazardous condition. (Repealed.)

~~The levels of mercury which were found in the edible flesh of the fish are considered hazardous for human consumption; but the act of catching fish and releasing the fish back into the stream does not present an undue hazard to health. Acting under the authority granted to the State Board of Health in §§ 32.1-2, 32.1-12, and Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia it is ordered that the taking of fish from the North Fork of the Holston River for human consumption from Saltville, Virginia, to the Virginia-Tennessee State Line is prohibited until further notice.~~

12VAC5-170-40. Penalty. (Repealed.)

~~Violation of this chapter is a class 1 misdemeanor as set forth in 32-1-27 of the Code of Virginia.~~

~~It is further ordered that certified copies of this order be forwarded to Governor and Attorney General; and the State Water Control Board, Boards of Supervisors of Smyth, Washington and Scott Counties.~~



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: Thursday August 8, 2013

TO: Virginia State Board of Health

FROM: Erik Bodin, Director - Office of Licensure and Certification

SUBJECT: Fast Track Action for the Regulations for the Licensure of Nursing Facilities (12VAC5-371)

Enclosed for your review is a Fast Track Action for the Regulations for the Licensure of Nursing Facilities (12VAC5-371).

Chapter 674 of the 2013 Virginia Acts of Assembly requires the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes, including existing policies and procedures set forth in the Board's guidelines governing electronic monitoring of nursing home residents' rooms and described in the publication "Electronic Monitoring of Residents' Rooms." The proposed Fast Track Action intends to create a new section 191 in 12VAC5-371 (Regulations for Licensure of Nursing Facilities) pertaining to electronic monitoring in resident rooms. The proposed section provides the framework to address policies and procedures, informed consent, admission, discharge or transfer. The proposed regulatory section includes the equipment request process and notice procedures, retention and ownership of tapes or recordings and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

The Board of Health is requested to approve the Fast Track Action. Should the Board of Health approve the Fast Track Action, it will be submitted to the Office of the Attorney General to begin the Executive Branch review as specified in the Administrative Process Act. Following Executive Branch review and approval the Fast Track will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 30 public comment period will begin. Fifteen days after the close of the public comment period, the regulation becomes effective unless during the public comment period an objection to the fast track regulation is received.



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	12 VAC 5-371
Regulation title	Regulations for the Licensure of Nursing Facilities
Action title	This action will create a section in the regulation pertaining to electronic monitoring of nursing facility residents.
Date this document prepared	April 18, 2013

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.

In response to the passage of HB2130/SB974 (2013), VDH/OLC intends to create a new section 191 in 12VAC5-371 (Regulations for Licensure of Nursing Facilities) pertaining to electronic monitoring in resident rooms. The proposed action codifies a 2007 guideline the department developed to assist facilities with the privacy intricacies related to installing electronic monitoring equipment. Installing such equipment is not mandatory; however, if installed, facilities must safeguard resident's autonomy and rights according to current federal and state privacy laws and regulations. Subsequently, the guideline and proposed section provide the framework to address policies and procedures, informed consent, admission, discharge or transfer. The regulation includes the equipment request process and notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

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.

The acronyms that appear in this document are as follow:

VDH/OLC means the Department of Health/Office of Licensure and Certification

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 this action to create 12VAC5-371-191 Electronic monitoring in resident rooms on September 12, 2013.

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.

House Bill 2130/SB974 (2013) requires the Board of Health to promulgate regulations governing the implementation of electronic monitoring in resident rooms. Per the legislation, the VDH/OLC's current guidance document (Electronic Monitoring in Residents' Rooms, July 2007) is the template for the regulation. Therefore, the promulgation of the regulation and the authority to promulgate such regulation is mandated.

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 regulation protects and promotes public health, safety and welfare through the establishment of a framework regulation that sets standards regarding electronic monitoring in nursing facility resident rooms. Since the promulgation of the current chapter in 1997, interest in electronic monitoring of resident rooms has grown. Family members, seeking to monitor the quality of care their loved ones receive, have expressed interest in placing video cameras or other means of electronic surveillance in the rooms of their family member in a nursing facility. Advocacy groups have joined in this effort to propose federal laws that would explicitly permit a nursing facility resident and/or family member to install electronic monitoring equipment with a facility's knowledge. Direction is needed to assure resident privacy and autonomy supersedes the utilization of electronic monitoring regardless of the family member or advocate demand.

HB2130/SB974 requires the Board of Health to promulgate regulations that provide a framework for nursing facilities for implementing electronic monitoring or permitting electronic monitoring when requested by a resident or a resident's legal representative.

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.

As per HB2130/SB974, the content of the proposed section in the regulation is to be based upon and "include existing policies and procedures set forth in the Board's guidelines governing electronic monitoring of nursing home residents' rooms and described in the publication "Electronic Monitoring of Residents' Rooms." The 2007 VDH/OLC guidance was developed with the assistance and input of the Virginia State Police to accurately reflect state and federal privacy laws. As a result, the guideline has been widely utilized without further need for revision since its inception. Therefore, the department believes the proposed regulation will be noncontroversial, allowing use of the fast-track promulgation process.

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.

As directed in HB2130/SB974, the department intends to create a section pertaining to electronic monitoring in nursing facility resident rooms. The proposed action will provide facilities the framework to assure a resident's right to personal privacy and personal autonomy is not violated or that the facility does not violate current federal and state privacy laws regarding filming and electronic monitoring. The proposed regulation addresses policies and procedures, informed consent, resident's right to implement or refuse electronic monitoring, including admission, discharge or transfer. In addition, the regulation outlines request and notice procedures, retention of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

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.

Family members, having concern for the care and safety of their loved one in a nursing facility, have expressed interest in utilizing electronic equipment in a resident's room. The proposed new section of the regulation clarifies issues related to electronic monitoring and ensures nursing facilities have policies and procedures in place for such activities. Federal and state laws and regulations stipulate that a resident of a nursing facility has the right to privacy and confidentiality of his or her person, including the privacy of their bodies. HB2130/SB974 does not mandate that nursing facilities provide electronic monitoring of its residents; rather the legislation provides the direction that facilities can follow when residents or resident family members request electronic monitoring. However, such monitoring cannot be conducted without the authorized written consent of the resident, regardless of the wishes of the family.

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 applicable federal requirements specific to electronic monitoring in nursing facility resident rooms; therefore this regulation does not exceed any federal requirements. In addition, the department worked closely with the Virginia Bureau of State Police to assure that the guideline from which this proposed section was drafted did not violate federal and state electronic surveillance laws.

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 required action.

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.

Since 2007, the VDH/OLC has had in place guidance on electronic monitoring in nursing facilities. However, the General Assembly thought regulation, based on the guidance from the VDH/OLC, was needed. This regulation is clearly mandated by law; there are no other available alternatives to comply with the law.

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>None, promulgation of the proposed regulation is mandated. Since the regulation does not require that a facility implement electronic monitoring; enforcement will be based on receipt of any consumer allegations of possible violations, which are expected to be rare.</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>None, unless the locality operates a nursing facility in which electronic monitoring is requested. However, all costs of the equipment installation and monitoring can be charged to the resident or family seeking the monitoring.</p>
<p>Benefits expected as a result of this regulatory proposal.</p>	<p>Small electronics suppliers and electrical contractors would profit from the selling and installing the equipment or electrical connections necessary.</p>
<p>Projected cost to the <u>state</u> to implement and enforce this regulatory proposal.</p>	<p>The legislation does not require that nursing facilities install or implement an electronic monitoring equipment program. In addition, any cost associated with installation can be charged to the resident or resident family. Based on feedback regarding the referenced guideline in the legislation, families did not proceed with the monitoring once they learn they can be charged for the total costs of implementation.</p>
<p>Projected cost to <u>localities</u> to implement and enforce this regulatory proposal.</p>	<p>None, there are no costs unless the facility receives a request to install equipment. The regulation provides that such costs can be charged to the family seeking implementation of the electronic monitoring.</p>
<p>All projected costs of this regulatory proposal for <u>affected individuals, businesses, or other entities</u>. 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>Provides the controls necessary to assure that resident autonomy and rights to personal privacy are not violated.</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.

There are no alternatives that meet the intent of the law.

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.

There is no direct 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
191	Provides the framework for policies and procedures, informed consent, right of implementation/refusal, retention of tapes and recordings, and reporting of abuse, neglect, accident or injury discovered via electronic monitoring.	§§ 18.2-386.1 and 32.1-138 of the Code of Virginia; § 483.10(e) of the Code of Federal regulations, 12VAC5-371-150	Provides the assurance that a resident’s dignity and right to personal, bodily privacy and autonomy are not violated.

Enter any other statement here

**DEPARTMENT OF HEALTH
NH Electronic Monitoring**

12VAC5-371-191. Electronic monitoring in resident rooms.

A. Each nursing facility shall adopt policies and procedures for electronic monitoring in the facility. Such policies and procedures shall include, but are not limited to:

1. Identification of the designated staff person responsible for handling requests for electronic monitoring and for coordinating the installation, operation, and dismantling of all equipment;

2. An outline of the resident or resident's legal representative's responsibility for electronic monitoring operations, such as the removal and replacement of tapes and for implementing privacy protections or unauthorized dissemination of the recordings;

3. An outline of the costs the facility may charge the resident or the resident's legal representative for electronic monitoring. Such costs shall be reasonable and may include reimbursement costs for equipment and tapes, installation, compliance with the life safety code and the building and electrical codes, maintenance or removal of the equipment, posting and removing public notices, or structural repairs to the building resulting from the removal of the equipment;

4. The process for handling covert monitoring, if discovered;

5. The process for maintaining recordings or tapes, including the designation of custodial ownership and the storage location of the tapes;

6. The process the resident or resident's legal representative should follow to report untoward or questionable incidences regarding health, safety or quality of care that is discovered through electronic monitoring to the facility administration and the OLC, including the OLC's Complaint Hotline telephone number; and

7. The process for residents, legal representatives or staff to report suspected abuse, neglect, accident or injury that is discovered through electronic monitoring.

B. Residents and legal representatives of residents shall be notified of the facility's policies and procedures for electronic monitoring upon admission and annually thereafter.

C. All requests for electronic monitoring shall be made in writing and signed by the resident or the resident's legal representative if the resident has been properly assessed incapable of requesting and authorizing the monitoring. Family members cannot insist on monitoring over the objections of the resident or the resident's roommate.

D. Residents and legal representatives of residents, if applicable, shall be fully informed of the right of a resident to implement electronic monitoring in the room in which he resides, the right of any resident to consent or refuse to consent to electronic monitoring in any room in which he resides, and the options available to any resident in cases in which he refuses to consent to electronic monitoring in any room in which he resides, including transfer to another room. The informed consent of all residents assigned to the monitored room must be obtained prior to installation of electronic monitoring equipment. A copy of the signed consent of all residents assigned to the monitored room shall be kept in each resident's respective medical record and with the staff person designated in subsection A. All residents assigned to the monitored room shall be permitted to impose conditions for consent to electronic monitoring.

E. Electronic monitoring equipment shall be installed in a manner that is safe for residents, staff or visitors. The equipment shall be fixed and unable to rotate. Facilities shall make

reasonable physical accommodation for the monitoring equipment, including providing a reasonably secure place to mount the device and access to power sources for the device.

F. The facility shall conspicuously post and maintain a notice at the entrance to the resident's room stating that an electronic monitoring device is in operation. Facilities shall notify all staff and their OLC Long Term Care Supervisor that electronic monitoring is in use.

G. Only authorized monitoring is permitted. Covert monitoring is prohibited by law. Any monitoring of oral communication is subject to both federal and state wiretap laws and requires additional privacy protections to be in place.

H. Facilities shall have the option of retaining ownership of the recordings. If the facility chooses to retain ownership of the recordings, the recordings shall become part of the resident's medical record and the facility shall:

1. Accommodate family viewing of any recordings, including but not limited to:

a. Providing appropriate playing or viewing equipment;

b. Privacy during viewing; and

c. Viewing times that are convenient to the resident's family.

2. Make the recordings available in accordance with all state and federal regulations that pertain to medical records.

I. A nursing facility shall not refuse to admit an individual and shall not discharge or transfer a resident solely because he has requested to implement or has implemented electronic monitoring in any room in which he resides, in accordance with this section, because the facility has discovered covert monitoring on the part of the resident or the resident's legal representative, or because he refuses to consent to electronic monitoring in any room in which he resides.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 12, 2013

TO: Virginia State Board of Health

FROM: Erik Bodin, Director - Office of Licensure and Certification

RE: Notice of Intended Regulatory Action for the Regulations for the Licensure of Hospitals (12VAC5-410)

Enclosed for your review is the Notice of Intended Regulatory Action for the Regulations for the Licensure of Hospitals (12VAC5-410).

Section 32.1-127 of the Code of Virginia mandates the Board of Health to establish regulations which include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to assure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities.

The Department of Health received a Petition for Rulemaking on April 5, 2013. The petition requested that the State Board of Health amend its regulations concerning architectural drawings and specifications requirements for nursing facilities, contained in the Regulations of Licensure of Hospitals(12 VAC5-410.), on the grounds that the regulation conflicts with the provisions of §32.1-127.001 of the Code of Virginia. The petition was published in the Virginia Register of Regulations. A 21-day public comment period on the petition ended on May 26, 2013. Two hundred comments were received during the public comment period. After review of the petition the Virginia Department of Health determined to grant the petition. The Notice of Intended Regulatory Action proposed to make amendments to 12VAC5-410 in order to make the regulations comply with the provisions of §32.1-127.001 of the Code of Virginia.

The Board of Health is requested to approve the Notice of Intended Regulatory Action. Should the Board of Health approve the Notice of Intended Regulatory Action, it will be

submitted for Executive Branch review as specified in the Administrative Process Act. Following Executive Branch review and approval the Notice of Intended Regulatory Action will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 30 day public comment period will begin.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-410-650 and 1350
Regulation title	Regulations for the Licensure of Hospitals
Action title	Revising the construction standards for inpatient and outpatient hospitals
Date this document prepared	8/2/2013

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*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

This regulatory action is taken in response to a Petition for Rulemaking. This action will bring the regulations into conformance with the provisions of §32.1-127.001 of the Code of Virginia, which was enacted in 2005. That Code section states that “Notwithstanding any law or regulation to the contrary,” the Board of Health shall promulgate regulations for the licensure of hospitals and nursing homes that include minimum standards for design and construction that are consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health (the Guidelines). However, the regulations currently state that the Virginia Uniform Statewide Building Code takes precedence over the Guidelines. That regulatory provision is contrary to the requirements of §32.1-127.001.

The department plans to amend regulatory sections 650 and 1350 of chapter 410 pertaining to building and construction codes for inpatient and outpatient hospitals. The purpose of the amendment will be to specify that hospitals shall comply with Part 1 and sections 2.1-2.6 – based on the type of hospital – of the Guidelines, and that the Guidelines take precedence over the Virginia Uniform Statewide Building Code. The department further intends to specify in the regulations that entities licensed as of the effective date of the amendments may continue to be licensed in their current buildings. However, all new construction, renovation, modification, structural revision, etc of any space within a hospital will require full compliance with this provision for the entire area of the modified space.

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 regulation is promulgated under the authority of §32.1-127 of the Code of Virginia which grants the Board of Health the legal authority to promulgate hospital regulations "in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established in matters of public health and safety."

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The department is responsible for regulating medical care facilities and related services, and recognizes the need to update the hospital regulations to better reflect national standards of care for individuals receiving services in Virginia's 176 inpatient and outpatient hospitals. The Facilities Guideline Institute, and its Guidelines, is nationally recognized as the authority regarding the design and construction of medical care facilities. Therefore, the department is incorporating the Guidelines by reference for the hospital licensure regulations.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The department intends to amend the regulations to specify that hospitals shall comply with Part 1 and sections 2.1-2.6 – based on the type of hospital – of the Guidelines, and that the Guidelines take precedence over the Virginia Uniform Statewide Building Code. The department further intends to specify in the regulations that entities licensed as of the effective date of the amendments may continue to be licensed in their current buildings. However, all new construction, renovation, modification, structural revision, etc of any space within a hospital will require full compliance with this provision for the entire area of the modified space. No acronyms were used in developing the amendment or this document.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The amendment is clearly and directly mandated by law.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to;

Erik Bodin
Director
Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Ste. 401
Henrico, Virginia 23233
Tel: 804-367-2102
Fax: 804-527-4500
Emails: Erik.Bodin@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 day of the public comment period.

The department considers this amendment to be straightforward; therefore a panel will not be used for its development.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Family impact

Assess the potential 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.

There is no direct impact on the family or the family structure as a result of this amendment.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: Thursday August 8, 2013

TO: Virginia State Board of Health

FROM: Erik Bodin, Director - Office of Licensure and Certification

SUBJECT: Notice of Intended Regulatory Action for the Regulations for the Licensure of Nursing Facilities (12VAC5-371)

Enclosed for your review is the Notice of Intended Regulatory Action for the Regulations for the Licensure of Nursing Facilities (12VAC5-371).

Section 32.1-127 of the Code of Virginia mandates the Board of Health to establish regulations which include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to assure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities.

The Department of Health received a Petition for Rulemaking on April 5, 2013. The petition requested that the State Board of Health amend its regulations concerning architectural drawings and specifications requirements for nursing facilities, contained in the Regulations of Licensure of Nursing Facilities (12 VAC5-371.), on the grounds that the regulation conflicts with the provisions of §32.1-127.001 of the Code of Virginia. The petition was published in the Virginia Register of Regulations. A 21-day public comment period on the petition ended on May 26, 2013. No comments were received during the public comment period. After review of the petition the Virginia Department of Health determined to grant the petition. The Notice of Intended Regulatory Action proposed to make amendments to 12VAC5-371 in order to make the regulations comply with the provisions of §32.1-127.001 of the Code of Virginia.

The Board of Health is requested to approve the Notice of Intended Regulatory Action. Should the Board of Health approve the Notice of Intended Regulatory Action, it will be submitted for Executive Branch review as specified in the Administrative Process Act. Following Executive Branch review and approval the Notice of Intended Regulatory Action will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 30 day public comment period will begin.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-371-410 and 420
Regulation title	Regulations for the Licensure of Nursing Facilities
Action title	Revising the construction standards for nursing facilities
Date this document prepared	8/2/2013

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*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

This regulatory action is taken in response to a Petition for Rulemaking. This action will bring the regulations into conformance with the provisions of §32.1-127.001 of the Code of Virginia, which was enacted in 2005. The Code section states that "Notwithstanding any law or regulation to the contrary," the Board of Health shall promulgate regulations for the licensure of hospitals and nursing homes that include minimum standards for design and construction that are consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health (the Guidelines). However, the regulations currently state that the Virginia Uniform Statewide Building Code takes precedence over the Guidelines. That regulatory provision is contrary to the requirements of §32.1-127.001.

The department plans to amend regulatory sections 410 and 420 of chapter 371 pertaining to building and construction codes for nursing facilities. The purpose of the amendment will be to specify that nursing facilities shall comply with Part 1 and section 4.1 and 4.2 of the Guidelines, and the Guidelines take precedence over the Virginia Uniform Statewide Building Code. The department further intends to specify in the regulations that entities licensed as of the effective date of the amendments may continue to be licensed in their current buildings. However, all new construction, renovation, modification, structural revision, etc of any space within a nursing facility will require full compliance with this provision for the entire area of the modified space.

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 regulation is promulgated under the authority of §32.1-127 of the Code of Virginia which grants the Board of Health the legal authority to promulgate nursing facility regulations "in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established in matters of public health and safety."

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The department is responsible for regulating medical care facilities and related services and recognizes the need to update the nursing facility regulations to better reflect national standards of care for individuals receiving services in Virginia's 278 nursing facilities. The Facilities Guideline Institute, and its Guideline, is nationally recognized as the authority regarding the design and construction of medical care facilities. Therefore, the department is incorporating the Guideline by reference for the nursing facility licensure regulations.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The department intends to amend the regulations to specify that nursing facilities shall comply with Part 1 and Section 4.1 and 4.2 of the Guidelines and that the Guidelines take precedence over the Virginia Uniform Statewide Building Code. The department further intends to specify in the regulations that entities licensed as of the effective date of the amendments may continue to be licensed in their current buildings. However, all new construction, renovation, modification, structural revision, etc of any space within a nursing facility will require full compliance with this provision for the entire area of the modified space. No acronyms were used in developing the amendment or this document.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The amendment is clearly and directly mandated by law.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to;

Erik Bodin
Director
Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Ste. 401
Henrico, Virginia 23233
Tel: 804-367-2102
Fax: 804-527-4500
Emails: Erik.Bodin@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 day of the public comment period.

The department considers this amendment to be straightforward; therefore a panel will not be used for its development.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Family impact

Assess the potential 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.

There is no direct impact on the family or the family structure as a result of this amendment.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: April 26, 2013

TO: Virginia State Board of Health

FROM: Karen E. Reed, M.A.
Acting Director of Administration- Office of Minority Health and Health Equity

SUBJECT: Final Rules and Regulations for the Identification of Medically Underserved Areas in Virginia (12VAC5-540).

Enclosed for your review are final Rules and Regulations for the Identification of Medically Underserved Areas in Virginia (12VAC5-540).

Section 32.1-122.5 of the Code of Virginia mandates the Board of Health to establish criteria to identify medically underserved areas within the Commonwealth. Section 32.1-122.5 further requires the criteria established by the Board to consist of quantifiable measures sensitive to the unique characteristics of urban and rural jurisdictions. The Rules and Regulations for the Identification of Medically Underserved Areas in Virginia (12VAC5-540) were promulgated in 1991 and have not been updated since that time; this regulatory action was implemented to make necessary revisions.

The proposed regulations pertaining to the currently submitted final regulations were published in the Virginia Register of Regulations on October 22, 2012. A 60-day public comment period on the proposed regulations ended on December 21, 2012. No comments were received during the public comment period. A review of the proposed regulations by the Virginia Department of Health revealed the proposed language was unclear. The agency has created some amendments to the proposed regulations in the final Rules and Regulations for the Identification of Medically Underserved Areas in Virginia (12VAC5-540). The final regulations are substantively similar to the proposed regulations, and have simply been amended for clarity.

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 and on the Virginia Regulatory Town Hall website, and a 30 day final adoption period will begin.



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-540
Regulation title	Rules and Regulations for the Identification of Medically Underserved Areas in Virginia
Action title	Update MUA determination process for timely accurate computations
Date this document prepared	April 30, 2013

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.

Section 32.1-122.5 of the Code of Virginia was enacted by Chapters 874 and 877 of the 1990 Virginia Acts of Assembly. Section 32.1-122.5 requires the Board of Health to establish criteria to identify medically underserved areas in the Commonwealth. The Virginia Medically Underserved Area designation is designed to encourage the appropriate distribution and expansion of health care services into areas where Virginia citizens often lack access to health care. State and private funding programs and agencies use these underserved criteria to support family centered primary health care services throughout the Commonwealth. The regulations were promulgated in July of 1991 and have not been reviewed since that time. The amended regulations would update the required data resources and specify how state facilities would be designated.

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.

At its meeting conducted on June 6th, 2013 the State Board of Health voted to approve final amendments to the Rules and Regulations for the Identification of Medically Underserved Areas in Virginia.

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.

Section 32.1-122.5 of the Code of Virginia as enacted by Chapters 874 and 877 of the 1990 Virginia Acts of Assembly mandated the Board of Health to establish criteria to identify medically underserved areas within the Commonwealth. Section 32.1-122.5 further requires these criteria to consist of quantifiable measures sensitive to the unique characteristics of urban and rural jurisdictions which may include the incidence of infant mortality, the availability of primary care resources, poverty levels, and other measures indicating the inadequacy of the primary health care system as determined by the Board. The Board of Health is also required to include criteria for the need for medical services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services. The Board of Health, in accordance with the Administrative Process Act (Section 2.2-4000 *et seq.* of the Code of Virginia) has adopted regulations to implement the provisions of the Act which became effective on July 3rd, 1991. The regulations have not been reviewed since that time. These final amendments update the required data resources and specify how state facilities would be designated.

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 regulations became effective on July 3rd, 1991. The regulations have not been reviewed since that time. The regulations require updating because certain state programs and private funding sources depend on the accuracy of the Virginia Medically Underserved Area designation process in awarding funds to health providers and to communities. All of the changes are in response to the availability of new data sources allowing more timely designation of underserved areas.

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 recommended changes are designed to:

1. Allow state facilities to be automatically designated as Virginia Medically Underserved Areas.
2. Incorporate new state incentive programs into the Virginia Medically Underserved Program description.
3. Allow new data sources to be used in computing Virginia Medically Underserved Areas.
4. Establish a minimum five year update and renewal cycle for designation of Virginia Medically Underserved Areas.

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, the agency and the Commonwealth is accurate and up to date regulations. The purpose of identifying medically underserved areas within the Commonwealth is to establish geographic areas in need of additional primary health care services. These areas may be selected by trained primary care physicians and other health professionals as practice sites in fulfillment of obligations that the physicians and other health professionals accepted in return for medical training and scholarship grant assistance. These requirements are currently in place for scholarships received from the Virginia Medical Scholarship Program and the Virginia Nurse Practitioner/Nurse Midwife Scholarship Program. Therefore accurate and up to date regulations will help to increase the availability of quality primary care physicians and other health professionals in medically underserved areas. Further these areas will be better positioned to retain qualified primary care physicians and other health care professionals due to the obligation created by accepting these scholarship funds. The Virginia Department of Health sees no disadvantage to the public, the agency or the Commonwealth associated with the proposed regulatory action. The proposed regulations also bring the designations in conformity with the Code by providing for the designation of state facilities operated by the Departments of Corrections, Juvenile Justice, and Mental Health, Mental Retardation and Substance Abuse Services.

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
30	The following five criteria, as	The following five criteria, as	Clarity. The intent of the

<p>available, and as indicated, shall be used to evaluate and identify medically underserved areas throughout the Commonwealth of Virginia and the criteria shall be applied at a minimum five year interval using the most recent data available to update the designations:</p> <ol style="list-style-type: none"> 1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce- or appropriate intercensal estimates of poverty accepted by the Health Resources and Services Administration Shortage Designation Branch for federal health professional shortage area and medically underserved area designations. 2. Percentage of population that is 65 years of age or older. The source for these data shall be the Bureau of the Census of the U.S. Department of Commerce, or the latest estimates from the Weldon Cooper Center for Public Service at the University of Virginia, or the Economic Services Division of the Virginia Employment Commission. 3. The primary care physician to population ratio. The source for these data shall be the Virginia Department of Health Professions, Board of Medicine physician profile database. Primary care physicians are defined as board certified or self-designated generalist practitioners who practice family medicine, pediatrics, internal medicine, or 	<p>available, and as indicated, shall be used to evaluate and identify medically underserved areas throughout the Commonwealth of Virginia and the criteria shall be <u>utilized at a minimum once every five years</u> using the most recent data available to update the designations:</p> <ol style="list-style-type: none"> 1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce or appropriate intercensal estimates of poverty accepted by the Health Resources and Services Administration Shortage Designation Branch for federal health professional shortage area and medically underserved area designations. 2. Percentage of population that is 65 years of age or older. The source for these data shall be the Bureau of the Census of the U.S. Department of Commerce, or the latest estimates from the Weldon Cooper Center for Public Service at the University of Virginia, or the Economic Services Division of the Virginia Employment Commission. 3. The primary care physician to population ratio. The source for these data shall be the Virginia Department of Health Professions, or Board of Medicine physician profile database. Primary care physicians are defined as board certified or self-designated generalist practitioners who practice family medicine, pediatrics, internal medicine, or obstetrics/gynecology. 4. The four-year aggregate infant mortality rate. The source for these data shall be the most recent four-year infant mortality data for each jurisdiction from the Division of Health Statistics of the Virginia 	<p>proposed regulations was to ensure the medically underserved area designations were being calculated once every five years, however the language of the proposed regulations was unclear. The deemed designation of facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services as Virginia medically underserved areas was inappropriately placed in Section 40, this has been corrected in the final regulations.</p>
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	<p>obstetrics/gynecology.</p> <p>4. The four-year aggregate infant mortality rate. The source for these data shall be the most recent four-year infant mortality data for each jurisdiction from the Division of Health Statistics of the Virginia Department of Health.</p> <p>5. The most recent seasonally adjusted quarterly civilian unemployment rate for each jurisdiction. The source for these data shall be the Information Services Division of the Virginia Employment Commission</p>	<p>Department of Health.</p> <p>5. The most recent seasonally adjusted quarterly civilian unemployment rate for each jurisdiction. The source for these data shall be the Information Services Division of the Virginia Employment Commission.</p> <p>6. <u>Medical care services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services will be deemed Virginia medically underserved areas.</u></p>	
40	<p>A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the five criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the five criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the Level 2 range.</p> <p>The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio,</p>	<p>A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the five criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the five criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the Level 2 range.</p> <p>The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio, as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the</p>	<p>Clarity. The deemed designation of facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services as Virginia medically underserved areas was inappropriately placed in Section 40, this has been corrected in the final regulations.</p>

	<p>as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.</p> <p>The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.</p> <p>The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.</p> <p>The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.</p> <p>The values for each of the</p>	<p>Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.</p> <p>The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.</p> <p>The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.</p> <p>The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.</p> <p>The values for each of the ranges of the five criteria will be summed for each Virginia city and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average</p>	
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	<p>ranges of the five criteria will be summed for each Virginia city and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average value shall be considered medically underserved.</p> <p>B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The Board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved subareas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the Board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this</p>	<p>value shall be considered medically underserved.</p> <p>B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved subareas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this section for purposes of placement of health professionals.</p> <p>C. Medical care services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services will be deemed Virginia medically underserved areas</p>	
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	<p>section for purposes of placement of health professionals.</p> <p>C. Medical care services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services will be deemed Virginia medically underserved areas</p>		
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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 comments were 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, rationale, and consequences
12 VAC5-540-10		<p>Part I General Information Authority. In accordance with the provisions of § 32.1-122.5 of the Code of Virginia, the State Board of Health is required to establish criteria for determining medically underserved areas within the Commonwealth. The criteria are required to be quantifiable measures, sensitive to the unique characteristics of urban and rural jurisdictions.</p>	<p>Part I General Information Authority. In accordance with the provisions of § 32.1-122.5 of the Code of Virginia, the State Board of Health is required to establish criteria for determining medically underserved areas within the Commonwealth and include in <u>these criteria the need for medical care services in the state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services.</u> The criteria are required to be quantifiable measures, sensitive to the unique characteristics of urban</p>

			and rural jurisdictions. (Rationale: To conform with the Code requirements)
12VAC5-540-20		<p>Purpose.</p> <p>The purpose of identifying medically underserved areas within the Commonwealth is to establish geographic areas in need of additional primary health care services. These areas may be selected by trained primary care physicians and other health professionals as practice sites in fulfillment of obligations that the physicians and other health professionals accepted in return for medical training and scholarship grant assistance. Each year of practice in a medically underserved area satisfies the repayment requirement of a year of scholarship support from the Virginia Medical Scholarship Program. Additionally, these medically underserved areas will be eligible locations for practicing primary care physicians and other health professionals participating in the state or federal physician loan repayment programs. Further, these medically underserved areas may become eligible for assistance, state or federal, to establish primary care medical centers.</p>	<p>Purpose.</p> <p>The purpose of identifying medically underserved areas within the Commonwealth is to establish geographic areas in need of additional primary health care services. These areas may be selected by trained primary care physicians and other health professionals as practice sites in fulfillment of obligations that the physicians and other health professionals accepted in return for medical training and scholarship grant assistance. Each year of practice in a medically underserved area satisfies the repayment requirement of a year of scholarship support from the Virginia Medical Scholarship Program and the Virginia Nurse Practitioner/Nurse Midwife Scholarship Program. Additionally, these Virginia medically underserved areas (VMUA) will be eligible locations for practicing primary care physicians and other health professionals participating in the state physician loan repayment program. Further, these medically underserved areas may become eligible for assistance, state or federal, to establish primary care medical centers.</p> <p>Rationale: Eliminates specific programs from the regulations</p>
12VAC5-540-30		<p>Part II</p> <p>Designating Medically Underserved Areas</p> <p>12VAC5-540-30. Criteria for determining medically underserved areas.</p> <p>The following five criteria, as available, and as indicated, shall be used to evaluate and identify</p>	<p>Part II</p> <p>Designating <u>Virginia</u> Medically Underserved Areas</p> <p>The following five criteria, as available, and as indicated, shall be used to evaluate and identify medically underserved areas throughout the Commonwealth of Virginia <u>and the criteria shall</u></p>

		<p>medically underserved areas throughout the Commonwealth of Virginia:</p> <ol style="list-style-type: none"> 1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce. 2. Percentage of population that is 65 years of age or older. The source for these data shall be the Economic Services Division of the Virginia Employment Commission. 3. The primary care physician to population ratio. The source for these data shall be the Department of Family Practice of the Medical College of Virginia of Virginia Commonwealth University. 4. The four-year aggregate infant mortality rate. The source for these data shall be the Center of Health Statistics of the Virginia Department of Health. 5. The most recent annual civilian unemployment rate. The source for these data shall be Information Services Division of the Virginia Employment Commission. 	<p><u>be utilized at a minimum once every five years using the most recent data available to update the designations:</u></p> <ol style="list-style-type: none"> 1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce <u>or appropriate intercensorial estimates of poverty accepted by the Health Resources and Services Administration Shortage Designation Branch for federal health professional shortage area and medically underserved area designations.</u> 2. Percentage of population that is 65 years of age or older. The source for these data shall be the <u>Bureau of the Census of the U.S. Department of Commerce, or the latest estimates from the Weldon Cooper Center for Public Service at the University of Virginia, or the Economic Services Division of the Virginia Employment Commission.</u> 3. The primary care physician to population ratio. The source for these data shall be the Department of Family Practice of the Medical College of Virginia of Virginia Commonwealth University <u>Virginia Department of Health Professions, or Board of Medicine physician profile database. Primary care physicians are defined as board certified or self-designated generalist practitioners who practice family medicine, pediatrics, internal medicine, or obstetrics/gynecology.</u> 4. The four-year aggregate infant mortality rate. The source for these data shall be the Center <u>most recent four-year infant mortality data for each jurisdiction from the Division of</u>
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			<p>Health Statistics of the Virginia Department of Health.</p> <p>5. The most recent annual <u>seasonally adjusted quarterly civilian unemployment rate for each jurisdiction</u>. The source for these data shall be the <u>Information Services Division of the Virginia Employment Commission</u>.</p> <p>6. <u>Medical care services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services will be deemed Virginia medically underserved areas.</u></p> <p>Rationale: Provides flexibility in using databases which did not exist when the regulations for VMUA were initially promulgated and it establishes a review cycle for the designation process and to conform with the Code requirements that provisions be made for certain state facilities.</p>
12VAC5-540-40		<p>Application of the Criteria</p> <p>A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the five criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the five criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the</p>	<p>Application of the Criteria</p> <p>A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the five criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the five criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the</p>

		<p>Level 2 range.</p> <p>The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio, as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.</p> <p>The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.</p> <p>The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.</p> <p>The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.</p> <p>The values for each of the ranges of the five criteria will be</p>	<p>Level 2 range.</p> <p>The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio, as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.</p> <p>The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.</p> <p>The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.</p> <p>The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.</p> <p>The values for each of the ranges of the five criteria will be</p>
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		<p>summed for each Virginia city and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average value shall be considered medically underserved. The application of criteria for determining medically underserved cities and counties shall be performed annually and published by the board.</p> <p>B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved subareas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this section for purposes</p>	<p>summed for each Virginia city and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average value shall be considered medically underserved. The application of criteria for determining medically underserved cities and counties shall be performed annually and published by the board.</p> <p>B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The Board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved sub-areas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the Board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this section for purposes of placement of health</p>
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		of placement of health professionals.	professionals. Rationale: To conform to the requirements of 12VAC5-540-30 that designations be performed on at a minimum once every five years.
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Project 2199 - Proposed

DEPARTMENT OF HEALTH

Update MUA determination process for timely accurate computations

Part I
General Information

12VAC5-540-10. Authority.

In accordance with the provisions of § 32.1-122.5 of the Code of Virginia, the State Board of Health is required to establish criteria for determining medically underserved areas within the Commonwealth and include in these criteria the need for medical care services in the state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services. The criteria are required to be quantifiable measures, sensitive to the unique characteristics of urban and rural jurisdictions.

12VAC5-540-20. Purpose.

The purpose of identifying medically underserved areas within the Commonwealth is to establish geographic areas in need of additional primary health care services. ~~These areas may be selected by trained primary care physicians and other health professionals as practice sites in fulfillment of obligations that the physicians and other health professionals accepted in return for medical training and scholarship grant assistance. Each year of practice in a medically underserved area satisfies the repayment requirement of a year of scholarship support from the Virginia Medical Scholarship Program. Additionally, these medically underserved areas will be eligible locations for practicing primary care physicians and other health professionals participating in the state or federal physician loan repayment programs. Further, these medically underserved areas may become eligible for assistance, state or federal, to establish primary care medical centers.~~

Part II
Designating Medically Underserved Areas

12VAC5-540-30. Criteria for determining medically underserved areas.

The following ~~five~~ criteria, as available, and as indicated, shall be used to evaluate and identify medically underserved areas throughout the Commonwealth of Virginia and the criteria shall be utilized at a minimum once every five years using the most recent data available to update the designations:

1. Percentage of population with income at or below 100% of the federal poverty level. The source for these data shall be the most recent available publication of the Bureau of the Census of the U.S. Department of Commerce or appropriate intercensorial estimates of poverty accepted by the Health Resources and Services Administration Shortage Designation Branch for federal health professional shortage area and medically underserved area designations.
2. Percentage of population that is 65 years of age or older. The source for these data shall be the Bureau of the Census of the U.S. Department of Commerce, or the latest estimates from the Weldon Cooper Center for Public Service at the University of Virginia, or the Economic Services Division of the Virginia Employment Commission.
3. The primary care physician to population ratio. The source for these data shall be the Department of Family Practice of the Medical College of Virginia of Virginia Commonwealth University Virginia Department of Health Professions, or Board of Medicine physician profile database. Primary care physicians are defined as board

certified or self-designated generalist practitioners who practice family medicine, pediatrics, internal medicine, or obstetrics/gynecology.

4. The four-year aggregate infant mortality rate. The source for these data shall be the Center most recent four-year infant mortality data for each jurisdiction from the Division of Health Statistics of the Virginia Department of Health.

5. The most recent ~~annual~~ seasonally adjusted quarterly civilian unemployment rate for each jurisdiction. The source for these data shall be the Information Services Division of the Virginia Employment Commission.

6. Medical care services in state facilities operated by the Departments of Corrections, Juvenile Justice, and Behavioral Health and Developmental Services shall be deemed Virginia medically underserved areas.

12VAC5-540-40. Application of the criteria.

A. Determining medically underserved cities and counties. The criteria enumerated in 12VAC5-540-30 shall be used to construct a numerical index by which the relative degree of medical underservice shall be calculated for each city and county within the Commonwealth. Observations for each of the ~~five~~ criteria will be listed for each Virginia city and county. An interval scale will be used to assign a particular value to each observation. This will be done for each of the ~~five~~ criteria. Each interval scale will consist of four ranges or outcomes of observations. The ranges will be numerically equal. The four ranges will be labeled as Level 1, Level 2, Level 3, and Level 4. The numerical difference between the ranges will be established beginning with the Level 2 range.

The Level 2 range shall have the statewide average for each respective criterion, except the population to primary care physician ratio, as its upper limit. The Level 2 upper limit for the primary care physician to population ratio is established by dividing the difference between the Level 4 upper limit for this criterion and the Level 1 upper limit by two. Each observation which is equal to or less than the Level 2 upper limit, but greater than the Level 1 upper limit, will be assigned a numerical value of two.

The Level 1 range shall have an upper limit which is the quotient of the statewide average divided by two. For the ratio of population to primary care physician criterion, the upper limit of Level 1 shall be the ratio 2500:1 as recommended by the American Academy of Family Physicians. Each observation that is equal to or less than the Level 1 upper limit will be assigned a numerical value of one.

The Level 3 range shall have an upper limit that is equal to the sum of the upper limit of the Level 1 range and the upper limit of the Level 2 range. For the ratio of population to primary care physician criterion, the upper limit of level 3 shall be established at 3500:1, the federal standard for designating health manpower shortage areas. Each observation that is equal to or less than the Level 3 upper limit will be assigned a numerical value of three.

The Level 4 range will include any observation greater than the upper limit of Level 3 range. Each observation in the Level 4 range will be assigned a numerical value of four.

The values for each of the ranges of the ~~five~~ criteria will be summed for each Virginia city and county. Each Virginia city and county will have an assigned value of five or greater, to a maximum of 20. A statewide average value will be determined by summing the total city and county values and dividing by the number of cities and counties. Any city or county assigned a value that is greater than the statewide average value shall be considered medically underserved. ~~The application of criteria for determining medically underserved cities and counties shall be performed annually and published by the board.~~

B. Determining medically underserved areas within cities and counties. Geographic subsections of cities or counties may be designated as medically underserved areas when the

entire city or county is not eligible if the subsection has: (i) a population to primary care physician ratio equal to or greater than 3500:1; and (ii) a population whose rate of poverty is greater than the statewide average poverty rate; and (iii) a minimum population of 3,500 persons residing in a contiguous, identifiable, geographic area. The board shall from time to time, on petition of any person, or as a result of its own decision, apply criteria for determining medically underserved subareas of cities and counties. Once determined to be medically underserved, any subarea of a city or county shall appear on the next list of medically underserved areas published by the board. Areas which qualify as medically underserved areas under 12VAC5-540-40 A and that are within Standard Metropolitan Areas as defined by the U.S. Department of Commerce, must also qualify under this section for purposes of placement of health professionals.